July 16, 2008

Decision: PMPRB-06-D4-ADDERALL XR - Admissibility of Evidence

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

AND IN THE MATTER OF Shire BioChem Inc. (the "Respondent") and the medicine "Adderall XR"

This is the decision of the Adderall XR hearing panel (the "Panel") on a motion brought by Shire BioChem Inc. ("Shire") to introduce further evidence in this proceeding and to have the Panel establish the price for Dexedrine 5 mg tablets ("Dexedrine") for the purposes of determining the Maximum Non-Excessive ("MNE") price for Adderall XR in accordance with the decision of the Panel on the merits of this proceeding dated April 10, 2008 (the "Decision").

Admissibility of Evidence

1. The Panel believes generally in the principle that parties should lead all of their evidence during the evidentiary portion of a pricing hearing before the Board. On the other hand, the Board also believes that it has greater latitude to allow parties to present evidence, after they have closed their cases, than would be the case in civil proceedings where there has been a final order.

2. The Board accepts the submissions of Board Staff that the domestic price of Dexedrine and the reasonableness of the comparison of that price to the Federal Supply Schedule ("FSS") price in the U.S. were in issue in the main evidentiary portion of this proceeding. It would have been preferable to the Panel if the evidence, now adduced by Shire on this motion, had been adduced during that main evidentiary phase. Board Staff and panels of the Board should be able to presume that a patentee in a pricing hearing is putting forward all of the evidence on which it relies on an issue identified during the course of the proceeding.

3. That said, this is a unique case. The decision of the Panel on the merits of the pricing proceeding in the Decision could not have been predicted by the parties. Also, given the very late stage, during the proceeding, at which the domestic price of Dexedrine became material, the Panel would not consider it appropriate to hold Shire to a strict standard with respect to the introduction of fresh evidence.

4. It should be noted that, in the decision, the Board specifically seized itself of the proceeding until the final order was issued, for the purposes of the receipt of further evidence and argument, for the very reason that the substance of the decision and its implications could not have been predicted by either party.

5. Accordingly, the Board will admit the evidence tendered by both Shire and Board Staff regarding the price of Dexedrine and the relevance of that price to the appropriate MNE of Adderall XR.

The characterization of off-patent medicines as being excessively priced

6. The Panel accepts that it is appropriate for Board Staff, in the course of its investigations, to exclude, from a Domestic Therapeutic Class Comparison ("DTCC"), those patented medicines sold in Canada that would be presumed by the Guidelines to be excessively priced. In a regime where the Board is setting the MNE price of a medicine by reference to the prices of comparable medicines, it would not be logical to include, among those comparators, patented medicines that are themselves excessively priced.

7. However, the Panel believes that, in the *Patent Act* (the "Act") and the Excessive Price Guidelines, the concept of an excessive price is based on the premise that a medicine to which a patent pertains could be priced at excessive levels, given the potential market power associated with a patent. While the Board does not inquire into whether a pertaining patent actually confers market power on the patentee, this does not change the premise on which the concept is based.

8. Needless to say, that premise does not apply to a medicine to which no patent pertains. The Panel does not purport to preclude the possibility that an unpatented medicine could be excluded from a DTCC based on its price. However, for such a finding to be made, there would have to be evidence of an absence of competition or other market conditions on which the Board could conclude that the medicine should be thus excluded. In this case, the evidence is to the contrary.

Conclusion

9. Accordingly, given that:

   (i) Dexedrine is identified in the Decision as belonging in the DTCC to be used in setting the MNE of Adderall XR; and

   (ii) the Panel sees no reason not to use the highest domestic price of Dexedrine 5 mg tablets (on the evidence in this proceeding) in that DTCC;

the Panel considers it appropriate for the Saskatchewan formulary price of Dexedrine 5mg tablets to be used in the calculation of the MNE of Adderall XR.

10. The Panel requests that the parties provide a draft order incorporating this conclusion by August 21, 2008.

Board Members: Dr. Brien G. Benoit
Thomas (Tim) Armstrong

Board Counsel: Gordon Cameron

Appearances

For Board Staff: Barbara MacIsaac, Counsel
Benjamin Mills, Counsel

For the Respondent:
Malcolm Ruby, Counsel
Allan West, Counsel

For the Interveners: Martin Mason, Counsel
Graham Ragan, Counsel

Original signed by

Sylvie Dupont
Secretary of the Board