



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

**AND IN THE MATTER OF
Teva Canada Innovation G.P.-S.E.N.C. (the "Respondent")
and the medicine "Copaxone"**

REDETERMINATION 2013

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, Ottawa, Ontario, on October 9 and 10, 2013.

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, formerly Teva Neuroscience G.P.-S.E.N.C, is selling or has sold the medicine known as Copaxone 20mg/1.0 mL syringe (Drug Identification Number ("DIN") 02245619) 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 Copaxone 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 Copaxone 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 Copaxone 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 Copaxone:

- 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.

C. Procedure

- 4. The Hearing Panel has determined that it will base the second redetermination of the matter on the existing evidentiary record and up-to-date price information.
- 5. 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.
- 6. 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.

D. Statement of Allegations

- 7. As per the Board's instructions of June 11, 2013, Board Staff has filed an Amended Statement of Allegations dated June 24, 2013.

E. Response

- 8. If the Respondent wishes to file an amended Response, it shall do so no later than **July 19, 2013**, with the Secretary of the Board and serve the amended Response upon Board Staff, in accordance with section 18 of the Rules.

F. Reply

- 9. If Board Staff wishes to file an amended Reply, Board Staff shall do so no later than **August 9, 2013** and serve its amended Reply upon the Respondent, in accordance with section 19 of the Rules.

G. Case Management Conference

- 10. A Case Management Conference will be held with Counsel and the Secretary of the Board on **July 24, 2013**, in accordance with section 22 of the Rules.

H. List of Supporting Documents

- ✓ Amended Statement of Allegations of Board Staff dated June 24, 2013, and attachments
- ✓ *Patent Act* (sections 79 to 103)
- ✓ *Patented Medicines Regulations*
- ✓ Patented Medicine Prices Review Board Rules
- ✓ Compendium of Guidelines, Policies and Procedures

DATED at Ottawa, this June 28, 2013

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

Toll-free number: 1-877-861-2350
Direct line: (613) 954-8299
Fax: (613) 952-7626
E-mail: sylvie.dupont@pmprb-cepmb.gc.ca

TO: **RESPONDENT**

Mr. Jean Paul Rittman
VP & General Manager
Teva Canada Innovation
1080 Côte du Beaver Hall, Suite 1200
Montréal, Quebec
H2Z 1S8