

Decision: PMPRB-02-D2-REMICADE

**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”**

ORDER

Pursuant to the provisions of section 83 of the *Patent Act*, the Patented Medicine Prices Review Board (the “Board”) issued a Notice of Hearing on December 16, 2002, pertaining to allegations of the Board Staff that the medicine Remicade had been, and was being, sold by Schering Canada Inc. (“Schering”) in Canada at prices that exceeded the prices calculated in accordance with the Board’s Price Guidelines (the “Guidelines”). Schering responded to the allegations in the Notice of Hearing and Board Staff replied to that response. A pre-hearing conference was held, and the matter was set down for hearing commencing April 22, 2003.

On March 18, 2003, Schering filed a Voluntary Compliance Undertaking (“VCU”) by which Schering proposed to resolve all issues raised by the Notice of Hearing. Schering and Board Staff made a joint submission supporting the VCU and also presented their respective views on the merits of the positions and the accommodations that had been made in order to arrive at the VCU.

The Board has reviewed the VCU and the Joint Submission. The Board agrees with the parties that the VCU will provide for a reduction in the price of Remicade that brings the price within the Guidelines as determined by the median international price, and that the payment to the Crown of excess revenues in the amount of \$7,792,650 reflects a reasonable resolution of the issues arising out of the pricing of Remicade up to March 31, 2003.

Accordingly, the Board has decided to approve the Terms of the Undertaking in the VCU. By Order of this Board, which Order shall be entered as an order of the Federal Court of Canada:

1. The average transaction price of Remicade, as that price is determined in accordance with the Guidelines, shall be reduced so that it does not exceed \$909.5094 per vial for the period from April 1 to December 31, of 2003;

2. The maximum non-excessive price of Remicade in the years following 2003, as that price is determined in accordance with the Guidelines, shall be based on a 2003 benchmark price of \$909.5094 per vial;
3. Schering shall make a payment to Her Majesty the Queen in Right of Canada in the amount of \$7,792,650 within 30 days of this Order, in full satisfaction of its obligations to comply with and liability associated with the *Patent Act* and the Guidelines for the period from the date of the commencement of sales of Remicade to March 31, 2003; and
4. Schering shall:
 - (i) advise its existing customers of the price reduction established by the VCU and this Order and provide the Board with proof of such notifications forthwith after they have been delivered;
 - (ii) make a cheque in the amount of \$7,792,650 to be payable to the Receiver General of Canada and forward it to the Secretary of the Board no later than April 30, 2003.
5. The proceeding that was commenced by the issuance of the Notice of Hearing is hereby concluded.

Board Members: Robert G. Elgie
Réal Sureau
Thomas (Tim) Armstrong
Anthony Boardman
Ingrid Sketris

Board Counsel: Gordon Cameron

Sylvie Dupont
Secretary of the Board

March 31, 2003