



**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 "Evra"**

NOTICE OF HEARING

TAKE NOTICE that the Patented Medicine Prices Review Board (the "Board") will hold a hearing at its offices in Ottawa, Ontario, commencing on May 11, 2005, at 9:30 a.m., or as soon thereafter as the hearing may be held. A pre-hearing conference has also been scheduled for February 24, 2005, at 9:30 a.m.

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 Evra in any market in Canada at a price that, in the Board's opinion, is or was 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 Evra in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the Respondent to cause the maximum price at which the Respondent sells Evra 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 Evra in any market in Canada at a price that, in the Board's opinion was 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 Evra:

- a) reduce the price 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 price 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 sales of Evra at an excessive price, is of the opinion that the Respondent has engaged in a policy of selling Evra at an excessive price, 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 Evra at an excessive price.

C. Grounds for the Proposed Orders and the Material Facts

5. Board Staff has conducted an investigation into the price of Evra (norelgestromin/ethinyl estradiol) 150 mcg / 20 mcg per day patch (DIN 02246340), a patented medicine sold in Canada by the Respondent. 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 December 1st, 2004, 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.

E. Response

8. If the Respondent wishes to oppose the proposed order, the Respondent shall, no later than January 18, 2005, 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 January 18, 2005, 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.

9. If Board Staff wishes to make submissions in reply to the response, those reply submissions must be filed not later than February 1, 2005.

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 January 18, 2005.

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 January 25, 2005.

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 February 3, 2005.

G. Pre-hearing Conference

13. A pre-hearing conference is scheduled to commence at 9:30 a.m. on February 24, 2005, 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 and serve on all other parties on or before February 22, 2005, 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 February 10, 2005.

J. List of Supporting Documents

- ✓ Statement of Allegations of Board Staff dated December 1, 2004 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 December 23, 2004

Original signed by

Sylvie Dupont
Secretary of the Board

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

The Secretary of the Patented Medicine Prices Review Board
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AND TO:

MINISTERS

AND TO: The Honourable David Emerson, P.C., M.P.
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