Use of Patented Products for International Humanitarian Purposes Regulations (SOR/2005-143)
Enabling Statute: Patent Act
Regulation current to January 25th, 2011
Attention: See coming into force provision and notes, where applicable.

Use of Patented Products for International Humanitarian Purposes Regulations

SOR/2005-143

PATENT ACT

Use of Patented Products for International Humanitarian Purposes Regulations

P.C. 2005-861 May 10, 2005

Whereas, pursuant to subsection 21.08(2)[a] of the *Patent Act*, the Governor in Council has considered the humanitarian and non-commercial reasons underlying the issuance of authorizations under subsection 21.04(1)[a] of that Act;

Therefore, Her Excellency the Governor General in Council, on the recommendation of the Minister of Industry, pursuant to section 12[b] of the *Patent Act*, hereby makes the annexed *Use of Patented Products for International Humanitarian Purposes Regulations*.

a S.C. 2004, c. 23, s. 1
b S.C. 1993, c. 15, s. 29

USE OF PATENTED PRODUCTS FOR INTERNATIONAL HUMANITARIAN PURPOSES REGULATIONS

INTERPRETATION

1. In these Regulations, “Act” means the *Patent Act*.

COMMUNICATIONS

2. (1) Any correspondence and envelope that relate to an application under section 21.04 of the Act shall clearly indicate this fact. The correspondence shall be written in English or French and shall be addressed, together with the envelope, in English or French to the Commissioner.

(2) Correspondence shall be delivered to the Patent Office by hand or by mail and
(*a*) if it is delivered during the ordinary business hours of the Patent Office, it is considered to be received by the Commissioner on the day of the delivery; and
(*b*) if it is delivered outside the ordinary business hours of the Patent Office, it is considered to be received on the next business day.

3. (1) For the purposes of sections 21.01 to 21.2 of the Act, any correspondence to be sent to a patentee shall be sent to its representative in Canada, as shown in the records of the Patent Office or, if no representative has been appointed, to the patentee.

(2) Any correspondence sent to the patentee's representative in Canada is deemed to have been received by the patentee.

APPLICATION FOR AUTHORIZATION

4. For the purpose of subsection 21.04(2) of the Act, an application for authorization shall be in the form set out in Form 1 of the schedule and shall be signed by the applicant.

SOLEMN OR STATUTORY DECLARATIONS

5. (1) The solemn or statutory declaration referred to in paragraph 21.04(3)(*c*) of the Act shall be in the form set out in Form 2 of the schedule and shall be signed by the applicant.

(2) The solemn or statutory declarations referred to in clauses 21.04(3)(*d*)(i)(A) and (B) and (ii)(A) and (B) of the Act shall be in the form set out in Forms 3, 4, 5 and 6, respectively, of the schedule and shall be signed by the applicant.

(3) The solemn or statutory declarations referred to in clauses 21.04(3)(*d*)(iii)(A), (iv)(A) and (v)(A) of the Act shall be in the form set out in Form 7 of the schedule and shall be signed by the applicant.

(4) The solemn or statutory declaration referred to in paragraph 21.16(1)(*b*) of the Act shall be in the form set out in Form 8 of the schedule and shall be signed by the holder of the authorization.

AUTHORIZATION

6. For the purpose of subsection 21.05(1) of the Act, the authorization shall be in the form set out in Form 9 of the schedule.

WEBSITE

7. For the purpose of section 21.06 of the Act, the website of the holder of an authorization shall disclose the following information:

(*a*) if the pharmaceutical product named in the application is a drug as defined in section 2 of the *Food and Drugs Act*, the name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product, or if the pharmaceutical product is a medical device, the name of the medical device;

(*b*) the name of the country or WTO Member named in the application to which the pharmaceutical product is to be exported;

(*c*) if the country or WTO Member referred to in paragraph (*b*) is not itself the purchaser of the pharmaceutical product, the name of the person or entity — other than a governmental person or entity — referred to in paragraph 21.04(2)(*f*) of the Act, to which the product is to be sold, together with their postal address;

(*d*) the quantity of the pharmaceutical product that, under section 21.04 of the Act, has been authorized to be manufactured for export to the country or WTO Member referred to in paragraph (*b*);

(*e*) the distinguishing features of the pharmaceutical product — including its colour if applicable — and of its label and packaging, as required by regulations made under the *Food and Drugs Act*;

(*f*) the name and postal address of the shipping agent and any other party that, to the knowledge of the holder of the authorization, will be handling the pharmaceutical product while it is in transit from Canada to the country or WTO Member referred to in paragraph (*b*);

(*g*) if the consignee in the importing country or WTO Member is a person or entity other than the country or WTO Member referred to in paragraph (*b*), or the person or entity referred to in paragraph (*c*), as the case may be, the name and postal address of the consignee;

(*h*) the quantity of the pharmaceutical product contained in each shipment;

(*i*) the export tracking number issued by the Minister of Health in respect of each shipment; and

(*j*) the number of the bill of lading for each shipment.

ROYALTIES

8. (1) In this section, “Index” means the Human Development Index developed and maintained by the United Nations Development Programme.

(2) For the purpose of subsection 21.08(1) of the Act, the events on the occurrence of which a royalty is required to be paid, and the manner of determining the royalty, are as follows:
(*a*) if the total quantity of the pharmaceutical product that is authorized to be manufactured and exported is exported in a single shipment, the amount of the royalty determined in accordance with subsection (4) or (6), as the circumstances require, shall be paid in full within 45 days after the date of the export notice provided under section 21.07 of the Act; and
(*b*) if the quantity of the pharmaceutical product that is authorized to be manufactured and exported is exported in a series of shipments, a royalty shall be paid within 45 days after the date of the export notice provided under section 21.07 of the Act in an amount for a shipment that is the same proportion of the full amount of the royalty determined in accordance with subsection (4) or (6), as the circumstances require, as the quantity of the pharmaceutical product exported in the shipment is of the quantity of the pharmaceutical product that has been authorized to be manufactured and exported.
(3) If the name of the country or WTO Member to which an authorization relates appears on the Index, the rate for calculating the royalty that is required to be paid to the patentee or to each of the patentees, as the case may be, in respect of the authorization shall be determined by
(*a*) adding 1 to the total number of countries listed on the Index;
(*b*) subtracting from the sum determined under paragraph (*a*) the numerical rank on the Index of the country or WTO Member to which the pharmaceutical product is to be exported;
(*c*) dividing the difference determined under paragraph (*b*) by the total number of countries listed on the Index; and
(*d*) multiplying the quotient determined under paragraph (*c*) by 0.04.
(4) If the name of the country or WTO Member to which an authorization relates appears on the Index, the amount of royalty payable to the patentee or to each of the patentees, as the case may be, shall be determined
(*a*) when there is only one patentee, by multiplying the total monetary value, expressed in Canadian currency, of the agreement pertaining to the pharmaceutical product to be manufactured, sold and exported under the authorization by the royalty rate determined in accordance with subsection (3); and
(*b*) when there is more than one patentee, by dividing the amount determined under paragraph (*a*) by the number of patentees.
(5) If the name of the country or WTO Member to which an authorization relates does not appear on the Index, the rate for calculating the royalty that is required to be paid to the patentee or to each of the patentees, as the case may be, in respect of the applicable authorization shall be determined by
(*a*) adding 1 to the total number of countries listed on the Index;
(*b*) subtracting from the sum determined under paragraph (*a*) the average
(i) in the case of a country or WTO Member to which the pharmaceutical product is to be exported and whose name appears in Schedule 2 or 3 to the Act, of the numerical ranks on the Index of all of the countries and WTO Members whose names appear both on the Index and in the same Schedule to the Act as the country or WTO Member to which the pharmaceutical product is to be exported,
(ii) in the case of a country — other than a WTO Member — to which the pharmaceutical product is to be exported and whose name appears in Schedule 4 to the Act, of the numerical ranks on the Index of all of the WTO Members whose names appear both on the Index and in Schedule 3 to the Act, and
(iii) in the case of a WTO Member to which the pharmaceutical product is to be exported and whose name appears in Schedule 4 to the Act, of the numerical ranks

on the Index of all of the WTO Members whose names appear both on the Index and in Schedule 4 to the Act;
(*c*) dividing the difference determined under paragraph (*b*) by the total number of countries listed on the Index; and
(*d*) multiplying the quotient determined under paragraph (*c*) by 0.04.
(6) If the name of the country or WTO Member to which an authorization relates does not appear on the Index, the amount of royalty payable to the patentee or to each of the patentees, as the case may be, shall be determined
(*a*) when there is only one patentee, by multiplying the total monetary value, expressed in Canadian currency, of the agreement pertaining to the pharmaceutical product to be manufactured, sold and exported under the authorization by the royalty rate determined in accordance with subsection (5); and
(*b*) when there is more than one patentee, by dividing the amount determined under paragraph (*a*) by the number of patentees.

RENEWAL APPLICATION

9. For the purpose of section 21.12 of the Act, an application for the renewal of an authorization shall be in the form set out in Form 10 of the schedule and shall be signed by the holder of the authorization.

RENEWAL OF AUTHORIZATION

10. The renewal of an authorization by the Commissioner under section 21.12 of the Act shall be in the form set out in Form 11 of the schedule.

PRODUCT PRICE PUBLICATIONS

11. For the purpose of paragraph (*b*) of the definition “average price” in subsection 21.17(6) of the Act, the publications reporting the prices in Canada of pharmaceutical products sold by or with the consent of the patentee that are equivalent to the pharmaceutical product to which an authorization under section 21.04 of the Act relates are the following:
(*a*) the *Ontario Drug Benefit Formulary*, as amended from time to time;
(*b*) the *Drug Formulary* published by the Régie de l'assurance maladie du Québec, as amended from time to time; and
(*c*) the *PPS® Pharma Publication* published by Total Pricing Systems Inc., as amended from time to time.

COMING INTO FORCE

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12. These Regulations come into force on the day on which *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, being chapter 23 of the Statutes of Canada, 2004, comes into force.

* [Regulations in force May 14, 2005, *see* SI/2005-46.]

SCHEDULE
FORM 1
(Section 4)

APPLICATION FOR AUTHORIZATION UNDER SECTION 21.04 OF THE PATENT ACT

1. The undersigned hereby applies for an authorization under section 21.04 of the Act.

2. The pharmaceutical product that the undersigned intends to manufacture and sell for export under the authorization is
(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*———————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*).

3. The maximum quantity of the pharmaceutical product that the undersigned intends to manufacture and sell for export under the authorization is ————————.

4. For each patented invention to which the application relates, the name(s) of the patentee(s) of the invention, the name(s) and postal address(es) of the representative(s) of the patentee(s) or, if no representative has been appointed, the postal address(es) of the patentee(s), and the patent number(s) issued in respect of the invention are as follows:

	Name of Patentee	Name and Address of Patentee's Representative or Address of Patentee	Patent Number
(*a*)			
(*b*)			
(*c*)			
(*d*)			

5. The name of the WTO Member or country that has notified, respectively, the TRIPS Council or the Government of Canada in writing of its requirement for the pharmaceutical product named in the application, and to which the pharmaceutical product is to be exported, is————————.

6. The name, postal address and telephone number of the person or entity referred to in paragraph 21.04(2)(*f*) of the Act, to which the pharmaceutical product is to be sold, are as follows:

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7. For the purpose of subsection 21.06(1) of the Act, the website address of the undersigned is ————————

8. The name, postal address and telephone number of the undersigned are as follows:

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Dated at the day of , ————————

Signature of applicant

FORM 2

(Subsection 5(1))

SOLEMN OR STATUTORY DECLARATION UNDER PARAGRAPH 21.04(3)(*c*) OF THE PATENT ACT

In the matter of an application by ————————

(name of applicant) for export to ————————

(name of country or WTO Member) of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ————————

————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ————————

————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*);

1. The undersigned *(name of applicant)* hereby declares, in accordance with paragraph 21.04(3)(*c*) of the Act, that on *(date)*, being at least 30 days before the date of filing of the application for an authorization under section 21.04 of the Act, the undersigned

(*a*) sought from the patentee or, if there is more than one, from each of the patentees, namely, ————————

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(name(s) of the patentee(s)), by certified or registered mail addressed to ————————

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(name(s) and postal address(es) of the patentee(s) or the representative(s) of the patentee(s), if any), 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

(*b*) 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 required under paragraphs 21.04(2)(*a*) to (*g*) of the Act.

2. The name, postal address and telephone number of the undersigned are as follows:

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Dated at the day of , ————————

Signature of applicant

FORM 3

(Subsection 5(2))

SOLEMN OR STATUTORY DECLARATION UNDER CLAUSE 21.04(3)(*d*)(i)(A) OF THE PATENT ACT

In the matter of an application by ————————

(name of applicant) for export to *(name of WTO Member)* of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ————————

————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ————————

————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*);

1. The undersigned *(name of applicant)* hereby declares, in accordance with clause 21.04(3)(*d*)(i)(A) of the Act, that the pharmaceutical product to which the application relates

(*a*) is the pharmaceutical product specified in the notice in writing that the WTO Member has provided to the TRIPS Council; and

(*b*) is not patented in that WTO Member.

2. The name, postal address and telephone number of the undersigned are as follows:

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Dated at the day of , ———————

Signature of applicant

FORM 4

(Subsection 5(2))

SOLEMN OR STATUTORY DECLARATION UNDER CLAUSE 21.04(3)(*d*)(i)(B) OF THE PATENT ACT

In the matter of an application by ———————

(name of applicant) for export to ———————

(name of WTO Member) of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ———————

———————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ———————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*)

1. The undersigned *(name of applicant)* hereby declares, in accordance with clause 21.04(3)(*d*)(i)(B) of the Act, that the pharmaceutical product to which the application relates is the pharmaceutical product that is specified in the notice in writing that the WTO Member has provided to the TRIPS Council.

2. The name, postal address and telephone number of the undersigned are as follows:

———————

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Dated at the day of , ———————

Signature of applicant

FORM 5

(Subsection 5(2))

SOLEMN OR STATUTORY DECLARATION UNDER CLAUSE 21.04(3)(*d*)(ii)(A) OF THE PATENT ACT

In the matter of an application by ———————

(name of applicant) for export to ———————

(name of country) of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ———————

———————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ————————

————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*);

1. The undersigned *(name of applicant)* hereby declares, in accordance with clause 21.04(3)(*d*)(ii)(A) of the Act, that the pharmaceutical product to which the application relates

(*a*) is the pharmaceutical product specified in the notice in writing that the country has provided to the Government of Canada; and

(*b*) is not patented in that country.

2. The name, postal address and telephone number of the undersigned are as follows:

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Dated at the day of , ————————

Signature of applicant

FORM 6

(Subsection 5(2))

SOLEMN OR STATUTORY DECLARATION UNDER CLAUSE 21.04(3)(*d*)(ii)(B) OF THE PATENT ACT

In the matter of an application by ————————

(name of applicant) for export to ————————

(name of country) of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ————————

————————

(*(name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product)*); or

(*b*) if the pharmaceutical product is a medical device: ————————

————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*)

1. The undersigned *(name of applicant)* declares, in accordance with clause 21.04(3)(*d*)(ii)(B) of the Act, that the pharmaceutical product to which the application relates is the pharmaceutical product that is specified in the notice in writing that the country has provided to the Government of Canada.

2. The name, postal address and telephone number of the undersigned are as follows:

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Dated at the day of , ————————

Signature of applicant

FORM 7

(Subsection 5(3))

SOLEMN OR STATUTORY DECLARATION UNDER CLAUSE 21.04(3)(*d*)(iii)(A), (iv)(A) AND (v)(A) OF THE PATENT ACT

In the matter of an application by ————————
(name of applicant) for export to ————————
(name of country or WTO Member) of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ————————
————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ————————
————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*);

1. The undersigned *(name of applicant)* hereby declares, in accordance with clause 21.04(3)(*d*)(iii)(A), (iv)(A) or (v)(A) of the Act, as the case may be, that the pharmaceutical product to which the application relates is not patented in the country or WTO Member.

2. The name, postal address and telephone number of the undersigned are as follows:
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Dated at the day of , ————————

Signature of applicant

FORM 8

(Subsection 5(4))

SOLEMN OR STATUTORY DECLARATION UNDER PARAGRAPH 21.16(1)(*b*) OF THE PATENT ACT

In the matter of authorization number granted on (*date*) to *(name of holder of authorization)* for export to *(name of country or WTO Member)* of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ————————
————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or
————————

(*b*) if the pharmaceutical product is a medical device: ————————
————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*);

1. The undersigned *(name of holder of authorization)* hereby declares, in accordance with paragraph 21.16(1)(*b*) of the Act, that

(*a*) the total monetary value of the agreement, expressed in Canadian currency, as it relates to the pharmaceutical product authorized to be manufactured and sold is $; and

(*b*) the number of units of the pharmaceutical product to be sold under the terms of the agreement is ————————.

2. The name, postal address and telephone number of the undersigned are as follows:

———————

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Dated at the day of , ———————

Signature of holder of authorization

FORM 9

(Section 6)

AUTHORIZATION UNDER SECTION 21.04 OF THE PATENT ACT

In the matter of application for authorization number by *(name of applicant)* for export to *(name of country or WTO Member)* of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ———————

———————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ———————

———————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*); or

1. I hereby authorize *(name of applicant)*, whose postal address is , to make, construct and use, the patented invention(s) identified in patent number(s) solely for purposes directly related to the manufacture of the above-mentioned pharmaceutical product, and to sell it for export to the above-mentioned country or WTO Member.

2. The quantity of the pharmaceutical product authorized to be manufactured by this authorization is ———————

3. In accordance with section 21.09 of the Act, this authorization is valid for a period of two years beginning on the date shown below.

Granted at the day of , ———————

Signature of Commissioner of Patents

FORM 10

(Section 9)

APPLICATION FOR RENEWAL OF AUTHORIZATION UNDER SECTION 21.12 OF THE PATENT ACT

In the matter of an application for renewal of authorization by *(name of applicant)* for export to *(name of country or WTO Member)* of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ———————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ———————

———————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*);

1. The undersigned, whose postal address and telephone number are ———————— , hereby applies for a renewal of authorization number that was granted on *(date)* authorizing the making, construction and use of the patented invention(s) identified in the patent numbers below, solely for purposes directly related to the manufacture of *(unexported quantity)* of the above-mentioned pharmaceutical product and its sale for export to the above-mentioned country or WTO Member.

2. For each patented invention to which the application for renewal relates, the name(s) of the patentee(s) of the invention, the name(s) and postal address(es) of the representative(s) of the patentee(s) or, if no representative has been appointed, the postal address(es) of the patentee(s), and the patent number(s) issued in respect of the invention are as follows:

	Name of Patentee	Name and Address of Patentee's Representative or Address of Patentee	Patent Number
(*a*)			
(*b*)			
(*c*)			
(*d*)			

3. The undersigned hereby certifies that

(*a*) the quantities of the pharmaceutical product that were authorized under authorization number to be manufactured and sold for export under section 21.04 of the Act were not or will not be exported before the authorization ceases to be valid; and

(*b*) the undersigned has complied with the terms of the authorization and the requirements of sections 21.06 to 21.08 of the Act.

Dated at the day of , ————————

Signature of applicant

Sworn before me this day of , ————————

Signature of Commissioner for Oaths

FORM 11

(Section 10)

RENEWAL OF AUTHORIZATION UNDER SECTION 21.12 OF THE PATENT ACT

In the matter of an application for a renewal of an authorization by *(name of applicant)* for export to *(name of country or WTO Member)* of the following pharmaceutical product:

(*a*) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: ————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product*); or

(*b*) if the pharmaceutical product is a medical device: ————————

(*name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of theMedical Devices Regulations*);

And in the matter of authorization number that was granted in accordance with section 21.04 of the Act on *(date)* to make, construct and use the patented invention(s) identified in patent number(s) solely for purposes directly related to the manufacture of the quantity remaining to be shipped *(quantity)* of the above-

mentioned pharmaceutical product, and to sell it for export to *(name of country or WTO Member)*;

And whereas the applicant has not yet manufactured and exported the above-noted quantity of the pharmaceutical product on the date of its application for renewal;

I hereby renew the above-mentioned authorization in accordance with section 21.12 of the Act.

Dated at the day of , ————————

Signature of Commissioner of Patents