IN THE MATTER OF the *Patent Act* R.S. 1985, c. P-4, as amended by R.S. 1985, c. 33 (3rd Supp.), and as further amended by S.C. 1993, c. 2

AND IN THE MATTER OF Hoechst Marion Roussel Canada Inc. (Respondent) and the medicine "Nicoderm"

ABRIDGED 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, 18th Floor, Hearing Room 1, 333 Laurier Avenue West, Ottawa, Ontario, commencing on Monday, July 5, 1999 at 9:30 a.m., or as soon thereafter as the hearing may be held. A pre-hearing conference has also been scheduled for Friday, May 28,1999 at the Board's offices, Hearing Room 2, 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, while a patentee, sold the medicine known as Nicoderm 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. Proposed Order

2. In the event that the Board finds that the Respondent is selling or has, while a patentee, sold Nicoderm in any market in Canada at a price that, in the Board's opinion, is or was excessive, the Board may, by order, direct the Respondent to cause the maximum price at which the Respondent sells Nicoderm 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 Nicoderm in any market in Canada at a price that, in the Board's opinion is or 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 Nicoderm:

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; and/or

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 sale of Nicoderm at an excessive price, is of the opinion that the Respondent engaged in a policy of selling Nicoderm at an excessive price, the Board may, by order, in lieu of any of the orders proposed to be made 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 Nicoderm at an excessive price.

C. Grounds for the Proposed Orders and the Material Facts

The Staff of the Board have investigated the circumstances in which Nicoderm has been sold in Canada and allege as follows:

5. The Respondent sells a medicine in Canada under the brand name Nicoderm and has been doing so since July 1992. Nicoderm is sold pursuant to a Notice of Compliance issued by Health and Welfare Canada on May 12, 1992 and is available in strengths of 7 mg (DIN 02093111), 14 mg (DIN 02093138) and 21 mg (DIN 02093146).

6. Nicoderm is a transdermal nicotine patch. It delivers nicotine, the active component of tobacco smoke, through the skin via a patch into the circulation system continuously over 24 hours. It is indicated as an aid for smoking cessation for the partial relief of nicotine withdrawal symptoms.

7. Nicoderm is manufactured by Alza Corporation of the United States. The Respondent has exclusive rights to sell Nicoderm in Canada.

8. On May 6, 1998, in accordance with the requirements of the *Patented Medicines Regulations* (the "*Regulations*"), the Respondent submitted to the Board a Form 1 entitled "Medicine Identification Sheet" for Nicoderm reporting Canadian Patent No. 1,338,700 (“ ‘700 patent”) as a patent pertaining to Nicoderm and also reporting the Respondent as a person holding a licence other than a licence referred to under section 41 of the *Act* as it stood prior to the 1993 amendments to the *Act*.

9. The ‘700 patent pertains to a nicotine transdermal patch for the delivery of nicotine through the skin of a user. It was granted to Alza Corporation, U.S.A. on November 12, 1996 and will expire on November 12, 2013.

10. Alza Corporation holds several other Canadian patents and has applied for patents which pertain to nicotine patches. Among these are:

a) Canadian Patent No. 1,331,340: a method for prolonging the shelf life of a nicotine transdermal patch. It was granted to Alza Corporation, U.S.A. on August 9, 1994 and will expire on August 9, 2011 (" ‘340 patent").

b) Canadian Patent No. 1,333, 689: a nicotine transdermal patch with a method of controlling the rate of release of nicotine. It was granted to Alza Corporation, U.S.A. on December 27, 1994 and will expire on December 27, 2011 (" ‘689 patent").

c) Canadian Patent Application No. 2,032,446: a packaging material for a nicotine transdermal patch. It was filed by Alza Corporation, U.S.A. on December 17, 1990 and was laid open on June 22, 1991. In the event that the patent issues, it will expire on December 17, 2010 (" ‘446 application").

d) Canadian Patent Application No. 2,040,352: a transdermal patch for the delivery of nicotine through the skin of a user. It was filed by Alza Corporation, U.S.A. on April 12, 1991 and was laid open on October 17, 1991. In the event that the patent issues, it will expire on April 12, 2011 (" ‘352 application").

11. There are currently two other nicotine patches on the Canadian market: Habitrol and Nicotrol. They also deliver nicotine transdermally via a patch into the systemic circulation continuously and are indicated as a temporary aid to facilitate smoking cessation.

12. Habitrol is sold in Canada by Novartis Pharma Canada Inc. It was approved for sale in Canada the same day as Nicoderm and was introduced on the market in September 1992.

13. For purposes of the Guidelines, and as recommended by the Human Drug Advisory Panel (HDAP), Habitrol is used as the comparable medicine for price review purposes as it is the most similar to Nicoderm.

14. Based on the prices of Habitrol as set out in the VCU approved by the Board on October 19, 1994, the prices of Nicoderm are estimated to have exceeded the Guidelines by amounts ranging between **[severed]** and **[severed]** during the period from July 1, 1994 to December 31, 1997. As a result, the Respondent has received cumulative excess revenues estimated to be $2,353,014 over that period.

15. As of June 1, 1998, Health Canada approved the switch of these products from prescription to OTC status.

16. According to information filed with the Board by the Respondent, the average prices for two strengths of Nicoderm were within the Guidelines in 1998, but the price of the 7 mg patch exceeded the Guidelines by **[severed]**.

17. The information available is that the price of Nicoderm also exceeded the Guidelines during the period prior to August 9, 1994 when the patent applications referred to in paragraph 10 were open to public inspection.

18. By letter dated September 21, 1998, Board staff advised the Respondent that the price of Nicoderm exceeded the Guidelines. On March 9, 1999, the Respondent submitted a VCU that was not accepted by the Chairperson of the Board.

D. Procedure

19. The Board will conduct this proceeding in accordance with the proposed Patented Medicine Prices Review Board Rules respecting the Practice and Procedure ("Rules"), unless otherwise provided in this Notice of Hearing or in any subsequent communication from the Board.

20. The Board will conduct the hearing in public unless, and only to the extent the Board is satisfied that specific, direct and substantial harm would be caused to the Respondent by the disclosure of information or documents at the hearing.

E. Response

21. If the Respondent wishes to oppose the proposed order, the Respondent shall, no later than May 5, 1999, 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 May 5, 1999, 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.

Intervention

22. 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 19 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 May 5, 1999.

23. 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 18 of the Rules, for leave to intervene in the proceeding.

24. An application for leave to intervene shall be filed with the Board, shall state the reasons in support of the application and shall be served on the Respondent and Ministers on or before May 12, 1999.

25. The Respondent and Ministers 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 19, 1999.

Pre-hearing Conference

26. A pre-hearing conference is scheduled to commence at 9:30 a.m. on May 28, 1999, at the Board's offices, hearing room 2, 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 matters relating to the disclosure of information or documents made privileged by that subsection 87(1) of the *Act*;

d) determining requests for the confidentiality of any 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 20 of the Rules.

27. Parties participating in the pre-hearing conference shall file and serve on all other parties on or before May 21, 1999, 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 which 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.

Confidentiality Requests

28. Any claim for confidentiality, made in connection with a document to be 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 therefor, and where it is asserted that specific, direct and substantial harm would be caused to the party claiming onfidentiality, the party's claim shall contain sufficient details as to explain fully the nature and extent of such harm.

29. 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.

30. 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 therefor; and

b) any material in support of the reasons for public disclosure.

31. 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.

Preliminary Matters

32. Any preliminary matter proposed to be determined before the pre-hearing conference shall be commenced by a notice of motion filed with the Board, in accordance with section 25 of the Rules, and served on the Respondents and on all Ministers on or before May 20, 1999.

F. List of Supporting Documents

1. *Patent Act*
2. *Patented Medicines Regulations*, 1994
3. Patented Medicine Prices Review Board Rules (Proposed), April 14, 1999
4. Compendium of Guidelines, Policies and Procedures
5. Habitrol Voluntary Compliance Undertaking
6*****. Calculation of Excess Revenues for Nicoderm **[severed]**
7. Canadian Patent No. 1,331,340
8. Canadian Patent No. 1,333,689
9. Canadian Patent No. 1,338,700
10. Canadian Patent Application No. 2,032,446
11. Canadian Patent Application No. 2,040,352
12. Hoechst Marion Roussel facsimile of May 6, 1998 - Form 1, Medicine Identification Sheet

***** Protected - s.87(1), *Patent Act*

DATED at Ottawa, this April 20, 1999

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Sylvie Dupont-Kirby
Secretary of the Board

All information requests and or correspondence should be addressed to:

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