Patent Act (R.S., 1985, c. P-4)
Act current to January 25th, 2011
Attention: See coming into force provision and notes, where applicable.

Patent Act

P-4

An Act respecting patents of invention

SHORT TITLE

Short title

1. This Act may be cited as the *Patent Act*.

R.S., c. P-4, s. 1.

INTERPRETATION

Definitions

2. In this Act, except as otherwise provided,

“applicant”
« *demandeur* »

“applicant” includes an inventor and the legal representatives of an applicant or inventor;

“claim date”
« *Version anglaise seulement* »

“claim date” means the date of a claim in an application for a patent in Canada, as determined in accordance with section 28.1;

“Commissioner”
« *commissaire* »

“Commissioner” means the Commissioner of Patents;

“country”
« *pays* »

“country” includes a Member of the World Trade Organization, as defined in subsection 2(1) of the *World Trade Organization Agreement Implementation Act*;

“filing date”
« *date de dépôt* »

“filing date” means, in relation to an application for a patent in Canada, the date on which the application is filed, as determined in accordance with section 28;

“invention”
« *invention* »

“invention” means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;

“legal representatives”
« *représentants légaux* »

“legal representatives” includes heirs, executors, administrators, guardians, curators, tutors, assigns and all other persons claiming through or under applicants for patents and patentees of inventions;

“Minister”
« *ministre* »

“Minister” means the Minister of Industry or such other member of the Queen’s Privy Council for Canada as is designated by the Governor in Council as the Minister for the purposes of this Act;

“patent”
« *brevet* »

“patent” means letters patent for an invention;

“patentee”
« *breveté* » ou « *titulaire d’un brevet* »

“patentee” means the person for the time being entitled to the benefit of a patent;

“predecessor in title”
« *prédécesseur en droit* »

“predecessor in title” includes any person through whom an applicant for a patent in Canada claims the right to the patent;

“prescribed”
« *réglementaire* »

“prescribed” means prescribed by rules or regulations of the Governor in Council and, in the case of a fee, includes a fee determined in the manner prescribed;

“prescribed fee” [Repealed, R.S., 1985, c. 33 (3rd Supp.), s. 1]

“priority date” [Repealed, 1993, c. 15, s. 26]

“regulation” and “rule”
« *règlement* » et « *règle* »

“regulation” and “rule” include rule, regulation and form;

“request for priority”
« *demande de priorité* »

“request for priority” means a request under section 28.4.

“work on a commercial scale” [Repealed, 1993, c. 44, s. 189]

R.S., 1985, c. P-4, s. 2; R.S., 1985, c. 33 (3rd Supp.), s. 1; 1992, c. 1, s. 145(F); 1993, c. 2, s. 2, c. 15, s. 26, c. 44, s. 189; 1994, c. 47, s. 141; 1995, c. 1, s. 62.

HER MAJESTY

Binding on Her Majesty

2.1 This Act is binding on Her Majesty in right of Canada or a province.

1993, c. 44, s. 190.

PATENT OFFICE AND OFFICERS

Patent Office

3. There shall be attached to the Department of Industry, or to such other department of the Government of Canada as may be determined by the Governor in Council, an office called the Patent Office.

R.S., 1985, c. P-4, s. 3; 1992, c. 1, s. 145(F); 1995, c. 1, s. 63.

Commissioner of Patents

4. (1) The Governor in Council may appoint a Commissioner of Patents who shall, under the direction of the Minister, exercise the powers and perform the duties conferred and imposed on that officer by or pursuant to this Act.

Duties of Commissioner

(2) The Commissioner shall receive all applications, fees, papers, documents and models for patents, shall perform and do all acts and things requisite for the granting and issuing of patents of invention, shall have the charge and custody of the books, records, papers, models, machines and other things belonging to the Patent Office and shall have, for the purposes of this Act, all the powers that are or may be given by the *Inquiries Act* to a commissioner appointed under Part II of that Act.

Tenure of office and salary

(3) The Commissioner holds office during pleasure and shall be paid such annual salary as may be determined by the Governor in Council.

Delegation

(4) The Commissioner may, after consultation with the Minister, delegate to any person he deems qualified any of his powers, duties and functions under this Act, except the power to delegate under this subsection.

Appeal

(5) Any decision under this Act of a person authorized to make the decision pursuant to subsection (4) may be appealed in the like manner and subject to the like conditions as a decision of the Commissioner under this Act.

R.S., c. P-4, s. 4; 1984, c. 40, s. 57.

Assistant Commissioner

5. (1) An Assistant Commissioner of Patents may be appointed in the manner authorized by law and shall be a technical officer experienced in the administration of the Patent Office.

Absence or inability to act

(2) When the Commissioner is absent or unable to act, the Assistant Commissioner, or, if he also is at the same time absent or unable to act, another officer designated by the Minister, may exercise the powers and shall perform the duties of the Commissioner.

R.S., c. P-4, s. 5.

Staff

6. There may be appointed in the manner authorized by law such principal examiners, examiners, associate examiners and assistant examiners, clerks, stenographers and other assistants as are necessary for the administration of this Act.

R.S., c. P-4, s. 6.

Officers of Patent Office not to deal in patents

7. (1) No officer or employee of the Patent Office shall buy, sell, acquire or traffic in any invention, patent or right to a patent, or any interest therein, and every purchase, sale, assignment, acquisition or transfer of any invention, patent or right to a patent, or any interest therein, made by or to any officer or employee is void.

Restriction

(2) Subsection (1) does not apply to a sale by an original inventor or to an acquisition under the last will, or by the intestacy, of a deceased person.

R.S., c. P-4, s. 7.

Clerical errors

8. Clerical errors in any instrument of record in the Patent Office do not invalidate the instrument, but they may be corrected under the authority of the Commissioner.

R.S., 1985, c. P-4, s. 8; 1993, c. 15, s. 27.

Electronic or other submission of documents, information or fees

8.1 (1) Subject to the regulations, any document, information or fee that is authorized or required to be submitted to the Commissioner under this Act may be submitted in electronic or other form in any manner specified by the Commissioner.

Time of receipt

(2) For the purposes of this Act, any document, information or fee submitted in accordance with subsection (1) is deemed to be received by the Commissioner at the time provided by the regulations.

1993, c. 15, s. 27.

Storage of documents or information in electronic or other form

8.2 Subject to the regulations, any document or information received by the Commissioner under this Act in electronic or other form may be entered or recorded by any information storage device, including any system of mechanical or electronic data processing, that is capable of reproducing stored documents or information in intelligible form within a reasonable time.

1993, c. 15, s. 27.

Destroyed or lost patents

9. If any patent is destroyed or lost, a certified copy may be issued in lieu thereof on payment of the prescribed fee.

R.S., c. P-4, s. 9.

Inspection by the public

10. (1) Subject to subsections (2) to (6) and section 20, all patents, applications for patents and documents filed in connection with patents or applications for patents shall be open to public inspection at the Patent Office, under such conditions as may be prescribed.

Confidentiality period

(2) Except with the approval of the applicant, an application for a patent, or a document filed in connection with the application, shall not be open to public inspection before a confidentiality period of eighteen months has expired.

Beginning of confidentiality period

(3) The confidentiality period begins on the filing date of the application or, where a request for priority has been made in respect of the application, it begins on the earliest filing date of any previously regularly filed application on which the request is based.

Withdrawal of request

(4) Where a request for priority is withdrawn on or before the prescribed date, it shall, for the purposes of subsection (3) and to the extent that it is withdrawn, be considered never to have been made.

Withdrawn applications

(5) An application shall not be open to public inspection if it is withdrawn in accordance with the regulations on or before the prescribed date.

Prescribed date

(6) A prescribed date referred to in subsection (4) or (5) must be no later than the date on which the confidentiality period expires.

R.S., 1985, c. P-4, s. 10; R.S., 1985, c. 33 (3rd Supp.), s. 2; 1993, c. 15, s. 28.

Patents issued out of Canada

11. Notwithstanding the exception in section 10, the Commissioner, on the request of any person who states in writing the name of the inventor, if available, the title of the invention and the number and date of a patent said to have been granted in a named country other than Canada, and who pays or tenders the prescribed fee, shall inform that person whether an application for a patent of the same invention is or is not pending in Canada.

R.S., c. P-4, s. 11.

RULES AND REGULATIONS

Rules and regulations

12. (1) The Governor in Council may make rules or regulations

(*a*) respecting the form and contents of applications for patents;

(*b*) respecting the form of the Register of Patents and of the indexes thereto;

(*c*) respecting the registration of assignments, transmissions, disclaimers, judgments or other documents relating to any patent;

(*d*) respecting the form and contents of any certificate issued pursuant to this Act;

(*e*) prescribing the fees or the manner of determining the fees that may be charged in respect of the filing of applications for patents or the taking of other proceedings under this Act or under any rule or regulation made pursuant to this Act, or in respect of any services or the use of any facilities provided thereunder by the Commissioner or any person employed in the Patent Office;

(*f*) prescribing the fees or the manner of determining the fees that shall be paid to maintain in effect an application for a patent or to maintain the rights accorded by a patent;

(*g*) respecting the payment of any prescribed fees including the time when and the manner in which such fees shall be paid, the additional fees that may be charged for the late payment of such fees and the circumstances in which any fees previously paid may be refunded in whole or in part;

(*h*) for carrying into effect the terms of any treaty, convention, arrangement or engagement that subsists between Canada and any other country;

(*i*) for carrying into effect, notwithstanding anything in this Act, the Patent Cooperation Treaty done at Washington on June 19, 1970, including any amendments, modifications and revisions made from time to time to which Canada is a party;

(*j*) respecting the entry on, the maintenance of and the removal from the register of patent agents of the names of persons and firms, including the qualifications that must be met and the conditions that must be fulfilled by a person or firm before the name of the person or firm is entered thereon and to maintain the name of the person or firm on the register;

(*j.1*) respecting the submission of documents, information or fees under section 8.1, including

(i) the documents, information or fees that may be submitted in electronic or other form under that section,

(ii) the persons or classes of persons by whom they may be submitted, and

(iii) the time at which they are deemed to be received by the Commissioner;
(*j.2*) respecting the entering or recording of any document or information under section 8.2;
(*j.3*) prescribing the manner in which an application for a patent may be withdrawn and, for the purposes of subsections 10(4) and (5), prescribing the date, or the manner of determining the date, on or before which a request for priority or an application for a patent must be withdrawn;
(*j.4*) respecting requests for priority, including
(i) the period within which priority must be requested,
(ii) the manner in which and period within which the Commissioner must be informed of the matters referred to in subsection 28.4(2),
(iii) the documentation that must be filed in support of requests for priority, and
(iv) the withdrawal of requests for priority;
(*j.5*) respecting the time within which requests for examination must be made and prescribed fees must be paid under subsection 35(1);
(*j.6*) respecting the deposit of biological material for the purposes of section 38.1;
(*j.7*) respecting the manner in which amendments may be made to specifications or drawings furnished as part of an application for a patent;
(*j.8*) authorizing the Commissioner to extend, subject to any prescribed terms and conditions, the time fixed by or under this Act for doing anything where the Commissioner is satisfied that the circumstances justify the extension;
(*k*) prescribing any other matter that by any provision of this Act is to be prescribed; and
(*l*) generally, for carrying into effect the objects and purposes of this Act or for ensuring the due administration thereof by the Commissioner and other officers and employees of the Patent Office.

Effect

(2) Any rule or regulation made by the Governor in Council has the same force and effect as if it had been enacted herein.

R.S., 1985, c. P-4, s. 12; R.S., 1985, c. 33 (3rd Supp.), s. 3; 1993, c. 15, s. 29.

SEAL

Seal of office

13. (1) The Commissioner shall cause a seal to be made for the purposes of this Act and may cause to be sealed therewith every patent and other instrument and copy thereof issuing from the Patent Office.

Seal to be evidence

(2) Every court, judge and person shall take notice of the seal of the Patent Office, shall admit the impressions thereof in evidence in like manner as the impressions of the Great Seal are admitted in evidence and shall take notice of and admit in evidence, without further proof and without production of the originals, all copies or extracts certified under the seal of the Patent Office to be copies of or extracts from documents deposited in that Office.

R.S., c. P-4, s. 13.

PROOF OF PATENTS

Certified copies of patents as evidence

14. In any action or proceeding respecting a patent authorized to be had or taken in Canada under this Act, a copy of any patent granted in any other country, or any official document connected therewith, purporting to be certified under the hand of the proper officer of the government of the country in which the patent has been obtained, may be produced before the court or a judge thereof, and the copy of the patent or document purporting to be so certified may be admitted in evidence without production of the original and without proof of the signature or official character of the person appearing to have signed it.

R.S., c. P-4, s. 14.

PATENT AGENTS

Register of patent agents

15. A register of patent agents shall be kept in the Patent Office on which shall be entered the names of all persons and firms entitled to represent applicants in the presentation and prosecution of applications for patents or in other business before the Patent Office.

R.S., 1985, c. P-4, s. 15; R.S., 1985, c. 33 (3rd Supp.), s. 4.

Misconduct

16. For gross misconduct or any other cause that he may deem sufficient, the Commissioner may refuse to recognize any person as a patent agent or attorney either generally or in any particular case.

R.S., c. P-4, s. 16.

APPEALS

Practice on appeals

17. In all cases where an appeal is provided from the decision of the Commissioner to the Federal Court under this Act, the appeal shall be had and taken pursuant to the *Federal Courts Act* and the rules and practice of that Court.

R.S., 1985, c. P-4, s. 17; 2002, c. 8, s. 182.

Notice on appeal

18. (1) Whenever an appeal to the Federal Court from the decision of the Commissioner is permitted under this Act, notice of the decision shall be mailed by the Commissioner by registered letter addressed to the interested parties or their respective agents.

Time for taking appeal

(2) The appeal shall be taken within three months after the date of mailing of the notice, unless otherwise provided by or under this Act.

R.S., 1985, c. P-4, s. 18; 1993, c. 15, s. 30.

USE OF PATENTS BY GOVERNMENT

Government may apply to use patented invention

19. (1) Subject to section 19.1, the Commissioner may, on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government.

Terms of use

(2) Subject to section 19.1, the use of the patented invention may be authorized for such purpose, for such period and on such other terms as the Commissioner considers expedient but the Commissioner shall settle those terms in accordance with the following principles:
(*a*) the scope and duration of the use shall be limited to the purpose for which the use is authorized;
(*b*) the use authorized shall be non-exclusive; and
(*c*) any use shall be authorized predominantly to supply the domestic market.

Notice

(3) The Commissioner shall notify the patentee of any use of the patented invention that is authorized under this section.

Payment of remuneration

(4) Where the use of the patented invention is authorized, the authorized user shall pay to the patentee such amount as the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization.

Termination of authorization

(5) The Commissioner may, on application by the patentee and after giving all concerned parties an opportunity to be heard, terminate the authorization if the Commissioner is satisfied that the circumstances that led to the granting of the authorization have ceased to exist and are unlikely to recur, subject to such conditions as the Commissioner deems appropriate to protect the legitimate interests of the authorized user.

Authorization not transferable

(6) An authorization granted under this section is not transferable.

R.S., 1985, c. P-4, s. 19; 1993, c. 44, s. 191.

Conditions for authorizing use

19.1 (1) The Commissioner may not authorize the use of a patented invention under section 19 unless the applicant establishes that
(*a*) it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention; and
(*b*) its efforts have not been successful within a reasonable period.

Exception

(2) Subsection (1) does not apply in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.

Prescribed uses

(3) The Commissioner may not, under section 19, authorize any use that is a prescribed use unless the proposed user complies with the prescribed conditions.

Limitation on use of semi-conductor technology

(4) The Commissioner may not, under section 19, authorize any use of semi-conductor technology other than a public non-commercial use.

1993, c. 44, s. 191; 1994, c. 47, s. 142.

Appeal

19.2 Any decision made by the Commissioner under section 19 or 19.1 is subject to appeal to the Federal Court.

1993, c. 44, s. 191.

Regulations

19.3 (1) The Governor in Council may make regulations for the purpose of implementing, in relation to patents, Article 1720 of the Agreement.

Definition of “Agreement”

(2) In subsection (1), “Agreement” has the same meaning as in subsection 2(1) of the *North American Free Trade Agreement Implementation Act*.

1993, c. 44, s. 191.

GOVERNMENT OWNED PATENTS

Assignment to Minister of National Defence

20. (1) Any officer, servant or employee of the Crown or of a corporation that is an agent or servant of the Crown, who, acting within the scope of his duties and employment, invents any invention in instruments or munitions of war shall, if so required by the Minister of National Defence, assign to that Minister on behalf of Her Majesty all the benefits of the invention and of any patent obtained or to be obtained for the invention.

Idem

(2) Any person other than a person described in subsection (1) who invents an invention described in that subsection may assign to the Minister of National Defence on behalf of Her Majesty all the benefits of the invention and of any patent obtained or to be obtained for the invention.

Inventor entitled to compensation

(3) An inventor described in subsection (2) is entitled to compensation for an assignment to the Minister of National Defence under this Act and in the event that the consideration to be paid for the assignment is not agreed on, it is the duty of the Commissioner to determine the amount of the consideration, which decision is subject to appeal to the Federal Court.

Proceedings before Federal Court

(4) Proceedings before the Federal Court under subsection (3) shall be held in camera on request made to the court by any party to the proceedings.

Vesting on assignment

(5) An assignment to the Minister of National Defence under this Act effectually vests the benefits of the invention and patent in the Minister of National Defence on behalf of Her Majesty, and all covenants and agreements therein contained for keeping the invention secret and otherwise are valid and effectual, notwithstanding any want of valuable consideration, and may be enforced accordingly by the Minister of National Defence.

Person making assignment and person having knowledge thereof

(6) Any person who has made an assignment to the Minister of National Defence under this section, in respect of any covenants and agreements contained in such assignment for keeping the invention secret and otherwise in respect of all matters relating to that invention, and any other person who has knowledge of such assignment and of such covenants and agreements, shall be, for the purposes of the *Security of Information Act*, deemed to be persons having in their possession or control information respecting those matters that has been entrusted to them in confidence by any person holding office under Her Majesty, and the communication of any of that information by the first mentioned persons to any person other than one to whom they are authorized to communicate with, by or on behalf of the Minister of National Defence, is an offence under section 4 of the *Security of Information Act*.

Minister may submit application for patent

(7) Where any agreement for an assignment to the Minister of National Defence under this Act has been made, the Minister of National Defence may submit an application for patent for the invention to the Commissioner, with the request that it be examined for patentability, and if the application is found allowable may, before the grant of any patent thereon, certify to the Commissioner that, in the public interest, the particulars of the invention and of the manner in which it is to be worked are to be kept secret.

Secret application

(8) If the Minister of National Defence so certifies, the application and specification, with the drawing, if any, and any amendment of the application, and any copies of those documents and the drawing and the patent granted thereon shall

be placed in a packet sealed by the Commissioner under authority of the Minister of National Defence.

Custody of secret application

(9) The packet described in subsection (8) shall, until the expiration of the term during which a patent for the invention may be in force, be kept sealed by the Commissioner, and shall not be opened except under the authority of an order of the Minister of National Defence.

Delivery of secret application

(10) The packet described in subsection (8) shall be delivered at any time during the continuance of the patent to any person authorized by the Minister of National Defence to receive it, and shall, if returned to the Commissioner, be kept sealed by him.

Delivery to Minister

(11) On the expiration of the term of the patent, the packet described in subsection (8) shall be delivered to the Minister of National Defence.

Revocation

(12) No proceeding by petition or otherwise lies to have declared invalid or void a patent granted for an invention in relation to which a certificate has been given by the Minister of National Defence under subsection (7), except by permission of the Minister.

Prohibition of publication and inspection

(13) No copy of any specification or other document or drawing in respect of an invention and patent, by this section required to be placed in a sealed packet, shall in any manner whatever be published or open to the inspection of the public, but, except as otherwise provided in this section, this Act shall apply in respect of the invention and patent.

Waiver by Minister

(14) The Minister of National Defence may at any time waive the benefit of this section with respect to any particular invention, and the specification, documents and drawing relating thereto shall thereafter be kept and dealt with in the regular way.

Rights protected

(15) No claim shall be allowed in respect of any infringement of a patent that occurred in good faith during the time that the patent was kept secret under this section, and any person who, before the publication of the patent, had in good faith done any act that, but for this subsection would have given rise to a claim, is entitled, after the publication, to obtain a licence to manufacture, use and sell the

patented invention on such terms as may, in the absence of agreement between the parties, be settled by the Commissioner or by the Federal Court on appeal from the Commissioner.

Communication to Minister

(16) The communication of any invention for any improvement in munitions of war to the Minister of National Defence, or to any person or persons authorized by the Minister of National Defence to investigate the invention or the merits thereof, shall not, nor shall anything done for the purposes of the investigation, be deemed use or publication of the invention so as to prejudice the grant or validity of any patent for the invention.

Order to keep non-assigned application secret

(17) The Governor in Council, if satisfied that an invention relating to any instrument or munition of war, described in any specified application for patent not assigned to the Minister of National Defence, is vital to the defence of Canada and that the publication of a patent therefor should be prevented in order to preserve the safety of the State, may order that the invention and application and all the documents relating thereto shall be treated for all purposes of this section as if the invention had been assigned or agreed to be assigned to the Minister of National Defence.

Rules

(18) The Governor in Council may make rules for the purpose of ensuring secrecy with respect to applications and patents to which this section applies and generally to give effect to the purpose and intent thereof.

R.S., 1985, c. P-4, s. 20; 2001, c. 41, s. 36.

Agreement between Canada and other government

21. Where by any agreement between the Government of Canada and any other government it is provided that the Government of Canada will apply section 20 to inventions disclosed in any application for a patent assigned or agreed to be assigned by the inventor to that other government, and the Commissioner is notified by any minister of the Crown that the agreement extends to an invention in a specified application, the application and all the documents relating thereto shall be dealt with as provided in section 20, except subsections (3) and (4), as if the invention had been assigned or agreed to be assigned to the Minister of National Defence.

R.S., c. P-4, s. 21.

USE OF PATENTS FOR INTERNATIONAL HUMANITARIAN PURPOSES TO ADDRESS PUBLIC HEALTH PROBLEMS

Purpose

21.01 The purpose of sections 21.02 to 21.2 is to give effect to Canada's and Jean Chrétien's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2004, c. 23, s. 1.

Definitions

21.02 The definitions in this section apply in this section and in sections 21.03 to 21.19.

“authorization”
« *autorisation* »

“authorization” means an authorization granted under subsection 21.04(1), and includes an authorization renewed under subsection 21.12(1).

“General Council”
« *Conseil général* »

“General Council” means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

“General Council Decision”
« *décision du Conseil général* »

“General Council Decision” means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council Chairperson’s statement of that date.

“patented product”
« *produit breveté* »

“patented product” means a product the making, constructing, using or selling of which in Canada would infringe a patent in the absence of the consent of the patentee.

“pharmaceutical product”
« *produit pharmaceutique* »

“pharmaceutical product” means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product.

“TRIPS Agreement”
« *Accord sur les ADPIC* »

“TRIPS Agreement” means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

“TRIPS Council”
« *Conseil des ADPIC* »

“TRIPS Council” means the council referred to in the TRIPS Agreement.

“WTO”
« *OMC* »

“WTO” means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

2004, c. 23, s. 1.

Amending Schedules

21.03 (1) The Governor in Council may, by order,

(*a*) on the recommendation of the Minister and the Minister of Health, amend Schedule 1

(i) by adding the name of any patented product that may be used to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and, if the Governor in Council considers it appropriate to do so, by adding one or more of the following in respect of the patented product, namely, a dosage form, a strength and a route of administration, and

(ii) by removing any entry listed in it;

(*b*) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 2 by adding the name of any country recognized by the United Nations as being a least-developed country that has,

(i) if it is a WTO Member, provided the TRIPS Council with a notice in writing stating that the country intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, and

(ii) if it is not a WTO Member, provided the Government of Canada with a notice in writing through diplomatic channels stating that the country intends to import pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision, that it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of that decision;

(*c*) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 3 by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision; and

(*d*) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 4 by adding the name of

(i) any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, or

(ii) any country that is not a WTO Member and that is named on the Organization for Economic Co-operation and Development’s list of countries that are eligible for official development assistance and that has provided the Government of Canada with a notice in writing through diplomatic channels

(A) stating that it is faced with a national emergency or other circumstances of extreme urgency,

(B) specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the country to deal with the emergency or other urgency,

(C) stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and
(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.

Restriction - Schedule 3

(2) The Governor in Council may not add to Schedule 3 the name of any WTO Member that has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, only if faced with a national emergency or other circumstances of extreme urgency.

Removal from Schedules 2 to 4

(3) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend any of Schedules 2 to 4 to remove the name of any country or WTO Member if
(*a*) in the case of a country or WTO Member listed in Schedule 2, the country or WTO Member has ceased to be recognized by the United Nations as being a least-developed country or, in the case of a country that is not a WTO Member, the country has permitted any product imported into that country under an authorization to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision;
(*b*) in the case of a WTO Member listed in Schedule 3, the WTO Member has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, only if faced with a national emergency or other circumstances of extreme urgency;
(*c*) in the case of a WTO Member listed in Schedule 4, the WTO Member has revoked any notification it has given to the TRIPS Council that it will import pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision, only if faced with a national emergency or other circumstances of extreme urgency;
(*d*) in the case of a country listed in Schedule 4 that is not a WTO Member,
(i) the name of the country is no longer on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance,
(ii) the country no longer faces a national emergency or other circumstances of extreme urgency,
(iii) the country has permitted any product imported into that country under an authorization to be used for commercial purposes, or
(iv) the country has failed to adopt the measures referred to in Article 4 of the General Council Decision;
(*e*) in the case of any country or WTO Member listed in Schedule 3 or 4, the country or WTO Member has become recognized by the United Nations as a least-developed country; and
(*f*) in the case of any country or WTO Member listed in any of Schedules 2 to 4, the country has notified the Government of Canada, or the WTO Member has notified the TRIPS Council, that it will not import pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision.

Timeliness of orders

(4) An order under this section shall be made in a timely manner.

2004, c. 23, s. 1.

Authorization

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it for export to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application.

Contents of application

(2) The application must be in the prescribed form and set out

(*a*) the name of the pharmaceutical product to be manufactured and sold for export under the authorization;

(*b*) prescribed information in respect of the version of the pharmaceutical product to be manufactured and sold for export under the authorization;

(*c*) the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization;

(*d*) for each patented invention to which the application relates, the name of the patentee of the invention and the number, as recorded in the Patent Office, of the patent issued in respect of that invention;

(*e*) the name of the country or WTO Member to which the pharmaceutical product is to be exported;

(*f*) the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; and

(*g*) any other information that may be prescribed.

Conditions for granting of authorization

(3) The Commissioner shall authorize the use of the patented invention only if

(*a*) the applicant has complied with the prescribed requirements, if any;

(*b*) the Minister of Health has notified the Commissioner that the version of the pharmaceutical product that is named in the application meets the requirements of the *Food and Drugs Act* and its regulations, including the requirements under those regulations relating to the marking, embossing, labelling and packaging that identify that version of the product as having been manufactured

(i) in Canada as permitted by the General Council Decision, and

(ii) in a manner that distinguishes it from the version of the pharmaceutical product sold in Canada by, or with the consent of, the patentee or patentees, as the case may be;

(*c*) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least thirty days before filing the application,

(i) sought from the patentee or, if there is more than one, from each of the patentees, by certified or registered mail, a licence to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in

the application on reasonable terms and conditions and that such efforts have not been successful, and

(ii) provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information referred to in paragraphs (2)(*a*) to (*g*); and

(*d*) the applicant also provides the Commissioner with

(i) if the application relates to a WTO Member listed in Schedule 2, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that WTO Member, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(ii) if the application relates to a country listed in Schedule 2 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the country, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that country, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iii) if the application relates to a WTO Member listed in Schedule 3, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of

the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iv) if the application relates to a WTO Member listed in Schedule 4, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member is faced with a national emergency or other circumstances of extreme urgency and that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product, or

(v) if the application relates to a country listed in Schedule 4 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(*a*) of the General Council Decision, and the quantity of that product, needed by the country, and stating that it is faced with a national emergency or other circumstances of extreme urgency, that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, that it agrees that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that country, or

(B) a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product.

2004, c. 23, s. 1.

Form and content of authorization

21.05 (1) The authorization must be in the prescribed form and, subject to subsection (2), contain the prescribed information.

Quantity

(2) The quantity of the product authorized to be manufactured by an authorization may not be more than the lesser of

(*a*) the maximum quantity set out in the application for the authorization, and

(*b*) the quantity set out in the notice referred to in any of subparagraphs 21.04(3)(*d*)(i) to (v), whichever is applicable.

2004, c. 23, s. 1.

Disclosure of information on website

21.06 (1) Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the country or WTO Member to which it is to be exported, the quantity that is authorized to be manufactured and sold for export and the distinguishing features of the product, and of its label and packaging, as required by regulations made under the *Food and Drugs Act*, as well as information identifying every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported.

Obligation to maintain

(2) The holder must maintain the website during the entire period during which the authorization is valid.

Links to other websites

(3) The Commissioner shall post and maintain on the website of the Canadian Intellectual Property Office a link to each website required to be maintained by the holder of an authorization under subsection (1).

Posting on the website

(4) The Commissioner shall, within seven days of receipt, post on the website of the Canadian Intellectual Property Office each application for authorization filed under subsection 21.04(1).

2004, c. 23, s. 1.

Export notice

21.07 Before each shipment of any quantity of a product manufactured under an authorization, the holder of the authorization must, within fifteen days before the product is exported, provide to each of the following a notice, by certified or registered mail, specifying the quantity to be exported, as well as every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported:
(*a*) the patentee or each of the patentees, as the case may be;
(*b*) the country or WTO Member named in the authorization; and
(*c*) the person or entity that purchased the product to which the authorization relates.

2004, c. 23, s. 1.

Royalty

21.08 (1) Subject to subsections (3) and (4), on the occurrence of a prescribed event, the holder of an authorization is required to pay to the patentee or each patentee, as the case may be, a royalty determined in the prescribed manner.

Factors to consider when making regulations

(2) In making regulations for the purposes of subsection (1), the Governor in Council must consider the humanitarian and non-commercial reasons underlying the issuance of authorizations under subsection 21.04(1).

Time for payment

(3) The royalties payable under this section must be paid within the prescribed time.

Federal Court may determine royalty

(4) The Federal Court may, in relation to any authorization, make an order providing for the payment of a royalty that is greater than the royalty that would otherwise be required to be paid under subsection (1).

Application and notice

(5) An order may be made only on the application of the patentee, or one of the patentees, as the case may be, and on notice of the application being given by the applicant to the holder of the authorization.

Contents of order

(6) An order may provide for a royalty of a fixed amount or for a royalty to be determined as specified in the order, and the order may be subject to any terms that the Federal Court considers appropriate.

Conditions for making of order

(7) The Federal Court may make an order only if it is satisfied that the royalty otherwise required to be paid is not adequate remuneration for the use of the invention or inventions to which the authorization relates, taking into account
(*a*) the humanitarian and non-commercial reasons underlying the issuance of the authorization; and
(*b*) the economic value of the use of the invention or inventions to the country or WTO Member.

2004, c. 23, s. 1.

Duration

21.09 An authorization granted under subsection 21.04(1) is valid for a period of two years beginning on the day on which the authorization is granted.

2004, c. 23, s. 1.

Use is non-exclusive

21.1 The use of a patented invention under an authorization is non-exclusive.

2004, c. 23, s. 1.

Authorization is non-transferable

21.11 An authorization is non-transferable, other than where the authorization is an asset of a corporation or enterprise and the part of the corporation or enterprise that enjoys the use of the authorization is sold, assigned or otherwise transferred.
2004, c. 23, s. 1.

Renewal

21.12 (1) The Commissioner shall, on the application of the person to whom an authorization was granted and on the payment of the prescribed fee, renew the authorization if the person certifies under oath in the renewal application that the quantities of the pharmaceutical product authorized to be exported were not exported before the authorization ceases to be valid and that the person has complied with the terms of the authorization and the requirements of sections 21.06 to 21.08.

One renewal

(2) An authorization may be renewed only once.

When application must be made

(3) The application for renewal must be made within the 30 days immediately before the authorization ceases to be valid.

Duration

(4) An authorization that is renewed is valid for a period of two years beginning on the day immediately following the day of the expiry of the period referred to in section 21.09 in respect of the authorization.

Prescribed form

(5) Applications for renewal and renewed authorizations issued under subsection (1) must be in the prescribed form.
2004, c. 23, s. 1.

Termination

21.13 Subject to section 21.14, an authorization ceases to be valid on the earliest of
(*a*) the expiry of the period referred to in section 21.09 in respect of the authorization, or the expiry of the period referred to in subsection 21.12(4) if the authorization has been renewed, as the case may be,
(*b*) the day on which the Commissioner sends, by registered mail, to the holder of the authorization a copy of a notice sent by the Minister of Health notifying the Commissioner that the Minister of Health is of the opinion that the pharmaceutical product referred to in paragraph 21. 04(3)(*b*) has ceased to meet the requirements of the *Food and Drugs Act* and its regulations,
(*c*) the day on which the last of the pharmaceutical product authorized by the authorization to be exported is actually exported,
(*d*) thirty days after the day on which

(i) the name of the pharmaceutical product authorized to be exported by the authorization is removed from Schedule 1, or

(ii) the name of the country or WTO Member to which the pharmaceutical product was, or is to be, exported is removed from Schedule 2, 3 or 4, as the case may be, and not added to any other of those Schedules, and

(*e*) on any other day that is prescribed.

2004, c. 23, s. 1.

Termination by Federal Court

21.14 On the application of a patentee, and on notice given by the patentee to the person to whom an authorization was granted, the Federal Court may make an order, on any terms that it considers appropriate, terminating the authorization if the patentee establishes that

(*a*) the application for the authorization or any of the documents provided to the Commissioner in relation to the application contained any material information that is inaccurate;

(*b*) the holder of the authorization has failed to establish a website as required by section 21.06, has failed to disclose on that website the information required to be disclosed by that section or has failed to maintain the website as required by that section;

(*c*) the holder of the authorization has failed to provide a notice required to be given under section 21.07;

(*d*) the holder of the authorization has failed to pay, within the required time, any royalty required to be paid as a result of the authorization;

(*e*) the holder of the authorization has failed to comply with subsection 21.16(2);

(*f*) the product exported to the country or WTO Member, as the case may be, under the authorization has been, with the knowledge of the holder of the authorization, re-exported in a manner that is contrary to the General Council Decision;

(*g*) the product was exported, other than in the normal course of transit, to a country or WTO Member other than the country or WTO Member named in the authorization;

(*h*) the product was exported in a quantity greater than the quantity authorized to be manufactured; or

(*i*) if the product was exported to a country that is not a WTO Member, the country has permitted the product to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision.

2004, c. 23, s. 1.

Notice to patentee

21.15 The Commissioner shall, without delay, notify the patentee, or each of the patentees, as the case may be, in writing of any authorization granted in respect of the patentee's invention.

2004, c. 23, s. 1.

Obligation to provide copy of agreement

21.16 (1) Within fifteen days after the later of the day on which the authorization was granted and the day on which the agreement for the sale of the product to which the authorization relates was entered into, the holder of an authorization must provide by certified or registered mail, the Commissioner and the patentee, or each patentee, as the case may be, with

(*a*) a copy of the agreement it has reached with the person or entity referred to in paragraph 21.04(2)(*f*) for the supply of the product authorized to be manufactured and sold, which agreement must incorporate information that is in all material respects identical to the information referred to in paragraphs 21.04(2)(*a*), (*b*), (*e*) and (*f*); and
(*b*) a solemn or statutory declaration in the prescribed form setting out
(i) the total monetary value of the agreement as it relates to the product authorized to be manufactured and sold, expressed in Canadian currency, and
(ii) the number of units of the product to be sold under the terms of the agreement.

Prohibition

(2) The holder of an authorization may not export any product to which the authorization relates until after the holder has complied with subsection (1).
2004, c. 23, s. 1.

Application when agreement is commercial in nature

21.17 (1) If the average price of the product to be manufactured under an authorization is equal to or greater than 25 per cent of the average price in Canada of the equivalent product sold by or with the consent of the patentee, the patentee may, on notice given by the patentee to the person to whom an authorization was granted, apply to the Federal Court for an order under subsection (3) on the grounds that the essence of the agreement under which the product is to be sold is commercial in nature.

Factors for determining whether agreement is commercial in nature

(2) In determining whether the agreement is commercial in nature, the Federal Court must take into account
(*a*) the need for the holder of the authorization to make a reasonable return sufficient to sustain a continued participation in humanitarian initiatives;
(*b*) the ordinary levels of profitability, in Canada, of commercial agreements involving pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision; and
(*c*) international trends in prices as reported by the United Nations for the supply of such products for humanitarian purposes.

Order

(3) If the Federal Court determines that the agreement is commercial in nature, it may make an order, on any terms that it considers appropriate,
(*a*) terminating the authorization; or
(*b*) requiring the holder to pay, in addition to the royalty otherwise required to be paid, an amount that the Federal Court considers adequate to compensate the patentee for the commercial use of the patent.

Additional order

(4) If the Federal Court makes an order terminating the authorization, the Federal Court may also, if it considers it appropriate to do so, make an order, on any terms that it considers appropriate,

(*a*) requiring the holder to deliver to the patentee any of the product to which the authorization relates remaining in the holder's possession as though the holder had been determined to have been infringing a patent; or
(*b*) with the consent of the patentee, requiring the holder to export any of the product to which the authorization relates remaining in the holder's possession to the country or WTO Member named in the authorization.

Restriction

(5) The Federal Court may not make an order under subsection (3) if, under the protection of a confidentiality order made by the Court, the holder of the authorization submits to a Court-supervised audit and that audit establishes that the average price of the product manufactured under the authorization does not exceed an amount equal to the direct supply cost of the product plus 15 per cent of that direct supply cost.

Definitions

(6) The following definitions apply in this section.

"average price"
« *prix moyen* »

"average price" means
(*a*) in relation to a product to be manufactured under an authorization, the total monetary value of the agreement under which the product is to be sold, expressed in Canadian currency, divided by the number of units of the product to be sold under the terms of the agreement; and
(*b*) in relation to an equivalent product sold by or with the consent of the patentee, the average of the prices in Canada of that product as those prices are reported in prescribed publications on the day on which the application for the authorization was filed.

"direct supply cost"
« *coût direct de fourniture* »

"direct supply cost", in relation to a product to be manufactured under an authorization, means the cost of the materials and of the labour, and any other manufacturing costs, directly related to the production of the quantity of the product that is to be manufactured under the authorization.

"unit"
« *unité* »

"unit", in relation to any product, means a single tablet, capsule or other individual dosage form of the product, and if applicable, in a particular strength.

2004, c. 23, s. 1.

Advisory committee

21.18 (1) The Minister and the Minister of Health shall establish, within three years after the day this section comes into force, an advisory committee to advise them on the recommendations that they may make to the Governor in Council respecting the amendment of Schedule 1.

Standing committee

(2) The standing committee of each House of Parliament that normally considers matters related to industry shall assess all candidates for appointment to the advisory committee and make recommendations to the Minister and the Minister of Health on the eligibility and qualifications of those candidates.

2004, c. 23, s. 1; 2005, c. 18, s. 1.

Website for notices to Canada

21.19 The person designated by the Governor in Council for the purpose of this section must maintain a website on which is set out a copy of every notice referred to in subparagraphs 21.04(3)(*d*)(ii) and (v) that is provided to the Government of Canada through diplomatic channels by a country that is not a WTO Member. The copy must be added to the website as soon as possible after the notice has been provided to the Government of Canada.

2004, c. 23, s. 1.

Review

21.2 (1) A review of sections 21.01 to 21.19 and their application must be completed by the Minister two years after this section comes into force.

Tabling of report

(2) The Minister must cause a report of the results of the review to be laid before each House of Parliament on any of the first fifteen days on which that House is sitting after the report has been completed.

2004, c. 23, s. 1.

PATENTS RELATING TO NUCLEAR ENERGY

Communication to Canadian Nuclear Safety Commission

22. Any application for a patent for an invention that, in the opinion of the Commissioner, relates to the production, application or use of nuclear energy shall, before it is dealt with by an examiner appointed pursuant to section 6 or is open to inspection by the public under section 10, be communicated by the Commissioner to the Canadian Nuclear Safety Commission.

R.S., 1985, c. P-4, s. 22; R.S., 1985, c. 33 (3rd Supp.), s. 5; 1997, c. 9, s. 111.

GENERAL

Patented invention in vessels, aircraft, etc., of any country

23. No patent shall extend to prevent the use of any invention in any ship, vessel, aircraft or land vehicle of any country entering Canada temporarily or accidentally, if the invention is employed exclusively for the needs of the ship, vessel, aircraft or land vehicle, and not so used for the manufacture of any goods to be sold within or exported from Canada.

R.S., c. P-4, s. 23.

24. [Repealed, R.S., 1985, c. 33 (3rd Supp.), s. 6]

Cost of proceedings before the court

25. In all proceedings before any court under this Act, the costs of the Commissioner are in the discretion of the court, but the Commissioner shall not be ordered to pay the costs of any other of the parties.

R.S., c. P-4, s. 25.

Annual report

26. The Commissioner shall, in each year, cause to be prepared and laid before Parliament a report of the proceedings under this Act.

R.S., 1985, c. P-4, s. 26; R.S., 1985, c. 33 (3rd Supp.), s. 7.

Publication of list of patents

26.1 (1) The Commissioner shall, at least once in each year, publish a list of all patents issued in the year.

Publication and printing of documents

(2) The Commissioner may publish any document open to the inspection of the public under section 10 and may print or cause to be printed, for distribution or sale, any such document.

R.S., 1985, c. 33 (3rd Supp.), s. 7.

APPLICATION FOR PATENTS

Commissioner may grant patents

27. (1) The Commissioner shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.

Application requirements

(2) The prescribed application fee must be paid and the application must be filed in accordance with the regulations by the inventor or the inventor's legal representative and the application must contain a petition and a specification of the invention.

Specification

(3) The specification of an invention must
(*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
(*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
(*c*) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and

(*d*) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

Claims

(4) The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

Alternative definition of subject-matter

(5) For greater certainty, where a claim defines the subject-matter of an invention in the alternative, each alternative is a separate claim for the purposes of sections 2, 28.1 to 28.3 and 78.3.

When application to be completed

(6) Where an application does not completely meet the requirements of subsection (2) on its filing date, the Commissioner shall, by notice to the applicant, require the application to be completed on or before the date specified in the notice.

Specified period

(7) The specified date must be at least three months after the date of the notice and at least twelve months after the filing date of the application.

What may not be patented

(8) No patent shall be granted for any mere scientific principle or abstract theorem.

R.S., 1985, c. P-4, s. 27; R.S., 1985, c. 33 (3rd Supp.), s. 8; 1993, c. 15, s. 31, c. 44, s. 192.

Maintenance fees

27.1 (1) An applicant for a patent shall, to maintain the application in effect, pay to the Commissioner such fees, in respect of such periods, as may be prescribed.

(2) and (3) [Repealed, 1993, c. 15, s. 32]

R.S., 1985, c. 33 (3rd Supp.), s. 9; 1993, c. 15, s. 32.

Filing date

28. (1) The filing date of an application for a patent in Canada is the date on which the Commissioner receives the documents, information and fees prescribed for the purposes of this section or, if they are received on different dates, the last date.

Deemed date of receipt of fees

(2) The Commissioner may, for the purposes of this section, deem prescribed fees to have been received on a date earlier than the date of their receipt if the Commissioner considers it just to do so.

R.S., 1985, c. P-4, s. 28; R.S., 1985, c. 33 (3rd Supp.), s. 10; 1993, c. 15, s. 33.

Claim date

28.1 (1) The date of a claim in an application for a patent in Canada (the "pending application") is the filing date of the application, unless
(*a*) the pending application is filed by
(i) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or
(ii) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim;
(*b*) the filing date of the pending application is within twelve months after the filing date of the previously regularly filed application; and
(*c*) the applicant has made a request for priority on the basis of the previously regularly filed application.

Claims based on previously regularly filed applications

(2) In the circumstances described in paragraphs (1)(*a*) to (*c*), the claim date is the filing date of the previously regularly filed application.
1993, c. 15, s. 33.

Subject-matter of claim must not be previously disclosed

28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
(*a*) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
(*b*) before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
(*c*) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date; or
(*d*) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if
(i) the co-pending application is filed by
(A) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or
(B) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim,
(ii) the filing date of the previously regularly filed application is before the claim date of the pending application,
(iii) the filing date of the co-pending application is within twelve months after the filing date of the previously regularly filed application, and

(iv) the applicant has, in respect of the co-pending application, made a request for priority on the basis of the previously regularly filed application.

Withdrawal of application

(2) An application mentioned in paragraph (1)(*c*) or a co-pending application mentioned in paragraph (1)(*d*) that is withdrawn before it is open to public inspection shall, for the purposes of this section, be considered never to have been filed.

1993, c. 15, s. 33.

Invention must not be obvious

28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to
(*a*) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
(*b*) information disclosed before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the information became available to the public in Canada or elsewhere.

1993, c. 15, s. 33.

Request for priority

28.4 (1) For the purposes of sections 28.1, 28.2 and 78.3, an applicant for a patent in Canada may request priority in respect of the application on the basis of one or more previously regularly filed applications.

Requirements governing request

(2) The request for priority must be made in accordance with the regulations and the applicant must inform the Commissioner of the filing date, country or office of filing and number of each previously regularly filed application on which the request is based.

Withdrawal of request

(3) An applicant may, in accordance with the regulations, withdraw a request for priority, either entirely or with respect to one or more previously regularly filed applications.

Multiple previously regularly filed applications

(4) Where two or more applications have been previously regularly filed as described in paragraph 28.1(1)(*a*), subparagraph 28.2(1)(*d*)(i) or paragraph 78.3(1)(*a*) or (2)(*a*), either in the same country or in different countries,
(*a*) paragraph 28.1(1)(*b*), subparagraph 28.2(1)(*d*)(iii) or paragraph 78.3(1)(*b*) or (2)(*b*), as the case may be, shall be applied using the earliest filing date of the previously regularly filed applications; and

(*b*) subsection 28.1(2), subparagraph 28.2(1)(*d*)(ii) or paragraph 78.3(1)(*d*) or (2)(*d*), as the case may be, shall be applied using the earliest filing date of the previously regularly filed applications on the basis of which a request for priority is made.

Withdrawal, etc., of previously regularly filed applications

(5) A previously regularly filed application mentioned in section 28.1 or 28.2 or subsection 78.3(1) or (2) shall, for the purposes of that section or subsection, be considered never to have been filed if

(*a*) it was filed more than twelve months before the filing date of

(i) the pending application, in the case of section 28.1,

(ii) the co-pending application, in the case of section 28.2,

(iii) the later application, in the case of subsection 78.3(1), or

(iv) the earlier application, in the case of subsection 78.3(2);

(*b*) before the filing date referred to in paragraph (*a*), another application

(i) is filed by the person who filed the previously regularly filed application or by the agent, legal representative or predecessor in title of that person,

(ii) is filed in or for the country where the previously regularly filed application was filed, and

(iii) discloses the subject-matter defined by the claim in the application mentioned in paragraph (*a*); and

(*c*) on the filing date of the other application mentioned in paragraph (*b*) or, if there is more than one such application, on the earliest of their filing dates, the previously regularly filed application

(i) has been withdrawn, abandoned or refused without having been opened to public inspection and without leaving any rights outstanding, and

(ii) has not served as a basis for a request for priority in any country, including Canada.

1993, c. 15, s. 33; 2001, c. 34, s. 63.

Non-resident applicants

29. (1) An applicant for a patent who does not appear to reside or carry on business at a specified address in Canada shall, on the filing date of the application, appoint as a representative a person or firm residing or carrying on business at a specified address in Canada.

Nominee deemed representative

(2) Subject to this section, a nominee of an applicant shall be deemed to be the representative for all purposes of this Act, including the service of any proceedings taken under it, of the applicant and of any patentee of a patent issued on his application who does not appear to reside or carry on business at a specified address in Canada, and shall be recorded as such by the Commissioner.

New representatives

(3) An applicant for a patent or a patentee

(*a*) may, by giving notice to the Commissioner, appoint a new representative in place of the latest recorded representative, or may give notice to the Commissioner of a change in the address of the latest recorded representative; and

(*b*) shall so appoint a new representative or supply a new and correct address of the latest recorded representative on receipt of a request of the Commissioner stating that the latest recorded representative has died or that a letter addressed to the latest recorded representative at the latest recorded address and sent by ordinary mail has been returned undelivered.

Where no new appointment is made or no new address supplied

(4) Where the Commissioner makes a request under paragraph (3)(*b*) and no new appointment is made or no new and correct address is supplied by the applicant or patentee within three months, the Federal Court or the Commissioner may dispose of any proceedings under this Act without requiring service on the applicant or patentee of any process in the proceedings.

When fee payable

(5) No fee is payable on the appointment of a new representative or the supply of a new and correct address, unless that appointment or supply follows a request by the Commissioner under subsection (3), in which case the prescribed fee is payable.

R.S., 1985, c. P-4, s. 29; 1993, c. 15, s. 34.

30. [Repealed, 1993, c. 15, s. 35]

JOINT APPLICATIONS

Effect of refusal of a joint inventor to proceed

31. (1) Where an invention is made by two or more inventors and one of them refuses to make application for a patent or his whereabouts cannot be ascertained after diligent inquiry, the other inventors or their legal representatives may make application, and a patent may be granted in the name of the inventors who make the application, on satisfying the Commissioner that the joint inventor has refused to make application or that his whereabouts cannot be ascertained after diligent inquiry.

Powers of Commissioner

(2) In any case where

(*a*) an applicant has agreed in writing to assign a patent, when granted, to another person or to a joint applicant and refuses to proceed with the application, or

(*b*) disputes arise between joint applicants with respect to proceeding with an application,

the Commissioner, on proof of the agreement to his satisfaction, or if satisfied that one or more of the joint applicants ought to be allowed to proceed alone, may allow that other person or joint applicant to proceed with the application, and may grant a patent to him in such manner that all persons interested are entitled to be heard before the Commissioner after such notice as he may deem requisite and sufficient.

Procedure when one joint applicant retires

(3) Where an application is filed by joint applicants and it subsequently appears that one or more of them has had no part in the invention, the prosecution of the application may be carried on by the remaining applicant or applicants on satisfying

the Commissioner by affidavit that the remaining applicant or applicants is or are the sole inventor or inventors.

Joining applicants

(4) Where an application is filed by one or more applicants and it subsequently appears that one or more further applicants should have been joined, the further applicant or applicants may be joined on satisfying the Commissioner that he or they should be so joined, and that the omission of the further applicant or applicants had been by inadvertence or mistake and was not for the purpose of delay.

To whom granted

(5) Subject to this section, in cases of joint applications, the patent shall be granted in the names of all the applicants.

Appeal

(6) An appeal lies to the Federal Court from the decision of the Commissioner under this section.

R.S., c. P-4, s. 33; R.S., c. 10(2nd Supp.), s. 64.

IMPROVEMENTS

Improvements

32. Any person who has invented any improvement on any patented invention may obtain a patent for the improvement, but he does not thereby obtain the right of making, vending or using the original invention, nor does the patent for the original invention confer the right of making, vending or using the patented improvement.

R.S., c. P-4, s. 34.

33. and 34. [Repealed, 1993, c. 15, s. 36]

FILING OF PRIOR ART

Filing

34.1 (1) Any person may file with the Commissioner prior art, consisting of patents, applications for patents open to public inspection and printed publications, that the person believes has a bearing on the patentability of any claim in an application for a patent.

Pertinency

(2) A person who files prior art with the Commissioner under subsection (1) shall explain the pertinency of the prior art.

R.S., 1985, c. 33 (3rd Supp.), s. 11; 1993, c. 15, s. 37.

EXAMINATION

Request for examination

35. (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.

Required examination

(2) The Commissioner may by notice require an applicant for a patent to make a request for examination pursuant to subsection (1) or to pay the prescribed fee within the time specified in the notice, but the specified time may not exceed the time provided by the regulations for making the request and paying the fee.

(3) and (4) [Repealed, 1993, c. 15, s. 38]

R.S., 1985, c. P-4, s. 35; R.S., 1985, c. 33 (3rd Supp.), s. 12; 1993, c. 15, s. 38.

DIVISIONAL APPLICATIONS

Patent for one invention only

36. (1) A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.

Limitation of claims by applicant

(2) Where an application (the “original application”) describes more than one invention, the applicant may limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.

Limitation of claims on direction of Commissioner

(2.1) Where an application (the “original application”) describes and claims more than one invention, the applicant shall, on the direction of the Commissioner, limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.

Original application abandoned

(3) If an original application mentioned in subsection (2) or (2.1) becomes abandoned, the time for filing a divisional application terminates with the expiration of the time for reinstating the original application under this Act.

Separate applications

(4) A divisional application shall be deemed to be a separate and distinct application under this Act, to which its provisions apply as fully as may be, and

separate fees shall be paid on the divisional application and it shall have the same filing date as the original application.

R.S., 1985, c. P-4, s. 36; 1993, c. 15, s. 39.

DRAWINGS, MODELS AND BIOLOGICAL MATERIALS

Drawings

37. (1) In the case of a machine, or in any other case in which an invention admits of illustration by means of drawings, the applicant shall, as part of the application, furnish drawings of the invention that clearly show all parts of the invention.

Particulars

(2) Each drawing must include references corresponding with the specification, and the Commissioner may require further drawings or dispense with any of them as the Commissioner sees fit.

R.S., 1985, c. P-4, s. 37; 1993, c. 15, s. 40.

Models and specimens

38. (1) In all cases in which an invention admits of representation by model, the applicant, if required by the Commissioner, shall furnish a model of convenient size exhibiting its several parts in due proportion, and when an invention is a composition of matter, the applicant, if required by the Commissioner, shall furnish specimens of the ingredients, and of the composition, sufficient in quantity for the purpose of experiment.

Dangerous substances

(2) If the ingredients or composition referred to in subsection (1) are of an explosive or dangerous character, they shall be furnished with such precautions as are specified in the requisition therefor.

R.S., 1985, c. P-4, s. 38; R.S., 1985, c. 33 (3rd Supp.), s. 13.

Biological material may be deposited

38.1 (1) Where a specification refers to a deposit of biological material and the deposit is in accordance with the regulations, the deposit shall be considered part of the specification and, to the extent that subsection 27(3) cannot otherwise reasonably be complied with, the deposit shall be taken into consideration in determining whether the specification complies with that subsection.

Deposit not required

(2) For greater certainty, a reference to a deposit of biological material in a specification does not create a presumption that the deposit is required for the purpose of complying with subsection 27(3).

1993, c. 15, s. 41.

AMENDMENTS TO SPECIFICATIONS AND DRAWINGS

Amendments to specifications and drawings

38.2 (1) Subject to subsections (2) and (3) and the regulations, the specification and any drawings furnished as part of an application for a patent in Canada may be amended before the patent is issued.

Restriction on amendments to specifications

(2) The specification may not be amended to describe matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application.

Restriction on amendments to drawings

(3) Drawings may not be amended to add matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application.

1993, c. 15, s. 41.

39. to 39.26 [Repealed, 1993, c. 2, s. 3]

REFUSAL OF PATENTS

Refusal by Commissioner

40. Whenever the Commissioner is satisfied that an applicant is not by law entitled to be granted a patent, he shall refuse the application and, by registered letter addressed to the applicant or his registered agent, notify the applicant of the refusal and of the ground or reason therefor.

R.S., c. P-4, s. 42.

Appeal to Federal Court

41. Every person who has failed to obtain a patent by reason of a refusal of the Commissioner to grant it may, at any time within six months after notice as provided for in section 40 has been mailed, appeal from the decision of the Commissioner to the Federal Court and that Court has exclusive jurisdiction to hear and determine the appeal.

R.S., 1985, c. P-4, s. 41; R.S., 1985, c. 33 (3rd Supp.), s. 16.

GRANT OF PATENTS

Contents of patent

42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.

R.S., 1985, c. P-4, s. 42; R.S., 1985, c. 33 (3rd Supp.), s. 16.

FORM AND TERM OF PATENTS

Form and duration of patents

43. (1) Subject to section 46, every patent granted under this Act shall be issued under the seal of the Patent Office, and shall bear on its face the filing date of the application for the patent, the date on which the application became open to public inspection under section 10, the date on which the patent is granted and issued and any prescribed information.

Validity of patent

(2) After the patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in section 44 or 45, whichever is applicable.

R.S., 1985, c. P-4, s. 43; R.S., 1985, c. 33 (3rd Supp.), s. 16; 1993, c. 15, s. 42.

Term of patents based on applications filed on or after October 1, 1989

44. Subject to section 46, where an application for a patent is filed under this Act on or after October 1, 1989, the term limited for the duration of the patent is twenty years from the filing date.

R.S., 1985, c. P-4, s. 44; R.S., 1985, c. 33 (3rd Supp.), s. 16; 1993, c. 15, s. 42.

Term of patents based on applications filed before October 1, 1989

45. (1) Subject to section 46, where an application for a patent is filed under this Act before October 1, 1989, the term limited for the duration of the patent is seventeen years from the date on which the patent is issued.

Term from date of issue or filing

(2) Where the term limited for the duration of a patent referred to in subsection (1) had not expired before the day on which this section came into force, the term is seventeen years from the date on which the patent is issued or twenty years from the filing date, whichever term expires later.

R.S., 1985, c. P-4, s. 45; R.S., 1985, c. 33 (3rd Supp.), s. 16; 1993, c. 15, s. 42; 2001, c. 10, s. 1.

Maintenance fees

46. (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.

Lapse of term if maintenance fees not paid

(2) Where the fees payable under subsection (1) are not paid within the time provided by the regulations, the term limited for the duration of the patent shall be deemed to have expired at the end of that time.

R.S., 1985, c. P-4, s. 46; R.S., 1985, c. 33 (3rd Supp.), s. 16; 1993, c. 15, s. 43.

REISSUE OF PATENTS

Issue of new or amended patents

47. (1) Whenever any patent is deemed defective or inoperative by reason of insufficient description and specification, or by reason of the patentee's claiming more or less than he had a right to claim as new, but at the same time it appears that the error arose from inadvertence, accident or mistake, without any fraudulent or deceptive intention, the Commissioner may, on the surrender of the patent within four years from its date and the payment of a further prescribed fee, cause a new patent, in accordance with an amended description and specification made by the patentee, to be issued to him for the same invention for the then unexpired term for which the original patent was granted.

Effect of new patent

(2) The surrender referred to in subsection (1) takes effect only on the issue of the new patent, and the new patent and the amended description and specification have the same effect in law, on the trial of any action thereafter commenced for any cause subsequently accruing, as if the amended description and specification had been originally filed in their corrected form before the issue of the original patent, but, in so far as the claims of the original and reissued patents are identical, the surrender does not affect any action pending at the time of reissue or abate any cause of action then existing, and the reissued patent to the extent that its claims are identical with the original patent constitutes a continuation thereof and has effect continuously from the date of the original patent.

Separate patents for separate parts

(3) The Commissioner may entertain separate applications and cause patents to be issued for distinct and separate parts of the invention patented, on payment of the fee for a reissue for each of the reissued patents.

R.S., c. P-4, s. 50.

DISCLAIMERS

Patentee may disclaim anything included in patent by mistake

48. (1) Whenever, by any mistake, accident or inadvertence, and without any wilful intent to defraud or mislead the public, a patentee has
(*a*) made a specification too broad, claiming more than that of which the patentee or the person through whom the patentee claims was the inventor, or
(*b*) in the specification, claimed that the patentee or the person through whom the patentee claims was the inventor of any material or substantial part of the invention patented of which the patentee was not the inventor, and to which the patentee had no lawful right,
the patentee may, on payment of a prescribed fee, make a disclaimer of such parts as the patentee does not claim to hold by virtue of the patent or the assignment thereof.

Form and attestation of disclaimer

(2) A disclaimer shall be filed in the prescribed form and manner.

(3) [Repealed, 1993, c. 15, s. 44]

Pending suits not affected

(4) No disclaimer affects any action pending at the time when it is made, unless there is unreasonable neglect or delay in making it.

Death of patentee

(5) In case of the death of an original patentee or of his having assigned the patent, a like right to disclaim vests in his legal representatives, any of whom may exercise it.

Effect of disclaimer

(6) A patent shall, after disclaimer as provided in this section, be deemed to be valid for such material and substantial part of the invention, definitely distinguished from other parts thereof claimed without right, as is not disclaimed and is truly the invention of the disclaimant, and the disclaimant is entitled to maintain an action or suit in respect of that part accordingly.

R.S., 1985, c. P-4, s. 48; R.S., 1985, c. 33 (3rd Supp.), s. 17; 1993, c. 15, s. 44.

RE-EXAMINATION

Request for re-examination

48.1 (1) Any person may request a re-examination of any claim of a patent by filing with the Commissioner prior art, consisting of patents, applications for patents open to public inspection and printed publications, and by paying a prescribed fee.

Pertinency of request

(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.

Notice to patentee

(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.

R.S., 1985, c. 33 (3rd Supp.), s. 18; 1993, c. 15, s. 45.

Establishment of re-examination board

48.2 (1) Forthwith after receipt of a request for re-examination under subsection 48.1(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.

Determination to be made by board

(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.

Notice

(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.

Idem

(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.

Filing of reply

(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.

R.S., 1985, c. 33 (3rd Supp.), s. 18; 1993, c. 15, s. 46(F).

Re-examination proceeding

48.3 (1) On receipt of a reply under subsection 48.2(5) or in the absence of any reply within three months after notice is given under subsection 48.2(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.

Patentee may submit amendments

(2) In any re-examination proceeding under subsection (1), the patentee may propose any amendment to the patent or any new claims in relation thereto but no proposed amendment or new claim enlarging the scope of a claim of the patent shall be permitted.

Time limitation

(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).

R.S., 1985, c. 33 (3rd Supp.), s. 18.

Certificate of board

48.4 (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.

Certificate attached to patent

(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 certificate shall be sent by registered mail to the patentee.

Effect of certificate

(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 corrected 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.

Appeals

(4) Subsection (3) does not apply until the time for taking an appeal has expired under subsection 48.5(2) and, if an appeal is taken, subsection (3) applies only to the extent provided in the final judgment on the appeal.

R.S., 1985, c. 33 (3rd Supp.), s. 18; 1993, c. 15, s. 47.

Appeals

48.5 (1) Any decision of a re-examination board set out in a certificate issued under subsection 48.4(1) is subject to appeal by the patentee to the Federal Court.

Limitation

(2) No appeal may be taken under subsection (1) after three months from the date a copy of the certificate is sent by registered mail to the patentee.

R.S., 1985, c. 33 (3rd Supp.), s. 18.

ASSIGNMENTS AND DEVOLUTIONS

Assignee or personal representatives

49. (1) A patent may be granted to any person to whom an inventor, entitled under this Act to obtain a patent, has assigned in writing or bequeathed by his last will his right to obtain it, and, in the absence of an assignment or bequest, the

patent may be granted to the personal representatives of the estate of the deceased inventor.

Assignees may object

(2) Where an applicant for a patent has, after filing the application, assigned his right to obtain the patent, or where the applicant has either before or after filing the application assigned in writing the whole or part of his property or interest in the invention, the assignee may register the assignment in the Patent Office in such manner as may be determined by the Commissioner, and no application for a patent may be withdrawn without the consent in writing of every such registered assignee.

Attestation

(3) No assignment shall be registered in the Patent Office unless it is accompanied by the affidavit of a subscribing witness or established by other proof to the satisfaction of the Commissioner that the assignment has been signed and executed by the assignor.

R.S., 1985, c. P-4, s. 49; R.S., 1985, c. 33 (3rd Supp.), s. 19.

Patents to be assignable

50. (1) Every patent issued for an invention is assignable in law, either as to the whole interest or as to any part thereof, by an instrument in writing.

Registration

(2) Every assignment of a patent, and every grant and conveyance of any exclusive right to make and use and to grant to others the right to make and use the invention patented, within and throughout Canada or any part thereof, shall be registered in the Patent Office in the manner determined by the Commissioner.

Attestation

(3) No assignment, grant or conveyance shall be registered in the Patent Office unless it is accompanied by the affidavit of a subscribing witness or established by other proof to the satisfaction of the Commissioner that the assignment, grant or conveyance has been signed and executed by the assignor and by every other party thereto.

R.S., 1985, c. P-4, s. 50; R.S., 1985, c. 33 (3rd Supp.), s. 20.

When assignment void

51. Every assignment affecting a patent for invention, whether it is one referred to in section 49 or 50, is void against any subsequent assignee, unless the assignment is registered as prescribed by those sections, before the registration of the instrument under which the subsequent assignee claims.

R.S., c. P-4, s. 53.

Jurisdiction of Federal Court

52. The Federal Court has jurisdiction, on the application of the Commissioner or of any person interested, to order that any entry in the records of the Patent Office relating to the title to a patent be varied or expunged.

R.S., c. P-4, s. 54; R.S., c. 10(2nd Supp.), s. 64.

LEGAL PROCEEDINGS IN RESPECT OF PATENTS

Void in certain cases, or valid only for parts

53. (1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.

Exception

(2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention described to which the patentee is so found to be entitled.

Copies of judgment

(3) Two office copies of the judgment rendered under subsection (1) shall be furnished to the Patent Office by the patentee, one of which shall be registered and remain of record in the Office and the other attached to the patent and made a part of it by a reference thereto.

R.S., c. P-4, s. 55.

INFRINGEMENT

Jurisdiction of courts

54. (1) An action for the infringement of a patent may be brought in that court of record that, in the province in which the infringement is said to have occurred, has jurisdiction, pecuniarily, to the amount of the damages claimed and that, with relation to the other courts of the province, holds its sittings nearest to the place of residence or of business of the defendant, and that court shall decide the case and determine the costs, and assumption of jurisdiction by the court is of itself sufficient proof of jurisdiction.

Jurisdiction of Federal Court

(2) Nothing in this section impairs the jurisdiction of the Federal Court under section 20 of the *Federal Courts Act* or otherwise.

R.S., 1985, c. P-4, s. 54; 2002, c. 8, s. 182.

Liability for patent infringement

55. (1) A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damage sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement.

Liability damage before patent is granted

(2) A person is liable to pay reasonable compensation to a patentee and to all persons claiming under the patentee for any damage sustained by the patentee or by any of those persons by reason of any act on the part of that person, after the application for the patent became open to public inspection 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 public inspection under that section.

Patentee to be a party

(3) Unless otherwise expressly provided, the patentee shall be or be made a party to any proceeding under subsection (1) or (2).

Deemed action for infringement

(4) For the purposes of this section and sections 54 and 55.01 to 59, any proceeding under subsection (2) is deemed to be an action for the infringement of a patent and the act on which that proceeding is based is deemed to be an act of infringement of the patent.

R.S., 1985, c. P-4, s. 55; R.S., 1985, c. 33 (3rd Supp.), s. 21; 1993, c. 15, s. 48.

Limitation

55.01 No remedy may be awarded for an act of infringement committed more than six years before the commencement of the action for infringement.

1993, c. 15, s. 48.

Burden of proof for patented process

55.1 In an action for infringement of a patent granted for a process for obtaining a new product, any product that is the same as the new product shall, in the absence of proof to the contrary, be considered to have been produced by the patented process.

1993, c. 2, s. 4, c. 44, s. 193.

Exception

55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

(2) and (3) [Repealed, 2001, c. 10, s. 2]

Regulations

(4) The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing, regulations
(*a*) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee or other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;
(*b*) respecting the earliest date on which a notice, certificate, permit or other document referred to in paragraph (*a*) that is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;
(*c*) governing the resolution of disputes between a patentee or former patentee and any person who applies for a notice, certificate, permit or other document referred to in paragraph (*a*) as to the date on which that notice, certificate, permit or other document may be issued or take effect;
(*d*) conferring rights of action in any court of competent jurisdiction with respect to any disputes referred to in paragraph (*c*) and respecting the remedies that may be sought in the court, the procedure of the court in the matter and the decisions and orders it may make; and
(*e*) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (*a*) in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.

Inconsistency or conflict

(5) In the event of any inconsistency or conflict between
(*a*) this section or any regulations made under this section, and
(*b*) any Act of Parliament or any regulations made thereunder,
this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.

For greater certainty

(6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.
1993, c. 2, s. 4; 2001, c. 10, s. 2.

Patent not to affect previous purchaser

56. (1) Every person who, before the claim date of a claim in a patent has purchased, constructed or acquired the subject matter defined by the claim, has the right to use and sell 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.

Non-application

(2) Subsection (1) does not apply in respect of a purchase, construction or acquisition referred to in subsection (3) or (4).

Special case

(3) Section 56 of the *Patent Act*, as it read immediately before the day on which subsection (1) came into force, applies in respect of a purchase, construction or acquisition made before that day of an invention for which a patent is issued on the basis of an application filed after October 1, 1989 and before the day on which subsection (1) came into force.

Idem

(4) Section 56 of the *Patent Act*, as it read immediately before October 1, 1989, applies in respect of a purchase, construction or acquisition made before the day on which subsection (1) came into force of an invention for which a patent is issued before October 1, 1989 or is issued after October 1, 1989 on the basis of an application filed before October 1, 1989.

R.S., 1985, c. P-4, s. 56; R.S., 1985, c. 33 (3rd Supp.), s. 22; 1993, c. 44, ss. 194, 199.

Injunction may issue

57. (1) In any action for infringement of a patent, the court, or any judge thereof, may, on the application of the plaintiff or defendant, make such order as the court or judge sees fit,

(*a*) restraining or enjoining the opposite party from further use, manufacture or sale of the subject-matter of the patent, and for his punishment in the event of disobedience of that order, or

(*b*) for and respecting inspection or account,

and generally, respecting the proceedings in the action.

Appeal

(2) An appeal lies from any order made under subsection (1) in the same circumstances and to the same court as from other judgments or orders of the court in which the order is made.

R.S., c. P-4, s. 59.

Invalid claims not to affect valid claims

58. When, in any action or proceeding respecting a patent that contains two or more claims, one or more of those claims is or are held to be valid but another or others is or are held to be invalid or void, effect shall be given to the patent as if it contained only the valid claim or claims.

R.S., c. P-4, s. 60.

Defence

59. The defendant, in any action for infringement of a patent may plead as matter of defence any fact or default which by this Act or by law renders the patent

void, and the court shall take cognizance of that pleading and of the relevant facts and decide accordingly.

R.S., c. P-4, s. 61.

IMPEACHMENT

Impeachment of patents or claims

60. (1) A patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada or at the instance of any interested person.

Declaration as to infringement

(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 Federal Court against the patentee for a declaration that the process or article does not or would not constitute an infringement of the exclusive property or privilege.

Security for costs

(3) With the exception of the Attorney General of Canada or the attorney general of a province, the plaintiff in any action under this section shall, before proceeding therein, give security for the costs of the patentee in such sum as the Federal Court may direct, but a defendant in any action for the infringement of a patent is entitled to obtain a declaration under this section without being required to furnish any security.

R.S., c. P-4, s. 62; R.S., c. 10(2nd Supp.), s. 64.

61. [Repealed, R.S., 1985, c. 33 (3rd Supp.), s. 23]

JUDGMENTS

Judgment voiding patent

62. A certificate of a judgment voiding in whole or in part any patent shall, at the request of any person filing it to make it a record in the Patent Office, be registered in the Patent Office, and the patent, or such part as is voided, shall thereupon be and be held to have been void and of no effect, unless the judgment is reversed on appeal as provided in section 63.

R.S., 1985, c. P-4, s. 62; 1993, c. 15, s. 49.

Appeal

63. Every judgment voiding in whole or in part or refusing to void in whole or in part any patent is subject to appeal to any court having appellate jurisdiction in other cases decided by the court by which the judgment was rendered.

R.S., c. P-4, s. 65.

CONDITIONS

64. [Repealed, 1993, c. 44, s. 195]

Abuse of rights under patents

65. (1) The Attorney General of Canada or any person interested may, at any time after the expiration of three years from the date of the grant of a patent, apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act.

What amounts to abuse

(2) The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances:
(*a*) and (*b*) [Repealed, 1993, c. 44, s. 196]
(*c*) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;
(*d*) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted;
(*e*) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or
(*f*) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

(3) and (4) [Repealed, 1993, c. 44, s. 196]

Definition of “patented article”

(5) For the purposes of this section, the expression “patented article” includes articles made by a patented process.

R.S., 1985, c. P-4, s. 65; 1993, c. 2, s. 5, c. 15, s. 51, c. 44, s. 196.

Powers of Commissioner in cases of abuse

66. (1) On being satisfied that a case of abuse of the exclusive rights under a patent has been established, the Commissioner may exercise any of the following powers as he may deem expedient in the circumstances:
(*a*) he may order the grant to the applicant of a licence on such terms as the Commissioner may think expedient, including a term precluding the licensee from importing into Canada any goods the importation of which, if made by persons other than the patentee or persons claiming under him, would be an infringement of the patent, and in that case the patentee and all licensees for the time being shall be deemed to have mutually covenanted against that importation;
(*b*) [Repealed, 1993, c. 44, s. 197]
(*c*) if the Commissioner is satisfied that the exclusive rights have been abused in the circumstances specified in paragraph 65(2)(*f*), he may order the grant of licences to the applicant and to such of his customers, and containing such terms, as the Commissioner may think expedient;

(*d*) if the Commissioner is satisfied that the objects of this section and section 65 cannot be attained by the exercise of any of the foregoing powers, the Commissioner shall order the patent to be revoked, either forthwith or after such reasonable interval as may be specified in the order, unless in the meantime such conditions as may be specified in the order with a view to attaining the objects of this section and section 65 are fulfilled, and the Commissioner may, on reasonable cause shown in any case, by subsequent order extend the interval so specified, but the Commissioner shall not make an order for revocation which is at variance with any treaty, convention, arrangement, or engagement with any other country to which Canada is a party; or

(*e*) if the Commissioner is of opinion that the objects of this section and section 65 will be best attained by not making an order under the provisions of this section, he may make an order refusing the application and dispose of any question as to costs thereon as he thinks just.

Proceedings to prevent infringement

(2) A licensee under paragraph (1)(*a*) is entitled to call on the patentee to take proceedings to prevent infringement of the patent, and if the patentee refuses or neglects to do so within two months after being so called on, the licensee may institute proceedings for infringement in his own name as though he were the patentee, making the patentee a defendant, but a patentee added as defendant is not liable for any costs unless he enters an appearance and takes part in the proceedings.

Service on patentee

(3) Service on a patentee added as a defendant may be effected by leaving the writ at his address or at the address of his representative for service as appearing in the records of the Patent Office.

Considerations by which Commissioner to be guided

(4) In settling the terms of a licence under paragraph (1)(*a*), the Commissioner shall be guided as far as possible by the following considerations:

(*a*) he shall endeavour to secure the widest possible use of the invention in Canada consistent with the patentee deriving a reasonable advantage from his patent rights;

(*b*) he shall endeavour to secure to the patentee the maximum advantage consistent with the invention being worked by the licensee at a reasonable profit in Canada; and

(*c*) he shall endeavour to secure equality of advantage among the several licensees, and for this purpose may, on due cause being shown, reduce the royalties or other payments accruing to the patentee under any licence previously granted.

R.S., 1985, c. P-4, s. 66; R.S., 1985, c. 33 (3rd Supp.), s. 24; 1993, c. 44, s. 197.

67. [Repealed, 1993, c. 44, s. 198]

Contents of applications

68. (1) Every application presented to the Commissioner under section 65 or 66 shall

(*a*) set out fully the nature of the applicant's interest, the facts on which the applicant bases his case and the relief that he seeks; and

(*b*) be accompanied by statutory declarations verifying the applicant's interest and the facts set out in the application.

Service

(2) The Commissioner shall consider the matters alleged in the application and declarations referred to in subsection (1), and, if satisfied that the applicant has a *bona fide* interest and that a case for relief has been made, he shall direct the applicant to serve copies of the application and declarations on the patentee or his representative for service and on any other persons appearing from the records of the Patent Office to be interested in the patent, and the applicant shall advertise the application in the *Canada Gazette* and the *Canadian Patent Office Record*.

R.S., c. P-4, s. 70.

Opposition and counter statement

69. (1) If the patentee or any person is desirous of opposing the granting of any relief under sections 65 to 70, he shall, within such time as may be prescribed or within such extended time as the Commissioner may on application further allow, deliver to the Commissioner a counter statement verified by a statutory declaration fully setting out the grounds on which the application is to be opposed.

Attendance for cross-examination

(2) The Commissioner shall consider the counter statement and declaration referred to in subsection (1) and may thereupon dismiss the application if satisfied that the allegations in the application have been adequately answered, unless any of the parties demands a hearing or unless the Commissioner himself appoints a hearing, and in any case the Commissioner may require the attendance before him of any of the declarants to be cross-examined or further examined on matters relevant to the issues raised in the application and counter statement, and he may, subject to due precautions against disclosure of information to rivals in trade, require the production before him of books and documents relating to the matter in issue.

Reference to Federal Court

(3) In any case where the Commissioner does not dismiss an application as provided in subsection (2), and
(*a*) if the parties interested consent, or
(*b*) if the proceedings require any prolonged examination of documents or any scientific or local investigation that cannot in the opinion of the Commissioner conveniently be made before him,
the Commissioner, with the approval in writing of the Minister, may order the whole proceedings or any issue of fact arising thereunder to be referred to the Federal Court, which has jurisdiction in the premises.

Idem

(4) Where the whole proceedings are referred under subsection (1), the judgment, decision or order of the Federal Court is final, and where a question or issue of fact is referred under that subsection, the Court shall report its findings to the Commissioner.

R.S., c. P-4, s. 71; R.S., c. 10(2nd Supp.), s. 64.

Licence deemed to be by deed

70. Any order for the grant of a licence under this Act, without prejudice to any other method of enforcement, operates as if it were embodied in a deed granting a licence executed by the patentee and all other necessary parties.

R.S., c. P-4, s. 72.

Appeal to Federal Court

71. All orders and decisions of the Commissioner under sections 65 to 70 are subject to appeal to the Federal Court, and on any such appeal the Attorney General of Canada or such counsel as he may appoint is entitled to appear and be heard.

R.S., c. P-4, s. 73; R.S., c. 10(2nd Supp.), s. 64.

72. [Repealed, R.S., 1985, c. 33 (3rd Supp.), s. 25]

ABANDONMENT AND REINSTATEMENT OF APPLICATIONS

Deemed abandonment of applications

73. (1) An application for a patent in Canada shall be deemed to be abandoned if the applicant does not

(*a*) reply in good faith to any requisition made by an examiner in connection with an examination, within six months after the requisition is made or within any shorter period established by the Commissioner;

(*b*) comply with a notice given pursuant to subsection 27(6);

(*c*) pay the fees payable under section 27.1, within the time provided by the regulations;

(*d*) make a request for examination or pay the prescribed fee under subsection 35(1) within the time provided by the regulations;

(*e*) comply with a notice given under subsection 35(2); or

(*f*) pay the prescribed fees stated to be payable in a notice of allowance of patent within six months after the date of the notice.

Deemed abandonment in prescribed circumstances

(2) An application shall also be deemed to be abandoned in any other circumstances that are prescribed.

Reinstatement

(3) An application deemed to be abandoned under this section shall be reinstated if the applicant

(*a*) makes a request for reinstatement to the Commissioner within the prescribed period;

(*b*) takes the action that should have been taken in order to avoid the abandonment; and

(*c*) pays the prescribed fee before the expiration of the prescribed period.

Amendment and re-examination

(4) An application that has been abandoned pursuant to paragraph (1)(*f*) and reinstated is subject to amendment and further examination.

Original filing date

(5) An application that is reinstated retains its original filing date.

R.S., 1985, c. P-4, s. 73; 1993, c. 15, s. 52.

OFFENCES AND PUNISHMENT

74. [Repealed, R.S., 1985, c. 33 (3rd Supp.), s. 26]

Offences

75. Every person who

(*a*) without the consent of the patentee, writes, paints, prints, moulds, casts, carves, engraves, stamps or otherwise marks on anything made or sold by him, and for the sole making or selling of which he is not the patentee, the name or any imitation of the name of any patentee for the sole making or selling of that thing,

(*b*) without the consent of the patentee, writes, paints, prints, moulds, casts, carves, engraves, stamps or otherwise marks on anything not purchased from the patentee, the words “Patent”, “Letters Patent”, “Queen’s (*or* King’s) Patent”, “Patented” or any word or words of like import, with the intent of counterfeiting or imitating the stamp, mark or device of the patentee, or of deceiving the public and inducing them to believe that the thing in question was made or sold by or with the consent of the patentee, or

(*c*) with intent to deceive the public offers for sale as patented in Canada any article not patented in Canada,

is guilty of an indictable offence and liable to a fine not exceeding two hundred dollars or to imprisonment for a term not exceeding three months or to both.

R.S., c. P-4, s. 78.

False representations, false entries, etc.

76. Every person who, in relation to the purposes of this Act and knowing it to be false,

(*a*) makes any false representation,

(*b*) makes or causes to be made any false entry in any register or book,

(*b.1*) submits or causes to be submitted, in an electronic form, any false document, false information or document containing false information,

(*c*) makes or causes to be made any false document or alters the form of a copy of any document, or

(*d*) produces or tenders any document containing false information,

is guilty of an indictable offence and liable on conviction to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding six months or to both.

R.S., 1985, c. P-4, s. 76; 1993, c. 15, s. 53.

Offence respecting patented medicines

76.1 (1) Every person who contravenes or fails to comply with section 80, 81, 82 or 88 or any order made thereunder is guilty of an offence punishable on summary conviction and liable

(*a*) in the case of an individual, to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding six months or to both; and

(*b*) in the case of a corporation, to a fine not exceeding twenty-five thousand dollars.

Idem

(2) Every person who contravenes or fails to comply with section 84 or any order made under section 83 is guilty of an offence punishable on summary conviction and liable
(*a*) in the case of an individual, to a fine not exceeding twenty-five thousand dollars or to imprisonment for a term not exceeding one year or to both; and
(*b*) in the case of a corporation, to a fine not exceeding one hundred thousand dollars.

Limitation period

(3) Proceedings for an offence under subsection (1) or (2) may be commenced within, but not later than, two years after the time when the subject-matter of the proceedings arose.

Continuing offence

(4) Where an offence under subsection (1) or (2) is committed or continued on more than one day, the person who committed the offence is liable to be convicted for a separate offence for each day on which the offence is committed or continued.

1993, c. 2, s. 6.

MISCELLANEOUS MATTERS

77. [Repealed, 1993, c. 15, s. 54]

Time limit deemed extended

78. (1) Where any time limit or period of limitation specified under or pursuant to this Act expires on a day when the Patent Office is closed for business, that time limit or period of limitation shall be deemed to be extended to the next day when the Patent Office is open for business.

When Patent Office closed for business

(2) The Patent Office shall be closed for business on Saturdays and holidays and on such other days as the Minister by order declares that it shall be closed for business.

Publication

(3) Every order made by the Minister under subsection (2) shall be published in the *Canadian Patent Office Record* as soon as possible after it is made.

R.S., c. P-4, s. 81.

TRANSITIONAL PROVISIONS

Patent applications filed before October 1, 1989

78.1 Applications for patents in Canada filed before October 1, 1989 shall be dealt with and disposed of in accordance with section 38.1 and with the provisions of this Act as they read immediately before October 1, 1989.

1993, c. 15, s. 55; 2001, c. 10, s. 3.

Patents issued before October 1, 1989

78.2 (1) Subject to subsection (3), any matter arising on or after October 1, 1989 in respect of a patent issued before that date shall be dealt with and disposed of in accordance with sections 38.1 and 45 and with the provisions of this Act, other than section 46, as they read immediately before October 1, 1989.

Patents issued on or after October 1, 1989 on the basis of previously filed applications

(2) Subject to subsection (3), any matter arising on or after October 1, 1989 in respect of a patent issued on or after that date on the basis of an application filed before that date shall be dealt with and disposed of in accordance with sections 38.1, 45, 46 and 48.1 to 48.5 and with the provisions of this Act, other than section 46, as they read immediately before October 1, 1989.

Application

(3) The provisions of this Act that apply as provided in subsections (1) and (2) shall be read subject to any amendments to this Act, other than the amendments that came into force on October 1, 1989 or October 1, 1996.

1993, c. 15, s. 55; 2001, c. 10, s. 3.

Previous version of section 43 applies

78.3 (1) Where a conflict, as defined in section 43 as it read immediately before October 1, 1989, exists between an application for a patent in Canada filed before October 1, 1989 (the “earlier application”) and an application for a patent in Canada filed on or after that date (the “later application”) and

(*a*) the later application is filed by a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent describing the same invention,

(*b*) the later application is filed within twelve months after the filing of the previously regularly filed application,

(*c*) the applicant in the later application has made a request for priority in respect of that application on the basis of the previously regularly filed application, and

(*d*) the earlier application is filed after the filing of the previously regularly filed application,

the applicant having the earlier date of invention shall be entitled to a patent and the applications shall be dealt with and disposed of in accordance with section 43, as it read immediately before October 1, 1989.

Exception

(2) Subsection (1) does not apply if
(*a*) the earlier application is filed by a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent describing the same invention;
(*b*) the earlier application is filed within twelve months after the filing of the previously regularly filed application mentioned in paragraph (*a*);
(*c*) the applicant in the earlier application has made a request for priority in respect of that application on the basis of the previously regularly filed application mentioned in paragraph (*a*); and
(*d*) the previously regularly filed application mentioned in paragraph (*a*) was filed before the filing of the previously regularly filed application mentioned in subsection (1).

1993, c. 15, s. 55.

Patent applications filed on or after October 1, 1989

78.4 Applications for patents in Canada filed on or after October 1, 1989, but before October 1, 1996, shall be dealt with and disposed of in accordance with subsection 27(2) as it read immediately before October 1, 1996 and with the provisions of this Act as they read on October 1, 1996.

1993, c. 15, s. 55; 2001, c. 10, s. 4.

Patents issued on or after October 1, 1989

78.5 Any matter arising in respect of a patent issued on the basis of an application filed on or after October 1, 1989, but before October 1, 1996, shall be dealt with and disposed of in accordance with the provisions of this Act and with subsection 27(2) as it read immediately before October 1, 1996.

1993, c. 15, s. 55; 2001, c. 10, s. 4.

Payment of prescribed fees

78.6 (1) If, before the day on which this section comes into force, a person has paid a prescribed fee applicable to a small entity, within the meaning of the *Patent Rules* as they read at the time of payment, but should have paid the prescribed fee applicable to an entity other than a small entity and a payment equivalent to the difference between the two amounts is submitted to the Commissioner in accordance with subsection (2) either before or no later than twelve months after that day, the payment is deemed to have been paid on the day on which the prescribed fee was paid, regardless of whether an action or other proceeding relating to the patent or patent application in respect of which the fee was payable has been commenced or decided.

Information to be provided

(2) Any person who submits a payment to the Commissioner in accordance with subsection (1) is required to provide information with respect to the service or proceeding in respect of which the fee was paid and the patent or application in respect of which the fee was paid.

No refund

(3) A payment submitted in accordance with subsection (1) shall not be refunded.

Action and proceedings barred

(4) No action or proceeding for any compensation or damages lies against Her Majesty in right of Canada in respect of any direct or indirect consequence resulting from the application of this section.

Application

(5) For greater certainty, this section also applies to applications for patents mentioned in sections 78.1 and 78.4.

2005, c. 18, s. 2.

PATENTED MEDICINES

INTERPRETATION

Definitions

79. (1) In this section and in sections 80 to 103,

“Board”
« *Conseil* »

“Board” means the Patented Medicine Prices Review Board continued by section 91;

“Consumer Price Index”
« *indice des prix à la consommation* »

“Consumer Price Index” means the Consumer Price Index published by Statistics Canada under the authority of the *Statistics Act*;

“Minister”
« *ministre* »

“Minister” means the Minister of Health or such other Member of the Queen’s Privy Council for Canada as is designated by the Governor in Council as the Minister for the purposes of this section and sections 80 to 103;

“patentee”
« *breveté* » ou « *titulaire d’un brevet* »

“patentee”, in respect of an invention pertaining to a medicine, means the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a licence continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, that other person in respect of those rights;

“regulations”
« *règlement* »

“regulations” means regulations made under section 101.

Invention pertaining to a medicine

(2) For the purposes of subsection (1) and sections 80 to 101, an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.

1993, c. 2, s. 7; 1996, c. 8, s. 32.

PRICING INFORMATION

Pricing information, etc., required by regulations

80. (1) A patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting
(*a*) the identity of the medicine;
(*b*) the price at which the medicine is being or has been sold in any market in Canada and elsewhere;
(*c*) the costs of making and marketing the medicine, where that information is available to the patentee in Canada or is within the knowledge or control of the patentee;
(*d*) the factors referred to in section 85; and
(*e*) any other related matters.

Idem

(2) Subject to subsection (3), a person who is a former patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting
(*a*) the identity of the medicine;
(*b*) the price at which the medicine was sold in any market in Canada and elsewhere during the period in which the person was a patentee of the invention;
(*c*) the costs of making and marketing the medicine produced during that period, whether incurred before or after the patent was issued, where that information is available to the person in Canada or is within the knowledge or control of the person;
(*d*) the factors referred to in section 85; and
(*e*) any other related matters.

Limitation

(3) Subsection (2) does not apply to a person who has not been entitled to the benefit of the patent or to exercise any rights in relation to the patent for a period of three or more years.

1993, c. 2, s. 7.

Pricing information, etc. required by Board

81. (1) The Board may, by order, require a patentee or former patentee of an invention pertaining to a medicine to provide the Board with information and documents respecting

(*a*) in the case of a patentee, any of the matters referred to in paragraphs 80(1)(*a*) to (*e*);
(*b*) in the case of a former patentee, any of the matters referred to in paragraphs 80(2)(*a*) to (*e*); and
(c) such other related matters as the Board may require.

Compliance with order

(2) A patentee or former patentee in respect of whom an order is made under subsection (1) shall comply with the order within such time as is specified in the order or as the Board may allow.

Limitation

(3) No order may be made under subsection (1) in respect of a former patentee who, more than three years before the day on which the order is proposed to be made, ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

1993, c. 2, s. 7.

Notice of introductory price

82. (1) A patentee of an invention pertaining to a medicine who intends to sell the medicine in a market in Canada in which it has not previously been sold shall, as soon as practicable after determining the date on which the medicine will be first offered for sale in that market, notify the Board of its intention and of that date.

Pricing information and documents

(2) Where the Board receives a notice under subsection (1) from a patentee or otherwise has reason to believe that a patentee of an invention pertaining to a medicine intends to sell the medicine in a market in Canada in which the medicine has not previously been sold, the Board may, by order, require the patentee to provide the Board with information and documents respecting the price at which the medicine is intended to be sold in that market.

Compliance with order

(3) Subject to subsection (4), a patentee in respect of whom an order is made under subsection (2) shall comply with the order within such time as is specified in the order or as the Board may allow.

Limitation

(4) No patentee shall be required to comply with an order made under subsection (2) prior to the sixtieth day preceding the date on which the patentee intends to first offer the medicine for sale in the relevant market.

1993, c. 2, s. 7.

EXCESSIVE PRICES

Order re excessive prices

83. (1) Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

Idem

(2) Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:
(*a*) reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;
(*b*) reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or
(*c*) pay to Her Majesty in right of Canada an amount specified in the order.

Idem

(3) Subject to subsection (4), where the Board finds that a former patentee of an invention pertaining to a medicine had, while a patentee, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the former patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the former patentee from the sale of the medicine at an excessive price:
(*a*) reduce the price at which the former patentee sells a medicine to which a patented invention of the former patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or
(*b*) pay to Her Majesty in right of Canada an amount specified in the order.

Where policy to sell at excessive price

(4) Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price, the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will, in the Board's opinion, offset not more than twice the amount of the excess revenues estimated by it to have been derived by the patentee or former patentee from the sale of the medicine at an excessive price.

Excess revenues

(5) In estimating the amount of excess revenues under subsection (2), (3) or (4), the Board shall not consider any revenues derived by a patentee or former patentee before December 20, 1991 or any revenues derived by a former patentee after the former patentee ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

Right to hearing

(6) Before the Board makes an order under this section, it shall provide the patentee or former patentee with a reasonable opportunity to be heard.

Limitation period

(7) No order may be made under this section in respect of a former patentee who, more than three years before the day on which the proceedings in the matter commenced, ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

1993, c. 2, s. 7; 1994, c. 26, s. 54(F).

Compliance

84. (1) A patentee or former patentee who is required by any order made under section 83 to reduce the price of a medicine shall commence compliance with the order 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 or former patentee.

Idem

(2) A patentee or former patentee who is directed by any order made under section 83 to pay an amount to Her Majesty shall pay that amount 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 or former patentee.

Debt due to Her Majesty

(3) An amount payable by a patentee or former patentee to Her Majesty under any order made under section 83 constitutes a debt due to Her Majesty and may be recovered in any court of competent jurisdiction.

1993, c. 2, s. 7.

Factors to be considered

85. (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

(*a*) the prices at which the medicine has been sold in the relevant market;

(*b*) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
(*c*) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
(*d*) changes in the Consumer Price Index; and
(*e*) such other factors as may be specified in any regulations made for the purposes of this subsection.

Additional factors

(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:
(*a*) the costs of making and marketing the medicine; and
(*b*) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

Research costs

(3) In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.
1993, c. 2, s. 7.

Hearings to be public

86. (1) A hearing under section 83 shall be held in public unless the Board 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 information or documents at a public hearing, in which case the hearing or any part thereof may, at the discretion of the Board, be held in private.

Notice of hearing to certain persons

(2) The Board shall give notice to the Minister of Industry or such other Minister as may be designated by the regulations and to provincial ministers of the Crown responsible for health of any hearing under section 83, and each of them is entitled to appear and make representations to the Board with respect to the matter being heard.
1993, c. 2, s. 7; 1995, c. 1, s. 62.

Information, etc., privileged

87. (1) Subject to subsection (2), any information or document provided to the Board under section 80, 81 or 82 or in any proceeding under section 83 is privileged, and no person who has obtained the information or document pursuant to this Act shall, without the authorization of the person who provided the information or

document, knowingly disclose the information or document or allow it to be disclosed unless it has been disclosed at a public hearing under section 83.

Disclosure, etc.

(2) Any information or document referred to in subsection (1)
(*a*) may be disclosed by the Board to any person engaged in the administration of this Act under the direction of the Board, to the Minister of Industry or such other Minister as may be designated by the regulations and to the provincial ministers of the Crown responsible for health and their officials for use only for the purpose of making representations referred to in subsection 86(2); and
(*b*) may be used by the Board for the purpose of the report referred to in section 100.

1993, c. 2, s. 7; 1995, c. 1, s. 62.

SALES AND EXPENSE INFORMATION

Sales and expense information, etc., to be provided

88. (1) A patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, or as the Board may, by order, require, provide the Board with such information and documents as the regulations or the order may specify respecting
(*a*) the identity of the licensees in Canada of the patentee;
(*b*) the revenue of the patentee, and details of the source of the revenue, whether direct or indirect, from sales of medicine in Canada; and
(*c*) the expenditures made by the patentee in Canada on research and development relating to medicine.

Additional information, etc.

(2) Where the Board believes on reasonable grounds that any person has information or documents pertaining to the value of sales of medicine in Canada by a patentee or the expenditures made by a patentee in Canada on research and development relating to medicine, the Board may, by order, require the person to provide the Board with any of the information or documents that are specified in the order, or with copies thereof.

Compliance with order

(3) A person in respect of whom an order is made under subsection (1) or (2) shall comply with the order within such time as is specified in the order or as the Board may allow.

Information, etc., privileged

(4) Subject to section 89, any information or document provided to the Board under subsection (1) or (2) is privileged, and no person who has obtained the information or document pursuant to this Act shall, without the authorization of the person who provided the information or document, knowingly disclose the information or allow it to be disclosed, except for the purposes of the administration of this Act.

1993, c. 2, s. 7.

Report

89. (1) The Board shall in each year submit to the Minister a report setting out
(*a*) the Board's estimate of the proportion, as a percentage, that the expenditures of each patentee in Canada in the preceding year on research and development relating to medicine is of the revenues of those patentees from sales of medicine in Canada in that year; and
(*b*) the Board's estimate of the proportion, as a percentage, that the total of the expenditures of patentees in Canada in the preceding year on research and development relating to medicine is of the total of the revenues of those patentees from sales of medicine in Canada in that year.

Basis of report

(2) The report shall be based on an analysis of information and documents provided to the Board under subsections 88(1) and (2) and of such other information and documents relating to the revenues and expenditures referred to in subsection 88(1) as the Board considers relevant but, subject to subsection (3), shall not be set out in a manner that would make it possible to identify a person who provided any information or document under subsection 88(1) or (2).

Exception

(3) The Board shall, in the report, identify the patentees in respect of whom an estimate referred to in subsection (1) is given in the report, and may, in the report, identify any person who has failed to comply with subsection 88(1) or (2) at any time in the year in respect of which the report is made.

Tabling of report

(4) 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.

1993, c. 2, s. 7.

INQUIRIES

Inquiries

90. The Board shall inquire into any matter that the Minister refers to the Board for inquiry and shall report to the Minister at the time and in accordance with the terms of reference established by the Minister.

1993, c. 2, s. 7.

PATENTED MEDICINE PRICES REVIEW BOARD

Establishment

91. (1) The Patented Medicine Prices Review Board is hereby continued, and shall consist of not more than five members to be appointed by the Governor in Council.

Tenure

(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.

Reappointment

(3) A member of the Board, on the expiration of a first term of office, is eligible to be reappointed for one further term.

Acting after expiration of appointment

(4) A person may continue to act as a member of the Board after the expiration of the person's term of appointment in respect of any matter in which the person became engaged during the term of appointment.

Remuneration and expenses

(5) The members of the Board shall be paid such remuneration as may be fixed by the Governor 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.

1993, c. 2, s. 7.

Advisory panel

92. (1) The Minister may establish an advisory panel to advise the Minister on the appointment of persons to the Board, which panel shall include representatives of the provincial ministers of the Crown responsible for health, representatives of consumer groups, representatives of the pharmaceutical industry and such other persons as the Minister considers appropriate to appoint.

Consultation

(2) The Minister shall consult with an advisory panel established under subsection (1) for the purpose of making a recommendation to the Governor in Council with respect to the appointment of a person to the Board.

1993, c. 2, s. 7.

Chairperson and Vice-chairperson

93. (1) The Governor in Council shall designate one of the members of the Board to be Chairperson of the Board and one of the members to be Vice-chairperson of the Board.

Duties of Chairperson

(2) The Chairperson is the chief executive officer of the Board and has supervision over and direction of the work of the Board, including

(*a*) the apportionment of the work among the members thereof and the assignment of members to deal with matters before the Board and to sit at hearings of the Board and to preside at hearings or other proceedings; and

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

Duties of Vice-chairperson

(3) If the Chairperson is absent or incapacitated or if the office of Chairperson is vacant, the Vice-chairperson has all the powers and functions of the Chairperson during the absence, incapacity or vacancy.

1993, c. 2, s. 7.

Staff

94. (1) Such officers and employees as are necessary for the proper conduct of the work of the Board shall be appointed in accordance with the *Public Service Employment Act*.

Idem

(2) Persons appointed under subsection (1) shall be deemed to be employed in the public service for the purposes of the *Public Service Superannuation Act*.

Technical assistance

(3) The Board may engage on a temporary basis the services of persons having technical or specialized knowledge to advise and assist in the performance of its duties and, with the approval of the Treasury Board, the Board may fix and pay the remuneration and expenses of those persons.

1993, c. 2, s. 7; 2003, c. 22, s. 225(E).

Principal office

95. (1) The principal office of the Board shall be in the National Capital Region described in the schedule to the *National Capital Act*.

Meetings

(2) The Board may meet at such times and places in Canada as the Chairperson deems advisable.

1993, c. 2, s. 7.

General powers, etc.

96. (1) 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.

Rules

(2) The Board may, with the approval of the Governor in Council, make general rules

(*a*) specifying the number of members of the Board that constitutes a quorum in respect of any matter; and
(*b*) for regulating the practice and procedure of the Board.

By-laws

(3) The Board may make by-laws for carrying out the work of the Board, the management of its internal affairs and the duties of its staff.

Guidelines

(4) Subject to subsection (5), the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any patentee.

Consultation

(5) Before the Board issues any guidelines, it shall consult with the Minister, the provincial ministers of the Crown responsible for health and such representatives of consumer groups and representatives of the pharmaceutical industry as the Minister may designate for the purpose.

Non-application of *Statutory Instruments Act*

(6) The *Statutory Instruments Act* does not apply to guidelines issued under subsection (4).

1993, c. 2, s. 7.

Proceedings

97. (1) All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit.

Differences of opinion among members

(2) In any proceedings before the Board,
(*a*) in the event of a difference of opinion among the members determining any question, the opinion of the majority shall prevail; and
(*b*) in the event of an equally divided opinion among the members determining any question, the presiding member may determine the question.

1993, c. 2, s. 7.

Orders

98. (1) The Board may, in any order, direct
(*a*) that the order or any portion thereof shall come into force at a future time, on the happening of a contingency, event or condition specified in the order or on the performance to the satisfaction of the Board, or a person named by it, of any terms specified in the order; and
(*b*) that the whole or any portion of the order shall have effect for a limited time or until the happening of a specified event.

Interim orders, etc.

(2) The Board may make interim orders or reserve further directions for an adjourned hearing of a matter.

Rescission and variation

(3) The Board may vary or rescind any order made by it and may re-hear any matter.

Certificates

(4) Where any person satisfies the Board that the Board would not have sufficient grounds to make an order under section 83 in respect of the person, the Board may, after the person pays any fees required to be paid by the regulations, issue to the person a certificate to that effect, but no certificate is binding on the Board.

1993, c. 2, s. 7.

Enforcement of orders

99. (1) Any order of the Board may be made an order of the Federal Court or any superior court of a province and is enforceable in the same manner as an order of the court.

Procedure

(2) To make an order of the Board an order of a court, the usual practice and procedure of the court in such matters may be followed or, in lieu thereof, the Board may file with the registrar of the court a certified copy of the Board's order, and thereupon the order becomes an order of the court.

Effect of variation or rescission

(3) Where an order of the Board that has been made an order of a court is varied or rescinded by a subsequent order of the Board, the subsequent order of the Board shall be made an order of the court in the manner described in subsection (1), and the order of the court shall be deemed to have been varied or rescinded accordingly.

Option to enforce

(4) Nothing in this section prevents the Board from exercising any of its powers under this Act.

1993, c. 2, s. 7.

Report of Board

100. (1) The Board shall in each year submit to the Minister a report on its activities during the preceding year.

Idem

(2) The report shall contain

(*a*) a summary of pricing trends in the pharmaceutical industry; and
(*b*) the name of each patentee in respect of whom an order was made under subsection 80(2) during the year and a statement as to the status of the matter in respect of which the order was made.

Report summary

(3) The summary referred to in paragraph (2)(*a*) may be based on information and documents provided to the Board by any patentee under section 80, 81 or 82 or in any proceeding under section 83, but shall not be set out in a manner that would make it possible to identify that patentee.

Tabling of report

(4) 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.

1993, c. 2, s. 7.

REGULATIONS

Regulations

101. (1) Subject to subsection (2), the Governor in Council may make regulations
(*a*) specifying the information and documents that shall be provided to the Board under subsection 80(1) or (2) or 88(1);
(*b*) respecting the form and manner in which and times at which such information and documents shall be provided to the Board and imposing conditions respecting the provision of such information and documents;
(*c*) specifying a period for the purposes of subsection 80(2);
(*d*) specifying factors for the purposes of subsection 85(1) or (2), including factors relating to the introductory price of any medicine to which a patented invention pertains;
(*e*) designating a Minister for the purposes of subsection 86(2) or paragraph 87(2)(*a*);
(*f*) defining, for the purposes of sections 88 and 89, the expression “research and development”;
(*g*) requiring fees to be paid before the issue of any certificate referred to in subsection 98(4) and specifying those fees or the manner of determining those fees;
(*h*) requiring or authorizing the Board to perform such duties, in addition to those provided for in this Act, as are specified in the regulations, including duties to be performed by the Board in relation to the introductory price of any medicine to which a patented invention pertains; and
(*i*) conferring on the Board such powers, in addition to those provided for in this Act, as will, in the opinion of the Governor in Council, enable the Board to perform any duties required or authorized to be performed by it by any regulations made under paragraph (*h*).

Recommendation

(2) No regulations may be made under paragraph (1)(*d*), (*f*), (*h*) or (*i*) except on the recommendation of the Minister, made after the Minister has consulted with the

provincial ministers of the Crown responsible for health and with such representatives of consumer groups and representatives of the pharmaceutical industry as the Minister considers appropriate.

1993, c. 2, s. 7.

MEETINGS WITH MINISTER

Meetings with Minister

102. (1) The Minister may at any time convene a meeting of the following persons:
(*a*) the Chairperson and such members of the Board as the Chairperson may designate;
(*b*) the provincial ministers of the Crown responsible for health or such representatives as they may designate;
(*c*) such representatives of consumer groups and representatives of the pharmaceutical industry as the Minister may designate; and
(*d*) such other persons as the Minister considers appropriate.

Agenda

(2) The participants at a meeting convened under subsection (1) shall consider such matters in relation to the administration or operation of sections 79 to 101 as the Minister may determine.

1993, c. 2, s. 7.

AGREEMENTS WITH PROVINCES

Agreements with provinces

103. The Minister may enter into agreements with any province respecting the distribution of, and may pay to that province out of the Consolidated Revenue Fund, amounts received or collected by the Receiver General under section 83 or 84 or in respect of an undertaking given by a patentee or former patentee that is accepted by the Board in lieu of holding a hearing or making an order under section 83, less any costs incurred in relation to the collection and distribution of those amounts.

1993, c. 2, s. 7; 1994, c. 26, s. 55(F); 1999, c. 26, s. 50.

SCHEDULE 1

(Definition "pharmaceutical product" in section 21.02 and paragraph 21.03(1)(a))

abacavir (ABC)	tablet, 300 mg (as sulfate); oral solution, 100 mg (as sulfate)/5 mL
abacavir + lamivudine + zidovudine	tablet, 300 mg (as sulfate) + 150 mg + 300 mg
aciclovir	tablet, 200 mg; powder for injection, 250 mg (as sodium salt) in vial
amphotericin B	powder for injection, 50 mg in vial
amprenavir	tablet, 150 mg; capsule, 50 mg or 150 mg; oral solution, 15 mg/mL
azithromycin	capsule, 250 mg or 500 mg; suspension, 200 mg/5 mL
beclometasone	inhalation (aerosol), 50 micrograms per dose (dipropionate) or 250 micrograms (dipropionate) per dose
ceftazidime	powder for injection, 250 mg (as pentahydrate) in vial

ceftriaxone	injection, 500 mg (as sodium); powder for injection, 250 mg (as sodium salt) in vial
ciclosporin	capsule, 25 mg; concentrate for injection, 50 mg/mL in 1-mL ampoule (for organ transplantation)
ciprofloxacin	tablet, 250 mg (as hydrochloride)
ciprofloxacin	tablet, 250 mg or 500 mg
daunorubicin	powder for injection, 50 mg (as hydrochloride) in vial
delavirdine	capsule or tablet, 100 mg (as mesylate)
didanosine (ddI)	buffered chewable, dispersible tablet, 25 mg, 50 mg, 100 mg, 150 mg, 200 mg; buffered powder for oral solution, 100 mg, 167 mg, 250 mg, packets; unbuffered enteric coated capsule, 125 mg, 200 mg, 250 mg, 400 mg
diphtheria antitoxin	injection, 10 000 IU or 20 000 IU in vial
diphtheria vaccine	
doxorubicin	powder for injection, 10 mg or 50 mg (hydrochloride) in vial
efavirenz (EFV or EFZ)	capsule, 50 mg, 100 mg or 200 mg; oral solution, 150 mg/5 mL
eflornithine	injection, 200 mg (hydrochloride)/mL in 100-mL bottles
enalapril	tablet, 2.5 mg
erythromycin	capsule or tablet, 250 mg (as stearate or ethyl succinate); powder for oral suspension, 125 mg (as stearate or ethyl succinate); powder for injection, 500 mg (as lactobionate) in vial
etoposide	capsule, 100 mg; injection, 20 mg/mL in 5-mL ampoule
factor IX (complex coagulation factors II, VII, IX, X) concentrate	dried
hepatitis B vaccine	
ibuprofen	tablet, 200 mg or 400 mg
indinavir (IDV)	capsule, 200 mg, 333 mg or 400 mg (as sulfate)
insulin injection (soluble)	injection, 40 IU/mL in 10-mL vial or 100 IU/mL in 10-mL vial
intermediate-acting insulin	injection, 40 IU/mL in 10-mL vial; 100 IU/mL in 10-mL vial (as compound insulin zinc suspension or isophane insulin)
isoniazid + pyrazinamide + rifampin	tablet, 50 mg + 300 mg + 120 mg
ivermectin	scored tablet, 3 mg or 6 mg
lamivudine (3TC)	capsule or tablet, 150 mg; oral solution 50 mg/5 mL
lamivudine + nevirapine + zidovudine	tablet, 150 mg + 200 mg + 300 mg
lamivudine + zidovudine	tablet, 150 mg + 300 mg
levodopa + carbidopa	tablet, 100 mg + 10 mg or 250 mg + 25 mg
levofloxacin	tablet, 250 mg or 500 mg
lithium carbonate	capsule or tablet, 300 mg
lopinavir + ritonavir (LPV/r)	capsule, 133.3 mg + 33.3 mg; oral solution, 400 mg + 100 mg/5 mL
metoclopramide	tablet, 10 mg (hydrochloride); injection, 5 mg (hydrochloride)/mL in 2-mL ampoule
metronidazole	tablet, 250 mg or 500 mg; injection, 500 mg in 100-mL vial; suppository, 500 mg or 1 g; oral suspension, 200 mg (as benzoate)/5 mL
morphine	injection, 10 mg in 1-mL ampoule (sulfate or hydrochloride); oral solution, 10 mg (hydrochloride or sulfate)/5 mL; tablet, 10 mg (sulfate)
nelfinavir (NFV)	tablet, 250 mg (as mesilate); oral powder, 50 mg/g
nevirapine (NVP)	tablet, 200 mg; oral suspension, 50 mg/5 mL
nifedipine	sustained release formulations, tablet, 10 mg
nitrofurantoin	tablet, 100 mg
ofloxacin	tablet, 200 mg or 400 mg

oseltamivir phosphate	capsule, 75 mg; powder for oral suspension, 12 mg/mL
potassium chloride	powder for solution
ranitidine	tablet, 150 mg (as hydrochloride); oral solution, 75 mg/5 mL; injection, 25 mg/mL in 2-mL ampoule
ritonavir	capsule, 100 mg; oral solution, 400 mg/5 mL
salbutamol	tablet, 2 mg or 4 mg (as sulfate); inhalation (aerosol), 100 micrograms (as sulfate) per dose; syrup, 2 mg/5 mL; injection, 50 micrograms (as sulfate)/mL in 5-mL ampoule; respirator solution for use in nebulizers, 5 mg (as sulfate)/mL
saquinavir (SQV)	capsule, 200 mg
stavudine (d4T)	capsule, 15 mg, 20 mg, 30 mg or 40 mg; powder for oral solution, 5 mg/5 mL
testosterone	injection, 200 mg (enantate) in 1-mL ampoule
timolol	solution (eye drops), 0.25% or 0.5% (as maleate)
verapamil	tablet, 40 mg or 80 mg (hydrochloride); injection, 2.5 mg (hydrochloride)/mL in 2-mL ampoule
zalcitabine	capsule or tablet, 0.375 mg or 0.750 mg
zidovudine (ZDV or AZT)	tablet, 300 mg; capsule, 100 mg or 250 mg; oral solution or syrup, 50 mg/5 mL; solution for IV infusion injection, 10 mg/mL in 20-mL vial

2004, c. 23, Sch. 1; SOR/2005-276; SOR/2006-204.

SCHEDULE 2

(Paragraph 21.03(1)(b))

Afghanistan
Afghanistan

Angola
Angola

Bangladesh
Bangladesh

Benin
Bénin

Bhutan
Bhoutan

Burkina Faso
Burkina Faso

Burundi
Burundi

Cambodia
Cambodge

Cape Verde
Cap-Vert

Central African Republic
République centrafricaine

Chad
Tchad

Comoros
Comores

Democratic Republic of the Congo
République démocratique du Congo

Djibouti

Djibouti

Equatorial Guinea
Guinée équatoriale

Eritrea
Érythrée

Ethiopia
Éthiopie

Gambia
Gambie

Guinea
Guinée

Guinea-Bissau
Guinée-Bissau

Haiti
Haïti

Kiribati
Kiribati

Lao People's Democratic Republic
République démocratique populaire lao

Lesotho
Lesotho

Liberia
Libéria

Madagascar
Madagascar

Malawi
Malawi

Maldives
Maldives

Mali
Mali

Mauritania
Mauritanie

Mozambique
Mozambique

Myanmar
Myanmar

Nepal
Népal

Niger
Niger

Rwanda
Rwanda

Samoa
Samoa

Sao Tome and Principe
Sao Tomé-et-Principe

Senegal
Sénégal

Sierra Leone

Sierra Leone

Solomon Islands
Îles Salomon

Somalia
Somalie

Sudan
Soudan

Timor-Leste
Timor-Leste

Togo
Togo

Tuvalu
Tuvalu

Uganda
Ouganda

United Republic of Tanzania
République-Unie de Tanzanie

Vanuatu
Vanuatu

Yemen
Yémen

Zambia
Zambie

2004, c. 23, Sch. 2.

SCHEDULE 3

(Paragraph 21.03(1)(c))

Albania
Albanie

Antigua and Barbuda
Antigua-et-Barbuda

Argentina
Argentine

Armenia
Arménie

Bahrain, Kingdom of
Bahreïn, Royaume de

Barbados
Barbade

Belize
Belize

Bolivia
Bolivie

Botswana
Botswana

Brazil
Brésil

Brunei Darussalam

Brunéi Darussalam

Bulgaria
Bulgarie

Cameroon
Cameroun

Chile
Chili

China
Chine

Colombia
Colombie

Congo
Congo

Costa Rica
Costa Rica

Côte d'Ivoire
Côte d'Ivoire

Croatia
Croatie

Cuba
Cuba

Dominica
Dominique

Dominican Republic
République dominicaine

Ecuador
Équateur

Egypt
Égypte

El Salvador
El Salvador

Fiji
Fidji

Former Yugoslav Republic of Macedonia
Ex-République yougoslave de Macédoine

Gabon
Gabon

Georgia
Géorgie

Ghana
Ghana

Grenada
Grenade

Guatemala
Guatemala

Guyana
Guyana

Honduras
Honduras

India

Inde

Indonesia
Indonésie

Jamaica
Jamaïque

Jordan
Jordanie

Kenya
Kenya

Kyrgyz Republic
République kirghize

Liechtenstein
Liechtenstein

Malaysia
Malaisie

Mauritius
Maurice

Moldova
Moldova

Mongolia
Mongolie

Morocco
Maroc

Namibia
Namibie

Nicaragua
Nicaragua

Nigeria
Nigéria

Oman
Oman

Pakistan
Pakistan

Panama
Panama

Papua New Guinea
Papouasie-Nouvelle-Guinée

Paraguay
Paraguay

Peru
Pérou

Philippines
Philippines

Romania
Roumanie

Saint Kitts and Nevis
Saint-Kitts-et-Nevis

Saint Lucia
Sainte-Lucie

Saint Vincent and the Grenadines

Saint-Vincent-et-les-Grenadines

South Africa
Afrique du Sud

Sri Lanka
Sri Lanka

Suriname
Suriname

Swaziland
Swaziland

Thailand
Thaïlande

Trinidad and Tobago
Trinité-et-Tobago

Tunisia
Tunisie

Uruguay
Uruguay

Venezuela
Venezuela

Zimbabwe
Zimbabwe

2004, c. 23, Sch. 3.

SCHEDULE 4

(Paragraph 21.03(1)(d))

Cyprus
Chypre

Czech Republic
République tchèque

Estonia
Estonie

Hong Kong, China
Hong Kong, Chine

Hungary
Hongrie

Israel
Israël

Korea
Corée

Kuwait
Koweït

Latvia
Lettonie

Lithuania
Lituanie

Macao, China
Macao, Chine

Malta

Malte

Mexico
Mexique

Poland
Pologne

Qatar
Qatar

Singapore
Singapour

Slovak Republic
République slovaque

Slovenia
Slovénie

Chinese Taipei
Taipei chinois

Turkey
Turquie

United Arab Emirates
Émirats arabes unis

2004, c. 23, Sch. 4.

RELATED PROVISIONS

— R.S., 1985, c. 33 (3rd Supp.), ss. 31 and 32, as amended by 1992, c. 1, s. 145(F) (Sch. VIII, item 22):

Payments to provinces

31. (1) The Minister of Consumer and Corporate Affairs shall pay to each province for each of the fiscal years commencing in the period April 1, 1987 to March 31, 1991, for the purpose of research and development relating to medicine, an amount equal to the product obtained by multiplying

(*a*) the quotient obtained by dividing

(i) twenty-five million dollars

by

(ii) the total population of all provinces for the fiscal year in respect of which the payment is made,

by

(*b*) the population of the province for the fiscal year in respect of which the payment is made.

Time and manner of payment

(2) Payment of any amount under this section shall be made out of the Consolidated Revenue Fund at such times and in such manner as the Governor in Council may, by regulation, prescribe.

Determination of population

(3) For the purposes of this section, the population of a province for a fiscal year shall be the population of that province on June 1 of that year as determined and published by the Chief Statistician of Canada.

— R.S., 1985, c. 33 (3rd Supp.), ss. 31 and 32, as amended by 1992, c. 1, s. 145(F) (Sch. VIII, item 22):

Prohibition

32. (1) Notwithstanding anything in section 39 of the *Patent Act* or in any licence granted under that section, no person shall, under a licence granted prior to March 28, 1989 under that section in respect of a patent pertaining to the medicine Diltiazem hydrochloride, have or exercise any right to
(*a*) import Diltiazem hydrochloride, if it is to be sold for consumption in Canada; or
(*b*) make Diltiazem hydrochloride for sale for consumption in Canada.

Duration of prohibition

(2) The prohibition under subsection (1) expires on March 28, 1989.

Actions and proceedings barred

(3) No action or proceedings for any compensation or damages lie against Her Majesty in right of Canada as a result of the application of subsection (1) to a licence referred to in that subsection.
— 1993, c. 2, ss. 9 to 14:

Definitions

9. In this section and sections 10 to 13,
“commencement day”
« *date d’entrée en vigueur* »

“commencement day” means the day on which section 3 of this Act comes into force;
“former Act”
« *loi antérieure* »

“former Act” means the *Patent Act*, as it read immediately before the commencement day.
— 1993, c. 2, ss. 9 to 14:

Pending proceedings

10. Any proceeding pending before the Patented Medicine Prices Review Board immediately before the commencement day shall be taken up and continued under and in accordance with sections 79 to 101 of the *Patent Act*, as enacted by section 7 of this Act, as if the proceeding had been commenced on or after that day.
— 1993, c. 2, ss. 9 to 14:

Licences continued

11. (1) A licence that has been granted under section 39 of the former Act before December 20, 1991 and that has not been terminated before the commencement day shall continue in effect according to its terms and, subject to subsection (2), sections 39 to 39.14 of the former Act shall continue to apply in respect of that licence as if they had not been repealed by section 3 of this Act.

Exception

(2) For the purposes of applying sections 39 to 39.14 of the former Act in respect of a licence continued by subsection (1), the prohibitions set out in subsections 39.11(1) and 39.14(1) of the former Act do not apply in respect of any medicine or medicines in respect of which an order has been made under paragraph 39.15(3)(*d*) of the former Act, if that order is in force immediately before the commencement day.
— 1993, c. 2, ss. 9 to 14:

Licences ceasing to have effect

12. (1) Every licence granted under section 39 of the former Act on or after December 20, 1991 shall cease to have effect on the expiration of the day preceding the commencement day, and all rights or privileges acquired or accrued under that licence or under the former Act in relation to that licence shall thereupon be extinguished.

Actions for infringement barred

(2) For greater certainty, no action for infringement of a patent lies under the *Patent Act* in respect of any act that is done before the commencement day under a licence referred to in subsection (1) in accordance with the terms of that licence and sections 39 to 39.17 of the former Act.

— 1993, c. 2, ss. 9 to 14:

Actions and proceedings barred

13. No action or proceeding for any compensation or damages lies against Her Majesty in right of Canada in respect of any direct or indirect consequence resulting from the application of section 11 or 12 or the repeal of sections 39 to 39.17 of the former Act.

— 1993, c. 2, ss. 9 to 14:

Review of certain sections

14. (1) On the expiration of four years after this Act is assented to, the provisions of the *Patent Act* enacted by this Act shall be 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 the purpose of the review referred to in subsection (2).

Idem

(2) The committee shall undertake a comprehensive review of the provisions of the *Patent Act* enacted by this Act and shall, within one year after the review is undertaken or within such further time as the House or Houses that designated or established the committee may authorize, submit a report thereon, including such recommendations as the committee may wish to make pertaining to those provisions.

— 1993, c. 44, s. 191(2):

No liability

(2) Her Majesty in right of Canada or a province is not, by reason only of the enactment of subsection (1), liable for any use of a patented invention before the day on which subsection (1) comes into force.