Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

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

AND IN THE MATTER OF Schering Canada Inc. (the "Respondent") and the medicine "Remicade"

NOTICE OF HEARING

TAKE NOTICE that the Patented Medicine Prices Review Boaòd (the "Board") will hold a hearing at its offices in the Standard Life Centre, 18th Floor, 333 Laurier Avenue West, Ottawa, Ontario, commencing on April 7, 2003 at 9:30 a.m., or as soon thereafter as the hearing may be held. A pre-hearing conference has also been scheduled for February 12, 2003, at 9:30 a.m., at the Board=s offices, 18th Floor, Hearing Room 1.

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 Remicade 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. Order

2. In the event that the Board finds that the Respondent is selling or has, while a patentee, sold Remicade 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 Remicade 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 Remicade 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 Remicade:

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 sale of Remicade at an excessive price, is of the opinion that the Respondent engaged in a policy of selling Remicade at an excessive price, the Board may, by order, in lieu of any of the orders that could 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 Remicade at an excessive price.

C. Grounds for the Orders and the Material Facts

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

5. The Respondent sells a medicine in Canada under the brand name Remicade and has been doing so since June 2001. Remicade is sold pursuant to a Notice of Compliance issued by Health Canada on June 6, 2001 for the treatment of Crohn's disease and a Notice of Compliance issued on September 27, 2001 for the treatment of rheumatoid arthritis (DIN 02244016).

6. Remicade is a genetically-engineered sterile lyophilized concentrate for intravenous injection. This selective immunomodulating agent is made from a specially developed antibody (termed a monoclonal antibody) called cA2, which acts against tumor necrosis factor (TNF alpha). It is supplied in vials which contain 100 mg of the active ingredient.

7. Remicade is manufactured by Centocor Inc. USA. The Respondent has exclusive rights to sell Remicade in Canada.

8. On August 3, 2001, in accordance with the requirements of the *Patented Medicines Regulations, 1994* (the "Regulations"), the Respondent, as the reporting patentee, submitted to the Board a Form 1 entitled "Medicine Identification Sheet" for Remicade reporting Canadian Patent 2,106,299.

9. In accordance with practice, Remicade was referred to the Board's Human Drug Advisory Panel ("HDAP").

10. As Remicade has been approved for more than one indication, it was necessary

to first determine the primary approved indication for purposes of the Board's Excessive Price Guidelines. The Compendium of Guidelines, Policies and Procedures (the "Guidelines") provides the following guidance with respect to the determination of primary indication:

> New DINs with multiple approved indications (that are new chemical entities or new, non-comparable dosage forms of existing chemical entities) will be categorized based ***on the approved indication for which the medicine offers the greatest therapeutic advantage in relation to alternative therapies for the same indication in a significant patient population***. This would exclude rare medical conditions or diseases (i.e. low incidence and prevalence in Canada). [emphasis added]
>
> This approved indication will be considered the "primary use" indication for the purposes of selecting comparable medicines. (*ref. Scientific Review Procedures, paragraph 4.3)*

11. With respect to the approved indications for use in rheumatoid arthritis and Crohn's disease, the HDAP concluded that Remicade offers the greater therapeutic advantage relative to existing therapies for its use in Crohn's disease. As a result, and in conformance with the Guidelines, it concluded that Remicade should be categorized for price review purposes with respect to its indicated use in the treatment of Crohn's disease and that it be assigned a category 2 as its clinical benefit in the treatment of Crohn's disease is a major therapeutic breakthrough.

12. The Guidelines further provide that:

> The introductory price of a Category 2 new drug product will be presumed to be excessive if it exceeds the prices of all comparable drug products, based on a Therapeutic Class Comparison Test, and the median of the international prices identified in an international Price Comparison Test. (*ref. Excessive Price Guidelines, paragraph 8.4*)

13. The HDAP did not identify any appropriate comparators for inclusion in a Therapeutic Class Comparison as there are no other approved medicines that are used in the same way as Remicade in the treatment of Crohn's disease. In light of the HDAP's conclusion, the price of Remicade was compared to the median of the international prices identified in an International Price Comparison ("IPC") Test. The IPC Test is based on the prices in the seven countries listed in the Regulations.

14. Based on the price information filed with the Board by the Respondent, the average price for Remicade is estimated to have exceeded the maximum non-excessive ("MNE") price as calculated by the Guidelines with reference to the median international price for Remicade in 2001 and continues to exceed the MNE price in 2002 by more than 20%. As a result, from its introduction for sale in Canada in June 2001 to the end of June 2002, the Respondent is estimated to have accumulated revenues in excess of the Guidelines of more than $9 million from the sale of Remicade.

D. Procedure

15. The Board will conduct this proceeding in accordance with the proposed Patented Medicine Prices Review Board Rules (the "Rules"), unless otherwise provided in this Notice of Hearing or in any subsequent communication from the Board. For the purposes of establishing the schedule for this proceeding, the Board has, in accordance with subsection 9(1) of the Rules, extended certain of the periods otherwise provided by the Rules to accommodate the occurrence of the holiday season between the issuance of this Notice and certain of the steps in the proceeding.

16. 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

17. If the Respondent wishes to dispute the allegations that have been made by Board Staff, the Respondent shall, no later than **January 13, 2003**, 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 January 13, 2003, 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.

F. Intervention

18. 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 **January 13, 2003**.

19. 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 **January 7, 2003**.

20. 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 **January 30, 2003**.

G. Pre-hearing Conference

21. A pre-hearing conference is scheduled to commence at 9:30 a.m. on February 12, 2003, at the Boaòd's offices, 18th floor, Hearing Room 1, 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 pursuant to 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 21 of the Rules.

22. Parties participating in the pre-hearing conference shall file and serve on all other parties on or before **February 5, 2003**, 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.

H. Confidentiality Requests

25. 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 confidentiality, the party's claim shall contain sufficient details as to explain fully the nature and extent of such harm.

26. 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.

27. 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.

28. 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.

I. Preliminary Matters

29. Any preliminary matter proposed to be determined in advance of the pre-hearing conference shall be commenced by a notice of motion filed with the Board, in accordance with section 26 of the Rules, and served on the Respondent and on all Ministers on or before **January 22, 2003**.

J. List of Supporting Documents

1) *Patent Act*
2) *Patented Medicines Regulations, 1994*
3) Patented Medicine Prices Review Board Rules (Proposed)
4) Compendium of Guidelines, Policies and Procedures

DATED at Ottawa, this December 16, 2002.

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Sylvie Dupont
Secretary of the Board

All information requests and or correspondence should be addressed to:

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AND TO:

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