



**IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4,
as amended**

**AND IN THE MATTER OF Janssen-Ortho Inc.
(the "Respondent") and the medicine "Concerta"**

NOTICE OF HEARING

TAKE NOTICE that the Patented Medicine Prices Review Board (the "Board") will hold a hearing at its offices in the Standard Life Centre, 333 Laurier Avenue West, 18th Floor, Ottawa, Ontario, commencing on December 6, 2006, at 9:30 a.m., or as soon thereafter as the hearing may be held. A pre-hearing conference has also been scheduled for September 15, 2006, at the Board's offices.

A. Purpose of the Hearing

1. The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act* (the "Act"), the Respondent is selling or has sold the medicine known as Concerta in any market in Canada at prices that, in the Board's opinion, are or were excessive and if so, what order, if any, should be made.

B. Power of Board With Respect to Excessive Prices

2. In the event that the Board finds that the Respondent is selling Concerta in any market in Canada at prices that, in the Board's opinion, are excessive, the Board may, by order, direct the Respondent to cause the maximum prices at which the Respondent sells Concerta in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

3. In addition, in the event that the Board finds that the Respondent has, while a patentee, sold Concerta in any market in Canada at prices that, in the Board's opinion were excessive, the Board may, by order, direct the Respondent to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenue determined by it to have been derived by the Respondent from the sale of Concerta:

- a) reduce the prices at which the Respondent sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

- b) reduce the prices at which the Respondent sells one other medicine to which a patented invention of the Respondent pertains in any market in Canada, to such extent and for such period as is specified in the order;
- c) pay to Her Majesty in Right of Canada an amount specified in the order.

4. In addition, in the event that the Board, having regard to the extent and duration of the sale of Concerta at excessive prices, is of the opinion that the Respondent has engaged in a policy of selling Concerta at excessive prices, the Board may, by order, in lieu of any order it may make pursuant to paragraph 3 hereof, direct the Respondent to do any one or more of the things referred to in that paragraph as will, in the Board's opinion, offset not more than twice the amount of excess revenue estimated by it to have been derived by the Respondent from the sale of Concerta at excessive prices.

C. Grounds for the Proposed Orders and the Material Facts

5. Board Staff has conducted an investigation into the price of Concerta (methylphenidate hydrochloride), a patented medicine sold in Canada by the Respondent in tablets of 18 mg, 27 mg, 36 mg and 54 mg (DINs 02247732, 02250241, 02247733 and 02247734). The material facts relied upon by Board Staff for the purpose of the Notice of Hearing and the Order sought from the Board are described in the Statement of Allegations of Board Staff dated July 14, 2006, a copy of which is attached.

D. Procedure

6. The Board will conduct this proceeding in accordance with the proposed Patented Medicine Prices Review Board Rules ("Rules"), unless otherwise provided in this Notice of Hearing or in any subsequent communication from the Board.

7. The Board will conduct the hearing in public unless the Board is satisfied on representations made by the Respondent that specific, direct and substantial harm would be caused to the Respondent 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.

8. The Board's mandate includes the requirement to complete its hearings as expeditiously as the circumstances and considerations of fairness permit. The Board has established a schedule for this proceeding, a copy of which is attached, that includes deadlines for filing and serving materials and for a public hearing. Parties are required to retain counsel and witnesses whose schedules will permit them to meet this schedule. Unless the Board orders otherwise, parties who miss filing deadlines will lose the right to file the material in question. Where practicable, the Board will consult with parties for the purpose of scheduling further events in this proceeding, but if such

consultations do not result in agreement on the scheduling of such events, the Board will establish the schedule and parties will be required to comply with it.

E. Response

9. If the Respondent wishes to oppose the proposed order, the Respondent shall, no later than August 9, 2006, file with the Board and serve upon all other parties, in accordance with section 18 of the Rules, a response dated and signed by the Respondent. Take notice that if the Respondent has not filed a response by August 9, 2006, or within such longer period as the Board may by order provide, the Board may make such findings and orders pursuant to section 83 of the Act as it deems appropriate.

F. Intervention

10. Ministers referred to in subsection 86(2) of the Act ("Ministers"), who intend to appear and make representations before the Board shall, in accordance with section 20 of the Rules, file with the Board and serve on the Respondent and all other Ministers a statement of intervention, dated and signed by the said Ministers, on or before August 9, 2006.

11. Any person other than the Respondent or Ministers who claims an interest in the subject matter of this proceeding may apply to the Board, in accordance with section 19 of the Rules, for leave to intervene in the proceeding, on or before August 22, 2006.

12. The Respondent and Ministers may make representations with respect to any application to intervene by filing their representations with the Board and serving a copy thereof on the Applicant on or before August 29, 2006.

G. Pre-hearing Conference

13. A pre-hearing conference is scheduled to commence at 9:30 a.m. on September 15, 2006, at the Board's offices, 18th Floor, for the purpose of, inter alia, the following:

- a) receiving and considering representations and deciding whether disclosure at the hearing of information or documents would cause specific, direct and substantial harm to the Respondent and, if so, determining whether the hearing or any part thereof shall be held in private and the procedure to be followed at such hearing pursuant to subsection 86(1) of the Act;
- b) determining applications for leave to intervene in the proceeding;

- c) determining the application of subsection 87(1) and related provisions of the Act and the Rules to information or documents, including the attachments referenced in the Statement of Allegations of Board Staff;
- d) determining requests for the confidentiality of any document to be filed in the proceeding;
- e) determining matters relating to the production of documents;
- f) determining motions respecting interlocutory or preliminary matters;
- g) determining whether written submissions may be made by parties in addition to or in lieu of oral evidence or representations at the hearing; and
- h) determining any other matter provided for under section 21 of the Rules.

14. Parties participating in the pre-hearing conference shall file with the Board and serve on all other parties on or before September 13, 2006, a memorandum providing:

- a) a concise statement of any issue that the party intends to raise at the pre-hearing conference together with, for each issue, an identification of the decision sought by the party and the submissions of the party in support of its position;
- b) an identification of all documents and information that the party requests to be treated as confidential or privileged in the proceeding together with the submissions of the party in support of each request;
- c) any application a party intends to make pursuant to subsection 86(1) of the Act together with the party's submissions relating thereto;
- d) any general submissions the party wishes to make respecting the conduct of the proceeding; and
- e) the official language or languages that the party wishes to use.

H. Confidentiality Requests

15. Any claim for confidentiality, made in connection with a document filed with the Board or requested by the Board or any party, shall be filed with the Board and served on all parties and accompanied by the reasons therefor, and where it is asserted that specific, direct and substantial harm would be caused to the party claiming confidentiality, the party's claim shall contain sufficient details as to explain fully the nature and extent of such harm.

16. A party claiming confidentiality in connection with a document shall indicate whether the party objects to providing an abridged version of the document to other parties and, if so, shall state the party's reasons for the objection.

17. Any party wishing the disclosure of a document filed with the Board in relation to which there has been a claim for confidentiality may file with the Board and serve on all parties within seven days of being served with the claim for confidentiality:

- a) a request for such disclosure setting out the reasons therefor; and
- b) any material in support of the reasons for public disclosure.

18. A party claiming confidentiality may file a reply with the Board and serve a copy thereof on the party requesting public disclosure within seven days of being served with the request for disclosure.

I. Preliminary Matters

19. Any preliminary matter proposed to be determined by way of an order of the Board shall be dealt with at the pre-hearing conference and shall be commenced by a notice of motion filed with the Board, in accordance with section 26 of the Rules, and served on all parties on or before August 30, 2006.

J. List of Supporting Documents

- ✓ Statement of Allegations of Board Staff dated July 14, 2006, and Attachments
- ✓ *Patent Act* (sections 79 to 103)
- ✓ *Patented Medicines Regulations, 1994*
- ✓ Patented Medicine Prices Review Board Rules (Proposed)
- ✓ Compendium of Guidelines, Policies and Procedures

DATED at Ottawa, this July 24, 2006

Original signed by

Sylvie Dupont
Secretary of the Board

All information requests and/or correspondence should be addressed to:

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AND TO:

MINISTERS

AND TO: The Honourable Maxime Bernier, P.C., M.P.
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AND TO: The Ministers responsible for health in each province and territory:

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