



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

**AND IN THE MATTER OF sanofi-aventis Canada Inc.
(the "Respondent") and the medicine "Penlac Nail Lacquer"**

NOTICE OF HEARING

TAKE NOTICE that the Patented Medicine Prices Review Board (the "Board") will hold a hearing at its offices in the Standard Life Centre, 333 Laurier Avenue West, 18th Floor, Ottawa, Ontario, commencing on July 23, 2007 at 9:30 a.m., or as soon thereafter as the hearing may be held. A pre-hearing conference has also been scheduled for June 6, 2007, 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 Penlac Nail Lacquer ("Penlac") 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 Penlac 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 Penlac 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 Penlac 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 Penlac:

- 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 Penlac at an excessive price, is of the opinion that the Respondent has engaged in a policy of selling Penlac 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 Penlac 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 Penlac Nail Lacquer (Ciclopirox Topical Solution, 8 % w/w) (Drug Identification Number ("DIN") 02250535), a patented medicine currently sold in Canada by the Respondent. Penlac is sold in Canada in 6 gram glass bottles containing 6.6ml of solution. 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 March 2, 2007, a copy of which is attached.

D. Procedure

6. 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.**

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.

8. 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.

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

10. Parties are required to file six (6) 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, converted (i.e., not scanned) Portable Document Format (PDF) files of any documents they create or that they acquire in electronic form and scanned PDF files of any documents that cannot be converted.

E. 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 no later than April 2, 2007.

F. Response

12. If the Respondent wishes to oppose the proposed order, the Respondent shall, no later than April 16, 2007, 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 April 16, 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.

13. The Respondent should note that the Response constitutes a relatively general statement of the Respondent's position. The evidence of the Respondent, in support of that position, is due July 4, 2007 as per the Schedule of Events.

G. Reply

14. If Board Staff wishes to reply to the Response, Board Staff shall, no later than May 7, file with the Board and serve its reply upon the Respondent and all other parties.

H. Intervention

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 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 April 16, 2007.

16. 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 April 23, 2007.

17. The Respondent, Ministers 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 May 2, 2007.

I. Pre-hearing Conference

18. A pre-hearing conference is scheduled to commence on June 6, 2007, at 9:30 a.m., 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 other 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.

19. Parties participating in the pre-hearing conference shall file and serve on all other parties on or before June 1, 2007, 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.

J. Confidentiality Requests

20. 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.

21. 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.

22. 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.

23. 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. Preliminary Matters

24. 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 May 11, 2007.

L. List of Supporting Documents

- ✓ Statement of Allegations of Board Staff dated March 2, 2007 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 March 26, 2007



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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RESPONDENT

TO: sanofi-aventis Canada Inc.
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AND TO:

MINISTERS

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

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