Conseil d'examen du prix des médicaments brevetés

October 17, 2011

Decision: PMPRB-08-D3-ratio-Salbutamol HFA

- Merits

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

AND IN THE MATTER OF ratiopharm Inc. ("ratiopharm") and the medicine "ratio-Salbutamol HFA"

ORDER

Pursuant to the provisions of section 86 of the *Patent Act*, the Patented Medicine Prices Review Board (the "Board") issued a Notice of Hearing on July 18, 2008 to determine whether ratiopharm is selling or has sold the patented medicine ratio-Salbutamol HFA in any market in Canada at a price that is or was excessive and, if so, what order, if any, should be made.

Upon conducting its hearing, the Board issued Reasons on May 27, 2011. On consent, the date for Board Staff to submit a draft order to implement the decision of the Board set out in the Reasons was extended to September 9, 2011.

Upon reviewing the submissions in support of the draft order, including affidavits by Ginette Tognet and Daniel Youtoff, sworn September 9, 2011 and September 8, 2011, respectively, the Board, pursuant to section 83 of the *Patent Act* orders as follows:

a) The MNE prices of ratio-Salbutamol HFA in Canada for the reporting periods from July 1, 2002 to June 30, 2010 inclusive shall be as follows:





Reporting Period	MNE
July - December 2002	\$0.0614
January - December 2003	\$0.0238
January - December 2004	\$0.0238
January - December 2005	\$0.0246
January - December 2006	\$0.0246
January - December 2007	\$0.0254
January - December 2008	\$0.0262
January - December 2009	\$0.0258 (\$0.0262) ¹
January – June 2010	\$0.0265

¹ Excess revenues for 2009 calculated based on an MNE price using the forecast CPI as it was higher than actual CPI for 2009.

- b) The amount of excess revenues for ratio-Salbutamol HFA, without taking into account any reduction for rebates, whether for prompt pay, returns, continuing education (CE) or performance enhancement program (PEP) payments, for the reporting periods from July 1, 2002 to June 2010 is set out in Exhibit "E" of the affidavit of Ginette Tognet, sworn September 9, 2011.
- c) ratiopharm shall pay to Her Majesty in right of Canada, within 60 days after the determination by the Federal Court of a judicial review application that has been brought from the Board's Decision (Federal Court File No. T-1058-11), the sum of \$65,898,842.76 to offset excess revenues for ratio-Salbutamol HFA from July 2002 to the end of the January to June 2010 reporting period.

Board Members: Dr. Brien Benoit

Anne Warner La Forest

Board Counsel: Gordon Cameron

Andrée Wylie

Original signed by

Sylvie Dupont Secretary of the Board