

Patented Medicine Prices Review Board Conseil d'examen du prix des médicaments brevetés

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

AND IN THE MATTER OF ratiopharm Inc. (the "Respondent")

NOTICE OF HEARING

TAKE NOTICE that the Patented Medicine Prices Review Board (the "Board") will hold a hearing at its offices at 333 Laurier Avenue West, 18th Floor, Ottawa, Ontario, on a date to be set by the Board.

A. Purpose of the Hearing

1. The purpose of this proceeding is to receive the evidence and argument of the Staff of the Board ("Board Staff") and the Respondent on the Application by Board Staff dated July 15, 2008 (the "Application", a copy of which is attached), for an Order pursuant to sections 81 and 88 of the *Patent Act* (the "Act") requiring the Respondent to provide the Board with the information and documents referred to in sections 80, 81 and 88 of the Act and in sections 3, 4 and 5 of the *Patented Medicines Regulations* (the "Regulations"), on the terms set out in Appendix 1 of Board Staff's Application.

B. Power of Board With Respect to Failure to File

2. In the event that the Board finds that the Respondent is a patentee subject to the jurisdiction of the Board, the Board may, by order, direct the Respondent to provide the Board with the information described in the Regulations.

C. Grounds for the Proposed Orders and the Material Facts

3. The grounds for the proposed Order sought from the Board and the material facts relied upon by Board Staff for the purpose of the Notice of Hearing are described in the attached Application.

D. <u>Procedure</u>

4. The Board has a public interest mandate to conduct its hearings as expeditiously as the paramount need for fairness permits. 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.

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5. 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.

6. While the Board attempts to consult with parties when practicable regarding the scheduling of its public hearings, parties are expected to retain counsel and witnesses who can make themselves available on the hearing days that are scheduled by the Board.

7. Parties are required to file five (5) paper copies of documents that are required to be filed in accordance with the Board's Rules. In addition, all parties are requested to provide, on compact disc(s) or by email, (1) converted (i.e., not scanned) Portable Document Format (PDF) files of any documents they create or that they acquire in electronic form; and (2) scanned PDF files of any documents that cannot be converted.

E. <u>Notice of Appearance</u>

8. Parties are to advise the Secretary of the Board, in writing (by e-mail or fax) and other parties of their legal representation no later than September 8, 2008.

F. <u>Response</u>

9. If the Respondent wishes to oppose the proposed order, the Respondent shall, no later than September 29, 2008, file with the Board and serve upon all other parties, a Response dated and signed by the Respondent. Take notice that if the Respondent has not filed a Response by September 29, 2008, or within such longer period as the Board may by order provide, the Board may make such findings and orders pursuant to sections 81 and 88 of the Act as it deems appropriate.

10. The Respondent should note that the Response should constitute a relatively general statement of the Respondent's position. The evidence of the Respondent, in support of that position, is due November 24, 2008.

G. <u>Reply</u>

11. If Board Staff wish to reply to the Response, Board Staff shall, no later than October 14, 2008, file with the Board and serve its Reply upon the Respondent and any intervenors.

H. Intervention

12. Any person 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 September 26, 2008.

13. The Respondent and Board Staff 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 October 10, 2008.

14. Parties participating in the hearing shall file and serve on all other parties on or before February 2, 2009, a memorandum providing:

- a) a concise statement of any issue that the party intends to raise at the hearing, 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 (Hearing to be public) 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.

I. <u>Confidentiality Requests</u>

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 therefore, 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 therefore; 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.

J. List of Supporting Documents

- ✓ Notice of Application of Board Staff, dated July 15, 2008
- ✓ Patent Act (sections 79 to 103)
- ✓ Patented Medicines Regulations
- ✓ Patented Medicine Prices Review Board Rules (Proposed)
- ✓ Compendium of Guidelines, Policies and Procedures
- ✓ Patentee's Guide to Reporting

DATED at Ottawa, this August 28, 2008

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 Standard Life Centre 333 Laurier Avenue West Suite 1400 Ottawa, Ontario - K1P 1C1

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RESPONDENT

TO: ratiopharm Inc. 6975 Creditview Road, Unit 5 Mississauga, Ontario L5N 8E9