



August 14, 2009

**Decision: PMPRB-08-D2-ratio-SALBUTAMOL HFA
- Preliminary Motions (May 2009)**

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

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

BOARD ORDER

This is the decision of the ratio-Salbutamol Hearing Panel (the "Panel") on two motions brought by Board Staff for: the addition of GlaxoSmithKline Inc. as respondent in these proceedings, and for the inspection and production of documents of ratiopharm Inc.

The Panel, having heard the parties on the Motions and having decided to grant a variation on the relief sought on the Motions, hereby orders that:

Board Staff Motion to Add GlaxoSmithKline Inc.

1. A subpoena issue to GlaxoSmithKline Inc. to produce on or before September 8, 2009, to the Patented Medicine Prices Review Board, in respect of all sales of the medicine ratio-Salbutamol HFA to ratiopharm Inc. in Canada since 2001, annual and monthly breakdowns of prices charged and quantities sold by GlaxoSmithKline Inc.
2. Board Staff shall, within 14 days of receiving the information as per the issued subpoena, no later than September 22, 2009, serve and file, if required an amended Statement of Allegations.

Board Staff Motion for Inspection/Production

3. ratiopharm Inc. ("ratiopharm") shall, on or before September 8, 2009, provide to the Board and to Board Staff the information and documents set out in Appendix I;
4. ratiopharm shall, within 14 days of providing the information in paragraph 3 above, no later than September 22, 2009, permit Welch LLP to inspect ratiopharm's books and accounts in respect of the purchase and sale of ratio-Salbutamol HFA as set out in Appendix II.

Related Scheduling and Confidentiality Directions

5. Subject to further direction by the Board, the schedule for the remaining steps in these proceedings shall be as follows:

Amended Statement of Allegations by Board Staff	September 22, 2009
Amended Response by ratiopharm	October 6, 2009
Amended Reply by Board Staff	October 21, 2009
Pre-hearing Conference	November 2, 2009
Amended Evidence by Board Staff	November 23, 2009
Amended Evidence by ratiopharm	December 14, 2009
Reply Evidence by Board Staff	January 6, 2010
Hearing	January 25-28, 2010

6. The parties may at any time seek direction from the Panel with respect to confidentiality issues or other procedural issues arising from this order.

Board Members: Dr. Brien G. Benoit
Anne La Forest

Board Counsel: Andrée Wylie

Appearances

For Board Staff: David Wilson, Counsel
Leslie Milton, Counsel
Marisa Victor, Counsel

For the Respondent:
Gavin MacKenzie, Counsel
Benoit Duchesne, Counsel
Judith Parisien, Counsel

For GlaxoSmithKline Inc.:

Sheila Block, Counsel
Conor McCourt, Counsel
Emily Kirkpatrick, Counsel

A handwritten signature in black ink, appearing to read "Sylvie Dupont". The signature is written in a cursive, flowing style.

Sylvie Dupont
Secretary of the Board

Information and Documents to be provided by ratiopharm

- a) All correspondence between ratiopharm and provincial authorities regarding the November 2004 increase in the price of ratio-Salbutamol HFA;
- b) All studies or analyses and internal documentation or correspondence prepared by or for ratiopharm in respect of its decision to increase the price of ratio-Salbutamol HFA in November 2004;
- c) Copies of any correspondence between ratiopharm and GlaxoSmithKline Inc. (other than the supply/licensing agreements that have been produced) regarding past and anticipated increases in the GlaxoSmithKline Inc. supply price for ratio-Salbutamol HFA.

Terms of Inspection Order

1. Welch LLP, on behalf of Board Staff, may conduct an on-site inspection at ratiopharm's offices so as to perform an audit of ratiopharm's transactions in respect of the purchase and sale of ratio-Salbutamol HFA in each of the following months: December 2002, December 2003, December 2004, July 2005, December 2005, December 2006, December 2007, May 2008, October 2008 and December 2008 (the "Sample Periods").
2. For the purposes of performing the inspection, Welch LLP shall have (i) access to and the right to make copies of all books, records, documents, accounts and other forms of records necessary to verify the amounts claimed by ratiopharm in respect of benefits or other costs of selling ratio-Salbutamol HFA in the Sample Periods, whether paper, electronic or digital form and whether recorded and maintained in computer or storage facilities in the possession of ratiopharm; and (ii) access to ratiopharm's in-house knowledgeable staff, to respond to Welch LLP's questions regarding ratiopharm's accounting processes and documentation.
3. ratiopharm shall take all reasonable steps to facilitate the inspection and direct Welch LLP to any document, record or information from which Welch LLP can ascertain the benefits and other costs incurred by ratiopharm in respect of its sales of ratio-Salbutamol HFA in the Sample Periods.
4. ratiopharm shall be permitted to have a legal and/or accounting representative present throughout the inspection.
5. Welch LLP shall provide ratiopharm with a full list, and duplicate set, of any copies made pursuant to this order before and copies are removed from the premises.
6. Any information, including copies, obtained by Welch LLP pursuant to this order shall be treated as subject to the confidentiality provisions in s. 87 of the *Patent Act*.
7. The terms of the inspection shall be subject to directions from the Panel in accordance with paragraph 6 of the main order.