



May 5, 2010

Decision: PMPRB-06-D5-Adderall XR
- Supplementary Board Order

**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"**

SUPPLEMENTARY ORDER

WHEREAS, pursuant to the provisions of section 83 of the *Patent Act*, R.S.C. 1985, c. P-4 (the "Act"), the Patented Medicine Prices Review Board (the "Board") issued a Notice of Hearing on January 18, 2006 to determine whether Shire BioChem Inc., now known as Shire Canada, ("Shire") is selling, or has sold, the medicine known as Adderall XR in any market in Canada at a price that is or was excessive and, if so, what order, if any should be made;

WHEREAS upon conducting its hearing and for the Reasons of the Board provided in *PMPRB-06-D3-Adderall XR – Merits*, issued on April 10, 2008, and *PMPRB-06-D4-Adderall XR – Admissibility of Evidence*, issued on July 16, 2008, the Board issued an Order dated August 27, 2008 ("Original Order");

WHEREAS Paragraph 5 of the Original Order provided:

5. The MNE prices for each of the 5, 10, 15, 20, 25 and 30 mg strengths of Adderall XR for the year 2009, and any subsequent year, are to be calculated on an annual basis in accordance with the CPI-Adjustment Methodology set out in Schedule 4 of the Patented Medicine Prices Review Board's Compendium of Guidelines, Policies and Procedures (the "Guidelines");

WHEREAS Paragraph 7 (b) of the Original Order provided:

7. In accordance with subsection 83(2) of the Act, Shire shall offset the amount of excess revenues estimated to have been derived by Shire from the sale of Adderall XR at excessive prices from September 12, 2002 until the date on which the price reductions referred to in paragraph (6) above come into effect as follows:

(b) With respect to the period from January 1, 2008 to the date on which the price reductions referred to in paragraph (6) come into effect, Shire shall pay to Her Majesty in Right of Canada a further amount equal to the amount of the excess revenues estimated by the Board to have been derived by Shire from the sale of Adderall XR in its 5, 10, 15, 20, 25 and 30 mg strengths at excessive prices and make the payment within 30 days of receipt of a notification from the Board of its estimate of excess revenues based on the information filed with the Board in response to paragraph (8) below;

WHEREAS Shire has requested that the amount that it owes for the period from January, 2008 to September 12, 2008, when the price reductions came into effect for the 5, 10, 15 and 20 mg strengths, be reduced to reflect credits that it provided for stock of said strengths sold before September 12, 2008, at the price which was found to be excessive, even though these credits were given after September 12, 2008;

WHEREAS Board Staff has advised the Board that it agrees with this request, and has calculated the amount of excess revenue owing, net of the credits referred to above, for the period January 1, 2008 to December 31, 2008 with respect to the 5, 10, 15 and 20 mg strengths to be \$539,966.80;

WHEREAS Board Staff and Shire have further agreed that for the period, January 1, 2009 to December 31, 2009, solely for the purpose of calculating excess revenues, to use the 2009 Forecast Consumer Price Index ("CPI") rather than the 2009 Actual CPI, resulting in excess revenue for the period January 1, 2009 to December 31, 2009 for the 10 and 15 mg strengths of \$4,964.42;

WHEREAS Board Staff and Shire have further agreed that for the periods January 1, 2009 to December 31, 2009 and January 1, 2010 to December 10, 2010, the MNE (N-NEAP) for the 5, 10, 15, 20, 25 and 30 mg strengths of Adderall XR shall be as follows:

2009	Strength	MNE
	5 mg	\$1.9342
	10 mg	\$2.1981
	15 mg	\$2.4620
	20 mg	\$2.7260
	25 mg	\$2.9899
	30 mg	\$3.2539

2010	Strength	N-NEAP
	5 mg	\$1.9811
	10 mg	\$2.2515
	15 mg	\$2.5219
	20 mg	\$2.7923
	25 mg	\$3.0625
	30 mg	\$3.3329

WHEREAS Board Staff recommends to the Board that the Original Order be modified by the issuance of a Supplementary Order reflecting the agreement between Shire and Board Staff as outlined above;

AND WHEREAS the Board agrees, on an exceptional basis, to accept the request of Shire and the recommendations of Board Staff;

THEREFORE IT IS HEREBY ORDERED:

1. With respect to the period from January 1, 2008 to December 31, 2008, Shire shall pay to Her Majesty in Right of Canada the sum of \$539,966.80 in respect of the excess revenues calculated by Board Staff to have been derived by Shire from the sale of Adderall XR in its 5, 10, 15 and 20 mg strengths at excessive prices and make the payment within 30 days of the date of this Supplementary Order;
2. With respect to the period from January 1, 2009 to December 31, 2009, excess revenues shall be calculated using Forecast Consumer Price index ("CPI") rather than the 2009 Actual CPI, and Shire shall pay to Her Majesty in Right of Canada the sum of \$4,964.42 in respect of excess revenues calculated by Board Staff to have been derived by Shire from the sale of Adderall XR in its 10 and 20 mg strengths at excessive prices and make the payment within 30 days of the date of this Supplementary Order;
3. For the periods, January 1, 2009 to December 31, 2009 and January 1, 2010 to December 10, 2010 the MNE (N-NEAP) for the 5, 10, 15, 20, 25 and 30 mg strengths of Adderall XR shall be as follows:

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

Board counsel: Gordon Cameron



Sylvie Dupont
Secretary of the Board