Canadian HIV/AIDS Legal Network | Réseau juridique canadien VIH/sida

Bill C-393 in the Senate: Amendments to the *Patent Act*

March 10, 2011

Bill C-393 passed with a large majority of votes in the House of Commons in Parliament on March 9, 2011 and is now before the Senate of Canada. Bill C-393 would make a number of changes to the sections of the Patent Act that currently constitute Canada's Access to Medicines Regime (CAMR). The text below lays out in full the sections of the Patent Act that constitute CAMR and tracks onto them the changes that would be made if Bill C-393, in the form passed by the House of Commons, were to become law. This illustrates how the final provisions of CAMR would read as a result of enacting Bill C-393.

PATENT ACT, R.S.C. 1985, c. P-4

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

Purpose

21.01 The purpose of sections 21.02 to 21.16 ~~21.2~~ is to ~~give effect to Canada's and Jean Chrétien's pledge to Africa by~~ facilitate~~ing~~ access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2004, c. 23, s. 1.

Definitions

21.02 The definitions in this section apply ~~in this section and~~ in sections 21.01 ~~21.03~~ to 21.16 ~~21.19~~.

"authorization"
« *autorisation* »

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

~~"General Council"~~
~~« *Conseil général* »~~

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

"General Council Decision"
« *décision du Conseil général* »

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

"patented product"
« *produit breveté* »

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

"pharmaceutical product"
« *produit pharmaceutique* »

"pharmaceutical product" means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product and any other patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, and includes any active ingredients necessary for its manufacture and diagnostic kits needed for its use.

"TRIPS Agreement"
« *Accord sur les ADPIC* »

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

"TRIPS Council"
« *Conseil des ADPIC* »

"TRIPS Council" means the council referred to in the TRIPS Agreement.

"WTO"
« *OMC* »

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

2004, c. 23, s. 1.

Amending Schedule 1

21.03 (1) The Governor in Council may, by order, on the recommendation of the Minister and the Minister of Health, amend Schedule 1

(a) 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

(b) by removing any entry listed in it.

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

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

~~(ii) by removing any entry listed in it;~~

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

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

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

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

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

~~(i) any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance~~

~~with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, or~~

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

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

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

~~(C) stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and~~

~~(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.~~

~~Restriction - Schedule 3~~

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

Amending Schedule 2

(2) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 2 to add the name of a country if the country is

(a) recognized by the United Nations as being a least-developed country; or

(b) named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance.

Removal from Schedules ~~2 to 4~~

(3) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend ~~any of~~ Schedule~~s~~ 2 ~~to 4~~ to remove the name of a ~~any~~ country ~~or WTO Member~~ if the country is neither

(a) recognized by the United Nations as being a least-developed country; nor

(b) named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance.

~~(*a*) in the case of a country or WTO Member listed in Schedule 2, the country or WTO Member has ceased to be recognized by the United Nations as being a least-developed country or, in the case of a country that is not a WTO Member, the country has permitted any product imported into that country under an authorization to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision;~~

~~(*b*) in the case of a WTO Member listed in Schedule 3, the WTO Member has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(*a*) of that decision, only if faced with a national emergency or other circumstances of extreme urgency;~~

~~(*c*) in the case of a WTO Member listed in Schedule 4, the WTO Member has revoked any notification it has given to the TRIPS Council that it will import pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision, only if faced with a national emergency or other circumstances of extreme urgency;~~

~~(*d*) in the case of a country listed in Schedule 4 that is not a WTO Member,~~

~~(i) the name of the country is no longer on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance,~~

~~(ii) the country no longer faces a national emergency or other circumstances of extreme urgency,~~

~~(iii) the country has permitted any product imported into that country under an authorization to be used for commercial purposes, or~~

~~(iv) the country has failed to adopt the measures referred to in Article 4 of the General Council Decision;~~

~~(*e*) in the case of any country or WTO Member listed in Schedule 3 or 4, the country or WTO Member has become recognized by the United Nations as a least-developed country; and~~

~~(*f*) in the case of any country or WTO Member listed in any of Schedules 2 to 4, the country has notified the Government of Canada, or the WTO Member has notified the TRIPS Council, that it will not import pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision.~~

Timeliness of orders

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

2004, c. 23, s. 1.

Authorization

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

Solemn or statutory declaration not required

(4) The solemn or statutory declaration referred to in paragraph (3)(c) is not required in the case of an application to the Commissioner for an authorization to supply the product named in the application to an eligible importing country for purposes of addressing a national emergency or other circumstances of extreme urgency in that country or for purposes of public non-commercial use, but in such cases, the Commissioner shall notify the patentee or patentees of the issuance of the compulsory licence as soon as reasonably practicable after it has been issued.

2004, c. 23, s. 1.

Form and content of authorization

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

~~Quantity~~

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

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

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

Labelling requirements

21.051 The holder of an authorization shall ensure that all products manufactured under the authorization are labelled in accordance with the prescribed requirements.

2004, c. 23, s. 1.

Disclosure of information on website

21.06 (1) Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the country or WTO Member to which it is to be exported, the quantity that is authorized to be manufactured and sold for export and the distinguishing features of the product, and of its label and packaging, as required by regulations

made under the *Food and Drugs Act*, as well as information identifying every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported.

Obligation to maintain

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

Links to other websites

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

Posting on the website

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

2004, c. 23, s. 1.

Export notice

21.07 Before each shipment of any quantity of a product manufactured under an authorization, the holder of the authorization must, within fifteen days before the product is exported, provide to each of the following a notice, by certified or registered mail, specifying the quantity to be exported, as well as every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported:

(*a*) the patentee or each of the patentees, as the case may be;

(*b*) the country or WTO Member named in the authorization; and

(*c*) the person or entity that purchased the product to which the authorization relates.

2004, c. 23, s. 1.

Royalty

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

Factors to consider when making regulations

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

Time for payment

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

Federal Court may determine royalty

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

Application and notice

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

Contents of order

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

Conditions for making of order

(7) The Federal Court may make an order only if it is satisfied that the royalty otherwise required to be paid is not adequate remuneration for the use of the invention or inventions to which the authorization relates, taking into account

(*a*) the humanitarian and non-commercial reasons underlying the issuance of the authorization; and

(*b*) the economic value of the use of the invention or inventions to the country or WTO Member.

2004, c. 23, s. 1.

Duration

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

2004, c. 23, s. 1.

Use is non-exclusive

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

2004, c. 23, s. 1.

Authorization is non-transferable

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

2004, c. 23, s. 1.

Renewal

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

One renewal

(2) An authorization may be renewed only once.

When application must be made

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

Duration

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

Prescribed form

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

2004, c. 23, s. 1.

Termination

21.13 Subject to section 21.14, an authorization ceases to be valid on the earliest of

(*a*) the expiry of the period referred to in section 21.09 in respect of the authorization, or the expiry of the period referred to in subsection 21.12(4) if the authorization has been renewed, as the case may be,

(*b*) the day on which the Commissioner sends, by registered mail, to the holder of the authorization a copy of a notice sent by the Minister of Health notifying the Commissioner

that the Minister of Health is of the opinion that the pharmaceutical product referred to in paragraph 21.04(3)(*b*) has ceased to meet the requirements of the *Food and Drugs Act* and its regulations,

(*c*) the day on which the last of the pharmaceutical product authorized by the authorization to be exported is actually exported,

(*d*) thirty days after the day on which

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

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

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

2004, c. 23, s. 1.

Termination by Federal Court

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

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

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

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

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

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

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

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

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

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

2004, c. 23, s. 1.

Notice to patentee

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

2004, c. 23, s. 1.

Obligation to provide copy of agreement

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

(*a*) a copy of the agreement ~~it has reached with the person or entity referred to in paragraph 21.04(2)(*f*) for the supply of the product authorized to be manufactured and sold, which agreement must incorporate information that is in all material respects identical to the information referred to in paragraphs 21.04(2)(*a*), (*b*), (*e*) and (*f*)~~; and

(*b*) a solemn or statutory declaration in the prescribed form setting out

(i) the total monetary value of the agreement as it relates to the product authorized to be manufactured and sold, expressed in Canadian currency, and

(ii) the number of units of the product to be sold under the terms of the agreement.

Prohibition

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

2004, c. 23, s. 1.

Application when agreement is commercial in nature

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

under subsection (3) on the grounds that the essence of the agreement under which the product is to be sold is commercial in nature.

Factors for determining whether agreement is commercial in nature

(2) In determining whether the agreement is commercial in nature, the Federal Court must take into account

(*a*) the need for the holder of the authorization to make a reasonable return sufficient to sustain a continued participation in humanitarian initiatives;

(*b*) the ordinary levels of profitability, in Canada, of commercial agreements involving pharmaceutical products, as defined in paragraph 1(*a*) of the General Council Decision; and

(*c*) international trends in prices as reported by the United Nations for the supply of such products for humanitarian purposes.

Order

(3) If the Federal Court determines that the agreement is commercial in nature, it may make an order, on any terms that it considers appropriate,

(*a*) terminating the authorization; or

(*b*) requiring the holder to pay, in addition to the royalty otherwise required to be paid, an amount that the Federal Court considers adequate to compensate the patentee for the commercial use of the patent.

Additional order

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

(*a*) requiring the holder to deliver to the patentee any of the product to which the authorization relates remaining in the holder's possession as though the holder had been determined to have been infringing a patent; or

(*b*) with the consent of the patentee, requiring the holder to export any of the product to which the authorization relates remaining in the holder's possession to the country or WTO Member named in the authorization.

Restriction

(5) The Federal Court may not make an order under subsection (3) if, under the protection of a confidentiality order made by the Court, the holder of the authorization submits to a Court-supervised audit and that audit establishes that the average price of the product manufactured

under the authorization does not exceed an amount equal to the direct supply cost of the product plus 15 per cent of that direct supply cost.

Definitions

(6) The following definitions apply in this section.
"average price"
«*prix moyen* »

"average price" means

(*a*) in relation to a product to be manufactured under an authorization, the total monetary value of the agreement under which the product is to be sold, expressed in Canadian currency, divided by the number of units of the product to be sold under the terms of the agreement; and

(*b*) in relation to an equivalent product sold by or with the consent of the patentee, the average of the prices in Canada of that product as those prices are reported in prescribed publications on the day on which the application for the authorization was filed.

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

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

"unit"
« *unité* »

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

2004, c. 23, s. 1.

Advisory committee

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

Standing committee

(2) The standing committee of each House of Parliament that normally considers matters related to industry shall assess all candidates for appointment to the advisory committee and

make recommendations to the Minister and the Minister of Health on the eligibility and qualifications of those candidates.

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

Website for notices to Canada

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

2004, c. 23, s. 1.

Review

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

Tabling of report

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

2004, c. 23, s. 1.

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SCHEDULE

Bill C-393 would also replace the current Schedules 2, 3 and 4 in the Patent Act, which set out different categories of eligible importing countries, combining them into a single new Schedule 2, as appears below. Note that listing all eligible importing countries in a single schedule does NOT mean each country on the list is in exactly the same position as a potential importer of pharmaceutical products exported under CAMR. The new Schedule 2 is simply a list of all countries that are eligible as potential importers.

However, some countries on the list have already agreed, under WTO law, that they are only entitled to use a mechanism such as CAMR in certain circumstances. In the list below, countries marked with a single asterisk are those that agreed at the WTO that they would only use a mechanism such as CAMR in "situations of national emergency or other circumstances of extreme urgency". Those countries marked with two asterisks are countries that have further committed that, upon accession to the European Union, they will opt out completely of using such a mechanism, even in cases of emergencies or other circumstances of extreme urgency.

For the original source of these conditions applying to various countries as importers, see the Chairperson's Statement accompanying the adoption of the WTO General Council's Decision of 30 August 2003 at http://www.wto.org/english/tratop_e/trips_e/gc_stat_30aug03_e.htm. Note also in this Chairperson's Statement that the following high-income countries have agreed to entirely opt out of using such a system as importers in any circumstance: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

SCHEDULE 2

Afghanistan
Afghanistan

Albania
Albanie

Angola
Angola

Antigua and Barbuda
Antigua-et-Barbuda

Argentina
Argentine

Armenia
Arménie

Bahrain, Kingdom of
Bahreïn, Royaume de

Bangladesh
Bangladesh

Barbados
Barbade

Belize
Belize

Benin
Benin

Bhutan
Bhoutan

Bolivia
Bolivie

Botswana
Botswana

Brazil
Brésil

Brunei Darussalam
Brunéi Darussalam

Bulgaria
Bulgarie

Burkina Faso
Burkina Faso

Burundi
Burundi

Cambodia
Cambodge

Cameroon
Cameroun

Cape Verde
Cap-Vert

Central African Republic
République centrafricaine

Chad
Tchad

Chile
Chili

China
Chine

Chinese Taipei*
Taipei chinois

Colombia
Colombie

Comoros
Comores

Congo
Congo

Costa Rica
Costa Rica

Côte d'Ivoire
Côte d'Ivoire

Croatia
Croatie

Cuba
Cuba

Cyprus**
Chypre

Czech Republic**
République tchèque

Democratic Republic of the Congo
République démocratique du Congo

Djibouti
Djibouti

Dominica
Dominique

Dominican Republic
République dominicaine

Ecuador
Équateur

Egypt
Égypte

El Salvador
El Salvador

Equatorial Guinea
Guinée équatoriale

Eritrea
Érythrée

Estonia**
Estonie

Ethiopia
Éthiopie

Fiji
Fidji

Former Yugoslav Republic of Macedonia
Ex-République yougoslave de Macédoine

Gabon
Gabon

Gambia
Gambie

Georgia
Géorgie

Ghana
Ghana

Grenada
Grenade

Guatemala
Guatemala

Guinea
Guinée

Guinea-Bissau
Guinée-Bissau

Guyana
Guyana

Haiti
Haïti

Honduras
Honduras

Hong Kong, China*
Hong Kong, Chine

Hungary**
Hongrie

India
Inde

Indonesia
Indonésie

Israel*
Israël

Jamaica
Jamaïque

Jordan
Jordanie

Kenya
Kenya

Kiribati
Kiribati

Korea*
Corée

Kuwait*
Koweït

Kyrgyz Republic
République kirghize

Lao People's Democratic Republic
République démocratique populaire lao

Latvia**
Lettonie

Lesotho
Lesotho

Liberia
Libéria

Liechtenstein
Liechtenstein

Lithuania**
Lituanie

Macao, China*
Macao, Chine

Madagascar
Madagascar

Malawi
Malawi

Malaysia
Malaisie

Maldives
Maldives

Mali
Mali

Malta**
Malte

Mauritania
Mauritanie

Mauritius
Maurice

Mexico*
Mexique

Moldova
Moldova

Mongolia
Mongolie

Morocco
Maroc

Mozambique
Mozambique

Myanmar
Myanmar

Namibia
Namibie

Nepal
Népal

Nicaragua
Nicaragua

Niger
Niger

Nigeria
Nigéria

Oman
Oman

Pakistan
Pakistan

Panama
Panama

Papua New Guinea
Papouasie-Nouvelle-Guinée

Paraguay
Paraguay

Peru
Pérou

Philippines
Philippines

Poland**
Pologne

Qatar*
Qatar

Romania
Roumanie

Rwanda
Rwanda

Saint Kitts and Nevis
Saint-Kitts-et-Nevis

Saint Lucia
Sainte-Lucie

Saint Vincent and the Grenadines
Saint-Vincent-et-les-Grenadines

Samoa
Samoa

Sao Tome and Principe
Sao Tomé-et-Principe

Senegal
Sénégal

Sierra Leone
Sierra Leone

Singapore*
Singapour

Slovak Republic**
République slovaque

Slovenia**
Slovénie

Solomon Islands
Îles Salomon

Somalia
Somalie

South Africa
Afrique du Sud

Sri Lanka
Sri Lanka

Sudan
Soudan

Suriname
Suriname

Swaziland
Swaziland

Thailand
Thaïlande

Timor-Leste
Timor-Leste

Togo
Togo

Trinidad and Tobago
Trinité-et-Tobago

Tunisia
Tunisie

Turkey*
Turquie

Tuvalu
Tuvalu

Uganda
Ouganda

United Arab Emirates*
Émirats arabes unis

United Republic of Tanzania
République-Unie de Tanzanie

Uruguay
Uruguay

Vanuatu
Vanuatu

Venezuela
Venezuela

Yemen
Yémen

Zambia
Zambie

Zimbabwe
Zimbabwe

INFORMATION NOTE:

Bill C-393 also includes a "sunset clause" regarding the duration of its changes to the Patent Act, which reads as follows:

CESSATION OF APPLICATION

Application of provisions maintained

8. The provisions of this Act that amend the *Patent Act* shall cease to apply on the day that is the **tenth** anniversary of the day on which this Act comes into force unless, before that day, the application of those provisions is subject to a comprehensive review by the standing committee designated by the House of Commons for that purpose, that committee recommends that they be maintained and the House of Commons approves that recommendation.