

**CANADA**

**Patent Act**

Current to November 16, 2022

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## **Short Title**

### **Short title**

1 This Act may be cited as the Patent Act.

## **Interpretation**

### **Definitions**

2 In this Act, except as otherwise provided,

**applicant** includes an inventor and the legal representatives of an applicant or inventor;

**certificate of supplementary protection** means a certificate issued by the Minister of Health under section 113;

**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** means the Commissioner of Patents;

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

**filing date** means the date on which an application for a patent in Canada is filed, as determined in accordance with section 28 or subsection 28.01(2) or 36(4);

**holder** means, with respect to a certificate of supplementary protection, the person for the time being that is entitled to the benefit of the certificate;

**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** includes heirs, executors, administrators of the estate, liquidators of the succession, guardians, curators, tutors, transferees and all other persons claiming through applicants for patents and patentees of inventions or through holders of certificates of supplementary protection;

**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** means letters patent for an invention;

**patent agent** has the same meaning as in section 2 of the College of Patent Agents and Trademark Agents Act;

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

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

**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**prescribed fee** [Repealed]

**priority date** [Repealed]

**regulation** includes a rule or form;

**regulation and rule** [Repealed]

**request for priority** means a request under section 28.4;

**rule** includes a regulation or form.

**work on a commercial scale** [Repealed]

## **Her Majesty**

### **Binding on Her Majesty**

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

## **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.

### **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, and documents relating to patents, shall perform and do all acts and things requisite for the granting and issuing of patents, shall have the charge and custody of the books, records 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.

### **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, inability to act or vacancy**

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

**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.

**Officers of Patent Office not to deal in patents, etc.**

7 (1) No officer or employee of the Patent Office shall buy, sell, acquire or traffic in any invention, patent, right to a patent, certificate of supplementary protection or right to such a certificate, or any interest in any of them, and every purchase, sale, acquisition or transfer of any of them, or of any interest in any of them, made by or to such an officer or employee is void or, in Quebec, null.

**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.

8 [Repealed]

**Electronic form and means**

8.1 (1) Subject to the regulations, any document, information or fee that is submitted to the Commissioner or the Patent Office under this Act may be submitted in any electronic form, and by any electronic means, that is specified by the Commissioner.

**Collection, storage, etc.**

(2) Subject to the regulations, the Commissioner and the Patent Office may use electronic means to create, collect, receive, store, transfer, distribute, publish, certify or otherwise deal with documents or information or to seal a patent or other document.

**Definition of electronic**

(3) In this section, electronic, in reference to a form or means, includes optical, magnetic and other similar forms or means.

**8.2 [Repealed]****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.

**Inspection by the public**

10 (1) Subject to subsections (2) to (6) and section 20, all patents, applications for patents and documents relating to patents or applications for patents that are in the possession of the Patent Office shall be open to public inspection at the Patent Office, under any conditions that may be prescribed.

**Confidentiality period**

(2) Except with the approval of the applicant, an application for a patent, or a document relating to the application, shall not be open to public inspection before a confidentiality period of 18 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.

## **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;
    - (a.1) defining drawing for the purposes of this Act and respecting the circumstances in which certain drawings may be furnished as part of applications for patents;
    - (a.2) respecting abstracts in applications for patents, including authorizing the Commissioner to amend or replace abstracts;
    - (a.3) respecting the consequences of a failure to comply with a notice given under subsection 27(7);
    - (a.4) respecting the processing and examination of applications for patents;
  - (b) respecting the form of the Register of Patents and of the indexes thereto;
  - (c) respecting the registration of transmissions, disclaimers, judgments or other documents relating to a patent or an application for a patent;
    - (c.1) respecting the recording of transfers of patents or applications for patents;
  - (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;

(g.1) authorizing the Commissioner to waive, subject to any prescribed terms and conditions, the payment of a fee if the Commissioner is satisfied that the circumstances justify it;

(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;

(i.1) for carrying into effect the Patent Law Treaty, done at Geneva on June 1, 2000, including any amendments and revisions made from time to time to which Canada is a party;

(j) [Repealed]

(j.001) [Repealed]

(j.002) [Repealed]

(j.01) respecting the circumstances in which an applicant, patentee or other person may or must be represented in business before the Patent Office by a patent agent whose license is not suspended or by another person;

(j.1) respecting the submission, including in electronic form and by electronic means, of documents and information to the Commissioner or the Patent Office, including the time at which they are deemed to be received by the Commissioner or the Patent Office;

(j.2) respecting the use of electronic means for the purposes of subsection 8.1(2);

(j.3) respecting the withdrawal of an application for a patent 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 is to be withdrawn;

(j.31) respecting additions to the specification and additions of drawings for the purposes of subsection 28.01(1);

(j.4) respecting requests for priority, including

- (i) the period within which priority is to be requested,
- (ii) the information and documents that are to be submitted in support of requests for priority,
- (iii) the period within which that information and those documents are to be submitted,
- (iv) the withdrawal of requests for priority, and



(v) the correction of requests for priority or of information or documents submitted in support of them and the effect of corrections on the duration of the confidentiality period referred to in subsection 10(3);

(j.41) respecting the application of subsection 28.4(6);

(j.5) respecting divisional applications, including the time period within which divisional applications may be filed and the persons who may file divisional applications;

(j.51) defining one invention for the purposes of section 36;

(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.71) respecting amendments to the specification or drawings for the purposes of subsection 38.2(1);

(j.72) respecting the replacement of all or part of the text matter of a specification or drawing contained in an application for a patent that is in a language other than English or French with a translation into English or French, for the purposes of paragraph 38.2(3) (b);

(j.73) respecting the conditions set out in subsection 46(5), including the circumstances in which subparagraph 46(5) (a) (ii) and paragraph 46(5) (b) do not apply;

(j.74) establishing a period for the purposes of subsection 55.11(2);

(j.75) establishing a period for the purposes of subsections 55.11(3), (7) and (9);

(j.76) respecting the reinstatement of applications for patents under subsection 73(3), including the circumstances in which subparagraph 73(3) (a) (ii) and paragraph 73(3) (b) do not apply;

(j.77) respecting communications between the Commissioner and any other person;

(j.8) authorizing the Commissioner to, during or after the end of the time period fixed under this Act in respect of any business before the Patent Office, for doing anything, extend that time period, subject to any prescribed terms and conditions, if the Commissioner considers that the circumstances justify the extension;

(j.81) respecting the correction of obvious errors in documents submitted to the Commissioner or the Patent Office or in patents

or other documents granted or issued under this Act, other than under sections 106 to 134, including

- (i) the determination of what constitutes an obvious error, and
- (ii) the effect of the correction;

(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.

**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.

**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.

## **Patent Agents**

15 [Repealed]

16 [Repealed]

## **Privileged communication**

**16.1 (1)** A communication that meets the following conditions is privileged in the same way as a communication that is subject to solicitor-client privilege or, in civil law, to professional secrecy of advocates and notaries and no person shall be required to disclose, or give testimony on, the communication in a civil, criminal or administrative action or proceeding:

- (a) it is between a patent agent and that their client;
- (b) it is intended to be confidential; and
- (c) it is made for the purpose of seeking or giving advice with respect to any matter relating to the protection of an invention.

### **waiver**

**(2)** Subsection (1) does not apply if the client expressly or implicitly waives the privilege.

### **Exceptions**

**(3)** Exceptions to solicitor-client privilege or, in civil law, to professional secrecy of advocates and notaries apply to a communication that meets the conditions set out in paragraphs (1)(a) to (c).

### **Patent agents – country other than Canada**

**(4)** A communication between an individual who is authorized to act as the equivalent of a patent agent under the law of a country other than Canada and that individual's client that is privileged under the law of that other country and that would be privileged under subsection (1) had it been made between a patent

agent and their client is deemed to be a communication that meets the conditions set out in paragraphs (1) (a) to (c).

**Individual acting on behalf of patent agent or client**

(5) For the purposes of this section, a patent agent or an individual who is authorized to act as the equivalent of a patent agent under the law of a country other than Canada includes an individual acting on their behalf and a client includes an individual acting on the client's behalf.

**Application**

(6) This section applies to communications that are made before the day on which this section comes into force if they are still confidential on that day and to communications that are made after that day. However, this section does not apply in respect of an action or proceeding commenced before that day.

**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.

**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.

## **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.

### **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.

**Appeal**

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

**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.

**Application by Minister**

19.4 (1) The Commissioner shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application.

**Contents of application**

(2) The application must

(a) set out the name of the patentee and the number, as recorded

in the Patent Office, of the patent issued in respect of the patented invention;

(b) include a confirmation that the Chief Public Health Officer, appointed under subsection 6(1) of the Public Health Agency of Canada Act, believes that there is a public health emergency that is a matter of national concern;

(c) include a description of the public health emergency; and

(d) specify a person, if any, that is to be authorized to make, construct, use and sell the patented invention for the purposes of responding to the public health emergency.

**Cessation of effect**

(3) The authorization ceases to have effect the earlier of

(a) the day on which the Minister of Health notifies the Commissioner that the authorization is no longer necessary to respond to the public health emergency set out in the application, and

(b) one year after the day on which it is granted.

**Notice**

(4) The Commissioner shall notify the patentee of any authorization that is granted under this section and provide them with the information referred to in subsection (2).

**Payment of remuneration**

(5) The Government of Canada and any person authorized under subsection (1) shall pay the patentee any amount that the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization and the extent to which they make, construct, use and sell the patented invention.

**Authorization not transferable**

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

**For greater certainty**

(7) For greater certainty, the use or sale, in relation to a public health emergency, of a patented invention that is made or constructed in accordance with an authorization granted under this section is not an infringement of the patent.

**Power of Federal Court**

(8) On the application of the patentee, the Federal Court may make an order requiring the Government of Canada or any person authorized under subsection (1) to cease making, constructing, using or selling the patented invention in a manner that is

inconsistent with the authorization granted under this section.

**Restriction**

(9) The Commissioner shall not make an authorization under subsection (1) after September 30, 2020.

**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.

**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.

## **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.

### **Definitions**

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

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

**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** 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** 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** 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** 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** means the council referred to in the TRIPS Agreement. **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. (OMC)

## **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 Development, 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 Development, 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 Development, 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 Development, 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.

**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.

#### **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.

**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).

**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.

### **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.

**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.

**Use is non-exclusive**

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

**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.

**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.

**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.

**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.

#### **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.

#### **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).

**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** 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**, 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**, 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.

**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.

**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.

**Review Examen**

**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.

**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.

## **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.

**24** [Repealed]

### **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.

### **Annual report**

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

**26.1 (1)** [Repealed]

### **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.

## **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.

### **Separate claims**

**(5)** For greater certainty, if 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, 56 and 78.3.

**Drawings**

(5.1) 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**

(5.2) Each drawing is to include references corresponding with the specification. The Commissioner may, as the Commissioner sees fit, require further drawings or dispense with the requirement to furnish any drawing.

**Requirements not met**

(6) If, on its filing date, an application does not meet the requirements of subsection (2), other than the payment of the application fee, the Commissioner shall, by notice, require the applicant to meet those requirements on or before the prescribed date.

**Application fee not paid**

(7) If, on the filing date of the application, the application fee is not paid, the Commissioner shall, by notice, require the applicant to pay the application fee and the prescribed late fee on or before the prescribed date.

**What may not be patented**

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

**Reference to previously filed application**

27.01 (1) Subject to the prescribed requirements and within the prescribed period, an applicant may submit to the Commissioner a statement to the effect that a reference to a specified previously filed application for a patent is being submitted instead of all or part of the specification contained in or a drawing that is required to be contained in the application. The prescribed period shall not end later than six months after the earliest date on which the Commissioner receives any document or information under subsection 28(1).

**Specification or drawing deemed in application**

(2) If the applicant submits the statement within the prescribed period and meets the prescribed requirements, the specification or drawing in the previously filed application is deemed to have been contained in the application on the date on which the Commissioner receives the statement.

**Maintenance fees**

**27.1 (1)** To maintain an application for a patent in effect, the prescribed fees shall be paid on or before the prescribed dates.

**Late fee and notice**

**(2)** If a prescribed fee is not paid on or before the applicable prescribed date,

(a) the prescribed late fee shall be paid, in addition to the prescribed fee; and

(b) the Commissioner shall send a notice to the applicant stating that the application will be deemed to be abandoned if the prescribed fee and late fee are not paid before the later of the end of six months after the applicable prescribed date and the end of two months after the date of the notice.

**Prescribed fee deemed paid on prescribed date**

**(3)** If the prescribed fee and late fee are paid before a notice is sent or, if a notice is sent, the prescribed fee and late fee are paid before the later of the end of six months after the applicable prescribed date and the end of two months after the date of the notice, the prescribed fee shall be deemed to have been paid on the applicable prescribed date.

**Patent not invalid**

**(4)** A patent shall not be declared invalid by reason only that the application on the basis of which the patent was granted was not maintained in effect.

**Filing date**

**28 (1)** Subject to subsections 28.01(2) and 36(4), the filing date of an application for a patent in Canada is the date on which the Commissioner receives the prescribed documents and information or, if they are received on different dates, the latest of those dates.

**Outstanding documents and information**

**(2)** The Commissioner shall notify an applicant whose application does not contain all of the documents and information referred to in subsection (1) of the documents and information that are outstanding and require that the applicant submit them within two months after the date of the notice.

**Application deemed never filed**

**(3)** If the Commissioner does not receive the outstanding documents and information within that two-month period, the application is deemed never to have been filed. However, any fees

paid in respect of the application shall not be refunded to the applicant.

**Addition to specification or addition of drawing to application**

**28.01 (1)** Subject to the regulations, an applicant may, within the prescribed period, add to the specification that is contained in their application or add a drawing to their application for a patent by submitting the addition to the Commissioner along with a statement by the applicant indicating that the addition is being made under this section. The prescribed period shall not end later than six months after the earliest date on which the Commissioner receives any document or information under subsection 28(1).

**Filing date**

**(2)** If an applicant submits an addition to the Commissioner under subsection (1) and the addition is not withdrawn within the prescribed period, the filing date of the application is the later of the date on which the Commissioner receives the addition and the filing date referred to in subsection 28(1), unless

(a) the applicant has, on the earliest date on which the Commissioner receives any document or information under subsection 28(1), made a request for priority in respect of the application under section 28.4;

(b) the addition is completely contained in a previously regularly filed application on which the request for priority is based;

(c) the applicant requests, in accordance with the regulations, that the filing date be the filing date referred to in subsection 28(1); and

(d) the applicant complies with any prescribed requirements.

**Addition deemed in application**

**(3)** In the circumstances set out in paragraphs (2)(a) to (d), the addition is deemed to have been contained in the application on its filing date for the purposes of subsections 38.2(2) and (3).

**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.

**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) before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim 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.

#### **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 before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim 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.

**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 for request**

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

**Request deemed never filed**

**(2.1)** Except for the purposes of subsection 10(3), a request for priority is deemed never to have been made if the request is not made in accordance with the regulations or if the applicant does not submit the information, other than the number of each previously regularly filed application, required under subsection (2).

**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)** If 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 or for the same country or in or for 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) on the filing date of one of the following applications, as the case may be, more than 12 months have elapsed since the filing date of the previously regularly filed application:

- (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 of the application referred to in one of subparagraphs (a) (i) to (iv), as the case may be, 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.

**Filing date deemed to be within 12 months**

(6) Subject to the regulations, for the purposes of paragraph 28.1(1)(b) and subparagraphs 28.2(1)(d)(iii) and 28.4(5)(a)(i) and (ii), the filing date of the pending application or the co-pending application, as the case may be, shall be deemed to be within 12 months after the filing date of the previously regularly filed application if

(a) the filing date of the pending application or the co-pending application, as the case may be, is more than 12 months after the filing date of the previously regularly filed application but within two months after the end of those 12 months; and

(b) the applicant, within the prescribed time,

(i) makes a request to the Commissioner for this subsection to apply,

(ii) states, in the request, that the failure to file the pending application or the co-pending application, as the case may be, within 12 months after the filing date of the previously regularly filed application was unintentional, and  
(iii) complies with any prescribed requirements.

**Powers of the Federal Court**

(7) If subsection (6) applies, the Federal Court may, by order, declare that subsection never to have produced its effects if the Federal Court determines that the failure referred to in subparagraph (6) (b) (ii) was intentional.

29 [Repealed]

30 [Repealed]

**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 transfer 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.

## **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.

**33** [Repealed]

**34** [Repealed]

## **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.

## **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.

### **Prescribed time**

**(2)** The request shall be made within the prescribed time and the prescribed fee shall be paid within that time.

### **Late fee and notice**

**(3)** If the request is not made or the prescribed fee is not paid within the prescribed time,

(a) the prescribed late fee shall be paid, in addition to the prescribed fee; and

(b) the Commissioner shall send a notice to the applicant stating that the application will be deemed to be abandoned if the request is not made and the prescribed fee and late fee are not paid before the end of two months after the date of the notice.

### **Request deemed made and prescribed fee deemed paid within prescribed time**

**(4)** If the request is made and the prescribed fee and late fee are paid before a notice is sent or, if a notice has been sent, the request is made and the prescribed fee and late fee are paid before the end of two months after the date of the notice, the request shall be deemed to have been made and the prescribed fee shall be deemed to have been paid within the prescribed time.

### **Required examination**

**(5)** The Commissioner may by a notice sent to the applicant, require that the request be made and the prescribed fee be paid within the prescribed time. However, the Commissioner is not authorized to send the notice if the prescribed time would end after the prescribed time referred to in subsection (2).

### **Non-application**

**(6)** If a notice is sent under subsection (5), subsections (2) to (4) do not apply.



## **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) is deemed to be abandoned and is not reinstated, the time for filing a divisional application ends on the later of the day on which the original application is deemed to be abandoned and the end of the prescribed time referred to in subsection 73(3).

### **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, except for the purposes of subsections 27(6) and (7), it shall have the same filing date as the original application.

## **Biological Materials**

37 [Repealed]

38 [Repealed]

### **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).

## **Amendments to Specifications and Drawings**

### **Amendments to specifications and drawings**

**38.2 (1)** Subject to subsections (2) to (3.1) and the regulations, the specification and drawings contained in an application for a patent in Canada may be amended before the patent is issued.

### **Restriction**

**(2)** The specification and drawings contained in an application, other than a divisional application, may not be amended to add matter that cannot reasonably be inferred from the specification or drawings contained in the application on its filing date.

### **Language other than English or French**

**(3)** However, if all or part of the text matter of the specification or drawings contained in the application on its filing date is in a language other than English or French, the specification and drawings may not be amended to add matter not reasonably to be inferred from both

(a) the specification or drawings contained in the application on its filing date, and

(b) the specification or drawings contained in the application immediately after the text matter is replaced by an English or French translation, in accordance with the regulations.

#### **Divisional application**

**(3.1)** The specification and drawings contained in a divisional application may not be amended to add matter

(a) that may not be or could not have been added, under subsection (2) or (3) or this subsection, to the specification and drawings contained in the application for a patent from which the divisional application results; or

(b) that cannot reasonably be inferred from the specification or drawings contained in the divisional application on the date on which the Commissioner, in respect of that application, receives the prescribed documents and information or, if they are received on different dates, on the latest of those dates.

#### **Non-application of subsections (2) to (3.1)**

**(4)** Subsections (2) to (3.1) do not apply if it is admitted in the specification that the matter is prior art with respect to the application.

#### **Application subject to regulations**

**(5)** Subsections (2) to (3.1) apply subject to any regulations made under paragraph 12(1)(j.81).

**39 to 39.26** [Repealed]

### **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.

#### **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.

## **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.

## **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.

## **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.

**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.

**Maintenance fees**

**46 (1)** To maintain the rights accorded by a patent issued under this Act in effect, the prescribed fees shall be paid on or before the prescribed dates.

**Late fee and notice**

**(2)** If a prescribed fee is not paid on or before the applicable prescribed date,

(a) the prescribed late fee shall be paid, in addition to the prescribed fee; and

(b) the Commissioner shall send a notice to the patentee stating that the term limited for the duration of the patent will be deemed to have expired if the prescribed fee and late fee are not paid before the later of the end of six months after the applicable prescribed date and the end of two months after the date of the notice.

**Prescribed fee deemed paid on prescribed date**

**(3)** If the prescribed fee and late fee are paid before a notice is sent or, if a notice is sent, the prescribed fee and late fee are paid before the later of the end of six months after the applicable prescribed date and the end of two months after the date of the notice, the prescribed fee shall be deemed to have been paid on the applicable prescribed date.

**Term limited deemed expired on prescribed date**

**(4)** If the prescribed fee and late fee are not paid before the later of the end of six months after the applicable prescribed date and the end of two months after the date of the notice, the term limited for the duration of the patent shall be deemed to have expired on the applicable prescribed date.

**Subsection (4) deemed never to have produced its effects**

(5) Subject to the regulations, if the term limited for the duration of a patent is deemed to have expired under subsection (4), that subsection is deemed never to have produced its effects if

- (a) the patentee, within the prescribed time,
  - (i) makes a request to the Commissioner for the term limited for the duration of the patent to never have been deemed to have expired,
  - (ii) states, in the request, the reasons for the failure to pay the prescribed fee and late fee before the later of the end of six months after the applicable prescribed date and the end of two months after the date of the notice, and
  - (iii) pays the prescribed fee, the late fee and any additional prescribed fee; and
- (b) the Commissioner determines that the failure occurred in spite of the due care required by the circumstances having been taken and informs the patentee of this determination.

**Powers of the Federal Court**

(6) If subsection (5) applies, the Federal Court may, by order, declare the term limited for the duration of the patent to have expired on the applicable prescribed date if the Federal Court determines either

- (a) that the statement of the reasons referred to in subparagraph (5) (a) (ii) contains a material allegation that is untrue, or
- (b) that, if paragraph (5) (b) applies, the failure referred to in subparagraph (5) (a) (ii) did not occur in spite of the due care required by the circumstances having been taken.

## **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.

### **Certificate of supplementary protection**

**(1.1)** Subsection (1) also applies in the case where the original patent is set out in a certificate of supplementary protection and the original patent's term has expired, except that in that case the issuance of the new patent, whose term remains expired, is for the purpose of establishing the rights, privileges and liberties granted under the certificate.

### **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.

## **Disclaimers**

### **Patentee may disclaim anything included in patent by mistake**

**48 (1)** Whenever, by any mistake, accident or inadvertence, and without any willful 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 the parts that the patentee does not claim to hold by virtue of the patent or a transfer of the patent.

### **Form and attestation of disclaimer**

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

**(3)** [Repealed]

### **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.

**(5)** [Repealed]

### **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.



## **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.

### **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.

**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).

**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.

**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.

## **Transfers**

### **Patent, application and right or interest in invention**

**49 (1)** A patent, an application for a patent, and the right or interest in an invention are transferable, in whole or in part.

### **Recording of transfer of application**

**(2)** The Commissioner shall, subject to the regulations, record the transfer of an application for a patent on the request of the applicant or, upon receipt of evidence satisfactory to the Commissioner of the transfer, on the request of a transferee of the application.

### **Recording of transfer of patent**

**(3)** The Commissioner shall, subject to the regulations, record the transfer of a patent on the request of the patentee or, upon receipt of evidence satisfactory to the Commissioner of the transfer, on the request of a transferee of the patent.

### **Transfer void**

**(4)** A transfer of a patent that has not been recorded is void against a subsequent transferee if the transfer to the subsequent transferee has been recorded.

### **Removal of recording**

**(5)** The Commissioner shall remove the recording of the transfer of an application for a patent or the transfer of a patent on receipt of evidence satisfactory to the Commissioner that the transfer should not have been recorded.

### **Limitation**

**(6)** The Commissioner is not authorized to remove the recording of a transfer of a patent for the reason only that the transferor had previously transferred the patent to another person.

**50 - 51** [Repealed]

### **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.

## **Standard-Essential Patents**

### **Subsequent patentee or holder bound**

**52.1 (1)** A licensing commitment in respect of a standard-essential patent that binds the patentee, binds any subsequent patentee and any holder of any certificate of supplementary protection that sets out that patent.

### **Subsequent holder bound**

**(2)** If a certificate of supplementary protection sets out a standard-essential patent, a licensing commitment that binds the holder of that certificate of supplementary protection, binds any subsequent holder of the certificate of supplementary protection.

### **Application**

**(3)** Subsections (1) and (2) apply despite any other Act of Parliament and any decision or order made under such an Act.

### **Regulations**

**52.2** The Governor in Council may make regulations, for the purposes of section 52.1, respecting what constitutes, or does not constitute, a licensing commitment or a standard-essential patent.

## **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.

(3) [Repealed]

**Admissible in evidence**

**53.1 (1)** In any action or proceeding respecting a patent, a written communication, or any part of such a communication, may be admitted into evidence to rebut any representation made by the patentee in the action or proceeding as to the construction of a claim in the patent if

(a) it is prepared in respect of

- (i) the prosecution of the application for the patent,
- (ii) a disclaimer made in respect of the patent, or
- (iii) a request for re-examination, or a re-examination proceeding, in respect of the patent; and

(b) it is between

- (i) the applicant for the patent or the patentee; and
- (ii) the Commissioner, an officer or employee of the Patent Office or a member of a re-examination board.

**Divisional application**

**(2)** For the purposes of this section, the prosecution of a divisional application is deemed to include the prosecution of the original application before that divisional application is filed.

**Reissued patent**

**(3)** For the purposes of this section, a written communication is deemed to be prepared in respect of the prosecution of the application for a reissued patent if it is prepared in respect of

- (a) the prosecution of the application for the patent that was surrendered and from which the reissued patent results; or
- (b) the application for reissuance.

## **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.

### **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 specification contained in the application for the patent became open to public inspection, in English or French, 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 specification became open to public inspection, in English or French, 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.

### **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.

### **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.

### **Exception – third party rights**

**55.11 (1)** This section applies only in respect of the following patents and certificates of supplementary protection that set out the following patents:

- (a) a patent that was granted on the basis of an application
  - (i) in respect of which the prescribed fee referred to in subsection 27.1(2) was not paid on or before the applicable prescribed date referred to in that subsection, without taking into account subsection 27.1(3),
  - (ii) in respect of which a request referred to in subsection 35(2) was not made and the prescribed fee referred to in that subsection was not paid within the prescribed time referred to in that subsection, without taking into account subsection 35(4), or
  - (iii) that was deemed abandoned under paragraph 73(1)(a), (b) or (e), under paragraph 73(1)(f) as it read at any time before the coming into force of this subparagraph or under subsection 73(2);
- (b) a patent that was granted on the basis of a divisional application that
  - (i) results, under subsection 36(2) or (2.1), from the division of an original application that is an application referred to in this paragraph or paragraph (a), and
  - (ii) was filed after the beginning of the period referred to in subsection (2) or, if it is earlier, the period referred to in subsection (3), that applies to the patent granted on the basis of the original application or that would apply to that patent



if it were granted; and

(c) a patent in respect of which the prescribed fee referred to in subsection 46(2) was not paid on or before the applicable prescribed date referred to in that subsection, without taking into account subsection 46(3).

**Act committed during period**

(2) If, during a period that is established by regulations made under paragraph 12(1) (j.74) that relates to a patent, a person, in good faith, committed an act that would otherwise constitute an infringement of that patent, that act is not an infringement of the patent.

**Act committed after period**

(3) Subject to subsection (4), if – during a period established by regulations made under paragraph 12(1) (j.75) that relates to a patent – a person, in good faith, committed an act that would otherwise constitute an infringement of that patent or made serious and effective preparations to commit that act, it is not an infringement of the patent or any certificate of supplementary protection that sets out the patent if the person commits the act after that period.

**Transfer**

(4) If the act referred to in subsection (3) is committed or the preparations to commit it are made in the course of a business and that business, or the part of that business in the course of which the act was committed or the preparations were made, is subsequently transferred,

(a) subsection (3) or paragraph (b), as the case may be, does not apply in respect of an act committed by the transferor after the transfer; and

(b) it is not an infringement of the patent or any certificate of supplementary protection that sets out the patent if the transferee commits the act after the transfer.

**Use or sale of article**

(5) The use or sale of an article is not an infringement of a patent or any certificate of supplementary protection that sets out the patent if that article was acquired, directly or indirectly, from a person who, at the time they disposed of it, could, under subsection (2) or (3) or paragraph (4) (b), sell the article without infringing the patent or the certificate.

**Use of service**

(6) The use of a service is not an infringement of a patent if

the service is provided by a person who, under subsection (2) or (3) or paragraph (4)(b), is able to provide it without infringing the patent.

**Use of article**

(7) Subject to subsection (8), the use of an article is not an infringement of a patent or any certificate of supplementary protection that sets out the patent if the article was acquired, directly or indirectly, from a person who, during a period that is established by regulations made under paragraph 12(1)(j.75) that relates to that patent, in good faith, made or sold, or made serious and effective preparations to make or sell, an article that is substantially the same as the one used, for that use.

**Transfer**

(8) If the making or selling referred to in subsection (7) was done or the preparations to do so were made in the course of a business and that business, or the part of that business in the course of which the making or selling was done or the preparations were made, is subsequently transferred, then

(a) subsection (7) or paragraph (b), as the case may be, does not apply in respect of an article that is made or sold by the transferor after the transfer; and

(b) it is not an infringement of a patent or a certificate of supplemental protection referred to in subsection (7) to use an article for the use referred to in that subsection if it was made or sold for that use by the transferee after the transfer.

**Use of service**

(9) Subject to subsection (10), the use of a service is not an infringement of a patent if the service is provided by a person who, during a period that is established by regulations made under paragraph 12(1)(j.75) that relates to that patent, provided, or made serious and effective preparations to provide, a service that is substantially the same as the one used, for that use.

**Transfer**

(10) If, during the period referred to in subsection (9), the service was provided or the preparations to provide it were made in the course of a business and that business, or the part of that business in the course of which the service was provided or the preparations to do so were made, is subsequently transferred, then, after the transfer

(a) the transferor is deemed to no longer be the person referred

to in subsection (9) for the purposes of that subsection; and  
(b) the transferee is deemed to be the person who provided the service for the purposes of subsection (9).

### **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]

### **Regulations**

**(4)** The Governor in Council may make regulations respecting the infringement of any patent that, directly or indirectly, could result or results from the making, construction, use or sale of a patented invention in accordance with subsection (1), including regulations

(a) respecting the conditions that must be fulfilled before a document – including a notice, certificate or permit – concerning any product to which a patent may relate may be issued to any 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 day on which such a document may be issued to a person and the earliest day on which it may take effect, and respecting the manner in which each day is to be determined;

(c) respecting the issuance, suspension or revocation of such a document in circumstances where, directly or indirectly, the document's issuance could result or results in the infringement of a patent;

(d) respecting the prevention and resolution of disputes with respect to the day on which such a document may be issued or take effect;

(e) respecting the prevention and resolution of disputes with respect to the infringement of a patent that could result directly or indirectly from the manufacture, construction, use or sale of a product referred to in paragraph (a);

(f) respecting the resolution of disputes with respect to the infringement of a patent that results directly or indirectly from

the manufacture, construction, use or sale of such a product;

(g) conferring rights of action with respect to disputes referred to in any of paragraphs (d) to (f);

(h) restricting or excluding the application of other rights of action under this Act or another Act of Parliament to disputes referred to in any of paragraphs (d) to (f);

(i) designating the court of competent jurisdiction in which a proceeding with respect to rights of action referred to in paragraph (g) is to be heard;

(j) respecting such proceedings, including the procedure of the court in the matter, the defences that may be pleaded, the remedies that may be sought, the joinder of parties and of rights of action and the consolidation of other proceedings, the decisions and orders the court may make and any appeals from those decisions and orders; and

(k) specifying who may be an interested person for the purposes of subsection 60(1) with respect to disputes referred to in paragraph (e).

**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.

**Exception – experimentation**

**55.3 (1)** An act committed for the purpose of experimentation relating to the subject-matter of a patent is not an infringement of the patent.

**Regulations**

(2) The Governor in Council may make regulations respecting

(a) factors that the court may consider, must consider or is not permitted to consider in determining whether an act is, or is not, committed for the purpose set out in subsection (1); and

(b) circumstances in which an act is, or is not, committed for the purpose set out in subsection (1).

**Exception – prior use**

**56 (1)** Subject to subsection (2), if – before the claim date of a claim in a patent – a person, in good faith, committed an act that would otherwise constitute an infringement of the patent in respect of that claim, or made serious and effective preparations to commit such an act, it is not an infringement of the patent or any certificate of supplementary protection that sets out the patent, in respect of that claim, if the person commits the same act on or after that claim date.

**Transfer**

**(2)** If the act referred to in subsection (1) is committed or the preparations to commit it are made in the course of a business and that business, or the part of that business in the course of which the act was committed or the preparations were made, is subsequently transferred,

(a) subsection (1) or paragraph (b), as the case may be, does not apply to an act committed by the transferor after the transfer; and

(b) it is not an infringement of the patent or any certificate of supplementary protection that sets out the patent, in respect of the claim, if the transferee commits the act after the transfer.

**Exception – use or sale of article**

**(3)** The use or sale of an article is not an infringement of a patent or any certificate of supplementary protection that sets out the patent if that article was acquired, directly or indirectly, from a person who, at the time they disposed of it, could sell it without infringing the patent or the certificate

(a) because the person, before the claim date of a claim in the patent, in good faith, committed an act that would otherwise constitute an infringement of the patent in respect of that claim and they disposed of the article before that claim date; or

(b) under subsection (1) or paragraph (2) (b).

**Exception – use of service**

**(4)** The use of a service is not an infringement of a patent if the service is provided by a person who, under subsection (1) or paragraph (2) (b), is able to provide it without infringing the patent.

**Non-application**

**(5)** Subsection (1) or paragraph (3) (a) does not apply if the person referred to in that subsection or that paragraph was able, as the case may be, to commit the act or make the preparations to

commit the act only because they obtained knowledge of the subject-matter defined by the claim, directly or indirectly, from the applicant of the application on the basis of which the patent was granted and they knew that the applicant was the source of the knowledge.

**Exception – use of article**

(6) Subject to subsection (7), the use of an article is not an infringement of a patent or any certificate of supplementary protection that sets out the patent, in respect of a claim, if the article was acquired, directly or indirectly, from a person who, before the claim date of that claim, in good faith, made or sold, or made serious and effective preparations to make or sell, an article that is substantially the same as the one used, for that use.

**Transfer**

(7) If the making or selling referred to in subsection (6) was done or the preparations to do so were made in the course of a business and that business, or the part of that business in the course of which the making or selling was done or the preparations were made, is subsequently transferred, then

(a) subsection (6) or paragraph (b), as the case may be, does not apply in respect of an article that is made or sold by the transferor after the transfer; and

(b) it is not an infringement of the patent or any certificate of supplementary protection that sets out the patent, in respect of a claim referred to in subsection (6), to use an article for the use referred to in that subsection if it was made or sold for that use by the transferee after the transfer.

**Non-application**

(8) Subsection (6) does not apply if the person referred to in that subsection was able to make or sell, or to make the preparations to make or sell, the article only because they obtained knowledge of the use defined by the claim, directly or indirectly, from the applicant of the application on the basis of which the patent was granted and they knew that the applicant was the source of the knowledge.

**Exception – use of service**

(9) Subject to subsection (10), the use of a service is not an infringement of a patent in respect of a claim if the service is provided by a person who, before the claim date of that claim, in good faith, provided, or made serious and effective preparations

to provide, a service that is substantially the same as the one used, for that use.

**Transfer**

(10) If the service referred to in subsection (9) was provided or the preparations to provide it were made in the course of a business and that business, or the part of that business in the course of which the service was provided or the preparations to do so were made, is subsequently transferred, then, after the transfer

(a) the transferor is deemed to no longer be the person referred to in subsection (9) for the purposes of that subsection; and

(b) the transferee is deemed to be the person who provided the service for the purposes of subsection (9).

**Non-application**

(11) Subsection (9) does not apply if the person referred to in that subsection was able to provide the service or make the preparations to provide it only because they obtained knowledge of the use defined by the claim, directly or indirectly, from the applicant of the application on the basis of which the patent was granted and they knew that the applicant was the source of the knowledge.

**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.

**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.

### **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.

### **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.

**61** [Repealed]



## **Judgments**

### **Judgment voiding patent**

**62** A patent, or part of a patent, that is voided by a judgment shall be and be held to have been void and of no effect, unless the judgment is reversed on appeal as provided in section 63.

### **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.

## **Conditions**

**64** [Repealed]

### **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]

(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]

**Definition of patented article**

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

**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]

(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.

(3) [Repealed]

#### **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.

67 [Repealed]

#### **Contents of applications**

68 (1) Every application presented to the Commissioner under section 65 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, the Commissioner shall direct the applicant to serve copies of the application and declarations on the patentee 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 both

(a) in the Canada Gazette; and

(b) on the website of the Canadian Intellectual Property Office or in any other prescribed location.

#### **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.

**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.

**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.

72 [Repealed]

**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

- (a) the applicant does not reply in good faith, within the prescribed time, to any requisition made by an examiner in connection with an examination;
- (b) the applicant does not comply with a notice given under subsection 27(6);
- (c) the prescribed fee and late fee referred to in a notice sent under paragraph 27.1(2)(b) are not paid before the later of the end of six months after the applicable prescribed date and the

end of two months after the date of the notice;

(d) the request referred to in a notice sent under paragraph 35(3)(b) is not made and the prescribed fee and late fee referred to in that notice are not paid before the end of two months after the date of the notice; or

(e) the request referred to in a notice sent under subsection 35(5) is not made and the prescribed fee referred to in that notice is not paid within the prescribed time.

(f) [Repealed]

#### **Deemed abandonment in prescribed circumstances**

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

#### **Reinstatement**

(3) Subject to the regulations, an application that is deemed to be abandoned is reinstated if

(a) the applicant, within the prescribed time,

(i) makes a request for reinstatement to the Commissioner,

(ii) states, in the request, the reasons for the failure to take the action that should have been taken in order to avoid the abandonment,

(iii) takes the action that should have been taken in order to avoid the abandonment, and

(iv) pays the prescribed fee; and

(b) the Commissioner determines that the failure occurred in spite of the due care required by the circumstances having been taken and informs the applicant of this determination.

#### **Powers of the Federal Court**

(3.1) The Federal Court may, by order, declare an application that is reinstated under subsection (3) to never have been reinstated if the Federal Court determines either

(a) that the statement of the reasons referred to in subparagraph

(3)(a)(ii) contains a material allegation that is untrue, or

(b) that, if paragraph (3)(b) applies, the failure referred to in subparagraph (3)(a)(ii) did not occur in spite of the due care required by the circumstances having been taken.

(4) [Repealed]

#### **Filing date**

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

#### **Patent not invalid**

73.1 (1) A patent shall not be declared invalid by reason only

that the application on the basis of which the patent was granted was deemed to be abandoned and was not reinstated.

**Exception**

(2) Subsection (1) does not apply if the Federal Court makes an order under subsection 73(3.1) in respect of the application on the basis of which the patent was granted.

**Offences and Punishment**

74 [Repealed]

**Offences**

75 (1) Every person is guilty of an indictable offence and is liable to a fine of not more than \$200 or to imprisonment for a term of not more than three months, or to both, who

(a) without the consent of the patentee, marks in any way on anything made or sold by the person, and for the sole making or selling of which they are 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, marks in any way on anything not purchased from the patentee, the words "Patent", "Letters Patent", "Queen's (or King's) Patent", "Patented" or any word or words with a similar meaning, 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 patentee's consent; or

(c) with intent to deceive the public, offers for sale as patented in Canada any article that is neither patented in Canada nor protected by a certificate of supplementary protection in Canada.

**Certificate of supplementary protection**

(2) Every person is guilty of an indictable offence and is liable to a fine of not more than \$200 or to imprisonment for a term of not more than three months, or to both, who

(a) during the term of a certificate of supplementary protection, without the consent of the certificate's holder, marks in any way on anything made or sold by the person, and for the sole making

or selling of which they are not the holder of a certificate of supplementary protection, the name or any imitation of the name of any holder of a certificate of supplementary protection for the sole making or selling of that thing;

(b) after a certificate of supplementary protection has been issued and before the end of its term, without the consent of the certificate's holder, marks in any way on anything not purchased from that holder the words "Certificate of Supplementary Protection", "Protected by a Certificate of Supplementary Protection" or any words with a similar meaning, with the intent of counterfeiting or imitating that holder's stamp, mark or device,

or of deceiving the public and inducing them to believe that the thing in question was made or sold by or with that holder's consent; or

(c) with the intent to deceive the public, offers for sale as protected by a certificate of supplementary protection in Canada any article that

(i) is neither patented in Canada nor protected by a certificate of supplementary protection in Canada, or

(ii) is patented in Canada but for which no certificate of supplementary protection has been issued.

**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.



### **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.

## **Written Demands**

### **Requirements**

**76.2 (1)** Any written demand received by a person in Canada, that relates to an invention that is patented in Canada or elsewhere or that is protected by a certificate of supplementary protection in Canada or by analogous rights granted elsewhere, must comply with the prescribed requirements.

### **Federal Court**

**(2)** Any person who receives a written demand that does not comply with the prescribed requirements, and any person who is aggrieved

as a result of the receipt by another person of such a written demand, may bring a proceeding in the Federal Court.

**Relief**

(3) If the Federal Court is satisfied that the written demand does not comply with the prescribed requirements, it may grant any relief that it considers appropriate, including by way of recovery of damages, punitive damages, an injunction, a declaration or an award of costs.

**Liability – special case**

(4) If a corporation sends a written demand that does not comply with the prescribed requirements, is notified of those requirements and of the demand's defects in respect of those requirements and does not, within a reasonable time after receiving the notice of those defects, remedy them, the corporation's officers, directors, agents or mandataries are jointly and severally, or solidarily, liable with the corporation if they directed, authorized, assented to, acquiesced in or participated in the sending of the demand.

**Due diligence**

(5) A person is not to be found liable under subsection (4) if they establish that they exercised due diligence to ensure that the written demand complies with the prescribed requirements.

**Regulations**

**76.3** The Governor in Council may make regulations for the purposes of section 76.2, including regulations

- (a) respecting what constitutes a written demand or an aggrievement;
- (b) respecting the requirements with which a written demand must comply;
- (c) respecting factors that the Federal Court may consider, must consider or is not permitted to consider in making an order under subsection 76.2(3); and
- (d) respecting the circumstances in which a defendant is not to be found liable in a proceeding brought under subsection 76.2(2).

## **Miscellaneous Matters**

77 [Repealed]

### **Time period extended**

**78 (1)** If a time period fixed under this Act, in respect of any business before the Patent Office, for doing anything ends on a prescribed day or a day that is designated by the Commissioner, that time period is extended to the next day that is not a prescribed day or a designated day.

### **Power to designate day**

**(2)** The Commissioner may, on account of unforeseen circumstances and if the Commissioner is satisfied that it is in the public interest to do so, designate any day for the purposes of subsection (1). If a day is designated, the Commissioner shall inform the public of that fact on the website of the Canadian Intellectual Property Office.

## **Transitional Provisions**

### **Definition of coming-into-force date**

**78.1 (1)** In sections 78.2, 78.21 and 78.5 to 78.56,

**Coming into-force date** means the day on which section 121 of the Economic Action Plan 2014 Act, No. 2 comes into force.

### **Definition of filing date**

**(2)** In sections 78.21, 78.22, 78.4, 78.5, 78.53 and 78.54, **filing date** means the date on which an application for a patent in Canada is filed, as determined in accordance with section 78.2.

### **Filing date**

**78.2** The filing date of an application for a patent is

(a) with respect to an original application,

(i) if all of the following elements were received by the Commissioner before October 1, 1989, the date on which they were received or, if they were received on different dates, the latest of those different dates:

(A) a statement that the granting of a patent is sought, executed by the applicant or by a patent agent on the

- applicant's behalf,
  - (B) a specification, including claims,
  - (C) any drawing referred to in the specification,
  - (D) an abstract of the part of the specification other than the claims,
  - (E) the fee set out in item 1 of Schedule II to the Patent Rules as that item read on the day on which the fee was received,
- (ii) if subparagraph (i) does not apply, one or more of the following elements were received by the Commissioner on or after October 1, 1989 and all of the following elements were received by the Commissioner before October 1, 1996, the date on which they were received or, if they were received on different dates, the latest of those different dates:
- (A) a petition executed by the applicant or by a patent agent on the applicant's behalf,
  - (B) a specification, including claims,
  - (C) any drawing referred to in the specification,
  - (D) an abstract of the part of the specification other than the claims,
  - (E) the fee set out in item 1 of Schedule II to the Patent Rules as that item read on the day on which the fee was received,
- (iii) if subparagraphs (i) and (ii) do not apply, one or more of the following elements were received by the Commissioner on or after October 1, 1996 and all of the following elements were received by the Commissioner before June 2, 2007, the date on which they were received or, if they were received on different dates, the latest of those different dates:
- (A) an indication, in English or French, that the granting of a Canadian patent is sought,
  - (B) the applicant's name,
  - (C) the address of the applicant or of their patent agent,
  - (D) a document, in English or French, that on its face appears to describe an invention,
  - (E) the fee set out in item 1 of Schedule II to the Patent Rules as that item read on the day on which the fee was received, and
- (iv) if subparagraphs (i) to (iii) do not apply, one or more of the following elements were received by the Commissioner on or after June 2, 2007 and all of the following elements were

received by the Commissioner before the coming-into-force date, the date on which they were received or, if they were received on different dates, the latest of those different dates:

- (A) an indication, in English or French, that the granting of a Canadian patent is sought,
  - (B) the applicant's name,
  - (C) the address of the applicant or of their patent agent,
  - (D) a document, in English or French, that on its face appears to describe an invention,
  - (E) either a small entity declaration, in accordance with section 3.01 of the Patent Rules as it read on the day on which the declaration was received, and the small entity fee set out in item 1 of Schedule II to those Rules as that item read on the day on which that fee was received or the standard fee set out in item 1 of that Schedule, as that item read on the day on which that standard fee was received; or
- (b) with respect to a divisional application, the filing date of the original application from which the divisional application results, determined in accordance with this section.

#### **Applications – no filing date**

**78.21** An application for a patent that is filed before the coming-into-force date and that does not have a filing date on the coming-into-force date shall be deemed never to have been filed.

#### **Applications – filing date before October 1, 1989**

**78.22** An application for a patent whose filing date is before October 1, 1989 shall be dealt with and disposed of in accordance with

- (a) the provisions of this Act as they read immediately before October 1, 1989, other than the definition legal representatives in section 2, subsections 4(2), 5(2) and 7(1), sections 8, 15 and 29, paragraph 31(2)(a) and sections 49 to 51 and 78; and
- (b) the definition legal representatives in section 2, subsections 4(2), 5(2) and 7(1), section 8.1, paragraph 31(2)(a) and sections 38.1, 49, 78 and 78.2.

#### **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).

**Applications – filing date October 1, 1989 to before October 1, 1996**

**78.4** Subject to sections 78.51 and 78.52, an application for a patent whose filing date is on or after October 1, 1989 but before October 1, 1996 shall be dealt with and disposed of in accordance with

(a) the provisions of this Act, other than the definition **filing date** in section 2, subsection 27(7), sections 27.01, 28 and 28.01 and subsection 28.4(6); and

(b) subsection 27(2) as it read immediately before October 1, 1996.

**Applications – filing date October 1, 1996 to before coming-into-force date**

**78.5** Subject to sections 78.51 and 78.52, an application for a patent whose filing date is on or after October 1, 1996 but before the coming-into-force date shall be dealt with and disposed of in accordance with the provisions of this Act, other than the definition **filing date** in section 2, subsection 27(7), sections 27.01, 28 and 28.01 and subsection 28.4(6).

**Abandonment before coming-into-force date**

**78.51** If an application for a patent was deemed to be abandoned under section 73 as it read immediately before the coming-into-force date, that section 73 applies in respect of that abandonment.

**Abandonment – requisition or notice before coming-into-force date**

**78.52 (1)** If, on or after the coming-into-force date, an applicant fails to do any act described in paragraph 73(1)(a), (b), (e) or (f), as those paragraphs read immediately before that date, in respect of a requisition made or notice given, as the case may be, before that date, section 73 as it read immediately before that date applies in respect of any abandonment resulting from the failure.

**Abandonment – section 97 of the Patent Rules**

**(2)** If, on or after the coming-into-force date, an applicant fails to do any act described in section 97 of the Patent Rules, as that section read immediately before that date, in respect of a requisition of the Commissioner that was given before that date, section 73 as it read immediately before that date applies

in respect of any abandonment resulting from the failure.

**Patents – filing date before October 1, 1989**

**78.53 (1)** Subject to subsection 78.55(2), any matter arising on or after the coming-into-force date, in respect of a patent granted on the basis of an application whose filing date is before October 1, 1989, shall be dealt with and disposed of in accordance with

(a) the provisions of this Act, other than the definitions claim date, filing date and request for priority in section 2, sections 10, 27 to 28.4, 34.1 to 36, 38.2 and 55, paragraphs 55.11(1)(a) and (b) and section 56; and

(b) sections 10 and 55 and subsections 61(1) and (3), as they read immediately before October 1, 1989.

**Special case**

**(2)** 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 October 1, 1996 of an invention for which a patent is issued on the basis of an application filed before October 1, 1989.

**Patents – filing date October 1, 1989 to before coming-into-force date**

**78.54** Subject to subsection 78.55(1) and section 78.56, any matter arising on or after the coming-into-force date in respect of a patent granted on the basis of an application whose filing date is on or after October 1, 1989 but before the coming-into-force date shall be dealt with and disposed of in accordance with the provisions of this Act, other than the definition filing date in section 2 and section 28.

**Application of section 46 – item 31 of Schedule II to Patent Rules**

**78.55 (1)** If the time, not including a period of grace, set out in item 31 of Schedule II to the Patent Rules to pay the applicable fee to maintain the rights accorded by a patent in effect ends before the coming-into-force date, section 46 as it read immediately before the coming-into-force date applies in respect of that fee.



## **Application of section 46 – item 32 of Schedule II to Patent**

### **Rules**

(2) If the time, not including a period of grace, set out in item 32 of Schedule II to the Patent Rules to pay the applicable fee to maintain the rights accorded by a patent in effect ends before the coming-into-force date, section 46 as it read immediately before the coming-into-force date applies in respect of that fee.

### **Non-application of subsection 27.1(4) and section 73.1**

**78.56** Subsection 27.1(4) and section 73.1 do not apply to a patent that was granted before the coming-into-force date or to a reissued patent if the original patent was granted before that date.

### **Reissued patents**

**78.57** For greater certainty, for the purposes of sections 78.53 and 78.54, a reissued patent is considered to be issued on the basis of the original application.

### **Regulations**

**78.58** For greater certainty, a regulation made under subsection 12(1) applies to an application for a patent referred to in section 78.22, unless the regulation provides otherwise.

### **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 section 78.22.

## **Patented or Protected Medicines**

### *Interpretation*

#### **Definitions**

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

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

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

**medicine** includes a drug, as defined in section 104, and a medicinal ingredient;

**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**, 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** means regulations made under section 101.

**rights holder** means, in respect of an invention pertaining to a medicine, a patentee and the person for the time being entitled to the benefit of a certificate of supplementary protection for that invention, and includes, if any other person is entitled to exercise rights in relation to the certificate, that other person in respect of those rights.

#### **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.

## *Pricing Information*

### **Pricing information, etc., required by regulations**

**80 (1)** A rights holder for an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with the information and documents that 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, if that information is available to the rights holder in Canada or is within the knowledge or control of the rights holder;
- (d) the factors referred to in section 85; and
- (e) any other related matters.

### **Former rights holder**

**(2)** Subject to subsection (3), a person who is a former rights holder for an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such the information and documents that 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 rights holder for the invention;
- (c) the costs of making and marketing the medicine produced during that period, whether incurred before or after the patent was issued or the certificate of supplementary protection took effect, if 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, for a period of three or more years, been entitled to the benefit of the patent or certificate of supplementary protection, as the case may be, or to exercise any rights in relation to the patent or certificate.

**Pricing information, etc. required by Board**

**81 (1)** The Board may, by order, require a rights holder or former rights holder for an invention pertaining to a medicine to provide the Board with information and documents respecting

- (a) in the case of a rights holder, any of the matters referred to in paragraphs 80(1)(a) to (e);
- (b) in the case of a former rights holder, any of the matters referred to in paragraphs 80(2)(a) to (e); and
- (c) any other related matters that the Board may require.

**Compliance with order**

**(2)** A rights holder or former rights holder in respect of whom an order is made under subsection (1) shall comply with the order within the time that 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 rights holder 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 certificate of supplementary protection, as the case may be, or to exercise any rights in relation to the patent or certificate.

**Notice of introductory price**

**82 (1)** A rights holder for 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)** If the Board receives a notice under subsection (1) from a rights holder or otherwise has reason to believe that a rights holder for 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 rights holder 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 rights holder in respect of whom an order is made under subsection (2) shall comply with the order

within the time that is specified in the order or as the Board may allow.

**Limitation that**

(4) No rights holder shall be required to comply with an order made under subsection (2) prior to the 60th day preceding the date on which the rights holder intends to first offer the medicine for sale in the relevant market.

*Excessive Prices*

**Order re excessive prices**

83 (1) If the Board finds that a rights holder for 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 rights holder to cause the maximum price at which the rights holder sells the medicine in that market to be reduced to the level that the Board considers not to be excessive and that is specified in the order.

**Order re excessive prices**

(2) Subject to subsection (4), If the Board finds that a rights holder for an invention pertaining to a medicine has, while a rights holder, 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 rights holder to do any one or more of the following things that will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the rights holder from the sale of the medicine at an excessive price:

(a) reduce the price at which the rights holder sells the medicine in any market in Canada, to the extent and the period that are specified in the order;

(b) to the extent and for the period that are specified in the order, reduce the price at which the rights holder sells, in any market in Canada, any other medicine to which a patented invention, or invention protected by a certificate of supplementary protection, of the rights holder pertains; or

(c) pay to Her Majesty in right of Canada an amount that is specified in the order.

**Order re excessive prices**

(3) Subject to subsection (4), if the Board finds that a former

rights holder for an invention pertaining to a medicine had, while a rights holder , 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 rights holder to do any one or more of the following things that will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the former rights holder from the sale of the medicine at an excessive price:

(a) to the extent and for the period that are specified in the order, reduce the price at which the former rights holder sells, in any market in Canada, a medicine to which a patented invention, or invention protected by a certificate of supplementary protection, of the former rights holder pertains; or

(b) pay to Her Majesty in right of Canada an amount that is specified in the order.

**If policy to sell at excessive price**

(4) If 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 rights holder or former rights holder 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 rights holder or former rights holder to do any one or more of the things referred to in that subsection that 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 rights holder or former rights holder 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 rights holder or former rights holder before December 20, 1991 or any revenues derived by a former rights holder after they ceased to be entitled to the benefit of the patent or certificate of supplementary protection, as the case may be, or to exercise any rights in relation to the patent or certificate.

**Right to hearing**

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

**Limitation period**

(7) No order may be made under this section in respect of a former rights holder 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 certificate of supplementary protection, as the case may be, or to exercise any rights in relation to the patent or certificate.

**Compliance**

**84 (1)** A rights holder or former rights holder 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 a greater period after that date that the Board determines is practical and reasonable, having regard to the circumstances of the rights holder or former rights holder.

**Compliance**

(2) A rights holder or former rights holder 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 a greater period after that date that the Board determines is practical and reasonable, having regard to the circumstances of the rights holder or former rights holder.

**Debt due to Her Majesty**

(3) An amount payable by a rights holder or former rights holder 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.

**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 rights holder in Canada of that medicine to total world sales.

**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.

**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.

*Sales and Expense Information*

**Sales and expense information, etc., to be provided**

**88 (1)** A rights holder for 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 the information and documents that the regulations or the order may specify respecting (a) the identity of the licensees in Canada of the rights holder; (b) the revenue of the rights holder, 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 rights holder in Canada on research and development relating to medicine.

**Additional information**

**(2)** If 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 rights holder or the expenditures made by a rights holder 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 of them.

**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.

**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 rights holder in Canada in the preceding year on research and development relating to medicine is of the revenues of those rights holder 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 rights holders in Canada in the preceding year on research and development relating to medicine is of the total of the revenues of those rights holders 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 rights holder 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.

#### *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.

#### *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.

#### **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.

#### **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.

#### **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.

**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.

**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 rights holder or former rights holder.

**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).

**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.

**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.

#### **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.

#### **Report of Board**

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

#### **Contents**

**(2)** The report shall contain

(a) a summary of pricing trends in the pharmaceutical industry; and

(b) the name of each rights holder and former right holders in respect of whom an order was made under subsection 81(1) or 82(2) or section 83 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 rights holder and former right holders 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 rights holder and former right holders.

#### **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.

#### *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, or invention protected by a certificate of supplementary protection, 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 the duties, in addition to those provided for in this Act, that 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, or invention protected by a certificate of supplementary protection, 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.

*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.

*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 rights holder or former rights holder 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.

## **Supplementary Protection for Inventions – Medicinal Ingredients**

### *Interpretation*

#### **Definitions**

**104** The following definitions apply in this section and in sections 105 to 134.

**authorization for sale** has the meaning assigned by regulations.

**drug** means a substance or a mixture of substances manufactured, sold or represented for use in

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or

(b) restoring, correcting or modifying organic functions in human beings or animals.

**Minister** means the Minister of Health.

#### **Interpretation**

**105 (1)** For the purposes of this section and sections 106 to 134, if a patent is reissued under section 47, it is deemed to have been granted on the day on which the original patent was granted and its application filing date is deemed to be the day on which the application for the original patent was filed.

#### **Human and veterinary uses**

**(2)** For the purposes of this section and sections 106 to 134, a medicinal ingredient or combination of medicinal ingredients contained in a drug authorized for human use and a medicinal ingredient or combination of medicinal ingredients contained in a drug authorized for veterinary use are to be treated as different medicinal ingredients or different combinations of medicinal ingredients, as the case may be.

#### **Same medicinal ingredient – human use**

**(3)** If medicinal ingredients contained in drugs authorized for human use differ from each other only with respect to a prescribed variation, they are to be treated as the same medicinal ingredient for the purposes of this section and sections 106 to 134.

#### **Same medicinal ingredient – veterinary use**

**(4)** If medicinal ingredients contained in drugs authorized for veterinary use differ from each other only with respect to a prescribed variation, they are to be treated as the same

medicinal ingredient for the purposes of this section and sections 106 to 134.

**Same combination – human use**

(5) If combinations of medicinal ingredients contained in drugs authorized for human use differ from each other only with respect to a variation in the ratio between those ingredients, they are to be treated as the same combination of medicinal ingredients for the purposes of this section and sections 106 to 134.

**Same combination – veterinary use**

(6) If combinations of medicinal ingredients contained in drugs authorized for veterinary use differ from each other only with respect to a variation in the ratio between those ingredients, they are to be treated as the same combination of medicinal ingredients for the purposes of this section and sections 106 to 134.

*Application for Certificate of Supplementary Protection*

**Application**

**106 (1)** On the payment of the prescribed fee, a patentee may apply to the Minister for a certificate of supplementary protection for a patented invention if all of the following conditions are met:

- (a) the patent is not void and it meets any prescribed requirements;
- (b) the filing date for the application for the patent is on or after October 1, 1989;
- (c) the patent pertains in the prescribed manner to a medicinal ingredient, or combination of medicinal ingredients, contained in a drug for which an authorization for sale of the prescribed kind was issued on or after the day on which this section comes into force;
- (d) the authorization for sale is the first authorization for sale that has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be;
- (e) no other certificate of supplementary protection has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be;
- (f) if an application for a marketing approval, equivalent to an

authorization for sale, was submitted in a prescribed country with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be, before the application for the authorization for sale was filed with the Minister, the application for the authorization for sale was filed before the end of the prescribed period that begins on the day on which the first such application for a marketing approval was submitted.

**Issuance – paragraph (1) (e)**

(2) Another certificate of supplementary protection is considered to have been issued for the purposes of paragraph (1) (e) even if that other certificate is subsequently held to be invalid or void or it never takes effect or ceases to have effect.

**When application to be filed**

(3) An application for a certificate of supplementary protection shall be filed with the Minister before the end of the prescribed period that begins on

(a) the day on which the authorization for sale is issued, if the patent is granted on or before that day; or

(b) the day on which the patent is granted, if the patent is granted after the day on which the authorization for sale is issued.

**Exception**

(4) Despite subsection (3), no application shall be filed within the prescribed period preceding the expiry of the term of the patent under section 44 without taking into account section 46.

**Contents of application**

(5) An application for a certificate of supplementary protection shall

(a) set out the number, as recorded in the Patent Office, of the patent – as well as the medicinal ingredient or combination of medicinal ingredients and the number of the authorization for sale – in relation to which the certificate is sought;

(b) if paragraph (1) (f) applies with respect to the application, specify the day on which the first application for a marketing approval that is equivalent to an authorization for sale was made and the country in which that application was made; and

(c) set out any prescribed information.

**One patent per application**

(6) Each application is permitted to set out only one patent.

**Information to be provided**

**107 (1)** An applicant shall provide the Minister with any additional information that the Minister considers necessary.

**Refusal**

**(2)** Whenever the Minister is satisfied that any of the requirements set out in section 106 are not met with respect to an application for a certificate of supplementary protection, the Minister may refuse the application. The Minister shall notify the applicant of a refusal and of the grounds for it.

**Order of priority – same authorization for sale**

**108 (1)** Subsections (2) to (4) apply in determining the priority of applications for a certificate of supplementary protection that set out the same authorization for sale.

**Patents granted on or before authorization for sale**

**(2)** An application setting out a patent that was granted on or before the day on which the authorization for sale was issued has the same priority as every other such application.

**Priority over patents granted after authorization for sale**

**(3)** An application setting out a patent that was granted on or before the day on which the authorization for sale was issued has priority over an application setting out a patent that is granted after that date.

**Patents granted after authorization for sale – priority**

**(4)** Priority among applications setting out patents that were granted after the day on which the authorization for sale was issued is established according to the date on which the patent was granted, with an earlier date having priority over a later date and patents granted on the same date having the same priority.

**Applications with same authorization for sale and priority**

**109** If two or more pending applications set out the same authorization for sale and have the same priority, the Minister shall provide each applicant with a written notice setting out the name and contact information of all the applicants, as well as the number, as recorded in the Patent Office, of the patent set out in each application.

**Declaration of non-compliance**

**110 (1)** A pending application for a certificate of supplementary

protection may be declared invalid or void by the Federal Court for non-compliance with section 106 at the instance of another applicant whose application for a certificate sets out the same authorization for sale and the same priority.

**Limitation**

(2) A proceeding to obtain a declaration under subsection (1) shall be commenced before the end of the prescribed period that begins on the day that is specified by the Minister in the written notice sent under section 109.

**Copy to Minister**

(3) Anyone who commences such a proceeding, or an appeal or application for leave to appeal with respect to such a proceeding, shall provide the Minister with a copy of

- (a) any document that commences the proceeding, appeal or application, immediately after the document is filed with the court; and
- (b) any document that marks the end of the proceeding, appeal or application, immediately after the document is issued by or filed with the court.

**Expiry of pending applications**

111 (1) If two or more applications that set out the same authorization for sale and have the same priority are still pending at the end of the prescribed period that begins on the day specified in the written notice sent under section 109, all of those applications expire at that end of that period. However, if any proceedings are brought under section 110 with respect to any of those applications, all of those applications – if two or more are still pending – expire at the end of the prescribed period that begins on the day on which the last of any of the proceedings to be completed is finally disposed of.

**Expiry of application with lower priority**

(2) A pending application that sets out the same authorization for sale as another application of higher priority expires on the day on which the Minister issues a certificate of supplementary protection in respect of that other application.

**Withdrawal**

112 An applicant for a certificate of supplementary protection may withdraw their application in accordance with the regulations.

## *Certificate of Supplementary Protection*

### **Issue of certificate**

**113** The Minister shall issue, to the patentee, a certificate of supplementary protection for the patented invention set out in the patentee's application if, on the day of issuance,

- (a) the Minister is satisfied that all requirements set out in section 106 are met;
- (b) the applicable period referred to in subsection 106(3) for filing the application has ended;
- (c) there is no other pending application that sets out the same authorization for sale and that has priority over, or the same priority as, the application; and
- (d) any court proceedings, brought under section 110 with respect to the application or to another pending application that sets out the same authorization for sale and that has priority over, or the same priority as, the application, have been finally disposed of.

### **Contents of certificate**

**114** A certificate of supplementary protection shall set out

- (a) the number, as recorded in the Patent Office, of the patent set out in the application;
- (b) the medicinal ingredient or combination of medicinal ingredients set out in the application;
- (c) a statement as to whether the certificate relates to use in humans or to veterinary use;
- (d) the number of the authorization for sale set out in the application; and
- (e) the day on which the certificate's term begins and the day on which the term ends, as determined under section 116.

### **Scope of supplementary protection**

**115 (1)** The issuance of a certificate of supplementary protection grants the certificate's holder and their legal representatives, during the certificate's term, the same rights, privileges and liberties that are granted by the patent set out in the certificate, but only with respect to the making, constructing, using and selling of any drug that contains the medicinal ingredient, or combination of medicinal ingredients, set out in the certificate, by itself or in addition to any other medicinal



ingredient.

**No infringement – export**

(2) Despite subsection (1), it is not an infringement of the certificate of supplementary protection for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.

**Validity**

116 (1) After the certificate is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the holder and the holder's legal representatives for its term.

**Taking effect**

(2) A certificate of supplementary protection takes effect on the expiry of the term under section 44, without taking into account section 46, of the patent set out in the certificate, but the certificate takes effect only if the patent remains valid until, and not void before, the expiry of that term.

**Calculation of term**

(3) The certificate's term is calculated by subtracting five years from the period beginning on the filing date of the application for the patent and ending on the day on which the authorization for sale set out in the certificate is issued, but in any event is for a maximum of two years.

**Reduction in period**

(4) Despite subsection (3), if the person to whom the authorization for sale set out in the certificate is issued is also the patentee, the Minister may, if he or she is of the opinion that that person's failure to act resulted in a period of unjustified delay in the process of obtaining the authorization for sale, reduce the term of the certificate when issuing it by the amount of that period.

**Never takes effect**

(5) A certificate of supplementary protection that has been issued never takes effect if the calculation of its term, including any reduction under subsection (3), produces a result of zero or a negative value.

**Revocation of certificate**

117 The Minister shall revoke a certificate of supplementary protection in the prescribed circumstances.

## *Transfer*

### **Transfer of patent**

**118 (1)** Despite subsection 49(1), a certificate of supplementary protection, or an application for one, is not transferable other than by the transfer of the patent, or part of the patent, that is set out in the certificate or application.

### **Whole of patent**

**(2)** If the whole of the patent is transferred, the certificate or application is transferred accordingly.

### **Part of patent**

**(3)** If part of the patent is transferred, any part of the certificate or application – including, as the case may be, the whole of it – that corresponds to the transferred part of the patent is transferred accordingly.

### **For greater certainty**

**(4)** For greater certainty, the transfer of part of an application for a certificate of supplementary protection does not result in its division into more than one application.

## *Administrative Matters*

### **Applications, fees and documents**

**119** Applications, fees and documents relating to certificates of supplementary protection shall be submitted to the Minister.

### **Inspection by public**

**120 (1)** The Minister shall ensure that the prescribed contents of all certificates of supplementary protection and applications for a certificate are made available for public inspection under the conditions that may be prescribed.

### **Non-application**

**(2)** Subsection (1) does not apply with respect to the contents of applications for a certificate that are refused, declared invalid or void, expired or withdrawn.

### **Copy in case of loss or destruction**

**121** The Minister may issue a certified copy of a certificate of supplementary protection to replace one that is lost or destroyed.

### **Issuance of patent under section 47**

**122 (1)** If a patent set out in a certificate of supplementary protection or in a pending application for such a certificate is surrendered, and a new patent is issued, under section 47, the holder of the certificate or the applicant shall, before the end of the prescribed period that begins on the day on which the new patent is issued, provide the Minister with written notice of the number, as recorded in the Patent Office, of the new patent to which the certificate or application relates.

#### **One patent**

**(2)** If more than one new patent is issued under section 47, the holder of the certificate or the applicant shall provide the number for only one of the new patents.

#### **New certificate**

**(3)** If notice is provided under subsection (1) by a holder of a certificate, the Minister shall issue a new certificate of supplementary protection, setting out the new patent number, to replace the original certificate. The new certificate's term is the then unexpired term of the original certificate.

#### **Effect of new certificate**

**(4)** The new certificate is deemed to have been issued on the day on which the new patent is issued. The original certificate and the new certificate have the same effect in law, in any action commenced after the issuance of the new certificate for any cause accruing after that issuance, as if the new patent had been set out in the original certificate; however, insofar as the claims of the new patent and the original patent are identical, the issuance of the new certificate does not affect any action pending at the time of the issuance of the new certificate or abate any cause of action that existed at that time and the new certificate constitutes a continuation of the original certificate and has effect accordingly.

#### **Application**

**(5)** If notice is provided under subsection (1) by an applicant for a pending application, the Minister shall

- (a) amend the application to set out the new patent number; and
- (b) provide written notice of the amendment to any other applicant referred to in section 109 with respect to the application.

#### **Effect of amendment to application**

**(6)** The amended application has the same effect, for the purposes

of sections 106 to 113, as if the pending application had been originally filed in its amended form.

#### *Use of Certificates of Supplementary Protection by Government*

##### **Application**

**123** Sections 19 to 19.2 apply with respect to certificates of supplementary protection, with

(a) any reference to "patented invention" to be read, with any grammatical adaptations, as a reference to "invention protected by a certificate of supplementary protection"; and

(b) any reference to "patentee" to be read as a reference to "holder of the certificate of supplementary protection".

#### *Legal Proceedings in Respect of Certificates of Supplementary Protection*

##### **Admissible in evidence**

**123.1** A written communication, or any part of such a communication, that is admissible under section 53.1 in respect of a patent set out in a certificate of supplementary protection may be admitted into evidence to any action or proceeding respecting the certificate of supplementary protection to rebut any representation made by the holder of the certificate of supplementary protection in the action or proceeding as to the construction of a claim in the patent set out in the certificate of supplementary protection.

#### *Infringement and Impeachment*

##### **Action for infringement**

**124 (1)** An action for the infringement of a certificate of supplementary protection may be brought in the same manner as an action for the infringement of a patent, and the following provisions apply to the action:

(a) sections 54, 57 and 59, with any reference to "patent" to be read as a reference to "certificate of supplementary protection";

(b) subsection 55(1), and subsection 55(3) as it applies to that

subsection (1), with any reference to "patent" to be read as a reference to "certificate of supplementary protection", any reference to "patentee" to be read as a reference to "holder of the certificate of supplementary protection" and any reference to "grant" to be read as a reference to "taking of effect";

(c) section 55.01;

(d) section 55.1, with any reference to "patent" to be read as a reference to "certificate of supplementary protection" and any reference to "patented process" to be read as a reference to "process protected by the certificate of supplementary protection";

(e) subsections 55.2(1) and (6), with any reference to "patent" to be read as a reference to "certificate of supplementary protection" and any reference to "patented invention" to be read as a reference to "invention protected by the certificate of supplementary protection";

(f) subsection 55.3(1), with any reference to "patent" to be read as a reference to "certificate of supplementary protection";

(g) section 58, with the reference to "a patent that contains two or more claims" to be read as a reference to a "two or more claims in a patent that is set out in a certificate of supplementary protection" and with the reference to "the patent as if it" to be read as a reference to "the certificate as if the patent set out in it".

#### **Regulations – subsection 55.2(4)**

(2) The Governor in Council may make regulations respecting the infringement of any certificate of supplementary protection that, directly or indirectly, could result or results from the making, construction, use or sale of a patented invention or invention protected by a certificate of supplementary protection in accordance with subsection 55.2(1), including regulations described in paragraphs 55.2(4) (a) to (k), with

(a) any reference in those paragraphs to a "patent" to be read as a reference to a "certificate of supplementary protection"; and

(b) the reference in paragraph 55.2(4) (k) to "subsection 60(1)" to be read as a reference to "subsection 125(1)".

#### **Regulations**

(2.1) The Governor in Council may make regulations respecting

(a) factors that the court may consider, must consider or is not permitted to consider in determining whether an act is, or is not, committed for the purpose of experimentation relating to the

subject-matter of the certificate of supplementary protection;  
and

(b) circumstances in which an act is, or is not, committed for the purpose of experimentation relating to the subject-matter of the certificate of supplementary protection.

#### **Inconsistency or conflict**

(3) In the event of an inconsistency or conflict between regulations made under subsection (2) and any Act of Parliament or regulations made under such an Act, the regulations made under subsection (2) prevail to the extent of the inconsistency or conflict.

#### **Impeachment**

**125 (1)** A certificate of supplementary protection, or any claim in the patent set out in such a certificate, may be declared invalid or void – including on the basis that the certificate was issued despite non-compliance with any of the requirements, as they existed at the time that the certificate was issued, of subsection 106(1) or that the patent set out in the certificate no longer complies with the requirements, as they existed at that time, set out in paragraph 106(1)(c) – by the Federal Court at the instance of the Attorney General of Canada or any interested person.

#### **Application**

(2) Subsections 60(2) and (3) apply with respect to a certificate of supplementary protection, with any reference to “patentee” to be read as a reference to “holder of a certificate of supplementary protection” and any reference to “patent” to be read as a reference to “certificate of supplementary protection”.

#### **Judgment voiding certificate or claim**

**126 (1)** A certificate of supplementary protection, or a claim in the patent set out in such a certificate, that is voided by a judgment shall be and be held to have been void and of no effect, unless the judgment is reversed on appeal as provided in subsection (2).

#### **Appeal**

(2) Every judgment voiding a certificate of supplementary protection or any claim in the patent set out in such a certificate, and every judgment refusing to do so, is subject to appeal to any court having appellate jurisdiction in other cases

decided by the court by which the judgment was rendered.

### *Abuse of Rights*

#### **Abuse of patent rights**

**127 (1)** The Commissioner may, in respect of application under section 65, exercise any of the powers under any of paragraphs 66(1) (a), (d) and (e) with respect to an issued certificate of supplementary protection if he or she is satisfied that a case of abuse of the exclusive rights under the patent that is set out in the certificate has been established.

#### **Abuse – application to Commissioner**

**(2)** The Attorney General of Canada or an interested person may, at any time after a certificate of supplementary protection takes effect and after the expiry of three years from the date of the grant of the patent set out in the certificate, apply to the Commissioner alleging that there has been an abuse of the exclusive rights granted under a certificate of supplementary protection issued with respect to that patent and asking for relief under this Act.

#### **What amounts to abuse**

**(3)** The exclusive rights under a certificate of supplementary protection are abused in any of the following circumstances:

(a) the demand in Canada for a drug that contains the medicinal ingredient or a combination of the medicinal ingredients set out in the certificate is not being met to an adequate extent and on reasonable terms;

(b) by reason of the refusal of the certificate's holder 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;

(c) any trade or industry in Canada, or any person or class of persons engaged in such a trade or industry, is unfairly prejudiced by the conditions attached by the certificate's holder to the purchase, hire, licence, use or working of the invention protected by the certificate.

**Provisions that apply**

**128** Sections 66 to 71, other than paragraph 66(1)(c), apply for the purposes of section 127, with

- (a) any reference to "patent", other than with respect to the Patent Office, to be read as a reference to "certificate of supplementary protection";
- (b) any reference to "patentee" to be read as a reference to "holder of the certificate of supplementary protection";
- (c) any reference in paragraphs 66(1)(d) and (e) and subsection 68(1) to "section 65" to be read as a reference to "section 127";
- (d) any reference in subsection 69(1) or section 71 to "sections 65 to 70" to be read as a reference to "sections 66 to 70 and 127"; and
- (e) the reference in subsection 69(3) to "the Minister" to be read as a reference to "the Minister of Industry".

*General***Electronic form and means**

**129 (1)** Subject to the regulations, any document, information or fee that is submitted to the Minister under this Act may be submitted in any electronic form, and by any electronic means, that is specified by the Minister.

**Collection, storage, etc.**

**(2)** Subject to the regulations, the Minister may use electronic means to create, collect, receive, store, transfer, distribute, publish, certify or otherwise deal with documents or information under sections 106 to 134.

**Definition**

**(3)** In this section, electronic, in reference to a form or means, includes optical, magnetic and other similar forms or means.

**Certified copies as evidence**

**130** In any action or proceeding respecting a certificate of supplementary protection authorized to be had or taken in Canada under this Act, a copy purporting to be certified by the Minister of any such certificate, or of any other document that is made by or filed with the Minister and is connected to such a certificate, may be produced before the court or other tribunal, or a judge or member of the court or tribunal, and the copy



purporting to be so certified may be admitted in evidence without production of the original and without proof of the Minister's certification.

#### **Costs of proceedings**

**131** In all proceedings before any court under this Act, including, for greater certainty, an application for judicial review of a decision of the Minister under this Act, the costs of the Minister are in the discretion of the court, but the Minister shall not be ordered to pay the costs of any other of the parties.

#### **Time limit deemed extended**

**132 (1)** If any time period fixed under any of sections 106 to 134 in respect of dealings with the Minister ends on a prescribed day or a day that is designated by the Minister, that time period is extended to the next day that is not a prescribed day or a designated day.

#### **Power to designate day**

**(2)** The Minister may, on account of unforeseen circumstances and if the Minister is satisfied that it is in the public interest to do so, designate any day for the purposes of subsection (1). If a day is designated, the Minister shall inform the public of that fact on the Department of Health's website.

#### **Service Fees Act**

**133** The Service Fees Act does not apply in respect of the fees referred to in section 106 or 134.

#### **Regulations**

**134 (1)** The Governor in Council may make rules or regulations

- (a) defining the term authorization for sale;
- (b) respecting the form and contents of applications for certificates of supplementary protection;
- (c) respecting the processing of such applications;
- (d) respecting the determination of when, for the purpose of paragraph 106(1)(f), an application for an authorization for sale was filed and, for the purpose of subsection 106(3), an application for a certificate of supplementary protection is filed;
- (e) prescribing the fees or the manner of determining the fees

that may be charged in respect of the filing of applications for certificates of supplementary protection, the issuance of such certificates or the taking of other proceedings under sections 106 to 133 or under any rule or regulation made under this section, or in respect of any services or the use of any facilities provided by the Minister under those sections or such a rule or regulation;

(f) respecting the circumstances in which any patentee or holder of a certificate of supplementary protection may or must be represented by another person in respect of a certificate of supplementary protection or an application for such a certificate;

(g) respecting the submission, including in electronic form and by electronic means, of documents and information to the Minister, including the time at which they are deemed to be received by the Minister;

(h) respecting the use of electronic means for the purposes of subsection 129(2), including requiring the use of those electronic means;

(i) respecting the withdrawal of an application for a certificate of supplementary protection;

(j) respecting communications between the Minister and any other person;

(k) respecting the correction of obvious errors in documents submitted to the Minister, in certificates of supplementary protection or in other documents issued under sections 106 to 133, including

(i) the determination by the Minister of what constitutes an obvious error, and

(ii) the effect of the correction; and

(l) generally, for carrying into effect the objects and purposes of sections 104 to 133 or for ensuring their due administration by the Minister.

**For greater certainty**

(2) For greater certainty, the Governor in Council may make rules or regulations under paragraphs 12(1)(d), (g), (h) and (k) for the purposes of this section and sections 104 to 133.

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

SCHEDULE 2 (Paragraph 21.03(1)(b)) (omitted)

SCHEDULE 3 (Paragraph 21.03(1)(c)) (omitted)

SCHEDULE 4 (Paragraph 21.03(1)(d)) (omitted)