Patented Medicines (Notice of Compliance) Regulations*

Patent Act

TABLE OF CONTENTS

	Sections
Short Title	1
Interpretation	2
Register	3
Patent List	4 – 5
Right of Action	6
Notice of Compliance	7 – 8
Service	9

SOR/93–133
Registration 12 March, 1993

P.C. 1993–502
12 March, 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)[1] of the Patent Act, is pleased hereby to make the annexed Regulations respecting a notice of compliance pertaining to patented medicines.

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 medicine itself" includes a claim in the patent for the medicine itself when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents; *(revendication pour le médicament en soi)*

"claim for the use of the medicine" means a claim for the use of the medicine for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof; *(revendication pour l'utilisation du médicament)*

"court" means the Federal Court of Canada 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" means a substance intended or capable of being used for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof; *(médicament)*

"Minister" means the Minister of National Health and Welfare; *(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 of all patents that is submitted pursuant to section 4; *(liste de brevets)*

"register" means the register maintained by the Minister under section 3. *(registre)*

"second person" means the person referred to in subsection 5(1) or (1.1), as the case may be. *(seconde personne)*

SOR/98–166, s. 1;
SOR/99–379, s. 1.

Register

3.—(1) The Minister shall maintain a register of any information submitted under section 4. To maintain it, the Minister may refuse to add or may delete any information that does not meet the requirements of that section.

(2) The register shall be open to public inspection during business hours.

(3) No information submitted pursuant to section 4 shall be included on the register until after the issuance of the notice of compliance in respect of which the information was submitted.

(4) For the purpose of deciding whether information submitted under section 4 should 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.

Patent List

4.—(1) A person who files or has filed a submission for, or has been issued, a notice of compliance in respect of a drug that contains a medicine may submit to the Minister a patent list certified in accordance with subsection (7) in respect of the drug.

(2) A patent list submitted in respect of a drug must

(a) indicate the dosage form, strength and route of administration of the drug;

(b) set out any Canadian patent that is owned by the person, or in respect of which the person has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list, that contains a claim for the medicine itself or a claim for the use of the medicine and that the person wishes to have included on the register;

(c) contain a statement that, in respect of each patent, the person applying for a notice of compliance is the owner, has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list;

(d) set out the date on which the term limited for the duration of each patent will expire pursuant to section 44 or 45 of the *Patent Act*; and

(e) set out the address in Canada for service on the person of any notice of an allegation referred to in paragraph 5(3)*(b)* or *(c)*, or the name and address in Canada of another person on whom service may be made, with the same effect as if service had been made on the person.

(3) Subject to subsection (4), a person who submits a patent list must do so at the time the person files a submission for a notice of compliance.

(4) A first person may, after the date of filing of a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or an amendment to an existing patent list, that includes the information referred to in subsection (2).

(5) When a first person submits a patent list or an amendment to an existing patent list in accordance with subsection (4), the first person must identify the submission to which the patent list or the amendment relates, including the date on which the submission was filed.

(6) A person who submits a patent list must keep the list up to date but may not add a patent to an existing patent list except in accordance with subsection (4).

(7) A person who submits a patent list or an amendment to an existing patent list under subsection (1) or (4) must certify that

(a) the information submitted is accurate; and

(b) the patents set out on the patent list or in the amendment are eligible for inclusion on the register and are relevant to the dosage form, strength and route of administration of the drug in respect of which the submission for a notice of compliance has been filed.

SOR/98–166, s. 3.

5.—(1) Where a person files or has filed a submission for a notice of compliance in respect of a drug and compares that drug with, or makes reference to, another drug for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics and that other drug has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the register in respect of the other drug,

(a) state that the 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 pursuant to paragraph 4(2)*(c)* is false,

(ii) the patent has expired,

(iii) the patent is not valid, or

(iv) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.

(1.1) Subject to subsection (1.2), where subsection (1) does not apply and where a person files or has filed a submission for a notice of compliance in respect of a drug that contains a medicine found in another drug that has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been

submitted, the person shall, in the submission, with respect to each patent included on the register in respect of the other drug containing the medicine, where the drug has the same route of administration and a comparable strength and dosage form,

(a) state that the 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 pursuant to paragraph 4(2)*(c)* is false,

(ii) the patent has expired,

(iii) the patent is not valid, or

(iv) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.

(1.2) Where a person referred to in subsection (1.1) has served, in accordance with paragraph (3)*(b)* or *(c)*, a notice of allegation on a first person in respect of a patent included on the register, the person is not required to serve a notice of allegation in respect of the same submission, the same allegation and the same patent on another first person.

(2) Where, after a second person files a submission for a notice of compliance but before the notice of compliance is issued, a patent list or an amendment to a patent list is submitted in respect of a patent pursuant to subsection 4(4), the second person shall amend the submission to include, in respect of that patent, the statement or allegation that is required by subsection (1) or (1.1), as the case may be.

(3) Where a person makes an allegation pursuant to paragraph (1)*(b)* or (1.1)*(b)* or subsection (2), the person shall

(a) provide a detailed statement of the legal and factual basis for the allegation;

(b) if the allegation is made under any of subparagraphs (1)*(b)*(i) to (iii) or (1.1)*(b)*(i) to (iii), serve a notice of the allegation on the first person;

(c) if the allegation is made under subparagraph (1)*(b)*(iv) or (1.1)*(b)*(iv),

(i) serve on the first person a notice of the allegation relating to the submission filed under subsection (1) or (1.1) at the time that the person files the submission or at any time thereafter, and

(ii) include in the notice of allegation a description of the dosage form, strength and route of administration of the drug in respect of which the submission has been filed; and

(d) serve proof of service of the information referred to in paragraph *(b)* or *(c)* on the Minister.

SOR/98–166, ss. 4, 9;
SOR/99–379, s. 2.

Right of Action

6.—(1) A first person may, within 45 days after being served with a notice of an allegation pursuant to paragraph 5(3)*(b)* or *(c)*, 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 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) In a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application

(a) if the court is satisfied that the patents at issue are not eligible for inclusion on the register or are irrelevant to the dosage form, strength and route of administration of the drug for which the second person has filed a submission for a notice of compliance; or

(b) on the ground that the application is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process.

(6) For the purposes of an application referred to in subsection (1), where a second person has made an allegation under subparagraph 5(1)*(b)*(iv) or (1.1)*(b)*(iv) in respect of a patent and where that patent was granted for the medicine itself when prepared or produced by the methods or processes of manufacture particularly described and claimed 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 for a notice of compliance filed by the second person 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.

(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(6).

SOR/98–166, ss. 5, 9;
SOR/99–379, 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 any allegation pursuant to paragraph 5(3)*(b)* or *(c)* 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 medicine itself and no claim for the use of the medicine 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)* on consent of the first and second persons 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)* on consent of the first and second persons 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.

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 is satisfied on the evidence that another 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) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1).

(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).

SOR/98–166, ss. 8, 9.

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:

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.]

[*] Disclaimer: This document is not the official version (more).
Source: http://laws.justice.gc.ca/en/P–4/SOR–93–133/161377.html
Regulation current to February 21, 2006

[1] S.C. 1993, c. 2, s. 4