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

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. (the "Respondent") and the medicine "Soliris"

NOTICE OF HEARING

TAKE NOTICE that the Patented Medicine Prices Review Board (the "Board") will hold a hearing in its offices in the Standard Life Centre, 333 Laurier Avenue West, 18th Floor, Ottawa, Ontario, on a date to be determined by the Hearing Panel no later than March 6, 2015.

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 Soliris 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 Soliris 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 Soliris 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 Soliris 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 Soliris:

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. Any other remedies Board Staff may seek and the Board may permit.

C. Grounds for the Proposed Orders and the Material Facts

5. Board Staff has conducted an investigation into the price of Soliris (Drug Identification Number (“DIN”) 02322285, a patented medicine currently sold in Canada by the Respondent. Soliris is sold in Canada in 10mg/mL. 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 January 15, 2015, a copy of which is attached.

D. Procedure

6. The Board has a public interest mandate to conduct its hearings as expeditiously as fairness permits. The Board will conduct this proceeding in accordance with the Patented Medicine Prices Review Board Rules (the "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 and evidence filed 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. Case Management Conference

8. A Case Management Conference will be held with Counsel and the Secretary of the Board on or before March 6, 2015, in accordance with section 22 of the Rules, for the purpose of

(a) fixing the hearing schedule;
(b) establishing the official language the parties wish to use during the proceeding;
(c) discussing the filing of evidence by the parties;
(d) considering the procedure to be followed and means of expediting the hearing, including determining whether written submissions will be submitted;
(e) determining the expected duration of the hearing;
(f) facilitating the exchange among the parties of information and documents to be submitted at the hearing; and
(g) identifying other issues to be resolved.

9. Witnesses are to be ready to testify throughout the days that will be set out for evidentiary matters, standing by where required in order to avoid delays or unutilized scheduled time.

10. Parties are required to file three (3) paper copies of documents. If a document is filed electronically, the three (3) paper copies must be filed with the Secretary of the Board within 48 hours of electronic filing. In addition, electronic documents must be filed as Portable Document Format (PDF) or in any format authorized by the Secretary, in accordance with section 14 of the Rules.

F. Notice of Appearance

11. Parties are to advise the Secretary of the Board, in writing (by e-mail or fax) and other parties of their legal representation.

G. Response

12. If the Respondent wishes to oppose the proposed order set out in the Statement of Allegations, the Respondent shall, no later than February 9, 2015, file with the Secretary of 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 February 9, 2015, or within such longer period as the Board may by order provide, the Board may make any finding and issue any order pursuant to section 83 of the Act as it deems appropriate.

13. The Respondent should note that the Response constitutes a relatively general statement of the Respondent’s position.

H. Reply

14. If Board Staff wishes to reply to the Response, Board Staff shall, within 20 days after being served with the response, file with the Secretary of the Board and serve its reply upon the Respondent and all other parties.

I. Appearance by Minister

15. 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 21 of the Rules, file with the Secretary of the Board and serve on all parties a notice of appearance, dated and signed by the said Ministers, on or before February 9, 2015.

J. Intervention

16. Any person, other than the Respondent and the Ministers, who claims an interest in the subject matter of this proceeding, may make a motion to the Board, in accordance with section 20 of the Rules, for leave to intervene in the proceeding.

K. Confidentiality Requests

17. Subsection 86(1) of the *Act* provides that "*A hearing under section 83 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*."

18. 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 Secretary of the Board and served on all parties and accompanied by the reasons thereof. 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.

19. 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.

K. List of Supporting Documents

- ✓ Statement of Allegations of Board Staff dated January 15, 2015 and attachments
- ✓ *Patent Act* (sections 79 to 103)
- ✓ *Patented Medicines Regulations*
- ✓ Patented Medicine Prices Review Board Rules of Practice and Procedure
- ✓ Compendium of Policies, Guidelines and Procedures

DATED at Ottawa, this January 20, 2015

Original signed by

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Guillaume Couillard
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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TO

RESPONDENT

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MINISTERS

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

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