**Regulations Respecting a Notice of Compliance Pertaining to Patented Medicines (SOR/93-133)**
Enabling Statute: Patent Act
Regulation current to January 25th, 2011
Attention: See coming into force provision and notes, where applicable.

# Patented Medicines (Notice of Compliance) Regulations

SOR/93-133

Registration March 12, 1993

## PATENT ACT

### Patented Medicines (Notice of Compliance) Regulations

P.C. 1993-502 March 12, 1993

His Excellency the Governor General in Council, on the recommendation of the Minister of Consumer and Corporate Affairs, pursuant to subsection 55.2(4)* of the *Patent Act*, is pleased hereby to make the annexed Regulations respecting a notice of compliance pertaining to patented medicines.

* S.C. 1993, c. 2, s. 4

REGULATIONS RESPECTING A NOTICE OF COMPLIANCE PERTAINING TO PATENTED MEDICINES

### SHORT TITLE

**1.** These Regulations may be cited as the *Patented Medicines (Notice of Compliance) Regulations*.

### INTERPRETATION

**2.** In these Regulations,

"claim for the dosage form" means a claim for a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug that includes within its scope that medicinal ingredient or formulation; (*revendication de la forme posologique*)

"claim for the formulation" means a claim for a substance that is a mixture of medicinal and non-medicinal ingredients in a drug and that is administered to a patient in a particular dosage form; (*revendication de la formulation*)

"claim for the medicinal ingredient" includes a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, and also includes a claim for different polymorphs of the medicinal ingredient, but does not include different chemical forms of the medicinal ingredient; (*revendication de l'ingrédient médicinal*)

"claim for the medicine itself" [Repealed, SOR/2006-242, s. 1]

"claim for the use of the medicinal ingredient" means a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms; (*revendication de l'utilisation de l'ingrédient médicinal*)

"claim for the use of the medicine" [Repealed, SOR/2006-242, s. 1]

“court” means the Federal Court or any other superior court of competent jurisdiction; (*tribunal*)

“expire” means, in relation to a patent, expire, lapse or terminate by operation of law; (*expiré*)

“first person” means the person referred to in subsection 4(1); (*première personne*)

“medicine” [Repealed, SOR/2006-242, s. 1]

“Minister” means the Minister of Health; (*ministre*)

“notice of compliance” means a notice issued under section C.08.004 of the *Food and Drug Regulations*; (*avis de conformité*)

“patent list” means a list submitted under subsection 4(1); (*liste de brevets*)

“register” means the register of patents and other information maintained by the Minister in accordance with subsection 3(2); (*registre*)

“second person” means the person referred to in subsection 5(1) or (2) who files a submission or supplement referred to in those subsections. (*seconde personne*)
SOR/98-166, s. 1; SOR/99-379, s. 1; SOR/2006-242, s. 1; err. (E), Vol. 140, No. 23; SOR/2008-211, s. 1.

## REGISTER AND PATENT LIST

**3.** (1) The following definitions apply in this section and in section 4.

“identification number” means a number, preceded by the letters “DIN”, that is assigned for a drug in accordance with subsection C.01.014.2(1) of the *Food and Drug Regulations*. (*identification numérique*)

“new drug submission” means a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*, but excludes a new drug submission that is based solely on the change of name of the manufacturer. (*présentation de drogue nouvelle*)

“supplement to a new drug submission” means a supplement to a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*, but excludes a supplement to a new drug submission that is based solely on one or more of the matters mentioned in any of paragraphs C.08.003(2)(*b*) and (*d*) to (*g*) and subparagraphs C.08.003(2)(*h*)(iv) and (v) of those Regulations. (*supplément à une présentation de drogue nouvelle*)

(2) The Minister shall maintain a register of patents and other information submitted under section 4. To maintain the register, the Minister may refuse to add or may delete any patent or other information that does not meet the requirements of that section.

(3) If a patent is listed on the register in respect of a new drug submission or supplement to a new drug submission for a drug for which the identification number has been cancelled under paragraph C.01.014.6(1)(*a*) of the *Food and Drug Regulations*, the Minister shall delete the patent from the register 90 days after the date of cancellation.

(4) Subsection (3) does not apply if the identification number is cancelled under paragraph C.01.014.6(1)(*a*) of the *Food and Drug Regulations* because of a change in manufacturer.

(5) If, after an identification number is cancelled under paragraph C.01.014.6(1)(*a*) of the *Food and Drug Regulations*, an identification number is assigned for the same drug, the Minister shall add to the register the patent that was deleted under

subsection (3) when the Minister receives the document required by section C.01.014.3 of the *Food and Drug Regulations* in respect of the drug.
(6) The register shall be open to public inspection during business hours.
(7) No patent on a patent list or other information submitted under section 4 shall be added to the register until after the Minister has issued a notice of compliance in respect of the new drug submission or the supplement to a new drug submission, as the case may be, to which the patent or information relates.
(8) For the purpose of deciding whether a patent, patent list or other information will be added to or deleted from the register, the Minister may consult with officers or employees of the Patent Office.
SOR/98-166, s. 2; SOR/2006-242, s. 2.
**3.1** (1) The Minister shall not delete from the register a patent on a patent list that was submitted before June 17, 2006, unless
(*a*) the patent has expired;
(*b*) a court has, under subsection 60(1) of the *Patent Act*, declared that the patent is invalid or void;
(*c*) the identification number assigned to the drug in respect of which the patent is listed is cancelled under paragraph C.01.014.6(1)(*a*) of the *Food and Drug Regulations*; or
(*d*) the patent is found, under paragraph 6(5)(*a*), not to be eligible for inclusion on the register.
(2) The Minister shall not refuse to add to the register a patent on a patent list that was submitted before June 17, 2006 solely on the basis that the patent is not relevant to the submission for a notice of compliance to which the patent list relates.
SOR/2008-211, s. 2.
**4.** (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.
(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains
(*a*) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;
(*b*) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;
(*c*) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or
(*d*) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.
(3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and
(*a*) in the case of a change in formulation, the patent contains a claim for the changed formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;
(*b*) in the case of a change in dosage form, the patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or
(*c*) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.
(4) A patent list shall contain the following:
(*a*) an identification of the new drug submission or the supplement to a new drug submission to which the list relates;

(*b*) the medicinal ingredient, brand name, dosage form, strength, route of administration and use set out in the new drug submission or the supplement to a new drug submission to which the list relates;
(*c*) for each patent on the list, the patent number, the filing date of the patent application in Canada, the date of grant of the patent and the date on which the term limited for the duration of the patent will expire under section 44 or 45 of the *Patent Act*;
(*d*) for each patent on the list, a statement that the first person who filed the new drug submission or the supplement to a new drug submission to which the list relates is the owner of the patent or has an exclusive licence to the patent, or has obtained the consent of the owner of the patent to its inclusion on the list;
(*e*) the address in Canada for service, on the first person, of a notice of allegation referred to in paragraph 5(3)(*a*) or the name and address in Canada of another person on whom service may be made with the same effect as if service were made on the first person; and
(*f*) a certification by the first person that the information submitted under this subsection is accurate and that each patent on the list meets the eligibility requirements of subsection (2) or (3).
(5) Subject to subsection (6), a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates.
(6) A first person may, after the date of filing of a new drug submission or a supplement to a new drug submission, and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement, submit a patent list, including the information referred to in subsection (4), in relation to the submission or supplement.
(7) A first person who has submitted a patent list must keep the information on the list up to date but, in so doing, may not add a patent to the list.
(8) The Minister shall insert on the patent list the date of filing and submission number of the new drug submission or the supplement to a new drug submission in relation to which the list was submitted.
SOR/98-166, s. 3; SOR/2006-242, s. 2; err. (E), Vol. 140, No. 23.
**4.1** (1) In this section, “supplement to the new drug submission” means a supplement to a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*.
(2) A first person who submits a patent list in relation to a new drug submission referred to in subsection 4(2) may, if the list is added to the register, resubmit the same list in relation to a supplement to the new drug submission, but may not submit a new patent list in relation to a supplement except in accordance with subsection 4(3).
SOR/2006-242, s. 2.
**5.** (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the register in respect of the other drug,
(*a*) state that the second person accepts that the notice of compliance will not issue until the patent expires; or
(*b*) allege that
(i) the statement made by the first person under paragraph 4(4)(*d*) is false,
(ii) the patent has expired,
(iii) the patent is not valid, or

(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.
(2) If a second person files a supplement to a submission referred to in subsection (1) seeking a notice of compliance for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug with, or makes reference to, another drug that has been marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the supplement, with respect to each patent on the register in respect of the other drug,
(*a*) state that the second person accepts that the notice of compliance will not issue until the patent expires; or
(*b*) allege that
(i) the statement made by the first person under paragraph 4(4)(*d*) is false,
(ii) the patent has expired,
(iii) the patent is not valid, or
(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the supplement is filed.
(3) A second person who makes an allegation under paragraph (1)(*b*) or (2)(*b*) shall
(*a*) serve on the first person a notice of allegation relating to the submission or supplement filed under subsection (1) or (2) on or after its date of filing;
(*b*) include in the notice of allegation
(i) a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission or supplement has been filed, and
(ii) a detailed statement of the legal and factual basis for the allegation;
(*c*) include in the material served a certification by the Minister of the date of filing of the submission or supplement; and
(*d*) serve proof of service of the documents and information referred to in paragraphs (*a*) to (*c*) on the Minister.
(4) A second person is not required to comply with
(*a*) subsection (1) in respect of a patent added to the register in respect of the other drug on or after the date of filing of the submission referred to in that subsection, including a patent added under subsection 3(5); and
(*b*) subsection (2) in respect of a patent added to the register in respect of the other drug on or after the date of filing of the supplement referred to in that subsection, including a patent added under subsection 3(5).
(5) For the purposes of subsections (3) and (4), if subsection (1) or (2) applies to a submission or supplement referred to in paragraph C.07.003(*b*) of the *Food and Drug Regulations*, if the drug to which the comparison or reference is made is an innovative drug within the meaning of subsection C.08.004.1(1) of those Regulations and if the date of filing of the submission or supplement is less than six years from the day on which the first notice of compliance was issued in respect of the innovative drug, the deemed date of filing of the submission or supplement is six years after the date of issuance of the notice of compliance.
(6) A second person who has served a notice of allegation on a first person under paragraph (3)(*a*) shall retract the notice of allegation and serve notice of the retraction on the first person within 90 days after either of the following dates:
(*a*) the date on which the Minister notifies the second person under paragraph C.08.004(3)(*b*) of the *Food and Drug Regulations* of their non-compliance with the

requirements of section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1 of those Regulations; or
(*b*) the date of the cancellation by the second person of the submission or supplement to which the allegation relates.
(7) A first person who has applied for a prohibition order under subsection 6(1) in response to a notice of allegation shall, if the notice is retracted in accordance with subsection (6), apply without delay for a discontinuance of the proceedings.
SOR/98-166, ss. 4, 9; SOR/99-379, s. 2; SOR/2006-242, s. 2; err. (E), Vol. 140, No. 23.

## RIGHT OF ACTION

**6.** (1) A first person may, within 45 days after being served with a notice of allegation under paragraph 5(3)(*a*), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the notice of allegation.
(2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.
(3) The first person shall, within the 45 days referred to in subsection (1), serve the Minister with proof that an application referred to in that subsection has been made.
(4) Where the first person is not the owner of each patent that is the subject of an application referred to in subsection (1), the owner of each such patent shall be made a party to the application.
(5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part
(*a*) in respect of those patents that are not eligible for inclusion on the register; or
(*b*) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.
(5.1) In a proceeding in respect of an application under subsection (1), the court shall not dismiss an application in whole or in part solely on the basis that a patent on a patent list that was submitted before June 17, 2006 is not eligible for inclusion on the register.
(6) For the purposes of an application referred to in subsection (1), if a second person has made an allegation under subparagraph 5(1)(*b*)(iv) or (2)(*b*)(iv) in respect of a patent and the patent was granted for the medicinal ingredient when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, it shall be considered that the drug proposed to be produced by the second person is, in the absence of proof to the contrary, prepared or produced by those methods or processes.
(7) On the motion of a first person, the court may, at any time during a proceeding,
(*a*) order a second person to produce any portion of the submission or supplement filed by the second person for a notice of compliance that is relevant to the disposition of the issues in the proceeding and may order that any change made to the portion during the proceeding be produced by the second person as it is made; and
(*b*) order the Minister to verify that any portion produced corresponds fully to the information in the submission or supplement.
(8) A document produced under subsection (7) shall be treated confidentially.
(9) In a proceeding in respect of an application under subsection (1), a court may make any order in respect of costs, including on a solicitor-and-client basis, in accordance with the rules of the court.
(10) In addition to any other matter that the court may take into account in making an order as to costs, it may consider the following factors:
(*a*) the diligence with which the parties have pursued the application;

(*b*) the inclusion on the certified patent list of a patent that should not have been included under section 4; and
(*c*) the failure of the first person to keep the patent list up to date in accordance with subsection 4(7).
SOR/98-166, ss. 5, 9; SOR/99-379, s. 3; SOR/2006-242, s. 3; err. (E), Vol. 140, No. 23; SOR/2008-211, s. 3.

## NOTICE OF COMPLIANCE

**7.** (1) The Minister shall not issue a notice of compliance to a second person before the latest of
(*a*) [Repealed, SOR/98-166, s. 6]
(*b*) the day on which the second person complies with section 5,
(*c*) subject to subsection (3), the expiration of any patent on the register that is not the subject of an allegation,
(*d*) subject to subsection (3), the expiration of 45 days after the receipt of proof of service of a notice of allegation under paragraph 5(3)(*a*) in respect of any patent on the register,
(*e*) subject to subsections (2), (3) and (4), the expiration of 24 months after the receipt of proof of the making of any application under subsection 6(1), and
(*f*) the expiration of any patent that is the subject of an order pursuant to subsection 6(1).
(2) Paragraph (1)(*e*) does not apply if at any time, in respect of each patent that is the subject of an application pursuant to subsection 6(1),
(*a*) the patent has expired; or
(*b*) the court has declared that the patent is not valid or that no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed.
(3) Paragraphs (1)(*c*), (*d*) and (*e*) do not apply in respect of a patent if the owner of the patent has consented to the making, constructing, using or selling of the drug in Canada by the second person.
(4) Paragraph (1)(*e*) ceases to apply in respect of an application under subsection 6(1) if the application is withdrawn or discontinued by the first person or is dismissed by the court hearing the application.
(5) If the court has not yet made an order under subsection 6(1) in respect of an application, the court may
(*a*) shorten the time limit referred to in paragraph (1)(*e*) if the first and second persons consent to it or if the court finds that the first person has failed, at any time during the proceeding, to reasonably cooperate in expediting the application; or
(*b*) extend the time limit referred to in paragraph (1)(*e*) if the first and second persons consent to it or if the court finds that the second person has failed, at any time during the proceeding, to reasonably cooperate in expediting the application.
SOR/98-166, ss. 6, 9; SOR/2006-242, s. 4; SOR/2010-212, s. 1.

**8.** (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period
(*a*) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that
(i) the certified date was, by the operation of *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or
(ii) a date other than the certified date is more appropriate; and

(*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.
(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).
(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.
(4) If a court orders a first person to compensate a second person under subsection (1), the court may, in respect of any loss referred to in that subsection, make any order for relief by way of damages that the circumstances require.
(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).
(6) The Minister is not liable for damages under this section.
SOR/98-166, ss. 8, 9; SOR/2006-242, s. 5; SOR/2010-212, s. 2(F).

## SERVICE

**9.** (1) Service of any document referred to in these Regulations shall be effected personally or by registered mail.
(2) Service by registered mail shall be deemed to be effected on the addressee five days after mailing.

## RELATED PROVISIONS

**— SOR/98-166, s. 9 :**

**9.** (1) Subsection 4(4) does not apply to an allegation if, before the coming into force of these Regulations, it was served on the first person, if proof of that service was served on the Minister and if the first person has commenced a proceeding under subsection 6(1).

(2) Subsections 6(5) and (9) and paragraphs 6(10)(*a*) and (*b*) of the Regulations, as enacted by section 5, apply to an application pending on the coming into force of these Regulations.

(3) Subsections 6(6) to (8) and paragraph 6(10)(*c*) of the Regulations, as enacted by section 5, apply to an application commenced on or after the coming into force of these Regulations.

(4) Paragraph 7(1)(*e*) of the Regulations, as enacted by subsection 6(2), applies to an application made on or after the coming into force of these Regulations. Paragraph 7(1)(*e*) of the Regulations as it read before the coming into force of these Regulations, continues to apply to an application pending at the time of that coming into force.

(5) Subsection 7(5) of the Regulations, as enacted by subsection 6(3), applies to an application pending on the coming into force of these Regulations.

(6) Section 8 of the Regulations, as enacted by section 8, applies to an application pending on the coming into force of these Regulations.]

**— SOR/2006-242, s. 6 :**

**6.** Section 4 of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, does not apply to patents on a patent list submitted prior to June 17, 2006.

**— SOR/2006-242, s. 7 :**

**7.** (1) Subsection 5(1) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, applies to a second person who has filed a submission referred to in subsection 5(1) prior to the coming into force of these Regulations and the date of filing of the submission is deemed to be the date of the coming into force of these Regulations.

**(2) Subsection 5(2) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by section 2 of these Regulations, applies to a second person who has filed a supplement to a submission referred to in subsection 5(2) prior to the coming into force of these Regulations and the date of filing of the supplement is deemed to be the date of the coming into force of these Regulations.**

**— SOR/2006-242, s. 8 :**

**8.** Subsection 8(4) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by subsection 5(2) of these Regulations, does not apply to an action commenced under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* prior to the coming into force of these Regulations.

**— SOR/2008-211, s. 4:**

**4.** (1) Words and expressions used in this section have the same meaning as in the *Patented Medicines (Notice of Compliance) Regulations*.

**(2) If, after March 29, 2007, the Minister deleted from the register a patent on a patent list that was submitted before June 17, 2006 solely on the basis that the patent was not relevant to the submission for a notice of compliance to which the patent list relates, the first person may, within 30 days after the day on which these Regulations come into force, deliver a written request to the Minister asking that the patent be added to the register.**

**(3) The Minister shall, within 30 days after the day on which the request referred to in subsection (2) is received, add the patent to the register.**

**(4) If, after March 29, 2007, the Minister refused to add to the register a patent on a patent list submitted before June 17, 2006 solely on the basis that the patent was not relevant to the submission for a notice of compliance to which the patent list relates, the first person may, within 30 days after the day on which these Regulations come into force, deliver a written request to the Minister asking that the patent be added to the register.**

**(5) The Minister shall, within 30 days after the later of the day on which the request referred to in subsection (4) is received and the day on which the notice of compliance referred to in that subsection is issued, add the patent to the register.**

**(6) A second person is not required to comply with subsection 5(1) of the *Patented Medicines (Notice of Compliance) Regulations* in respect of a patent added to the register under subsection (3) or (5) on or after the date of filing of the submission referred to in that subsection 5(1).**

**(7) A second person is not required to comply with subsection 5(2) of the *Patented Medicines (Notice of Compliance) Regulations* in respect of a patent added to the register under subsection (3) or (5) on or after the date of filing of the supplement referred to in that subsection 5(2).**

**(8) Subsection 6(5.1) of the *Patented Medicines (Notice of Compliance) Regulations* does not apply to a motion of the second person brought under subsection 6(5) of those Regulations before the date of the publication of these Regulations in Part I of the *Canada Gazette*.**