



Patented Medicine
Prices
Review Board
Since 1987

The mandate of the Patented Medicine Prices Review Board is to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and to report on pharmaceutical trends of all medicines and on R&D spending by patentees.

PMPRB | Notice and Comment

May 2011

Rules of Practice and Procedure for Board Hearings

Notice and Comment issued by the PMPRB: May 16, 2011

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Rules of Practice and Procedure for Board Hearings

The Patented Medicine Prices Review Board (the Board) has published for comment its proposed revised Rules of Practice and Procedure pertaining to the hearing process.

Interested parties are invited to submit their written comments on the proposed revised Rules of Practice and Procedure by **June 30, 2011**, to:

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Section 96 of the *Patent Act* gives the Board certain powers, rights and privileges of a superior court of record. The Board monitors the price at which patentees sell patented medicines, and may, following a public hearing, issue a remedial order with respect to excessive pricing. The Board may also issue an order to require a patentee to file prescribed information or to address a failure to comply with a previous Board order.

The *Patent Act* provides that the PMPRB may, with the approval of the Governor in Council, make general rules for regulating the practice and procedure of Board hearings.

The Rules of Practice and Procedure (Rules) constitute a published standard set of procedures for all participants to follow in proceedings before the Board. The Rules set out the Board's procedures in accordance with the requirement under the *Patent Act* to resolve matters before it as informally and expeditiously as the circumstances and considerations of fairness permit. They provide a fair opportunity for interested parties to participate in the Board's hearings.

The current Rules have generally fulfilled their intended purpose. However, the Board is of the view that the Rules should be amended to better reflect current practices in recent proceedings and facilitate case management.

The proposed Rules have been drafted to codify the Board's practices and procedures. They take into consideration relevant current practices in other federal administrative tribunals and Courts.

For more information on the Notice and Comment process on the Board's Rules of Practice and Procedure, please contact Sylvie Dupont at 613-954-8299.

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Proposed Rules of Practice and Procedure for Hearings of the Patented Medicine Prices Review Board

INTERPRETATION

1. The definitions in this section apply in these Rules.

“Act” means the *Patent Act*. (*Loi*)

“Chairperson” means the Chairperson of the Board designated under subsection 33(1) of the Act (*président*)

“counsel” means any lawyer licensed to practice law in any province or territory in Canada and who is authorized by a party or person to represent that party or person before the Board. (*conseiller juridique*)

“party” means

- (a) A respondent;
- (b) Officers and employees (Board Staff) appointed under subsection 94(1) of the Act and any person engaged under subsection 94(3) of the Act;
- (c) A minister referred to in subsection 86(2) of the Act; or
- (d) A person who has been granted leave to intervene under rule 20. (*partie*)

“person” includes an unincorporated organization or entity. (*personne*)

“respondent” means a patentee, or a former patentee, against whom an order of the Board under the Act is proposed to be made. (*intimé*)

“Secretary” means the Director of Board Secretariat or anyone acting on his/her behalf. (*secrétaire*)

“Minister” means the Minister of Industry Canada, or such other Minister as may be designated by the regulations, and provincial ministers of the Crown responsible for health. (*minister*)

“Hearing” includes a conference held under the Rules.

BOARD

2. For the purposes of these Rules, the members of the Board assigned by the Chairperson pursuant to subsection 93(2) of the Act to deal with a matter constitute the Board.

APPLICATION

3. These Rules apply in respect of any proceeding before the Board.

QUORUM

4. In any proceeding, a quorum of the Board consists of two members.

GENERAL

5. (1) No proceeding or any part of a proceeding shall be defeated by reason only of a defect in form or procedure.
- (2) Where any procedural matter or question that is not provided for in the Act, in these Rules, or in any regulations made pursuant to the Act arises in the course of any proceeding, it shall be dealt with in any manner that the Board directs in order to ensure the fair and expeditious conduct of the proceeding.

- (3) The Board may, for the purpose of ensuring the fair and expeditious conduct of any proceeding, exempt any person from the requirements of all or any of these Rules.
- (4) These Rules shall be interpreted and applied so as to secure the just, most expeditious and least expensive determination of any proceeding on its merits.

PROCEDURE AND EVIDENCE

- 6. (1) In relation to any proceeding, the Board may
 - (a) receive any evidence that it considers appropriate;
 - (b) take notice of facts that may be judicially noticed and of any generally recognized scientific or technical facts, information or opinions concerning patented medicines;
 - (c) add parties at any stage of the proceeding;
 - (d) permit the amendment of any document issued by or filed with the Board; and
 - (e) decide on any question of procedure that might arise.
 - (2) The Board may, at any time, direct that
 - (a) a party provide any information, particulars or documents in paper or electronic formats that the Board considers relevant to any proceeding; and
 - (b) any particular facts requested of or provided by a party be supported by affidavit; and
 - (c) a party preserve documents and electronically stored information that the Board considers relevant to any proceeding.
 - (3) All affidavits shall be filed with the Secretary.
7. Witnesses appearing before the Board shall testify under oath or solemn affirmation, and be examined by the party calling the witness and cross-examined by parties adverse in interest.

EXPERT WITNESSES

- 8. (1) Every expert who provides evidence on behalf of a party in relation to a proceeding before the Board, must do so in a manner that:
 - (a) is fair, objective and non-partisan;
 - (b) is related only to matters that are within the expert's area of expertise; and
 - (c) provides such additional assistance as the Board may reasonably require to determine a matter at issue.
- (2) The duty in subsection (1) prevails over any obligation owed by the expert to the party by whom or on whose behalf he or she is engaged.
- (3)
 - (a) No expert witness evidence is admissible in a proceeding before the Board in respect of any issue unless the issue has been defined by the pleadings, in a pre-hearing conference order, or is called for the purpose of rebutting evidence of an expert witness introduced by another party.
 - (b) No more than two expert witnesses may be called by a party, per issue without leave of the Board.
- (4) Every party who, in a proceeding before the Board, intends to introduce evidence given by an expert witness shall
 - (a) file with the Secretary and serve on each of the parties in accordance with the Board's schedule of events, an affidavit of the expert witness which shall contain:

- (i) a statement of the issues addressed in the affidavit;
- (ii) a description of the qualifications of the expert on the issues addressed in the affidavit;
- (iii) the expert's current curriculum vitae attached to the affidavit as a schedule;
- (iv) the facts and assumptions on which the opinions in the affidavit are based;
- (v) a summary of the opinions expressed;
- (vi) in the case of an affidavit that is provided in response to another expert's report, an indication of the points of agreement and of disagreement with the other expert's opinions;
- (vii) the reasons for each opinion expressed;
- (viii) identify and produce any literature or other materials specifically relied on in support of the opinions;
- (ix) a summary of the methodology used, to arrive at the conclusion put forward, including any examinations, tests or other investigations on which the expert has relied, including details of the qualifications of the person who carried them out, and whether a representative of any other party was present; and
- (x) any caveats or qualifications necessary to render the affidavit complete and accurate, including those relating to any insufficiency of data or research and an indication of any matters that fall outside the expert's field of expertise.

(b) Ensure that the expert witness is available for examination and cross-examination at the hearing.

(5) Examination in chief of any expert witness shall not, without the Board's consent, exceed 90 minutes.

TIME LIMITS

9. (1) The Board may, at any time and on any conditions that it considers appropriate, extend or abridge the time limits set out in these Rules for doing any act or giving, serving or filing any notice or document.
- (2) Where a time limit set out in these Rules expires on a Saturday or a holiday, the period is extended to the next business day.
- (3) Any document that is served after five p.m. at the recipient's local time is deemed to be served at 9:00 a.m. on the next business day.

NOTICE AND SERVICE

10. (1) Unless otherwise provided in these Rules, the giving of notice or the service of any document under these Rules shall be effected
- (a) by personal service in accordance with rule 11;
 - (b) by courier, in which case service is deemed to have been made the day of delivery of the document;
 - (c) by electronic transmission of a copy of the document to the address for service, in which case service is deemed to have been made on the day of the transmission; or
 - (d) in any other manner that the Board may direct.
- (2) Where a document is required to be filed pursuant to these Rules or a direction of the Board, the person who files the document shall, concurrently with the filing, serve a copy of the document on every person who is, at the time of service, a party to the proceeding.
- (3) Proof of service of any document required to be served shall, at the request of the Board, be filed with the Secretary.
- (4) Proof of service of any notice or document on a person shall be constituted by an affidavit of service, signed by the person who served the document and stating the time, date, place and manner of service.

- (5) Where these Rules require or permit the giving of notice to or the service of any document on a respondent who does not reside or carry on business at a specified address in Canada, the giving of notice or the service may be effected by giving notice to or serving the representative of the respondent appointed pursuant to section 29 of the Act.
- (6) Five true paper copies of each document that is served by a party shall be filed with the Secretary and one electronic copy in accordance with rule 14, unless the Secretary specifies otherwise.

PERSONAL SERVICE

11. Personal service of a document shall be effected
- (a) in the case of an individual, by leaving a copy of the document with the individual;
 - (b) in the case of a partnership, by leaving a copy of the document with one of the partners;
 - (c) in the case of a corporation, by leaving a copy of the document with an official of the corporation or with a person apparently in charge of the head office or any branch of the corporation in Canada;
 - (d) in the case of a Minister, by leaving a copy of the document with the Minister or a person apparently in charge of the office; and
 - (e) where a counsel has filed a notice of appearance on behalf of a person referred to in any of paragraphs (a) to (d), by leaving a copy of the document with the counsel.

ADDRESS FOR SERVICE

12. The address for service shall be
- (a) where there is a counsel for the party, the business address of the counsel as shown on the last document filed by the counsel;
 - (b) where there is no counsel for the party,
 - (i) in the case of a Minister, the address of the office of the Minister, or
 - (ii) in the case of any other person, the address of the person as shown on the last document filed by the person that shows their address; and
 - (c) where a notice of change of address for service has been filed, the new address.

COUNSEL

13. (1) A counsel who files a notice of appearance on behalf of a person shall be the counsel for that person beginning on the date of that filing, and shall remain so unless a change is effected in accordance with subsection (2) or (3).
- (2) A person may change the person's counsel by filing a notice of change of counsel with the Board, together with proof of service of that notice on that counsel and on all other parties.
- (3) A counsel may withdraw from a proceeding by filing with the Board a notice of withdrawal, together with proof of service of that notice on all parties.

FILING

14. (1) The filing of a document with the Board shall be effected
- (a) by personal service of the document on the Secretary;
 - (b) by delivery of the document by courier or by registered or certified mail to the Secretary; or
 - (c) by transmitting the document electronically to the Secretary.

- (2) Any documents filed electronically shall meet the following requirements:
 - (a) Both the paper and electronic versions of documents must contain the same cover, table of contents and page numbers;
 - (b) electronic documents shall be identified by the drug name, or company if the hearing does not relate to a specific drug, the name of the party filing the document, the document and the date (i.e.: identified by the drug identified by the drug name, or company, if the hearing does not relate to a specific drug, the name of the party, the document and the date (i.e. Nicoderm-HMRC-Smith affidavit- March 2008.pdf); and
 - (c) electronic documents created by a party or which a party acquires in electronic form shall be converted, not scanned, in Portable Document Format (PDF) files and, any document that cannot be converted shall be a scanned PDF file.
- (3) The date of receipt marked on a document by the Secretary is deemed to be the date on which the document was provided to, sent to or filed with the Board.
- (4) Five true paper copies of each document that is served by a party shall be filed with the Secretary within 24 hours of electronic filing, unless the Secretary specifies otherwise.
- (5) On the request of a party or an interested person filing a document with the Board, the Secretary shall provide the party or interested person with confirmation of that filing.
- (6) Parties shall bind documents filed with the Secretary as follows
 - (a) Board Staff in a blue cover;
 - (b) respondent in a green cover;
 - (c) intervener in a yellow cover; and
 - (d) statutory party in an orange cover.
- (7) Parties shall mark as CONFIDENTIAL pages containing confidential information which have been filed with the Secretary.

NOTICE OF HEARING

15. (1) Proceedings shall be initiated by issuance of a notice of hearing signed by the Secretary.
 - (2) A notice of hearing shall be served personally on the respondent and the ministers referred to in subsection 86(2) of the Act and on any other person that the Board may direct, in accordance with rule 11.
 - (3) A notice of hearing shall be accompanied by
 - (a) a statement of allegation in the case of an allegation of excessive pricing, which shall contain the material facts, allegations and order sought by Board Staff in the proceeding; or
 - (b) a notice of application in the case of an allegation of failure to file, which shall contain a statement of the relief sought by the party, the grounds for the relief and the material facts on which the party intends to rely.
16. (1) Where the Board intends to hold a hearing pursuant to the Act, the notice of hearing shall
 - (a) specify the date and time of the case management conference, which shall not be earlier than 45 days after the date of service of the notice of hearing on the respondent unless the Board otherwise directs;
 - (b) contain a statement of the purpose of the hearing;
 - (c) state that the hearing shall be public unless, on representations made by a respondent, the Board is satisfied that specific, direct and substantial harm would be caused to the respondent by the disclosure of the information or documents relating to the hearing;
 - (d) be accompanied by a schedule of events; and
 - (e) contain any other information that the Board considers appropriate.
 - (2) The secretary shall give public notice of each hearing by publication in the Canada Gazette and in any other manner that the Chairperson may direct.

RECORD OF PROCEEDING

17. Subject to section 87 and subsection 88(4) of the Act, where the Board issues a notice of hearing, the Secretary shall establish a record of the proceeding that includes
- (a) the notice of hearing;
 - (b) any document filed with the Board by a party in relation to the proceeding;
 - (c) any direction, decision, notice or order of the Board in relation to the proceeding;
 - (d) the transcript of any pre-hearing conference;
 - (e) the transcript of the hearing in relation to the proceeding; and
 - (f) any other document or information that is directed by the Board to be placed on the record of the proceeding.

RESPONSE

18. (1) A respondent who wishes to oppose an order proposed in a statement of allegation or a notice of application shall, within 20 days after being served with the notice of hearing, file with the Board and serve on all other parties a response dated and signed by the respondent.
- (2) A response shall be divided into paragraphs that are numbered consecutively and shall set out
- (a) an admission or denial of each ground or material fact set out in the statement of allegations or Notice of Application;
 - (b) the grounds on which the proposed order is opposed and the material facts on which the respondent is relying;
 - (c) the name and address of the individual on whom service of any document in the proceeding may be effected.
- (3) Where a respondent has not filed a response within the period set out in subsection (1), the Board may, if it is satisfied that a copy of the notice of hearing was served on the respondent and if it has received any evidence that it may require, make any finding and order pursuant to section 83 of the Act that it deems appropriate.

REPLY

19. (1) If Board Staff wishes to reply to the response it shall, within 20 days after being served with the response, file with the Board and serve on all other parties a reply dated and signed by Board Staff.
- (2) A reply shall be divided into paragraphs that are numbered consecutively and shall set out an admission or denial of each ground or material fact set out in the response.
- (3) If Board Staff does not file a reply, it is deemed to have denied each ground and each material fact set out in the response.

INTERVENTION

20. (1) Any person who claims an interest in the subject-matter of a proceeding may, within any period and under any conditions that the Board may specify, bring a motion to the Board for leave to intervene in the proceeding.
- (2) A motion for leave to intervene shall
- (a) set out the name and address of the proposed intervener and of any counsel representing the intervener;
 - (b) state the grounds in support of the motion;
 - (c) state the issues that the proposed intervener intends to address; and
 - (d) be filed with the Board and served on the parties in accordance with rule 10.
- (3) The parties who are served with a motion for leave to intervene may make representations with respect to the motion by filing their representations with the Board and serving a copy of the representations on the moving party referred to the subsection (1) and on every person who is, at the time of service, a party to the proceeding.

- (4) Subject to subsection 86(1) of the Act, where a person has moved to intervene in a proceeding the Board may grant or deny the intervention and impose such conditions or restrictions on the intervention as are considered to be appropriate after considering the following factors:
- (a) whether the person has an interest in the proceeding that is sufficient to warrant the intervention;
 - (b) whether the intervention will prejudice any party to the proceeding;
 - (c) whether the intervention will interfere with the fair and expeditious completion of the proceeding; and
 - (d) such other factors as are considered by the Board to be relevant to the proposed intervention.

APPEARANCE BY MINISTERS

21. (1) A Minister referred to in subsection 86(2) of the Act who intends to appear and make representations with respect to a matter before the Board shall, within 20 days after being served with the notice of hearing, file with the Board and serve on all parties a notice of appearance dated and signed by the Minister.
- (2) A notice of appearance shall be divided into paragraphs that are numbered consecutively and shall set out
- (a) a concise statement of the representations that the minister intends to make and the material facts on which the minister is relying;
 - (b) a list of the documents that may be used in evidence to support the material facts on which the minister is relying; and
 - (c) the name and address of the individual on whom service of any document intended for the minister may be effected.
- (3) A Minister referred to in subsection 86(2) of the Act who has not filed a notice of appearance within the period set out in subsection (1) need no longer be served by the parties.

CASE MANAGEMENT

22. (1) The Secretary shall convene a teleconference with counsel to be held no later than 45 days following the issuance of the notice of hearing for the purpose of
- (a) fixing the hearing schedule;
 - (b) determining the official language the parties wish to use during the proceeding;
 - (c) addressing the filing of evidence by the parties;
 - (d) considering and expediting the procedure to be followed at the hearing, including determining whether the hearing should be with or without submissions in writing;
 - (e) determining the expected duration of the hearing; and
 - (f) facilitating the exchange of information and documents and exhibits among the parties to be submitted at the hearing;

Facilitate identification of other issues which would require direction from the hearing panel.

PRE-HEARING CONFERENCE

23. (1) The parties shall appear before the Board at any date, time and place that the Board may fix, for a pre-hearing conference for the purpose of
- (a) verifying or simplifying the issues;
 - (b) receiving and considering representations referred to in subsection 86(1) of the Act and determining, in accordance with rule 24, whether the hearing shall be held in private; and
 - (c) resolving any other matter that may aid in facilitating the conduct of the hearing.

- (2) The Board may direct that matters referred to in subsection (1) be dealt with by way of written submissions to be filed in any manner that the Board determines or by way of teleconference or videoconference.
- (3) The Board may, at any time before or during a pre-hearing conference, require any party who participates in the conference to file and serve, in any manner that the Board may determine, a written submission setting out any information that the Board considers necessary to expedite the proceeding, including a concise statement of any issues of substance or procedure that the party intends to raise at the hearing.
- (4) The Board may, where necessary, postpone, suspend or adjourn and reconvene a pre-hearing conference on any conditions that the Board considers appropriate.

PUBLIC HEARING

- 24. A hearing of the Board shall be held in public unless the Board is satisfied on representations made by the person to whom the hearing relates that specific, direct and substantial harm would be caused to the person by the disclosure of information or documents at a public hearing, in which case the hearing or any part thereof may at the discretion of the Board be held in private.

SUBPOENAS

- 25. (1) In any proceeding, the Board may, on its own motion or on motion by a party, issue a subpoena for the attendance of witnesses and for the production or inspection of documents.
- (2) Where a party applies to the Board for a subpoena, the party shall provide reasons for the issuance of the subpoena and shall identify the person and documents or information to be named in the subpoena and their relevance to the proceeding.
- (3) A subpoena issued by the Board shall be signed by the Secretary and served by the Board or the party who requested the issuance of the subpoena, as the case may be, by personal service in accordance with rule 11 on the person summoned to appear before the Board, at least five days before the day fixed for the person's appearance.

MOTION FOR INTERLOCUTORY RELIEF

- 26. (1) Interlocutory matters shall be commenced by notice of motion.
- (2) A notice of motion shall
 - (a) set out the order sought, the grounds for the motion and the official language or languages that the moving party wishes to use at the hearing of the motion;
 - (b) be accompanied by an affidavit setting out all the facts on which the motion is based that do not appear on the record of hearing;
 - (c) be accompanied by a memorandum setting out a summary of the points in issue, a concise statement of submissions, a concise statement of the order sought and a list of authorities to be referred to ; and
 - (d) be signed and dated by the moving party.
- (3) The moving party shall file with the Board the notice of motion and accompanying memorandum and affidavit and shall serve a copy of each of them on each party to the hearing in accordance with rule 10.
- (4) The date fixed for the hearing of a motion shall not be earlier than two days after the date of service of the documents referred to in subsection (3), unless the Board orders otherwise.
- 27. (1) Subject to subsection (2), the testimony before the Board when it is hearing a motion on an interlocutory matter shall be by affidavit.

- (2) The Board, before or during the hearing of a motion on an interlocutory matter, may grant leave for
 - (a) a witness to give testimony orally in relation to any issues raised by the motion;
 - (b) the cross-examination of any person making an affidavit; and
- 28. (1) Where a pre-hearing conference is held pursuant to rule 23, any motion for interlocutory relief shall be made at the pre-hearing conference, unless the Board orders otherwise.
- (2) Where no pre-hearing conference is held or the pre-hearing conference has ended before the filing of a notice of motion, any motion on an interlocutory matter shall be heard by the Board at any date, time and place that is fixed by the Board.

HEARINGS

- 29. Unless otherwise directed by the Chairperson, a hearing shall be held at the principal office of the Board.
- 30. Any party other than an individual shall be represented by counsel in all proceedings.
- 31. (1) The Board may, where necessary, postpone, suspend or adjourn and reconvene a hearing.
- (2) Where the Board postpones a hearing, the Board shall give notice of the postponement to the parties as soon as possible.
- (3) Where any party who has been served with a notice of hearing in accordance with these Rules fails to attend the hearing or to be represented by counsel at the hearing, the Board may proceed in the absence of that party.

SUBMISSIONS

- 32. The Board may direct that written submissions be submitted by the parties in addition to or in lieu of oral representations and may give any directions relevant to a timeframe that it considers appropriate.

DIRECTIONS, DECISIONS AND ORDERS

- 33. The Board may reconvene a hearing to receive further evidence relating to the subject-matter of the original hearing or may rehear any matter in whole or in part before giving any direction or making any decision or order in respect thereof.
- 34. The Board may give directions and make decisions and orders in any form that it considers appropriate.
- 35. (1) Where the Board makes an order under the Act, the Board shall issue written reasons for the order and shall endeavour to issue such reasons within 180 days of the completion of the hearing on the merits.
- (2) Order of the Board under the Act shall be published in the *Canada Gazette* and may be published in any other publication that the Chairperson directs.
- 36. The effective date of any direction, decision or order of the Board is the date on which it is given or made, unless the Board specifies a later date.
- 37. The Board may
 - (a) vary or rescind any procedural direction, decision or order made or given pursuant to these Rules; and
 - (b) correct a technical irregularity in any direction, decision or order made or given by the Board.

COMING INTO FORCE

- 38. These rules come into force on the day on which they are registered.

**Published on the PMPRB Web site, May 16, 2011 for Notice and Comments
no later than June 30, 2011 – to sylvie.dupont@pmprb-cepmb.gc.ca**