

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

AND IN THE MATTER OF Baxalta Canada Corporation (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 determined by the Hearing Panel.

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 Notice of Application by Board Staff dated March 1, 2016 (the "Application", a copy of which is attached), for an Order pursuant to section 81 of the *Patent Act* (the "*Act*") requiring the Respondent to provide the Board with the information and documents referred to in section 80 of the *Act* and in sections 3 and 4 of the *Patented Medicines Regulations* (the "*Regulations*"), on the terms set out in the 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 *Patented Medicine Prices Review Board Rules of Practice and Procedure* (the "*Rules*"), unless otherwise provided in this Notice of Hearing or in any subsequent communication from the Board.
- 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.

E. <u>Case Management Conference</u>

- 6. A Case Management Conference will be held with Counsel and the Secretary of the Board (the "Secretary") on May 6, 2016, 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.
- 7. 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.
- 8. Parties are required to file four (4) paper copies of documents. If a document is filed electronically, the four (4) paper copies must be filed with the Secretary 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

9. Parties are to advise the Secretary, in writing (by e-mail or fax) and other parties of their legal representation no later than May 2, 2016.

G. Response

- 10. If the Respondent wishes to oppose the proposed order set out in the Application, the Respondent shall, no later than April 11, 2016, 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 April 11, 2016, or within such longer period as the Board may by order provide, the Board may make such findings and orders pursuant to section 81 of the *Act* as it deems appropriate.
- 11. The Respondent should note that the Response should constitute a relatively general statement of the Respondent's position.

H. Reply

12. If Board Staff wishes to reply to the Response, Board Staff shall, no later than 20 days after being served with the response, file with the Board and serve its reply upon the Respondent and all other parties.

I. Intervention

13. Any person, other than the Respondent, who claims an interest in the subject matter of this proceeding, may make a motion to the Board by May 2nd, 2016, in accordance with section 20 of the *Rules*, for leave to intervene in the proceeding.

J. <u>Confidentiality Requests</u>

- 14. 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 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.
- 15. 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.
- 16. 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.

17. 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.

K. <u>List of Supporting Documents</u>

- ✓ Notice of Application of Board Staff, dated March 1st, 2016
- ✓ 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 March 22, 2016

Guillaume Couillard Secretary of the Board All information requests and/or correspondence should be addressed to:

Secretary of the Board Patented Medicine Prices Review Board Standard Life Centre 333 Laurier Avenue West Suite 1400 Ottawa, Ontario K1P 1C1

Toll-free number: 1-877-861-2350 Direct line: (613) 954-8299 Fax: (613) 952-7626

E-mail: guillaume.couillard@pmprb-cepmb.gc.ca

RESPONDENT

TO: Larysa Ricketts
Associate Director, Regulatory Affairs and Quality Assurance
Baxalta Canada Corporation
7125 Mississauga Rd.
Mississauga, Ontario
L5N 0C2