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The Amended Canadian Patent Act: General Amendments and Pharmaceutical Patents Compulsory Licensing Provisions

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Abstract

On November 19, 1987, the Canadian Senate gave final approval to a number of far-reaching and controversial amendments to the Canadian Patent Act ("Amending Act"). On the same day, following Senate approval, the Bill C-22 became law upon royal assent. The Patent Act, enacted in 1935, had remained largely unchanged, notwithstanding amendments in 1952 and 1969. The present amendments therefore constitute an unprecedented overhaul of the Candian law of patents.

THE AMENDED CANADIAN PATENT ACT: GENERAL AMENDMENTS AND PHARMACEUTICAL PATENTS COMPULSORY LICENSING PROVISIONS

*Milan Chromecek**

INTRODUCTION

On November 19, 1987, the Canadian Senate gave final approval to a number of far-reaching and controversial amendments to the Canadian Patent Act ("Amending Act").[1] On the same day, following Senate approval, the Bill C-22[2] became law upon royal assent.[3] The Patent Act, enacted in 1935, had remained largely unchanged, notwithstanding amendments in 1952 and 1969. The present amendments therefore constitute an unprecedented overhaul of the Canadian law of patents.[4]

Significantly, the amending legislation was passed only after a prolonged fight between the elected, Conservative-domi-

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1. The Patent Act, CAN. REV. STAT. ch. P-4 (1970).

2. Bill C-22, 33d Parliament, 2d Sess., 35-36 Eliz. II (1986-87).

3. Section 5(1) of the Interpretation Act, CAN. REV. STAT. ch. I-23 (1970), provides that the Clerk of the Parliament shall endorse on every Act the date of assent, and the date of such assent shall be the date of commencement of the Act, if no other date of commencement is therein provided. The Amending Act is entitled An Act To Amend the Patent Act and To Provide for Certain Matters in Relation Thereto, ch. 41, 1987 Can. Stat. [hereinafter Amending Act].

4. The amendments are part of the overall effort of the Federal Government to modernize the Canadian intellectual and industrial property laws. For example, Bill C-60, 33d Parliament, 2d Sess., 35-36 Eliz. II (1986-87), introduced on May 27, 1987, marked the first of two phases of the copyright law reform and certain amendments to the Industrial Design Act, CAN. REV. STAT. ch. I-8 (1970), and the Competition Act, ch. 26, 1986 Can. Stat., and other statutes. The Copyright Act, CAN. REV. STAT. ch. C-30 (1970), was enacted in 1924. It has remained intact since that date, and still refers in § 2 to "perforated rolls" and in § 25(1) imposes as one of the penal sanctions "hard labour." In addition, for the first time both the provincial and federal levels of government considered the law of trade secrets, and recommended the enactment of the Uniform Trade Secrets Act (see Trade Secrets Institute of Law Research and Reform, Edmonton, and a Federal-Provincial Working Party, Report of July 1986). Finally, in 1979 the Government introduced Bill S-11, 30th Parliament, 4th Sess., 27-28 Eliz. II (1978-79), including certain proposals for the amendment of the Trade Marks Act, CAN. REV. STAT. ch. T-10 (1970).

nated House of Commons and the appointed Senate, in which the Liberal party holds a significant majority. In fact, it took more than fifteen months[5] of what was occasionally a fierce battle between the House of Commons and the Senate before the latter desisted and allowed the passage of the Amending Act more or less in its original form. Parliament thus avoided a full constitutional crisis.[6]

The amendments cover essentially two main areas. First, the Amending Act contains general provisions designed to bring the Patent Act into line with similar statutes of other industrialized countries and to modernize the law to take account of Canada's economic and industrial development. The general amendments include a number of changes, the most important being as follows:

— the introduction of the "first-to-file" system to replace the current "first-to-invent" system, and the introduction of a modified grace period;
— the extension of the period of protection from seventeen years as of the date of grant of the patent to twenty years as of the date of filing of the patent application;
— the allowance of per se product claims in medicine and food patents; and
— the enablement of Canada to adhere to the Patent Cooperation Treaty.[7]

The Senate did not object to general amendments.

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5. The Minister of Consumer and Corporate Affairs, Canada, presented a draft Bill C-22 to the public on June 27, 1986.

6. To many it came as a surprise that the Senate should choose to bring the fight over patent law reform to the brink of constitutional crisis, because it was generally agreed that the statute was obsolete and in need of major changes. Members of the Senate are appointed by the Governor General, and therefore in reality by the Cabinet; the Senate thus is not an elective body. Under the Constitution Act, 1867, the Senate has the same powers as the elected House of Commons, with the exception of money bills, which must originate in the House of Commons, British North America Act, 1867, 30-31 Vict. ch. 3, § 53. However, as one commentator points out, the Senate as a matter of principle defers to the will of the House of Commons because it recognizes its lack of political mandate to oppose the House. P. HOGG, CONSTITUTIONAL LAW OF CANADA 201 (2d ed. 1985). The Senate's decision to exercise its powers to block the legislation originating in the House could therefore lead to a virtual deadlock that would paralyze and conceivably bring down the Federal government.

7. Patent Cooperation Treaty, *done* June 19, 1970, 28 U.S.T. 7645, T.I.A.S. No. 8733, 9 I.L.M. 978, and amended and modified on February 3, 1984. Canada signed the Treaty in 1970, but has yet to carry its terms into effect.

Second, the Amending Act substantially modifies the scheme of the compulsory licensing of patented medicines by increasing the patent protection granted to pharmaceutical inventions. The main features of such modifications are the following:

— the introduction of the system of deferrals delaying the exercise of rights of holders of compulsory licenses to manufacture and/or import the pharmaceuticals subject to patent protection for the periods determined by the statute; and
— the establishment of the Patented Medicine Prices Review Board exercising control over patented medicine prices in Canada and monitoring compliance by the pharmaceutical industry with its commitments to invest in research and development in Canada.

It is this second part of the Bill C-22 amendments that triggered ferocious opposition from the Senate, which took the position that such an amendment would cause substantial increases in prices of drugs.[8] The Senate Liberal majority also felt some lingering suspicion that the patent law reform was one of the conditions stipulated by the U.S. side in the negotiations of the Free Trade Agreement between the United States and Canada,[9] to which the federal Liberal party is opposed.[10] The Government has denied the existence of such a direct connection between the patent law reform and the Free Trade Agreement negotiations.[11] However, the Free Trade Agreement, if ratified, may greatly influence the intellectual and industrial property laws in Canada by means of further amendments harmonizing the laws of the two countries.[12] The new

8. Nineteenth Report of the Standing Senate Committee on Banking, Trade and Commerce, the Senate of Canada, Ottawa, October 1987, at 16-17 [hereinafter Senate Report].

9. *Id.* at 13.

10. The Canada-U.S. Free Trade Agreement concluded in Washington, D.C., on October 4, 1987, and tabled by the Government in the House of Commons on December 11, 1987, was signed by the U.S. President Ronald Reagan and the Canadian Prime Minister Brian Mulroney on January 2, 1988.

11. *See* Senate Report, *supra* note 8, at 13.

12. In fact, article 2004 of the final text of the Canada-U.S. Free Trade Agreement, which is entitled Intellectual Property, provides that "the Parties shall cooperate in the Uruguay Round of multilateral trade negotiations and in other international forums to improve protection of intellectual property." *See* Canada-U.S. Free Trade Agreement, *supra* note 10, art. 2004.

activist attitude displayed by the Senate with respect to the patent law reform may be a precursor of bigger things to come with respect to the ratification of not only the Canada-U.S. Free Trade Agreement but also conceivably to the future amendments of the Copyright Act[13] and perhaps other laws.[14]

I. *GENERAL AMENDMENTS*

The Minister of Consumer and Corporate Affairs, Canada, stated in his opening remarks to the Legislative Committee of the House of Commons that the purpose of the amendments was to bring the Patent Act into line with comparable statutes of Canada's major trading partners, and to modernize the Act to meet the challenges of a dynamic, high-tech, growing, and sophisticated economy.[15] To this end, a number of general amendments were made in Bill C-22 with respect to conditions for patentability, priority claims and dates, prosecution of patent applications, and conditions governing issued patents.

A. *Conditions for Patentability*

1. First-to-File System and Elimination of Conflict Procedure

The Amending Act replaces the current "first-to-invent" system with the "first-to-file" system under which the person who first files his application is entitled to its registration over any subsequent application regarding the same invention. Canada has been one of the few countries in the world operating on the basis of the first-to-invent system.[16] The Canadian

13. CAN. REV. STAT. ch. C-30 (1970).

14. Notably the Meech Lake Constitutional Accord, signed on June 3, 1987, the purpose of which was to enable the Province of Quebec to sign the Canadian Constitution of 1982. *See generally* P. HOGG, MEECH LAKE CONSTITUTIONAL ACCORD ANNOTATED 1-7 (1988).

15. *See* Hon. Harvie Andre, Minister of Consumer and Corporate Affairs, Canada, Notes for Opening Remarks to the Legislative Committee on Bill C-22 to the House of Commons 1 (Dec. 16, 1986).

16. The U.S. patent law also operates in the "first-to-invent" system as defined in 35 U.S.C. § 102(g) (1982). However, the "interference" procedure in the U.S. appears to be quite costly and complex and it includes litigation between the parties in the U.S. Patent and Trademarks Office ("PTO"). The U.S. PTO's decisions can be appealed, either to the Court of Appeals for the Federal Circuit, 35 U.S.C. §§ 2, 14 (1982), or to a federal district court, 35 U.S.C. § 146 (1982 & Supp. III 1985). Consequently the U.S. "interference" procedure seems to be rarely used by first inventors to prevail over the "first-to-file" applicants who are generally able to preserve their rights. *See generally* Morgan, *"First To Invent" Versus "First To File": Is It Really*

"conflict" procedure enabled the first inventor who proved to the Commissioner of Patents that he was the first to make the invention to prevail over a subsequent "first-to-file" applicant.[17] Based on such evidence the Commissioner either rejected or allowed the claims in conflict unless, within a time period specified by the Commissioner, one of the applicants brought an action in the Federal Court of Canada for the determination of the applicants' respective rights.[18]

The rights of the first inventor stemmed from the provisions of section 28(1) of the Patent Act, which provided, *inter alia*, that an inventor could obtain a patent for an invention that was not known or used by any other person before he invented it. However, no conflict proceedings could be instituted against a patent that had been issued more than two years prior to the conflicting application without running afoul of other Patent Act provisions relating to the requirement of novelty. Specifically, section 28(1)(b) and (c) prohibited the grant of a patent for an invention that was described in any patent or printed publication published anywhere in the world or publicly used in Canada more than two years prior to the date of the filing of the application for such a patent.

The first-to-invent system and the conflict procedure have now been replaced by the first-to-file system under amended section 28(1)(a) and (b), which grants the right to a patent, subject to other relevant conditions of the amended Patent Act, to an inventor who applies for it first.[19] As between any conflicting applications for the same invention, the one having

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"Fairer", or Cost Effective? Some Myths and Realities of Interference Practice, 3 PAT. & TRADEMARK INST. CAN. REV. 265 (1986).

17. Patent Act, CAN. REV. STAT. ch. P-4, §§ 43, 45 (1970) (repealed by Amending Act, *supra* note 3, sec. 16); *id.* § 63 (governing the priority of inventions); Patent Rules, CAN. CONS. REGS. ch. 1250, rules 66-74 (1978).

18. *See* Patent Act, CAN. REV. STAT. ch. P-4, § 45(8) (1970) (repealed by Amending Act, *supra* note 3, sec. 16); Federal Court Act, ch. 1, § 20, 1970-71-72 Can. Stat. 1, 11-12; Federal Court Rules, CAN. CONS. REGS. ch. 663, rules 700-701 (1978). As there was no right of appeal from the Commissioner's decision, this was the only way that the Commissioner's decision could be altered or rather preempted. *See generally* I. GOLDSMITH, PATENTS OF INVENTION 138-40 (3d ed. 1981); Kierans, *Canadian Conflict Procedure*, 3 PAT. & TRADEMARK INST. CAN. REV. 281 (1986).

19. Amended § 28(1) reads as follows:

> 28. (1) Subject to this section, any inventor or legal representative of an inventor of an invention may, on presentation to the Commissioner of a petition setting out the facts (in this Act termed the filing of the application)

an earlier effective filing date[20] will be given priority. Unfortunately the law does not clarify the criteria to be used in determining whether the inventions are the same. The basis for determination could conceivably be anticipation (lack of novelty) or obviousness (lack of invention) by comparing, respectively, either the entire contents of the conflicting applications or analyzing them on a claim-by-claim basis. It would appear from the wording of amended section 28(1) that the Parliament opted for the test of anticipation because the section refers to "a patent *describing* the same invention."[21]

Another interesting question arises with respect to conflicting applications filed on the same date. The solution is

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and on compliance with all other requirements of this Act, obtain a patent granting to the applicant an exclusive property in such invention unless

(a) in the case of an application to which section 29 applies,

(i) an application for a patent describing the same invention was filed in Canada by any other person before the priority date of the application, or

(ii) an application for a patent describing the same invention and to which section 29 applies is filed in Canada by any other person at any time and the priority date of that application precedes the priority date of the application;

(b) in the case of any other application,

(i) an application for a patent describing the same invention was filed in Canada by any other person before the filing of the application, or

(ii) an application for a patent describing the same invention and to which section 29 applies is filed in Canada by any other person after the filing of the application and the priority date of that application precedes the date of filing of the application;

(c) the invention was, before the date of filing of the application or before the priority date of the application, if any, disclosed by a person other than a person referred to in paragraph (d) in such a manner that it became available to the public in Canada or elsewhere; or

(d) the invention was, more than one year before the date of filing of the application, disclosed by the applicant or by a person who obtained knowledge of the invention, directly or indirectly, from the applicant, in such a manner that it became available to the public in Canada or elsewhere.

Amending Act, *supra* note 3, sec. 8, § 28(1).

20. The effective filing date could be either the actual filing date in Canada, as provided by amended § 28(1)(b), or the priority date set forth in the Convention of Paris for the Protection of Industrial Property of 20th March, 1883, revised, *opened for signature* Dec. 14, 1900, 13 U.S.T. 1, 27-28 (official English trans.), T.I.A.S. No. 4931, at 27-28 [hereinafter Paris Convention], as provided by amended § 28(1)(a). The rights of applicants under the Patent Cooperation Treaty, *supra* note 7, or the Paris Convention are now governed by § 29 of the amended Patent Act, discussed *infra* notes 36-50 and accompanying text.

21. Amending Act, *supra* note 3, sec. 8, § 28(1) (emphasis added).

found in amended section 28(1.5), which provides that in such a case each application shall be examined and a patent allowed to issue without regard to the existence of the other application.[22] Therefore, the Commissioner would still have to determine the priority of one application over the other; however, it is not clear how he would do it. The first-to-file system certainly has its merits, but it may force an inventor to file premature applications early in the development of his invention, while the procedure allowing him to add supplementary disclosures resulting from additional development remains relatively cumbersome.[23]

2. The Absolute Novelty Requirement and New Grace Period

Under the old rules set out in section 28(1) of the Patent Act, a patent could not validly be issued if more than two years before the date of application therefor, the invention was (a) described in any patent or in any printed publication published anywhere in the world, or (b) the invention was in public use or on sale in Canada, whether by the applicant or by anyone else.[24] Thus the statute expressed the notion of anticipation, one of the key principles of Canadian patent law, stating in effect that where the public becomes possessed of an invention by any means whatsoever, no subsequent valid patent may be granted in respect of that invention.[25] The concept of anticipation recognizes that there is an invention, but it previously has been disclosed to the public.[26] However, the Canadian Patent Act provided for a relatively generous two-year grace period within which the applicant could still obtain his patent,

22. Amending Act, *supra* note 3, sec. 8, § 28(1.5).

23. An inventor may try to amend the disclosures, Patent Rules, CAN. CONS. REGS. ch. 1250, rules 52-57 (1978), or file a second application within 12 months of the date of filing of the first one, Amending Act, *supra* note 3, sec. 8, § 28(1.1). Section 28(1.1) permits him to preserve his filing day for the first application if the first application was not withdrawn, abandoned, or refused, was not laid open to public inspection, and has not served as a basis for a Paris Convention priority claim in any other country, *id.* sec. 8, § 28(1.2), and provided that the applicant invoked the special protection under § 28(1.2) within six months of filing of the second application, *id.* sec. 8, § 28(1.3).

24. Patent Act, CAN. REV. STAT. ch. P-4, § 28(1) (1970).

25. *See* I. GOLDSMITH, *supra* note 18, at 83.

26. Beloit Can. Ltd. v. Valmet OY, 8 Canadian Patent Reporter [C.P.R.] 3d 289, 293 (Fed. Ct. 1986).

anticipation notwithstanding. This system was abolished and the amended section 28(1)(c) introduces a requirement of absolute novelty, making it impossible to obtain a patent for an invention previously disclosed by a person other than the applicant in such a manner that it has become available to the public in Canada or elsewhere.[27] The existence of prior art anywhere in the world would therefore preclude the inventor from obtaining the Canadian patent. The absolute novelty requirement is subject to only one exception. Amended section 28(1)(d) allows the applicant himself or a person who obtained knowledge of the invention from the applicant[28] to so disclose the invention, provided he files his patent application within one year of such a disclosure.

The new rule thus introduces into Canadian patent law the principle of absolute novelty used in a majority of industrialized countries, the impact of which is softened, however, by the grace period. All patent applications are thus subject to the requirement of absolute novelty. Unfortunately, the amended provisions may lead to some uncertainty as to the scope of the relevant prior art. Prior art is not defined in section 28, but is defined elsewhere in the Amending Act as "consisting of patents and printed publications."[29] Such a definition does not appear sufficiently broad to encompass the entire universe of prior art, which is not necessarily expressed in the printed form.[30] In addition, the above definition appears to exclude from the relevant prior art "secret" patents[31] which are not made available to the public.

The relevance of earlier filed applications that are pub-

27. Amending Act, *supra* note 3, sec. 8, § 28(1)(c).

28. It appears that the manner in which a third party obtained the knowledge of the invention is irrelevant. This could mean that a disclosure by a person acting in breach of confidence or trust would have the same effect as a disclosure by a party acting in good faith.

29. Amending Act, *supra* note 3, sec. 11, § 36.1 (filing of prior art in protest against patent applications laid open to public inspection); *id.* sec. 18, § 51.1 (re-examination of issued patents).

30. The definition itself of what constitutes "printed matter" in the context of the patent law has been subject to frequent litigation in the past and would seem to exclude publication in manuscript or photographic form. *See, e.g.*, Saunders v. Airglide Deflectors Ltd., 50 C.P.R.2d 6 (Fed. Ct. Trial Div. 1980).

31. In Canada, Government-owned patent applications and such patents as the Minister of National Defense shall request may be kept secret in sealed packets. *See* Patent Act, CAN. REV. STAT. ch. P-4, § 20(3)-(11) (1970).

lished after the date of filing of the patent application in question is not clear. To the extent that the prior art appears to be expressed in terms of anticipation (based on the entire contents) rather than on the "claim-by-claim" basis,[32] and amended section 28(1)(a) and (b) require that an earlier application describing the same invention must be filed by a person other than the applicant, it would appear that such an earlier application would constitute a bar to the issue of the patent, being an application filed first. An application filed earlier by the same applicant will not constitute prior art, and if such an application is withdrawn before it is open for public inspection, it is deemed never to have been filed.[33]

3. Substances Intended for Food or Medicine

The general prohibition of claims for patent protection over substances prepared or produced by chemical processes and intended for food or medicine was repealed.[34] Such product claims are permissible effective November 19, 1987 (the date of royal assent), with the exception of inventions relating to naturally-occurring substances produced by microbiological processes, in respect of which the prohibition was maintained.[35]

B. *Convention Priority Claims and Priority Dates*

Some modifications have been made in section 29 of the Patent Act regarding the so-called Paris Convention priority claims.[36] Under the old system, an applicant was entitled to claim a Convention priority date if he filed his Canadian application within twelve months of the date of filing of the first foreign application but before the issue of a foreign patent for

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32. Amended § 28(1) speaks of a patent "describing the same invention." Amending Act, *supra* note 3, sec. 8, § 28(1).

33. *Id.* sec. 8, § 28(1.6).

34. *Id.* sec. 14, § 41(1) (repealing Patent Act, CAN. REV. STAT. ch. P-4, § 41(1) (1970)).

35. The inventors of such products can claim patent protection over only the methods or processes used in the production of the substances, but not over the end products themselves. Amending Act, *supra* note 3, sec. 14, § 41(1.1).

36. Section 29 implements the obligations under article 4 of the Paris Convention, *supra* note 20, 13 U.S.T. at 27-28, T.I.A.S. No. 4931, at 27-28. Canada ratified the Paris Convention in 1951 and is bound by the London revision of 1934.

the same invention.[37] The effective filing date in Canada was deemed to be the date of filing of the first foreign application, provided that the applicant requested the benefit of section 29 while his Canadian application was pending.[38] Amended section 2 of the Act defines "priority date" in the same terms, and the basic requirement of filing in Canada within twelve months is maintained.[39] The amended provisions of section 29(1) clarify that the meaning of the "same invention" is not to be interpreted on a claim-by-claim basis, but it is sufficient for a valid priority claim that the same invention be described in the first foreign application.[40] Furthermore, the applicant is now required to make his Convention priority claim within six months of the date of filing in Canada.[41] Amended section 29(3) implements the provisions of article 4C(4) of the Lisbon text of the Paris Convention.[42] Section 29(3) enables the applicant who has re-filed his patent application for the same invention in the foreign country to claim a Convention priority date being the date of re-filing of his second application. To be eligible to claim such priority date, the applicant's first application must have been withdrawn, abandoned, or refused on the date of re-filing of the second application.[43] Additionally, the first application must not have been laid open to public inspection or served as a basis of a priority claim in any country, and no rights may be left outstanding.[44]

The definition of priority date in amended section 2 is surely a step toward clarifying the provisions of the Patent Act.[45] Unfortunately, Parliament did not deem it necessary to

37. *Id.*

38. Patent Rules, CAN. CONS. REGS. ch. 1250, rule 36 (1978).

39. Amending Act, *supra* note 3, sec. 1, § 2.

40. *Id.* sec. 10, § 29(1).

41. *Id.* sec. 10, § 29(2).

42. Paris Convention, *supra* note 20, art. 4C(4), 13 U.S.T. at 27-28, T.I.A.S. No. 4931, at 27-28.

43. Amending Act, *supra* note 3, sec. 10, § 29(3).

44. *Id.*

45. There were some difficulties with the similarly vague wording of § 29(1) in the past, which led to the enactment of § 29(2), expressly providing that the Convention priority date notwithstanding a Canadian patent could not be granted in respect of any invention that has been publicly described, or in public use in Canada more than two years before the actual date of filing in Canada. Patent Act, CAN. REV. STAT. ch. P-4, § 29(2) (1970). The provisions of § 29(2) were designed to prevent any prolongation of a two-year grace period by interpreting the "filing date" as including a Convention priority date. *Id.* However, § 29(2) was repealed together with the rest

define "filing date"; this omission may lead to difficulties in interpretation. Some sections of the amended Patent Act maintain a distinction between a "priority date" and an actual "filing date in Canada" by incorporating specific references to both.[46] Other sections of both the amended Patent Act[47] and of the new provisions added by the Amending Act,[48] however, refer only to "applications filed" or "date of filing" while they contain no reference to "priority date" or any further qualifications.

Section 29(1) of the amended Patent Act provides that an application filed in a foreign country and entitled to a Convention priority claim has the same force and effect as the same application would have if filed in Canada on the priority date.[49] Because the deeming provision of section 29(1) is expressed in such broad language, an argument can be made that any unqualified reference to a "filing date" must be construed to mean an *effective* filing date (either a Convention priority date or actual filing date in Canada) and not an *actual* filing date, even though that was apparently not intended by Parliament.[50]

C. *Amendments Relating to the Prosecution of Applications*

1. Maintenance Fees

The payment of maintenance fees is now required under new section 28.1(1) in order to maintain the application in effect.[51] The modalities of payment will be prescribed upon promulgation of applicable regulations.[52] When an applicant fails to make the prescribed payment, his application shall be deemed abandoned.[53] Nevertheless, pursuant to section 28.1(3),[54] the applicant may petition the Commissioner to reinstate the application, and upon payment of a prescribed fee,

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of § 29 and replaced with amended provisions that do not address the issue. *See* Amending Act, *supra* note 3, sec. 10, § 29.

46. *See, e.g.*, Amending Act, *supra* note 3, sec. 2, § 10(2)(a), (b) (laying open the application to public inspection); *id.* sec. 8, § 28(1) (conditions of patentability).

47. *See, e.g., id.* sec. 16, § 46 (term).

48. *See, e.g., id.* secs. 27-29 (transitional provisions).

49. *See id.* sec. 10, § 29(1).

50. *See id.* sec. 9, § 28.1(3).

51. *Id.* sec. 9, § 28.1(1).

52. *Id.*

53. *Id.* sec. 9, § 28.1(3).

54. *Id.*

the original filing and priority dates will be retained.[55]

2. Public Inspection

New provisions have been introduced in amended section 10[56] of the Patent Act with respect to the laying open to public inspection of all patent applications and all documents filed in connection with patents eighteen months after the effective filing date. The wording of section 10 does not appear to allow for a protection of privileged or confidential information that the documents laid open to the public inspection may contain, even though elsewhere in the amended Patent Act the Parliament provided for such protection.[57]

3. Atomic Energy Inventions

The amended section 22 provides that every application for a patent for invention relating to atomic energy must be communicated by the Commissioner to the Atomic Energy Control Board prior to being laid open to the public inspec-

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55. Section 28.1(1) thus adds a new requirement complementing the requirements of § 32 of the Patent Act, which provides for abandonment of an application upon failure to "complete" the application within 12 months of the date of filing or upon failure to respond to an official action within six months of the date thereof. *Id.* sec. 9, § 28.1(1). Section 32 remains in force. However, unlike the reinstatement under § 28.1(3), which is automatic (upon petition and payment), reinstatement under § 32 is not mandatory and the applicant must satisfy the Commissioner that the failure was not reasonably avoidable. Patent Act, CAN. REV. STAT. ch. P-4, § 32 (1970).

56. The provisions read as follows:

> 10.(1) Subject to subsections (2) and (3) and section 20, all applications for patents and documents filed in connection with applications and all patents and documents filed in connection with patents shall be open to the inspection of the public at the Patent Office, under such conditions as may be prescribed.
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> (2) Except with the approval of the applicant, no application for a patent or document filed in connection with an application for a patent shall be open to the inspection of the public before the expiration of eighteen months after
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> (a) the priority date of the application, in the case of an application to which Section 29 applies; or
>
> (b) the date of filing of the application in Canada, in any other case.
>
> (3)No application for a patent that is withdrawn before the expiration of the period referred to in subsection (2) that is applicable with respect to the application shall be open to the inspection of the public.

Amending Act, *supra* note 3, sec. 2, § 10.

57. *See, e.g., id.* sec. 15, § 41.17(2) (reproduced *infra* note 93).

tion.[58] These provisions, however, seem inconsequential because the Board is not given any powers or jurisdiction over any patent application being so communicated.

4. Filing of Prior Art

The new section 36.1[59] permits any person to file with the Commissioner prior art to challenge the patentability of any claim of an application for a patent. Prior art is defined in the same section as "consisting of patents and printed publications."[60] This definition does not allow for filing of any evidence of prior public use and seems to be at variance with the provisions of amended section 28.[61] A person filing the prior art pursuant to these provisions would presumably learn of the patent application once it has been laid open to public inspection under amended section 10.[62] The introduction of the "protest" procedure into the Patent Act constitutes a very significant change because third parties are now given an opportunity to oppose the grant of a patent while the application is still pending. Under the previous regime, a third party was required to litigate in the Federal Court of Canada if it wished to invalidate an issued patent.[63] Formerly, third parties could not

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58. *See* Amending Act, *supra* note 3, sec. 5, § 22.

59. Section 36.1 reads as follows:

> 36.1(1) Any person may file with the Commissioner prior art consisting of patents and printed publicatons that the person believes has a bearing on the patentability of any claim in an application for a patent.
>
> (2) A person who files prior art with the Commissioner under subsection (1) shall explain the pertinency of the prior art.

Id. sec. 11, § 36.1.

60. *Id.*

61. *See supra* note 19.

62. *See supra* notes 56-57 and accompanying text.

63. *See* Patent Act, CAN. REV. STAT. ch. P-4, § 62 (1970). Section 62 remains in force and provides as follows:

> 62.(1) A patent or any claim in a patent may be declared invalid or void by the Exchequer Court at the instance of the Attorney General of Canada or at the instance of any interested person.
>
> (2) Where any person has reasonable cause to believe that any process used or proposed to be used or any article made, used or sold or proposed to be made, used or sold by him might be alleged by any patentee to constitute an infringement of an exclusive property or privilege granted thereby, he may bring an action in the Exchequer Court againt the patentee for a declaration that such process or article does not or would not constitute an infringement of such exclusive property or privilege.

Id. See generally I. GOLDSMITH, *supra* note 18, at 243-48.

intervene in the examination process, with the exception of the conflict procedure, which necessitated the filing by the opposing party of a conflicting patent application.[64]

5. Deferred Examination

Amended section 37(1)[65] provides that an examination of any patent application must be requested and will be conducted only upon payment of a prescribed fee. Pursuant to section 37(1) the examination may be requested not only by the applicant but also by any other person.[66] Section 37(3) provides that the applicant must request the examination within a prescribed period, if so required by the Commissioner, failing which the application is deemed to be abandoned pursuant to the amended section 37(2).[67] The section 37(2) abandonment is not fatal, and section 37(4) allows the application to be reinstated upon petition and payment of a prescribed fee, while the original filing and priority dates will be preserved.[68]

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64. The "conflict" procedure as set forth in § 45 of the Patent Act and Rules 66-74 of the Patent Rules has been abolished. *See supra* notes 16-23 and accompanying text.

65. Section 37 reads as follows:

> 37.(1) The Commissioner shall, on the request of any person made in such manner as may be prescribed and on payment of a prescribed fee, cause an application for a patent to be examined by competent examiners to be employed in the Patent Office for that purpose.
>
> (2) Subject to subsection (3), an application for a patent shall be deemed to have been abandoned if a request for an examination pursuant to subsection (1) is not made or the prescribed fee is not paid within such period as may be prescribed.
>
> (3) The Commissioner may by written notice require an applicant for a patent to make a request for examination pursuant to subsection (1) or to pay the prescribed fee within such period as may be specified in the notice, not exceeding the period prescribed under subsection (2), and if the applicant fails to comply with the notice the application for the patent shall be deemed to have been abandoned.
>
> (4) An application deemed to have been abandoned under this section may be reinstated on petition by the applicant presented to the Commissioner within such period as may be prescribed and on payment of a prescribed fee and on application so reinstated shall retain its original filing date and priority date, if any.

Amending Act, *supra* note 3, sec. 12, § 37.

66. *Id.* sec. 12, § 37(1).

67. *Id.* sec. 12, § 37(3).

68. *Id.* sec. 12, § 37(4).

D. *Amendments Relating to Issued Patents*

The amendments with respect to compulsory licensing of medicine patents should properly be included among the numerous amendments under this heading. However, because of their complexity and importance, these provisions are dealt with separately in Part II of this Article.

1. Term

Instead of a seventeen-year term of patent protection from the date the patent was issued, the amended Act introduces a twenty-year term from the date of filing of the application in Canada, if such application is filed after the coming into force of amended section 46.[69] The seventeen-year term is maintained in its original form where the application has been filed prior to that date.[70]

2. Maintenance Fees

Amended section 48[71] imposes an obligation upon the patentee to pay maintenance fees to keep his patent valid for the full term. Failure to make payment will cause the patent to lapse. This obligation applies only to patents issued after the coming into force of this section.[72] The wording of amended section 48 allows for regulations to be passed as to the modali-

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69. Section 46 of the amended Patent Act reads:

> 46. Subject to section 48, the term limited for the duration of every patent issued by the Patent Office under this Act the application for which patent was filed after the coming into force of the section shall be twenty years from the date of the filing of the application in Canada.

Id. sec. 16, § 46.

70. *Id.*

71. Section 48 of the amended Patent Act reads:

> 48.(1) A patentee of a patent issued by the Patent Office under this Act after the coming into force of this Section shall, to maintain the rights accorded by the patent, pay to the Commissioner such fees, in respect of such periods, as may be prescribed.
>
> (2) Where the fees payable by a patentee in respect of a period prescribed for the purposes of subsection (1) are not paid before the expiration of that period, the term limited for the duration of the patent shall be deemed to have lapsed on the expiration of such further period as may be prescribed.

Id. sec. 16, § 48.

72. *Id.*

ties of payment and restoration of lapsed patents.[73]

3. Re-Examination

The new section 51.1[74] provides for a re-examination of any patent claim upon request of any person and upon payment of a prescribed fee. As in the "protest" procedure against patent applications laid open to public inspection, a person requesting a re-examination must file with the Commissioner prior art consisting of patents and printed publications.[75] In addition, a requesting party must explain the pertinency of the filed prior art in a submission.[76] Interestingly enough, anticipation is the only ground upon which a re-examination may be requested, and there are no provisions in the new section that explain how a re-examination interacts with the existing procedures for a reissue[77] or a disclaimer.[78] A re-examination is conducted by an ad hoc Re-examination Board,[79] which shall determine within three months of the request whether any substantial new question is raised with re-

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73. *Id.*

74. Section 51.1 of the amended Patent Act reads:

> 51.1(1) Any person may request a re-examination of any claim of a patent by filing with the Commissioner prior art consisting of patents and printed publications and by paying a prescribed fee.
>
> (2) A request for re-examination under subsection (1) shall set forth the pertinency of the prior art and the manner of applying the prior art to the claim for which re-examination is requested.
>
> (3) Forthwith after receipt of a request for re-examination under subsection (1), the Commissioner shall send a copy of the request to the patentee of the patent in respect of which the request is made, unless the patentee is the person who made the request.

Id. sec. 18, § 51.1.

75. *Id.* sec. 18, § 51.1(1).

76. *Id.* sec. 18, § 51.1(2).

77. Section 50 of the Patent Act allows for a reissue of a patent that is deemed defective or inoperative by reason of insufficient description or specification, or by reason of the patentee claiming more or less than it had a right to claim as his invention. However, it must appear that such an error arose from inadvertent accident or mistake without any fraudulent or deceptive intention. Patent Act, CAN. REV. STAT. ch. P-4, § 50 (1970). *See generally* I. GOLDSMITH, *supra* note 18, at 169-74.

78. Section 51 of the Patent Act, which was only slightly amended, provides for the possibility of a disclaimer in respect of a claim that is too broad and consequently might lead to invalidation of the patent. The patentee is allowed to disclaim an entire claim or only part of a claim. Patent Act, CAN. REV. STAT. ch. P-4, § 51 (1970); *see also* Amending Act, *supra* note 3, sec. 17, § 51. *See generally* I. GOLDSMITH, *supra* note 18, at 175-77.

79. *See* Amending Act, supra note 3, sec. 18, § 51.2(2). Section 51.2 provides:

spect to patentability.[80] Any negative decision of the Board following this preliminary inquiry is final and not subject to appeal or review by a court.[81] Where the Board's determination is positive it will notify the patentee,[82] who will then be given a chance to file his reply within three months of such a notice.[83] The Board then proceeds to the re-examination, while allowing the patentee to propose any amendments to the patent or any new claims clarifying or conceivably narrowing the scope of the claims under re-examination. No enlargement of claims will be permitted.[84] The re-examination must be

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51.2(1) Forthwith after receipt of a request for re-examination under subsection 51.1(1), the Commissioner shall establish a re-examination board consisting of not fewer than three persons, at least two of whom shall be employees of the Patent Office, to which the request shall be referred for determination.

(2) A re-examination board shall, within three months following its establishment, determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request for re-examination.

(3) Where a re-examination board has determined that a request for re-examination does not raise a substantial new question affecting the patentability of a claim of the patent concerned, the board shall so notify the person who filed the request and the decision of the board is final for all purposes and is not subject to appeal or to review by any court.

(4) Where a re-examination board has determined that a request for re-examination raises a substantial new question affecting the patentability of a claim of the patent concerned, the board shall notify the patentee of the determination and the reasons therefor.

(5) A patentee who receives notice under subsection (4) may, within three months of the date of the notice, submit to the re-examination board a reply to the notice setting out submissions on the question of the patentability of the claim of the patent in respect of which the notice was given.

Amending Act, *supra* note 3, sec. 18, § 51.2(2).

80. *Id.* sec. 18, § 51.2(2).

81. *Id.* sec. 18, § 51.2(3). This particular subsection raises a number of issues relating to the impact such a negative finding of the Board may have upon subsequent infringement proceedings by the patentee against the requesting party, which are, however, beyond the scope of this Article.

82. *Id.* sec. 18, § 51.2(4).

83. *Id.* sec. 18, § 51.2(5).

84. Section 51.3, dealing with the re-examination proceeding, reads:

51.3(1) On receipt of a reply under subsection 51.2(5) or in the absence of any reply within three months after notice is given under subsection 51.2(4), a re-examination board shall forthwith cause a re-examination to be made of the claim of the patent in respect of which the request for re-examination was submitted.

(2) In any re-examination proceeding under subsection (1), the patentee may propose any amendment to the patent or any new claims in relation

completed within twelve months[85] and upon its completion the Board shall issue a certificate either (a) cancelling any claim of the patent which was determined unpatentable, (b) confirming any claim of the patent determined to be patentable, or (c) incorporating in the patent any proposed amendment or new claim determined to be patentable.[86] The effect of the certificate shall be retroactive with respect to any cancellation of claims.[87] On the other hand, any amendment will have effect only as of the date of the certificate, and will be valid for the unexpired term of the patent.[88] Any decision of the Re-examination Board set out in the certificate can be appealed to the Federal Court within three months of the date on which a copy of the certificate is sent to the patentee.[89] No provisions

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thereto but no proposed amendment or new claim enlarging the scope of a claim of the patent shall be permitted.

(3) A re-examination proceeding in respect of a claim of a patent shall be completed within twelve months of the commencement of the proceedings under subsection (1).

Id. sec. 18, § 51.3.

85. *Id.* sec. 18, § 51.3(3).

86. Id. sec. 18, § 51.4. Section 51.4 of the amended Patent Act reads:

51.4(1) On conclusion of a re-examination proceeding in respect of a claim of a patent, the re-examination board shall issue a certificate

(a) cancelling any claim of the patent determined to be unpatentable;

(b) confirming any claim of the patent determined to be patentable; or

(c) incorporating in the patent any proposed amended or new claim determined to be patentable.

(2) A certificate issued in respect of a patent under subsection (1) shall be attached to the patent and made part thereof by reference, and a copy of the cerfificate shall be sent by registered mail to the patentee.

(3) For the purposes of this Act, where a certificate issued in respect of a patent under subsection (1) (a) cancels any claim but not all claims of the patent, the patent shall be deemed to have been issued, from the date of grant, in the correct form;

(b) cancels all claims of the patent, the patent shall be deemed never to have been issued; or

(c) amends any claim of the patent or incorporates a new claim in the patent, the amended claim or new claim shall be effective, from the date of the certificate, for the unexpired term of the patent.

Id. sec. 18, § 51.4.

87. *Id.* sec. 18, § 51.4(3)(a).

88. *Id.* sec. 18, § 51.4(3)(c).

89. Section 51.5 of the amended Patent Act reads:

51.5(1) Any decision of a re-examination board set out in a certificate issued under subsection 51.4(1) is subject to appeal by the patentee to the Federal Court.

(2) No appeal may be taken under subsection (1) after three months

have been made governing the status of the patent pending appeal. A re-examination now provides a third party with the opportunity to set aside a patent without having to institute legal proceedings in the Federal Court of Canada for impeachment of a patent.

4. Miscellaneous and Consequential Amendments

Miscellaneous or consequential amendments include those designed to clarify or to remove inconsistencies in certain provisions of, or that flow logically from, some of the fundamental changes in the Patent Act. It is impracticable to list them all in this Article. Thus, only the important ones will be mentioned.

Potentially the most important miscellaneous amendment is section 12(1)(i), which grants regulatory authority to the Governor in Council to make rules or regulations for carrying into effect the terms of the Patent Cooperation Treaty.[90] This power is granted notwithstanding any other provisions in the Patent Act. Such authority will likely allow the Governor in Council, under the guise of making rules or regulations, to amend the Patent Act to comply with the provisions of the Treaty—an extraordinary power indeed.

Also important is the abolition of the marking provisions in sections 24 and 77 of the Patent Act. Pursuant to section 24, every patentee was required, when possible, to mark each patented article by the notice "Patented," followed by the year in which the patent issued. Failure to comply with this requirement was punishable by a fine not exceeding $100, and, upon failure to pay the fine, by imprisonment for not more than two months. While the marking requirements have been abolished, the penalty for false marking as provided in section 78 of the Patent Act remains in effect. Any person who falsely

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from the date a copy of the certificate is sent by registered mail to the patentee.

Id. sec. 18, § 51.5.

90. Section 12(1)(i) of the amended Patent Act reads:

> 12.(1) The Governor in Council may make rules or regulations . . .
> (i) notwithstanding anything in this Act, for carrying into effect the terms of the Patent Cooperation Treaty done at Washington on June 19, 1970 . . . .

Id. sec. 3, § 12(1)(i).

uses a patent notice or the name of a patentee with the intent to counterfeit, imitate an identification of the patentee, or deceive the public as to the origin of an article or to its being patented in Canada, continues to be liable for fines of up to $200 or imprisonment for up to three months, or both.

Under the heading of consequential amendments, the abolition of the caveat procedure pursuant to section 74, which was repealed, is particularly noteworthy. The caveat procedure protected an inventor by allowing him immediately to file a patent application for an invention that was not yet sufficiently perfected. Such an inventor (and no one else) could file a caveat describing the invention as fully as possible. A caveat was effective for only one year. During that period the subsequent filing of a patent application by a second inventor for the invention disclosed in the caveat required the Commissioner to notify the first inventor. The first inventor, in turn, was entitled to file his application within three months after the date of the notice. The Commissioner could then declare a "conflict" and trigger the general rules with respect to conflicting applications. The introduction of the first-to-file system and the resulting elimination of the conflict mechanism abolished the caveat procedure.

Other important consequential amendments relate to the retroactive enforceability of the exclusive rights of the patentee. In addition to damages for infringement after the grant of the patent, amended Section 57[91] allows a patentee to claim reasonable compensation for any damages sustained by reason of acts by the infringing party as of the date on which the patent application was laid open to public inspection. Amended

91. Section 57(1) of the amended Patent Act reads:

> 57.(1) Any person who infringes a patent is
> (a) liable to the patentee and to all persons claiming under the patentee for all damages sustained by the patentee or by any such person, after the grant of the patent, by reason of such infringement; and
> (b) liable to pay reasonable compensation to the patentee and to all persons claiming under the patentee for any damages sustained by the patentee or by any such person by reason of any act on his part, after the application for the patent became open to the inspection of the public under section 10 and before the grant of the patent, that would have constituted an infringement of the patent if the patent had been granted on the day the application became open to the inspection of the public under that section.

Id. sec. 21, § 57.(1).

Section 58,[92] on the other hand, provides that the rights of a person, who has purchased, constructed, or acquired the article embodying the invention prior to the date on which the patent application was laid open to public inspection, to use or vend such an article are unaffected by the subsequent grant of the patent. However, subject to the provisions of amended section 28(1) with respect to prior art,[93] such a personal right will not affect the validity of the patent.

Prior to the amendment, the cut-off date for the purposes of both sections 57 and 58 was the date on which the patent was issued, because that was the beginning of the patent term and also the first opportunity for the public to inspect the invention. The beginning of the term and the publication of the invention no longer coincide. As a result, Parliament seems to have made a policy decision that any third-party use of an unpublished invention must be presumed to be in good faith and should not be penalized, notwithstanding the retroactivity of the term.

The final consequential amendment that merits discussion is the repeal of section 63.[94] This section enabled a prior inventor to have set aside either a patent for the same invention obtained by a subsequent inventor or a claim in such a patent. This is a natural consequence of the introduction into the Ca-

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92. Section 58 of the amended Patent Act reads:

> 58. Every person who, before an application for a patent becomes open to the inspection of the public under section 10, has purchased, constructed or acquired the invention for which a patent is afterwards obtained under this Act, has the right of using and vending to others the specific article, machine, manufacture or composition of matter patented and so purchased, constructed or acquired without being liable to the patentee or the legal representatives of the patentee for so doing; but the patent shall not, as regards other persons, be held invalid by reason of such purchase, construction or acquisition or use of the invention by the person first mentioned, or by those to whom that person has sold it, unless it was purchased, constructed, acquired or used before the date of filing of the application or, in the case of an application to which section 29 applies, before the priority date of the application, and in consequence whereof the invention was disclosed in such a manner that it became available to the public in Canada or elsewhere.

Id. sec. 22, § 58.

93. *See supra* notes 25-33 and accompanying text.

94. *See* Amending Act, *supra* note 3, sec. 23, *repealing* Patent Act, CAN. REV. STAT. ch. P-4, § 63 (1970).

nadian Patent Act of the first-to-file rule in the amended section 28(1).

II. *AMENDMENTS RELATING TO COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS*

A. *Deferrals of Compulsory Licensing Rights and Related Amendments*

The Patent Act contains a number of compulsory licensing provisions designed to ensure the operation of patents in Canada. Section 68 of the Patent Act empowers the Commisioner to grant to an applicant a compulsory license where one or more abuses of exclusive rights by patentees listed in section 67 of the Act have been established,[95] and upon such terms as the Commissioner may deem expedient.[96] The Commissioner may grant such a compulsory license only after the expiration of three years from the date of the grant of the patent.[97] The reason for imposing the compulsory license system is that a patentee cannot be allowed to impede trade by use of the monopoly power of his patent. Additionally, the Federal Government may, at any time, use any patented invention upon paying the patentee reasonable compensation as determined by the Commissioner.[98] These compulsory licensing provisions remain unchanged.

However, the Amending Act effects profound changes in the provisions of section 41 of the Patent Act with respect to

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95. Section 67 makes the following acts abusive:

a) failure to make or to work a patented invention;

b) importation to the detriment of the country's trade or industry, or the home manufacturer;

c) failure to meet the demand to an adequate extent and on reasonable terms;

d) refusal to grant license upon reasonable terms if that denial is contrary to public interest and results in prejudice to the trade or industry of Canada or of particular concerns trading in Canada;

e) attachment of unfair conditions to the acquisition, use or working of the patented article or process;

f) use of a patent for a process that prejudices the manufacture, use or sale of materials used in that process. Patent Act, CAN. REV. STAT. ch. P-4, § 67(2) (1970).

For detailed analysis of the above provisions of the Patent Act see I. GOLDSMITH, *supra* note 18, at 253-60.

96. Patent Act, CAN. REV. STAT. ch. P-4, § 68 (1970).

97. *Id.* § 67(1).

98. *Id.* § 19.

compulsory licenses of food and drug patents.[99] The amended provisions are quite lengthy and complicated, and can be best understood in light of a brief summary of the existing compulsory licensing system related to pharmaceuticals.

According to section 41(3),[100] it is possible for anyone to obtain, upon application in a prescribed form,[101] a license to use a patented invention for the *manufacture* of food or medicine. The terms of the license, including the amount of royalty payable, are determined by the Commissioner. Furthermore, the provisions of section 41(4), enacted in 1969, provide for a similar license to be granted for the purposes of the *importation* of medicine under patent.[102] The compulsory license is available immediately after the issuance of the patent, and the Commissioner is under a statutory obligation to grant a compulsory license to any person, absent good cause for denial.[103] No proof of abuse of the patent is required. The Department of National Health and Welfare must be notified by the Commissioner of any application for a compulsory license,[104] and it can influence the Commissioner's decision by exercising its right to make submissions.[105] An application for a compulsory license must be decided upon by the Commissioner within eighteen months after the date of service upon the patentee.[106] However, the applicant may apply for an interim license after the expiration of six months from the date of service[107] for an initial period not exceeding six months.[108] Such an interim license is renewable for the further period or periods not exceeding a total of six months.[109]

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99. The compulsory licensing provisions with respect to manufacturing in Canada of patented food or medicine inventions have been part of the Patent Act since 1923. These provisions were substantially amended in 1969 by provisions expressly authorizing the grant of compulsory license with respect to the importation of pharmaceutical products protected by Canadian patents. *See* Act to Amend the Patent Act, the Trade Marks Act and the Food and Drugs Act, ch. 49, sec. 1, 1968-1969 Can. Stat. 1137, 1137-42.

100. Patent Act, CAN. REV. STAT. ch. P-4, § 41(3) (1970).

101. *See* Patent Rules, CAN. CONS. REGS. ch. 1250, rule 118 (1978), as amended.

102. Patent Act, CAN. REV. STAT. ch. P-4, § 41(4) (1970).

103. *Id.* § 41(3).

104. *Id.* § 41(13).

105. Patent Rules, CAN. CONS. REGS. ch.1250, rule 124(2), (3) (1978).

106. Patent Act, CAN. REV. STAT. ch. P-4, § 41(15) (1970).

107. *Id.* § 41(5).

108. *Id.* § 41(9).

109. *Id.*

The rationale for the compulsory licensing system is found in the Patent Act itself, which states in section 41(4) that "the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention."[110]

It is widely accepted in the pharmaceutical industry that in practice the "lowest possible price" portion of the statutorily stated purpose of the compulsory licensing system has been attained, while the "due reward" portion has not been fulfilled.[111] In fact it appears that the Commissioner had developed a fairly standard form of compulsory license granted under the provisions of section 41(4)[112] that was available virtually on demand.[113] The royalty rate was fixed in almost all cases at four percent of the licensee's net selling price of the licensed medicine in the final dosage form.[114] Because the Commissioner has been very reluctant to find "a good reason" for not granting the license[115] and the applicant has to comply only with a relatively simple procedural rule,[116] compulsory

110. *Id.* § 41(4).

111. Manson, *The Impact of Compulsory Licensing on Pharmaceutical Research*, 1 PAT. & TRADEMARK INST. CAN. REV. 164 (1984).

112. *See* I. GOLDSMITH, *supra* note 18, at 161-62.

113. *See* Murphy, *Pharmaceutical Compulsory Licensing*, 3 PAT. & TRADEMARK INST. CAN. REV. 11, 15-18 (1986).

114. The four percent royalty rate was first fixed in 1969 in Frank W. Horner Ltd. v. Hoffmann-La Roche Ltd., 61 C.P.R. 243, 245 (Comm'r Pats. 1970), with respect to the drug Diazepam. Even though its origins are unclear the four percent royalty rate has been consistently applied hence, regardless of particular circumstances surrounding the research and development of drugs considered. It was only recently that the Federal Court of Appeal in American Home Products Corp. v. ICN Canada Ltd., 5 C.P.R.3d 1, 9-10 (Fed. Ct. App.), *leave to appeal to the Supreme Court of Canada denied*, 7 C.P.R.3d 144 (Sup. Ct. 1985), indicated that the Commissioner should determine the fair royalty rate based on the evidence from both applicant and the patentee and on the case-by-case basis.

115. In the Commissioner's view, lower prices of drugs resulting from grants of compulsory licenses are in the public interest, thus, even when a material misrepresentation was made in the application, it was not found to be a "good reason" for denying it. *See, e.g.*, Gruppo Lepetit S.p.A. v. ICN Can. Ltd., [1978] 1 F.C. 35, 41-42, 33 C.P.R.2d 1, 6 (1977). Also the bankruptcy of an applicant has been found to be sufficient reason to deny the compulsory license. *See* Gilcross Ltd. v. Merck & Co., 4 C.P.R.2d 203 (Comm'r Pats. 1972). The courts consistently have refused to intervene and the Commissioner's decisions have been maintained on the basis of his discretionary powers. *See, e.g.*, Smith, Kline & French Laboratories Ltd. v. Frank W. Horner Ltd., 79 C.P.R.2d 1 (Fed. Ct. 1983).

116. Patent Rules 117-129 set out the procedure to be followed by the appli-

licenses under section 41(4) were issued almost automatically to any applicant at a fixed four-percent royalty rate. It should be noted that any manufacture, importation, or sale of medicine in Canada is subject to the requirements of the Food and Drugs Act[117] and the regulations thereunder. The grant of a compulsory license does not exempt the applicant from such requirements.[118] The applicant, just like any other manufacturer, must obtain a Notice of Compliance[119] ("NOC") from the federal authorities before releasing any drug on the Canadian market. No such requirements exist with respect to drugs exported from Canada.

The impact of compulsory licensing on pharmaceutical research and development in Canada has been quite serious. Apparently this was an important factor in the closing of a number of Canadian research and development pharmaceutical laboratories and in a loss of related employment.[120] The Federal Government, experiencing increasing pressure to strike a better balance between "the lowest possible price" to consumers and "due reward" to the inventors, eventually conducted an inquiry into the matter, which resulted in the Report of the Commission of the Inquiry on the Pharmaceutical Industry[121] (the "Eastman Report"). The Eastman Report, published in May 1985, set out a number of recommendations with respect to the compulsory licensing of drug patents, and the present amendments are largely the result of these recommendations.[122] The Federal Government decided to maintain the compulsory licensing system, however, in a substantially modi-

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cants. An applicant must file an application in a prescribed form accompanied by an affidavit verifying all material facts alleged in the application. The Commissioner then examines the application and if he does not see any good reason for not granting the license he instructs the applicant to serve a copy of his application upon the patentee. The patentee then has two months to file a counterstatement, supported by an affidavit. The Commissioner also notifies the Department of National Health and Welfare which can intervene, which the Department apparently has never done. Patent Rules, CAN. CONS. REGS. ch. 1250, rules 117-129 (1978). An oral hearing may be held, although this is entirely within the Commissioner's discretion.

117. CAN. REV. STAT. ch. F-27 (1970).

118. Patent Act, CAN. REV. STAT. ch. P-4, § 41(16) (1970).

119. A Notice of Compliance in respect of medicine is issued pursuant to § C.08.004 of the Food and Drug Regulations, CAN. CONS. REGS. ch. 870 (1978).

120. *See* Manson, *supra* note 110, at 168-69.

121. H. EASTMAN, R. FRASER, J. LASKIN & W. KENNEDY, REPORT OF THE COMMISSION OF INQUIRY ON THE PHARMACEUTICAL INDUSTRY (1985).

122. *See* Hon. Harvie Andre, Minister of Consumer Corporate Affairs, Canada,

fied form. The purpose of the revamped system is to encourage multinational corporations to spend more money in Canada on genuine pharmacological research and development, thus stimulating the manufacture of medicine in Canada, and to maintain control over the prices of newly-developed medicines through a review board.[123] In return for the increased protection, the Federal Government extracted commitments from the pharmaceutical industry for new investment in Canada of more than Can. $800,000,000.[124]

The basic principles of the compulsory licensing system have been preserved and the licenses will continue to be issued by the Commissioner in the same manner. There is no waiting period for the compulsory license applications, which may be made, at least in theory, at any time. Furthermore, there is no change in the amended Patent Act expressly affecting the four-percent royalty rate. The new rules found in section 41.11 of the amended Patent Act do not affect generic drugs currently on the market under compulsory licenses. These rules do, however, provide for a deferral, for a certain period, of rights that a holder of a compulsory license may otherwise have.[125]

Notes for Opening Remarks to Legislative Committee on Bill C-22 to the House of Commons 5 (Dec. 16, 1986).

123. *Id.* at 3-6.

124. Consumers and Corporate Affaires Canada, Information CACC No. 192 25026 E 87-04 (available at the *Fordham International Law Journal* office).

125. Section 41.11 of the amended Patent Act reads as follows:

> 41.11(1) Subject to this section but notwithstanding anything in section 41 or in any licence granted under that section, no person shall under a licence granted under that section in respect of a patent for an invention pertaining to a medicine, regardless of when the licence was granted, have or exercise any right,
>
> (a) where the invention is a process, to import the medicine in the preparation or production of which the invention has been used, if the medicine is for sale for consumption in Canada; or
>
> (b) where the invention is other than a process, to import the invention for medicine or for the preparation or production of medicine, if the medicine is for sale for consumption in Canada.
>
> (2) The prohibition under subsection (1) expires in respect of a medicine
>
> (a) seven years after the date of the notice of compliance that is first issued in respect of the medicine, where, on June 27, 1986, the notice of compliance has been so issued and
>
> (i) a licence has been granted under section 41 in respect of the medicine but no notice of compliance has been issued to the licensee in respect of the medicine, or
>
> (ii) a notice of compliance in respect of the medicine has been is-

The period of exclusive protection for the patentee may vary according to the date of issuance of a NOC and to whether the compulsory license is sought for manufacture or for importation into Canada.

It is interesting to note that such deferrals, inasmuch as they do not pertain to inventions made in Canada, do not cover medicines manufactured in Canada for sale and consumption abroad. No NOC is required for medicines exported from Canada and it will continue to be relatively easy to obtain compulsory licenses to manufacture medicines patented in Canada (but invented elsewhere) for export.

Under the provisions of the new section 41.11, the right to *import* a patented medicine for sale and consumption in Canada by a person who did not have, as of June 27, 1986, both a section 41 compulsory license and a NOC will be deferred for the following periods after the date of issuance of the first NOC:

(a) Seven years where the person (other than patentee) had either a compulsory license or a NOC issued but not both, as of June 27, 1986;[126] or

(b) Eight years where neither a compulsory license nor a NOC had issued on or before June 27, 1986, to anyone but the patentee;[127] or

(c) Ten years where the first NOC has been issued after

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sued to a person other than the patentee but no licence under section 41 in respect of the medicine has been granted to the person;

(b) eight years after the date of the notice of compliance that is first issued in respect of the medicine, where, on June 27, 1986, the notice of compliance has been so issued and neither a licence under section 41 has been granted in respect of the medicine nor a notice of compliance has been issued in respect of the medicine to a person other than the patentee; and

(c) ten years after the date of the notice of compliance that is first issued in respect of the medicine where that notice of compliance is issued after June 27, 1986.

(3) Subsection (1) does not apply in respect of a licence pertaining to a medicine after the date of expiration of the first patent granted in Canada in respect of that medicine.

(4) Subsection (1) does not apply in respect of any licence pertaining to a medicine where on June 27, 1986, a licence has been granted in respect of the medicine and a notice of compliance in respect of the medicine has been issued to the licensee.

Amending Act, *supra* note 3, sec. 15, § 41.11.

126. *Id.* sec. 15, § 41.11(2)(a).

127. *Id.* sec. 15, § 41.11(2)(b).

June 27, 1986.[128]

Therefore, the maximum protection against importation of patented medicines existing as of June 27, 1986, is eight years, while for any new medicines developed after that date the maximum period of protection is ten years. However, it is provided that any such deferral will cease to apply upon the expiration of the first Canadian patent for the medicine in question.[129] In addition, no deferral exists with respect to the importation for sale and consumption in Canada of medicines where a person (other than patentee) obtained both a compulsory license and a NOC prior to June 27, 1986.[130]

Under the provisions of new section 41.14, the right to *manufacture* a patented medicine for sale and consumption in Canada by a person who had obtained a compulsory license in respect thereof will be deferred for a period of seven years after the date of the first NOC if such NOC is issued after June 27, 1986.[131] The deferral of manufacturing rights is subject to the same limitations that apply to importation rights deferrals.

The deferral rules differ somewhat with respect to medicine inventions made and developed in Canada.[132]

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128. *Id.* sec. 15, § 41.11(2)(c).

129. *See id.* sec. 15, § 41.11(3).

130. *See id.* sec. 15, § 41.11(4).

131. Section 41.14 of the Amended Patent Act reads as follows:

> 41.14(1) Notwithstanding anything in section 41 or in any licence granted under that section, where the notice of compliance that is first issued in respect of a medicine is issued after June 27, 1986, no person shall, under a licence granted under that section in respect of a patent for an invention pertaining to the medicine, have or exercise any right,
>
> (a) where the invention is a process, to use the invention for the preparation or production of medicine, or
>
> (b) where the invention is other than a process, to make or use the invention for medicine or for the preparation or production of medicine for sale for consumption in Canada, until the expiration of seven years after the date of that notice of compliance.
>
> (2) Subsection (1) does not apply in respect of a licence pertaining to a medicine after the date of expiration of the first patent granted in Canada in respect of that medicine.

Id. sec. 15, § 41.14.

132. *See id.* sec. 15, § 41.16. Section 41.16 of the amended Patent Act reads as follows:

> 41.16(1) Where on application in prescribed form to the Commissioner, a patentee of an invention that is a medicine, satisfies the Commissioner, on such evidence and information as the Commissioner deems appropriate, that the medicine has, to such extent as is prescribed, been in-

Where the patentee satisfies the Commissioner that the

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vented and developed in Canada, the Commissioner shall, by order, where no licence under section 41 has been granted in respect of the invention, declare that the medicine is a medicine to which this section applies.

(2) The Commissioner shall not grant a licence under section 41 in respect of an invention that is a medicine to which this section applies except a licence for the making of the medicine.

(3) Notwithstanding anything in section 41 or in any licence granted under that section, no person shall under a licence granted under that section in respect of a patent for an invention that is a medicine to which this section applies, make the medicine

(a) until the expiration of seven years after the date of the notice of compliance that is first issued in respect of the medicine; and

(b) unless the Commissioner makes an order under subsection (4) or (10) in respect of the medicine.

(4) Where, on application in prescribed form to the Commissioner by the holder of a licence granted under section 41 in respect of a medicine to which this section applies and after providing the patentee to which the licence relates with a reasonable opportunity to be heard, the Commissioner finds that the patentee is not, after the seven years referred to in paragraph (3)(a) and at the time of the application is being considered, making the medicine in Canada for the purposes of completely or substantially supplying the Canadian market for that medicine, the Commissioner shall forthwith, by order, declare that, effective on the coming into force of the order, a holder of a licence granted under section 41 to make that medicine may under the license make that medicine.

(5) Every patentee of an invention that is a medicine to which this section applies shall provide the Board with

(a) in such form and manner and at such times and subject to such conditions as are prescribed, information and documents identifying the medicine and concerning

(i) the price at which the medicine is being sold or has been sold in any market in Canada and elsewhere, and

(ii) the costs of making and marketing the medicine where such information is available to the patentee in Canada or is within the knowledge or control of the patentee; and

(b) such additional information or documents with respect to the matters referred to in paragraph (a) as the Board may require, within such time as the Board may specify.

(5.1) Where, in the opinion of the Board, a patentee of an invention that is a medicine has, within such period as is prescribed, increased the price at which the medicine is sold in any market in Canada by a percentage in excess of the percentage increase in the Consumer Price Index, as published by the Statistics Canada under the authority of the *Statistics Act*, for that period, the Board may, by notice by writing, require the patentee to provide the Board with such information and documents concerning the costs of making and marketing the medicine as the Board may specify and as is available to the patentee in Canada or is within the knowledge or control of the patentee, and on the receipt of any such notice, the patentee shall comply therewith within such time as the Board may specify.

(6) Where, after providing every person against whom an order of the

Board under this subsection is proposed to be made with a reasonable opportunity to be heard, the Board finds that

(a) a patentee in respect of a medicine to which this section applies has failed to provide information or documents in accordance with subsection (5) or (5.1),

(b) the medicine is being sold in any market in Canada at a price that in the opinion of the Board is excessive, or

(c) the patentee has not complied with a previous order of the Board made under paragraph (e) in respect of that medicine

the Board may, by order,

(d) declare that, effective on the coming into force of the order, the medicine ceases to be a medicine to which this section applies, or

(e) where the Board makes a finding under paragraph (b) or (c) and does not deem it necessary to make an order under paragraph (d), direct the patentee to cause the price at which the patentee sells the medicine in the market referred to in paragraph (b) to be reduced to such extent as is specified in the direction so that in the maximum price at which the medicine is sold pursuant to the direction is not, in the opinion of the Board, excessive.

(7) A patentee shall commence compliance with an order made under paragraph (6)(e) within one month after the date of the order or within such greater period after the date as the Board determines is practical and reasonable having regard to the circumstances of the patentee.

(8) Subsections 41.15(5) to (8) apply, with such modifications as the circumstances require, in respect of a manner referred to in subsection (6) of this section that comes before the Board under this section.

(9) Every patentee of an invention that is a medicine to which this section applies shall provide the Commissioner with

(a) in such form and matter and at such times and subject to such conditions as are prescribed, information and documents concerning the activity of making the medicine; and

(b) such additional information or documents with respect to the matter referred to in paragraph (a) as the Commissioner may require, within such time as the Commissioner may specify.

(10) Where, after providing every person against whom an order of the Commissioner under this subsection is proposed to be made with a reasonable opportunity to be heard, the Commissioner finds that a patentee in respect of a medicine to which this section applies has failed to provide information or documents in accordance with subsection (9), the Commissioner may, by order, declare that, effective on the coming into force of the order, any holder of a licence granted under section 41 to make that medicine may under that licence make that medicine.

(11) Where an order is made under subsection (4), paragraph (6)(d) or subsection (10), the Commissioner shall forthwith inform the holder of each licence granted under section 41 in respect of any invention pertaining to the medicine to which the order relates of the terms of the order.

(12) Where an order is made under paragraph (6)(d) in respect of a medicine, the prohibitions set out in subsections 41.11(1) and 41.14(1) cease to apply in respect of the medicine effective on the date of the order.

Id. sec. 15, § 41.16. Note that there is no definition of "medicine invented and developed in Canada"; the criteria are to be prescribed by regulation.

medicine has been so invented and developed,[133] the latter may declare the invention in question to be entitled to the benefit of new section 41.16, thus according it preferential treatment.[134] Such preferential treatment entails the grant of a compulsory license only for *manufacture* of the medicine for sale and consumption in Canada. The grant of a manufacturing license will be deferred for a period of at least seven years after the issuance of the first NOC,[135] but the deferral may be extended, presumably until the expiration of the patent, provided that the patentee is making the medicine in Canada for the purposes of completely or substantially supplying the Canadian market for that medicine.[136] The preferential treatment may be forfeited, and the Commissioner may permit the exercise of a manufacturing and the grant of an importation compulsory license, should the patentee fail to provide the Commissioner with information and documents pertaining to the patentee's making of the medicine under section 41.16 protection in Canada[137] as prescribed by new section 41.16(9).[138] The Commissioner must conduct a public hearing[139] in these matters to give the patentee a reasonable op-

133. *See id.* sec. 15, § 41.16(1).

134. This is apparently in violation of article 2(1) of the Paris Convention containing the basic principle of "equal national treatment" of foreign applicants and patentees in the same manner as the nationals of each member-state of the Union, as well as in violation of article 2(2) of the Paris Convention, which provides that no condition as to the possession of a domicile or establishment in the country where protection is claimed may be required of persons entitled to the benefits of the Union. *See* Paris Convention, *supra* note 20, arts. 2(1), 2(2), 13 U.S.T. at 26, T.I.A.S. No. 4931, at 26.

135. Amending Act, *supra* note 2, sec. 15, § 41.16(3).

136. *Id.* sec. 15, § 41.16(4).

137. *Id.* sec. 15, § 41.16(10).

138. *Id.* sec. 15, § 41.16(9).

139. *See id.* sec. 15, § 41.17. Section 41.17 of the amended Patent Act reads as follows:

> 41.17(1) A hearing by the Board or Commissioner under section 41.15 or 41.16 shall be public unless the Board or Commissioner is satisfied on representations made by the person to whom the hearing relates that specific, direct and substantial harm would be caused to the person by the disclosure of the information or documentation to which the hearing relates.
>
> (2) Subject to subsection (3), information and documentation provided to the Board or Commissioner under section 41.15 or 41.16 is privileged and shall not, without the authorization of the person who provided the information and documentation, knowingly be or be permitted to be communicated, disclosed or made available by any person who has obtained that information and documentation pursuant to this Act unless the information

portunity to be heard.[140] However, information provided to the Commissioner under section 41.16 is privileged unless disclosed at a public hearing.[141] It is within the Commissioner's discretion not to conduct a hearing in public if he is satisfied that a specific, direct, and substantial harm would be caused to the person to whom the hearing relates.[142]

Because no right of appeal from the Commissioner's decision under section 41.16 is provided in the amended Act, it would seem that a decision of the Commissioner is final. Nevertheless, the Commissioner's decision is probably reviewable by the Federal Court of Canada under its general powers as provided in sections 18 and 28 of the Federal Court Act.[143] Under these provisions, the Federal Court may review purely administrative decisions of any federal board, commission, or other tribunal, and judicial or quasi-judicial decisions of the same bodies. The scope of any such review would, however,

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and documentation is disclosed at a public hearing held by the Board or Commissioner under that section.

(3) Information and documentation referred to in subsection (2) that is obtained

(a) by the Commissioner may be used by the Commissioner for the purpose of the report referred to in subsection (4) and may be communicated, disclosed or made available by the Commissioner to a person engaged in the administration of this Act under the direction of the Commissioner; or

(b) by the Board

(i) may be communicated, disclosed or made available by the Board to

(A) a person engaged in the administration of this Act under the direction of the Board, or

(B) the Minister of National Health and Welfare and a minister responsible for health in a province and any of their officials to be used solely for the purposes of making representations referred to in subsection 41.15(8), and

(ii) may be used by the Board for the purpose of the summary referred to in section 41.24.

(4) The Commissioner shall annually prepare and submit to the Minister a report on the Commissioner's activities under section 41.16 during the year in respect of which the report is made.

Id. sec. 15, § 41.17.

140. *See id.* sec. 15, § 41.16(10).

141. *Id.* sec. 15, § 41.17(2).

142. *See id.* sec. 15, § 41.17(1).

143. The Federal Court Act, CAN. REV. STAT. (2d Supp.) ch. 10, §§ 18, 29 (1970).

be severely curtailed by the discretionary nature of the Commissioner's decision.

The safeguard provisions also merit examination. New section 41.12[144] determines that all compulsory licenses granted, and all pending applications for compulsory licenses filed before the coming into force of amended section 41, retroactively become licenses to import *and* manufacture.[145] This result obtains regardless of the fact that the application or grant of the compulsory license may have included only the right to import. It is not entirely clear whether the deeming provisions of section 41.12 are subject to the deferrals provided for elsewhere in section 41.

Section 41.13[146] provides that where the prohibition as set out in section 41.11(1) does not apply (because there is no deferral) to a process for the preparation or production of a medicine, no deferral will be granted to a subsequent patent relating to a different process for a preparation or production of substantially the same medicine. It is submitted that the effect of section 41.13 is to bring back into the Canadian patent law, at least to a certain limited degree, the concept of the first-to-invent rule, which was elsewhere replaced with the first-to-file rule. Furthermore, such protection does not seem necessary because a holder of a compulsory license in respect of one

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144. Section 41.12 of the amended Patent Act reads:

> 41.12 Notwithstanding anything in section 41 or in any application for a licence made or a licence issued under that section prior to the coming into force of this section, every licence so applied for or granted in respect of a patent for an invention pertaining to a medicine shall be deemed, for the purposes of this Act, to have been applied for or granted to authorize, in addition to any other matters applied for or authorized thereby,
>
> (a) where the invention is a process, the use of the invention for the preparation or production of medicine; or
>
> (b) where the invention is other than a process, the making or use of the invention for medicine or for the preparation or production of medicine.

Amending Act, *supra* note 3, sec. 15, § 41.12.

145. *Id.* sec. 15, § 41.12(b).

146. Section 41.13 of the amended Patent Act reads as follows:

> 41.13 Where an invention in respect of which subsection 41.11(1) does not apply is a process for the preparation or production of medicine, nothing in that subsection applies in respect of a subsequent invention that is a process for the preparation or production of substantially the same medicine.

Id. sec. 15, § 41.13.

patent surely would not be infringing on the subsequent patent by his own manufacture of the medicine according to the original process. However, the holder of a compulsory license formerly would have had to overcome the reversed infringement proof of section 41(2).[147] It is this exposure to potential litigation in which such holder would have had to bear the onus of proving that a different process was used—a result that section 41.13 is probably designed to avoid. Section 41.13 would perhaps be more appropriate if its scope were narrowed to benefit only the original holder of the compulsory license and not any other potential applicant for a compulsory license in respect of a newly developed process wishing to avoid the statutory deferrals.

B. *Patented Medicine Prices Review Board*

As a balancing mechanism designed to offset the increased "due reward" portion of the compulsory licensing system against the lowest possible price for the consumers, the amended Patent Act establishes a regulatory board called the Patented Medicine Prices Review Board.[148] Section 41.18 also sets out guidelines for the Board's composition and adminis-

147. Section 41(2) of the Patent Act reads as follows:

(2) In an action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

Patent Act, CAN. REV. STAT. ch. P-4, § 41(2) (1970).

148. Section 41.18 of the amended Patent Act reads as follows:

41.18(1) There is hereby established a Board to be known as the Patented Medicine Prices Review Board consisting of not more than five members to be appointed by the Governor in Council.

(2) Each member of the Board shall hold office during good behaviour for a period of five years, but may be removed at any time by the Governor in Council for cause.

(3) The Governor in Council shall appoint one of the members to be chairman of the Board and one of the members to be vice-chairman of the Board.

(4) The chairman is the chief executive officer of the Board and has supervision over direction of the work of the Board including

(a) the apportionment of the work among the members thereof and the assignment of members to sit at hearings of the Board and to preside thereat; and

(b) generally the conduct of the work of the Board, the management of its internal affairs and the duties of the staff of the Board.

(5) If the chairman is absent or incapacitated or if the office of the

tration.[149] The Board's role is essentially twofold. The first aspect, directed toward individual patentees, is to provide a necessary measure of consumer protection in the pharmaceutical market by reviewing the prices of medicine put on the market by the patentees. This role of the Board is complemented by the added responsibilties and powers bestowed upon the Commissioner of Patents with respect to patented inventions invented and developed in Canada under the provisions of the new section 41.16.[150]

The second facet, which is aimed at the pharmaceutical industry in general, is to collect information from patentees concerning their revenues from sales of medicines, and, more significantly, concerning their research and development expenditures relating to medicine.

1. Review of Prices of Medicine

Under new section 41.15[151] every patentee of an invention

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chairman is vacant, the vice-chairman has all the powers and functions of the chairman during the absence, incapacity or vacancy.

(6) The members of the Board shall be paid such remuneration as may be fixed by the Governer in Council and are entitled to be paid reasonable travel and living expenses incurred by them in the course of their duties under this Act while absent from their ordinary place of residence.

Amending Act, *supra* note 3, sec. 15, § 41.18.

149. *See id.*

150. *Id.* sec. 15, § 41.16, *quoted supra* note 132.

151. Section 41.15 of the amended Patent Act reads as follows:

41.15(1) Every patentee of an invention pertaining to a medicine shall provide the Board with

(a) in such form and manner and at such times and subject to such conditions as are prescribed, information and documents identifying the medicine and concerning

(i) the price at which the medicine is being sold or has been sold in any market in Canada and elsewhere, and

(ii) the costs of making and marketing the medicine, where such information is available to the patentee in Canada or is within the knowledge or control of the patentee; and

(b) such additional information or documents with respect to the matters referred to in paragraph (a) as the Board may require, within such time as the Board may specify.

(1.1) Where, in the opinion of the Board, a patentee of an invention pertaining to a medicine has, within such period as is prescribed, increased the price at which the medicine is sold in any market in Canada by a percentage in excess of the percentage increase in the Consumer Price Index, as published by Statistics Canada under the authority of the *Statistics Act*, for that period, the Board may, by notice in writing, require the patentee to

pertaining to a medicine is required to provide the Board with

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provide the Board with such information and documents concerning the costs of making and marketing the medicine as the Board may specify and as is available to the patentee in Canada or is within the knowledge or control of the patentee, and on the receipt of any such notice, the patentee shall comply therewith within such time as the Board may specify.

(2) Where, after providing every person against whom an order of the Board under this subsection is proposed to be made with a reasonable opportunity to be heard, the Board finds that

(a) a patentee in respect of a medicine has failed to provide information or documents in accordance with subsection (1) or (1.1),

(b) a medicine pertaining to a patented invention is being sold in any market in Canada at a price that in the opinion of the Board is excessive, or

(c) the patentee has not complied with a previous order of the Board made under paragraph (e) in respect of that medicine, the Board may, by order,

(d) direct that, effective on the coming into force of the order, subsection 41.11(1) ceases to apply in respect of either or both of

(i) the patent for the invention pertaining to the medicine, or

(ii) any other patent of the patentee for an invention that pertains to one other medicine, whether granted before or after the coming into force of the order, or

(e) where the Board makes a finding under paragraph (b) or

(c) and does not deem it necessary to make an order under paragraph (d), direct the patentee to cause the price at which the patentee sells the medicine in the market referred to in paragraph (b) to be reduced to such extent as is specified in the direction so that the maximum price at which the medicine is sold pursuant to the direction is not, in the opinion of the Board, excessive.

(3) A patentee shall commence compliance with an order made under paragraph (2)(e) within one month after the date of the order or within such greater period after that date as the Board determines is practical and reasonable having regard to the circumstances of the patentee.

(4) Where an order is made under paragraph (2)(d) in respect of a medicine, the prohibition set out in subsection 41.14(1) ceases to apply in respect of the medicine effective on the date of the order.

(5) For the purposes of this section, in determining whether or not a medicine is being sold in any market in Canada at a price that is excessive, the Board shall, to such extent as the Board deems reasonable, take into consideration the following factors:

(a) the prices at which the patentee sold the medicine during the five years immediately preceding the determination;

(b) the prices of other medicines in the same therapeutic class sold in the market during the five years immediately preceding the determination;

(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada during the five years immediately preceding the determination; and

(d) the Consumer Price Index as published by Statistics Canada under the authority of the *Statistics Act*.

information and documents concerning the price at which a particular medicine is sold both in Canada and elsewhere.[152] The patentee must also supply information on the costs of making and marketing the medicine where such information is available to him or is within his knowledge and control.[153] Section 41.15(2) provides that where, after giving the patentee a reasonable opportunity to be heard, the Board determines that the price at which the patentee sells the medicine is excessive,[154] the Board may either direct the patentee to lower the price[155] or revoke the section 41.11(1) compulsory license deferral in respect of the patent for the medicine in question.[156] *In extremis* the Board may also revoke a deferral in respect of any other patent of the patentee pertaining to one other medicine regardless of when such other patent was

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(6) Where, after taking into consideration the relevant factors referred to in subsection (5), the Board is unable to determine whether or not the medicine is being sold in any market in Canada at a price that is excessive, the Board may, to such extent as the Board deems reasonable, take into consideration the following factors:

(a) the costs of making and marketing the medicine; and

(b) such other factors as are prescribed or in the opinion of the Board, are relevant in the circumstances.

(7) For the purposes of this section, in determining whether or not a medicine is being sold in any market in Canada at a price that is excessive, the Board shall not take into consideration research costs other than the Canadian portion of world costs related to the research leading to the invention, development and commercialization pertaining to that medicine, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine in relation to total world sales.

(8) The Board shall give notice to the Minister of National Health and Welfare and the ministers responsible for health in each province of a hearing in relation to a matter referred to in paragraph (2)(b) or (c) and each such minister is entitled to appear and make representations to the Board with respect to the matter being heard.

(9) Where an order under paragraph (2)(d) is made by the Board, the Commissioner shall forthwith inform the holder of each licence granted under section 41 in respect of any invention pertaining to the medicine to which the order relates of the terms of the order.

Amending Act, *supra* note 3, sec. 15, § 41.15.

152. *Id.* sec. 15, § 41.15(1)(a).

153. *Id.* The form, manner, time, and other conditions with which the patentee must comply in providing the required information and documents are to be prescribed.

154. *Id.* sec. 15, § 41.15(2)(b).

155. *Id.* sec. 15, § 41.15(2)(e).

156. *See id.* sec. 15, § 41.15(2)(d)(i).

granted.[157] The Board may also exercise its power of revocation with respect to deferrals where it finds that the patentee has failed to provide the required information or documents, or failed to comply with the previous order of the Board directing him to lower the price.[158] Revocation of deferrals is effective immediately as of the date of the order.[159]

Excessiveness of the price may be determined in two stages. First the Board shall consider the prices at which the patentee sold the medicine during the preceding five years and the prices of other medicines in the same therapeutic class sold in Canada and in other countries for the same period, in addition to the Consumer Price Index.[160] If, having considered the above pricing determination factors, the Board is unable to arrive at a conclusion, it may consider additional factors: namely, the cost of making and marketing the medicine as well as such other factors as are prescribed or, in the opinion of the Board, are relevant under the circumstances.[161] A determination as to the excessiveness of a price or as to non-compliance with a previous order directing a patentee to reduce the price is to be made at a public hearing.[162] The Board must notify the Minister of National Health and Welfare and Provincial Health Ministers of such a hearing and each Minister is entitled to appear and make representations to the Board.[163] As is the case with respect to the decisions of the Commissioner of Patents, the decisions of the Board appear to be final, but the possibility of review by the Federal Court of Canada also exists here, subject to the discretionary character of the Board's decisions.[164]

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157. *See id.* sec. 15, § 41.15(2)(d)(ii).

158. *Id.* sec. 15, § 41.15(2)(a), (c).

159. *Id.* sec. 15, § 41.15(4).

160. *Id.* sec. 15, § 41.15(5).

161. *Id.* sec. 15, § 41.15(6).

162. *See id.* sec. 15, § 41.17, *quoted supra* note 139. However, if the person to whom the hearing relates satisfies the Board that a public hearing would cause a specific, direct, and substantial harm to him, the Board may decide not to hold the hearing in public. Amending Act, *supra* note 3, sec. 15, § 41.17(1).

163. Amending Act, *supra* note 3, sec. 15, § 41.15(8).

164. *See* text accompanying *supra* note 143.

2. Monitoring of the Compliance by the Pharmaceutical Industry with Its Commitments to Invest in Research and Development in Canada

New section 41.25(1)[165] provides that every patentee must

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165. Section 41.25 of the amended Patent Act reads as follows:

41.25.(1) Every patentee of an invention pertaining to a medicine shall, in such form and manner and at such times and subject to such conditions as are prescribed, provide the Board with information concerning

(a) the name of any licensee in Canada of the patentee;

(b) revenue and details of the source of revenue of the patentee, whether direct or indirect, from sales in Canada of medicine; and

(c) expenditures made by the patentee in Canada towards the cost of research and development relating to medicine.

(2) Where the Board has reason to believe that any person has information pertaining to the value of sales of medicine in Canada or expenditures made by a patentee in Canada towards the cost of research and development relating to medicine, the Board may, by notice in writing, require the person to provide to the Board a return setting out the information in such manner as the Board may specify, and on the receipt of any such notice, the person shall comply therewith within such time as the Board may specify.

(3) Subject to subsections (4) and (5), information obtained by the Board under subsections (1) and (2) is privileged and shall not knowingly be or be permitted to be communicated, disclosed or made available by any person without the authorization of the person who provided the information.

(4) The Board shall annually prepare and submit to the Minister a report based on the information obtained by it under subsections (1) and (2) and on such other information relating to revenues and expenditures referred to in subsection (1) as may be available to the Board, and the report shall contain an analysis of the information set out in such a manner that it is possible to ascertain from the report, in respect of the year for which the report is made, the Board's estimate of

(a) the proportion, as a percentage, that the expenditures of each patentee in Canada towards the cost of research and development relating to medicine is of the revenue of the patentee from sales in Canada of medicines; and

(b) the proportion, as a percentage, that the total of the expenditures of patentees in Canada towards the cost of research and development relating to medicine is of the total of the revenues of those patentees from sales in Canada of medicines.

(5) The report under subsection (4) shall not be set out in such a manner that it is possible from the report to relate the particulars of any information obtained by the Board for the purpose of the report from an identifiable person to that person, except that the Board

(a) shall, in setting out in the report the Board's estimate of the proportion referred to in paragraph (4)(a) in relation to a patentee, identify the patentee; and

(b) may, in the report, identify any person who has failed to comply with subsection (1) or (2) at any time in the year in respect of which the report is made.

provide the Board with information concerning his revenues from sales in Canada of medicine, as well as his research and development expenditures made in Canada with respect to medicine. The Board may in fact require any other person who the Board has reason to believe possesses information pertaining to sales or to research and development with respect to medicine, to provide the Board with such information.[166] This information is privileged,[167] except to the extent necessary for the annual report submitted by the Board to the Minister of National Health and Welfare under section 41.25(4). The Board's annual report contains an analysis of the proportion (stated as percentages) of research and development expenditures of patentees in Canada in relation to revenues of the patentees of sales of medicine in Canada. The report also contains a breakdown with respect to each individual patentee. Pursuant to the provisions of section 41.24 the Board must also submit an annual report to the Minister responsible for its activities for a particular year containing a summary of pricing trends in the pharmaceutical industry.[168]

The Board has been granted powers, rights, and privileges in exercising its powers under both section 41.15 and section 41.25 equivalent to those vested in a superior court of record. Such authority includes hearing of witnesses, production of documents, enforcement of the Board's orders, and such other matters as are necessary for the due exercise of the Board's jurisdiction.[169]

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(6) The Minister shall cause a copy of the report to be laid before each House of Parliament on any of the first thirty days on which that House is sitting after the report is submitted to the Minister.

(7) The Governor in Council may make regulations defining, for the purposes of this section, the expressions "research and development."

Amending Act, *supra* note 3, sec. 15, § 41.25.

166. *Id.* sec. 15, § 41.25(2).

167. *Id.* sec. 15, § 41.25(3).

168. For its annual report under § 41.24(2) the Board may use the information provided to it by the patentees under §§ 41.15 and 41.16 in fulfillment of its functions aimed at individual patentees. *Id.* sec. 15, § 41.24(2).

169. Section 41.23(4) of the amended Patent Act reads:

41.23(4) The Board has, with respect to the attendance, swearing and examination of witnesses, the production and inspection of documents, the enforcement of its orders and other matters necessary or proper for the due exercise of its jurisdiction, all such powers, rights and privileges as are vested in a superior court of record.

Id. sec. 15, § 41.23(4).

III. *COMING INTO FORCE AND TRANSITIONAL PROVISIONS*

On November 19, 1987, the date of royal assent, Bill C-22 came into force as law except for certain sections that were to come into force on a date to be fixed by proclamation.

Section 33(1)[170] of the Amending Act in effect provides that all general amendments dealt with in Part I of this Article will come into force on a day to be fixed by proclamation.[171] Government sources indicate that the date for coming into force of all the general amendments has been set for October 1, 1988. It would likely be more realistic to expect the date to be closer to January 1, 1989. The overall implementation of the changes related to the regulations, examination procedures, and manuals, as well as to the internal functioning of the Patent Office, consists of numerous tasks and will extend over a six-year period. However, this does not include the establishment and functioning of the Patented Medicine Prices Review Board, a distinct entity completely independent of the Patent Office. Such proclamation will be done gradually so that the Government may draft such regulatory measures necessary for the proper implementation of the amendments.[172] Section 33(2)[173] of the Amending Act similarly provides that all amendments dealt with in Part II of this Article will be proclaimed in force on a later day. The Government proclaimed the amendments in sections 41.1 to 41.25 with respect to com-

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170. Section 33(1) of the Amending Act reads as follows:

> 33.(1) The definition "priority date" in section 2 of the *Patent Act*, as enacted by subsection 1(2) of this Act, sections 2, 5, 7 to 13 and 16 to 25 and subsection 30(1) of this Act, or any of those sections or subsections, shall come into force on a day or days to be fixed by proclamation.

Id. sec. 33(1).

171. This does not include the provisions discussed in Part I.A.3. of this Article (substances intended for food or medicine) and the portion of Part I.D.4. dealing with marking requirements, both of which came into force as of the date of royal assent.

172. Consumer and Corporate Affaires Canada, Implementation Project for Implementing Bill C-22 in the Patent Office, Activities 3, 4 (Oct. 14, 1987).

173. Section 33(2) reads as follows:

> (2) Sections 41.1 to 41.25 of the *Patent Act*, as enacted by section 15 of this Act, or any of those sections, subsections 30(2) and (3) of this Act or either of those subsections, and section 31 of this Act shall come into force on a day or days to be fixed by proclamation.

Amending Act, *supra* note 3, sec. 33(2).

pulsory licensing of medicine patents in force as of December 7, 1987.[174]

The transitional provisions in sections 27, 28, and 29 of the Amending Act that came into force as of November 19, 1987 (the date of royal assent) determine the law applicable to patent applications and issued patents, depending upon the dates on which applications are filed or patents granted.[175]

Section 27 of the Amending Act provides that applications for patents filed before the coming into force of the relevant provisions referred to in section 31(1) of the Amending Act shall be dealt with and disposed of in accordance with the Patent Act as it read immediately before the coming into force of those provisions.[176] It is not entirely clear whether, by filing date, it is meant the effective filing date (including Convention priority claims) or the actual date of filing in Canada, although it is probably the latter.[177] With respect to issued patents, section 28[178] of the Amending Act provides that the law governing patents issued before the coming into force of the relevant provisions of the Amending Act (except for any matter relating to the compulsory licensing of medicine patents), shall be that of the Patent Act as it read before the provisions came into force. Section 29[179] of the Amending Act provides that

174. *See* Registration SI/88-1, 122 Can. Gaz. pt. II, no. 1, at 335 (Jan. 6, 1988).

175. *See* Amending Act, *supra* note 3, secs. 27-29.

176. Section 27 of the Amending Act reads as follows:

> 27. Applications for patents filed before the coming into force of the provisions of this Act referred to in subsection 33(1) shall be dealt with and disposed of in accordance with the *Patent Act* as it read immediately before the coming into force of those provisions.

Id. sec. 27.

177. *See supra* notes 36-40 and accompanying text.

178. Section 28 of the Amending Act reads as follows:

> 28. Any matter arising after the coming into force of the provisions of this Act referred to in subsection 33(1) in respect of any patent issued before the coming into force of those provisions, except any matter arising under any of sections 41.1 to 41.25 of the *Patent Act*, as enacted by section 15 of this Act, shall be dealt with and disposed of in accordance with the *Patent Act* as it read immediately before the coming into force of those provisions.

Amending Act, *supra* note 3, sec. 28.

179. Section 29 of the Amending Act reads as follows:

> 29. Where a conflict, within the meaning of section 45 of the *Patent Act*, as that section read immediately before the coming into force of section 16 of this Act, exists between an application for a patent filed after the coming into force of section 16 of this Act and an application for a patent filed before the coming into force of that section, the applications shall be dealt

where two patent applications are in conflict within the meaning of section 45 of the Patent Act as it read immediately before repeal, and when one of the applications was filed before the coming into force of the relevant provision of the Amending Act, while the other was filed after, the old conflict rules are to be used in determining which one should be granted based on the first-to-invent rule. The reference to the "filing date" leaves some room for doubt whether such a date is the effective or actual filing date in Canada.[180]

CONCLUSION

The Amending Act is the result of the Federal Government's efforts to modernize the Canadian patent law and to strike a better balance between the lowest possible prices for medicine in Canada and due reward for inventors. With respect to the general amendments,[181] it is fair to say that overall they seem to have achieved their stated purposes of modernizing the law and of bringing it up to date with the similar statutes of Canada's major trading partners.

Adoption of the first-to-file system and elimination of the conflict procedure should engender greater certainty for patent owners in Canada by removing the threat of potential challenge by the prior inventor that now hangs over the head of any patentee until the second anniversary of the grant of the patent.[182] At the same time, it should encourage inventors to be more alert to the potential value of their discoveries and to proceed more diligently with the filing of their patent applications. The absolute novelty requirement and the modified and shortened grace period should undoubtedly have an effect similar to that of the introduction of the first-to-file system and elimination of the conflict procedure.[183]

On the other hand, while Parliament took steps toward clarifying some uncertainties relating to Convention priority

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with and disposed of in accordance with section 45 of the *Patent Act* as that section read immediately before the coming into force of section 16 of this Act.

Id. sec. 29.

180. *See supra* notes 36-50 and accompanying text.

181. *See supra* Part I.

182. *See supra* notes 16-23 and accompanying text.

183. *See supra* notes 25-35 and accompanying text.

claims and priority dates, it did not go far enough to resolve certain ambiguities.[184]

The introduction of maintenance fees[185] for both pending applications and issued patents, as well as deferred examination,[186] will force the inventors to prosecute their applications with seriousness and diligence. It should also facilitate the removal of "dead wood" from the Patent Office files.

The system of public inspection[187] and the protest and reexamination procedure[188] make it easier and less expensive to challenge both patent applications and issued patents on the basis of prior art. However, this system also limits the grounds and scope on which such a challenge can be mounted by allowing only the use of prior art that was made available to the public through patents or other printed publications. At the same time, persons wishing to challenge patents on other grounds still have an opportunity to proceed with the more expensive and complex action for impeachment in Federal Court.[189]

The modification of term[190] is a positive step in the sense that one can now determine with certainty the date as of which the term shall begin to run (date of filing), as well as the date as of which the patentee's rights, assuming the patent is granted, are enforceable (eighteen months from the effective filing date).

The new system of increased protection for patented medicine through deferrals combined with the price review powers of the Patented Medicine Prices Review Board[191] is designed to maintain control over the prices of medicine in Canada while stimulating investment in pharmaceutical industry research and development as well as in the manufacture of medicine in this country. The amended Patent Act provides[192] for a review of the deferral provisions relating to compulsory

184. *See supra* notes 36-50 and accompanying text.
185. *See supra* notes 51-55 and accompanying text.
186. *See supra* notes 65-68 and accompanying text.
187. *See supra* notes 56-57 and accompanying text.
188. *See supra* notes 74-89 and accompanying text.
189. *See id.*
190. *See supra* notes 69-70 and accompanying text.
191. *See supra* notes 151-64 and accompanying text.
192. Section 41.26(1) of the amended Patent Act reads:

licensing of medicine by the Governor in Council upon expiration of four years after the coming into force of section 41.11. In addition, section 41.26(3)[193] provides for a comprehensive review of the same provisions by a Parliamentary committee after the expiration of nine years.

The reviews are intended, *inter alia*, to ensure that the pharmaceutical industry will live up to its commitments to increase research and development expenditures in Canada. As a result, the provisions according extended patent protection may be repealed or modified, depending upon the performance of the industry. It seems clear that in both the fourth year and the ninth year reviews, great importance will be attached to the Board's reports as contemplated in section 41.25 of the amended Patent Act.[194] The success of the new amendments in achieving their desired goals thus will be revealed only with time.

41.26(1) After the expiration of four years after section 41.11 comes into force, the Governor in Council may, by order, where the Governor in Council determines that it is in the public interest to do so,

(a) reduce any number of years specified in any of paragraphs 41.11(2)(a), (b) and (c) or subsection 41.14(1) to such number of years or portion of a year as the Governor in Council deems appropriate in the circumstances; or

(b) declare that, effective on a date specified in the order, sections 41.1 to 41.25 cease to be in force, and in that case those sections are repealed on that date.

Amending Act, *supra* note 3, sec. 15, § 41.26(1).

193. Section 41.26(3) of the amended Patent Act reads:

41.26(3) After the expiration of nine years after section 41.11 comes into force, sections 41.11 to 41.25 shall stand referred to such committee of the House of Commons, of the Senate or of both Houses of Parliament as may be designated or established for that purpose and the committee shall, as soon as practicable thereafter, undertake a comprehensive review of the provisions and operation of those sections and shall, within one year after the review is undertaken or within such further time as the House of Commons may authorize, submit a report to Parliament thereon including such recommendations pertaining to the continuation of those sections and changes required therein as the committee may wish to make.

Id. sec. 15, § 41.26(3).

194. *Id.* sec. 15, § 41.25.