August 14, 2009

Decision: PMPRB-08-D2-ratio-Salbutamol HFA - Preliminary Motions (May 22, 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 ("HFA")

REASONS FOR DECISION

1. A Notice of Hearing was issued on July 18, 2008 by the Patented Medicine Prices Review Board (the "Board") whereby this panel of the Board (the "Panel") will receive evidence and arguments of Board Staff and the Respondent ratiopharm Inc. ("ratiopharm") to determine whether, under sections 83 and 85 of the *Patent Act* (the "Act"), ratiopharm is selling or has sold the medicine known as ratio-Salbutamol HFA ("HFA") in any market in Canada at a price that, in the Board's opinion, is or was excessive. For convenience, in these reasons, the Panel refers to the proceeding pursuant to the July 18, 2008 Notice of Hearing as the "Pricing Proceeding".

2. Board Staff has brought two preliminary motions in the Pricing Proceeding on May 22, 2009. The Panel heard the motions on July 8, 9 and 10, 2009. These are the reasons of the Panel on these two preliminary motions.

A. Board Staff's first motion – adding GlaxoSmithKline as a party to the Pricing Proceeding

3. In its first motion, Board Staff sought an order, pursuant to paragraphs 81 (1) (a) and 81 (1) (c) and sections 83, 85, 96 and 97 of the Act adding GlaxoSmithKline Inc. ("GSK") as a party to the Pricing Proceeding (the "Joinder Order"), requiring GSK to file with the Board the price at which GSK has sold or is selling HFA in any market in Canada (the "Filing Order") and permitting Board Staff to file an amended Statement of Allegations in the Pricing Proceeding and revising the scheduling governing the Pricing Proceeding.

4. At the hearing of its first motion, Board Staff filed a proposed order requiring GSK to be added as a respondent in the Pricing Proceeding, to provide the Board and Board Staff with, in respect of all sales of HFA to ratiopharm in Canada since 2001, annual and monthly breakdowns of prices charged and quantities sold by GSK and permitting Board Staff, within 14 days of receiving the information requested, to serve and file an amended Statement of Allegations (the "Proposed Order").

5. HFA is supplied in its final packaged form by GSK to ratiopharm for subsequent sale by ratiopharm. The relevant patents for HFA are owned by Glaxo Group U.K. and licensed to GSK. GSK has sold and is selling HFA to ratiopharm in Canada pursuant to licensing/supply agreements already filed with the Board. Pursuant to these agreements, during the period 2002 to the end of 2005, GSK's supply price was determined through the use of a supply price formula. Subject to a pre-determined floor price, ratiopharm was required to pay GSK a graduated percentage of its net revenues from the sale of HFA, the supply price thus set by reference to the level of ratiopharm's sales of HFA and ratiopharm's sale price for HFA. Thereafter, GSK's supply price of HFA to ratiopharm was fixed. ratiopharm, in its filings with the Board in respect of HFA, relies in part on its costs of acquiring HFA from GSK to argue that its list price for HFA has not been and is not excessive.

6. Board Staff submits that GSK is subject to the jurisdiction of the Board pursuant to section 79 of the Act in respect of the sale of HFA to ratiopharm in Canada and a necessary party to the Pricing Proceeding to determine whether ratiopharm has sold or is selling HFA in any market in Canada at excessive prices.

7. Both GSK and ratiopharm contest the Board's jurisdiction with respect to the sale of HFA. Both resist Board Staff's first motion and ask the Panel to dismiss it.

8. GSK argues that, even if Board jurisdiction exists, Board Staff has not demonstrated the necessary prerequisite for the granting of the Joinder Order, in part because Board Staff has not yet formulated allegations against GSK determined by the Board to warrant the issuance of a Notice of Hearing against the company. GSK submits, with respect to the Filing Order, that the information necessary or proper for the exercise of its jurisdiction can be obtained using the broad powers of the Board under subsection 96 (1) of the Act. In its view, subsection 96 (1) allows the Board, in the exercise of such powers, to issue a subpoena to GSK requiring it to provide the information sought by Board Staff in its Proposed Order. The view that, pursuant to all the powers of a superior court of record conferred on the Board by subsection 96 (1) of the Act with respect to the production or inspection of documents, the Board is empowered to issue such a subpoena to GSK is shared by ratiopharm and Board Staff. At the hearing, counsel for GSK, stated that GSK made no jurisdictional objection to a subpoena and would respond promptly to any subpoena of the Board.

9. ratiopharm, for its part, objects to the Joinder Order, largely on procedural and fairness grounds. It submits that it would be unfair to ratiopharm to unduly complicate, prolong and delay the Pricing Proceeding, contrary to subsection 97 (1) of the Act, by joining GSK as a party at this stage of the Pricing Proceeding. ratiopharm objects to the Filing Order, largely on the ground that it

has delivered to the Board all the documents that it intends to rely on at the Pricing Proceeding.

10. The Panel considers that, in the circumstances of this case, the information sought by Board Staff from GSK is necessary to a finding whether ratiopharm is selling or has sold HFA at a price that, in its opinion, is or was excessive contrary to section 83 of the Act. The Panel notes that there exists an interrelationship between the supply price and the acquisition price of HFA by ratiopharm and that ratiopharm relies on its cost of acquisition to justify its sale price.

11. With respect to ratiopharm's submission that it has delivered to the Board all the documents that it intends to rely on in the Pricing Proceeding, the Panel is of the view that the test of what is necessary to be provided to the Board is the relevance of the information for the proper exercise of its excessive pricing mandate and not whether it is the only information that a party intends to rely on to justify its price of a medicine.

12. The Panel is not persuaded, however, that it is necessary to issue either the Joinder Order or the Filing Order sought by Board Staff at this time, given that the Board can, pursuant to its powers under subsection 96 (1) of the Act, require GSK to provide to Board Staff the information it has set out in the Proposed Order. Pursuant to subsection 96 (1) of the Act, and in accordance with section 25 of the Proposed Patented Medicine Prices Review Board Rules, the Board will therefore issue a subpoena to GSK requiring the production of the information sought by Board Staff.

13. Board Staff's first motion is accordingly dismissed.

B. Board Staff's second motion – Inspection and Production

14. In its second motion, Board Staff sought an order, pursuant to paragraphs 81 (1)(a) and 81 (1)(c) and sections 96 and 97 of the Act, requiring ratiopharm to permit Welch LLP to inspect ratiopharm's books and accounts in respect of the purchase and sale of HFA, on terms set out in an appendix to the related Notice of Motion (the "Inspection Order") and requiring ratiopharm to provide to the Board and to Board Staff certain information and documents related to the purchase and sale of HFA set out in an appendix to the related Notice of Motion (the "Production Order").

15. Board Staff advised the Panel at the hearing that some of the information listed in its proposed Production Order was no longer required and filed a revised Production Order (PMPRB-EX-15).

16. ratiopharm has filed Form 2 information in respect of HFA, as required of patentees by the *Patented Medicines Regulations* (the "Regulations"), as well as information in the Pricing Proceeding, without prejudice to its position that it is not subject to the jurisdiction of the Board and not legally required to file such information or any price and sales information in respect of HFA. ratiopharm maintains that, in any event, Board Staff does not have the jurisdiction to reject, validate or verify the information contained in a Form 2 regulatory filing, nor the Board the jurisdiction to require the inspection and production of documents to allow it to do so.

17. Board Staff, for its part, submits that ratiopharm is subject to the excessive pricing authority of the Board, pursuant to sections 79 and 83 of the Act, with regard to the sale of HFA in any market in Canada.

18. The Statement of Allegations dated July 9, 2008, which led to the Pricing Proceeding is based on ratiopharm's Form 2 filings in respect of HFA, certified by ratiopharm to be accurate. However, on March 30, 2009, ratiopharm filed revised Form 2 information in respect of HFA for the period 2002 to 2008, stating that it had inadvertently left out some information in its previous calculations of average price per transaction and net revenue for HFA. This revised information results in a significant change in ratiopharm's reported annual information for HFA and in a dramatic drop in the excess revenues previously calculated by Board Staff in support of its Statement of Allegations in the Pricing Proceeding. The significant change in average transaction price for HFA is due in large part to the substantial deduction by ratiopharm of various rebates related to the sale of HFA.

19. In April 2009, ratiopharm provided to Board Staff several binders of documentation and affidavit evidence concerning the rebates claimed and its costs of acquiring and marketing HFA. This information was filed largely in response to Board Staff's requests for product-specific documents and calculations necessary to verify the pricing and costing information filed and the amounts claimed by ratiopharm in its revised Form 2 filings for HFA. ratiopharm has stated on the record that its business is product-centric and that sales, costs, and the value of returns, the rebates and the benefits which reduce the per unit sale price and per unit net revenue of a product are tracked specifically for that product. Nevertheless, the information provided to Board Staff by ratiopharm in respect of rebates, discounts and costs, including prompt pay discounts, the number and value of returns, continuing education ("CE") rebates, performance enhancement payments ("PEP") and distribution costs claimed for HFA consists largely of non-product-specific information and estimates. Such estimates are based largely on aggregate amounts reported in ratiopharm's accounting records and ratiopharm's audited financial statements for all products and attributed to HFA on an allocation basis as a percentage of the total amounts recorded for all products.

20. Board Staff questioned the nature of the material produced by ratiopharm and requested source documentation such as invoices, payment requests, cheque requisitions and rebate availability conditions matched to purchases of HFA in order to justify the rebates and costs claimed for HFA and verify the revised average price per package of HFA and the net revenue figures ratiopharm has produced. Nevertheless, according to Board Staff's evidence, ratiopharm produced virtually no such documentation. Board Staff submits that it is therefore not possible for it, or for the Panel, to verify the accuracy and relevance of the amounts claimed by ratiopharm in its revised File 2 filings, and the resulting prices reported by ratiopharm, for the purpose of determining in the Pricing Proceeding whether ratiopharm's price for HFA has been or is excessive. Board Staff evidence is that the documents filed do not, except in very few instances, indicate whether the benefits claimed by ratiopharm and the costs of distributing and marketing incurred by ratiopharm relate to HFA. Board Staff submits that, in the circumstances, an on-site inspection of ratiopharm's financial records related to HFA, on a sample basis, is required for the proper exercise of the Board's jurisdiction in the Pricing Proceeding.

21. ratiopharm filed, as part of its evidence in response to Board Staff's second motion, the affidavit of Ms. Shari Saracino, Vice-President of Sales and Marketing at ratiopharm, sworn on June 22, 2009, in support of ratiopharm's opposition to the Inspection Order. Ms. Saracino's affidavit speaks, in part, to the methods and systems used by ratiopharm to track and record, as they pertain to HFA, sales, the number of product returns and the payments for rebates and discounts. At the hearing, Ms. Saracino was cross-examined on her affidavit by counsel for Board Staff.

22. Ms. Saracino's testimony revealed that, at least from the perspective of what she described as ratiopharm's sales systems, invoices for prompt payment discounts exist by customer and by product, the actual number of returns by product is recorded, CE rebate payments to corporate customers are tracked by product and by customer and related invoices are available in some instances, PEP payments to non-corporate customers are recorded by specific product and specific customer and source documentation for rebate availability conditions exists. Ms. Saracino testified that, in her view, in most cases, this information could be produced. Ms. Saracino was unable to confirm how such information is entered into ratiopharms' financial systems as opposed to its sales systems. However, counsel for ratiopharm stated at the hearing that the product-centric nature of what is used in the business feeds up into the financial system used by ratiopharm.

23. ratiopharm's opposition to both the Inspection Order and the Production Order is based first, as noted earlier, on the position that the Board is without jurisdiction to reject, validate or verify the information provided in Form 2 regulatory filings pertaining to HFA and made pursuant to the Regulations. It argues that, once a

regulatory filing is made, the Board's jurisdiction in this regard is spent. There is, ratiopharm argues, no requirement under the Act or the Regulations, or in the Patentee's Guide to Reporting, or in Form 2, for a patentee to disclose or produce any financial or business documentation, much less source documentation, whether at the time of filing Form 2 information or when an amendment to an original Form 2 filing is made. Neither is there, in ratiopharm's view, any regulatory requirement for a respondent to provide Board Staff with evidence, information or documentation other than what it intends to rely on at a hearing on the merits. In this regard, ratiopharm points to its significant volumes of production to the Board to date.

24. ratiopharm argues further that, since there is no regulatory standard established for the filing of Form 2 information, pursuant to section 80 of the Act or section 4 of the Regulations, a patentee's internal financial and accounting mechanisms, consistent with generally accepted accounting principles (GAAP), must be the regulatory standard to be applied for a determination whether rebates and costs relate to a specific medicine. ratiopharm emphasizes that estimates are permissible under GAAP. At the hearing, counsel for the Respondent took the position that expectations one may have about how someone tracks one figure or another figure is immaterial to the reality that a business operates in the way it operates.

25. ratiopharm relies on federal and provincial statutes which contain express powers of enforcement through inspection, for example the *Income Tax Act* and the *Ontario Drug Benefit Act*, to argue that, since the Act contains no provision authorizing Board Staff to conduct a spot audit or to examine a company's financial records to validate the information contained in a Form 2 regulatory filing, it is fair to assume that it was not intended that Board Staff have this power.

26. Board Staff relies on subsection 96 (1) of the Act in response. Subsection 96 (1), which confers on the Board the broad powers of a superior court, empowers the Board, Board Staff argues, to issue an order for inspection. To the proposition of counsel for ratiopharm, that a superior court has no inherent power to order an on-site inspection, Board Staff responds that, pursuant to rule 32.01 made pursuant to the *Ontario Courts of Justice Act*, courts may make an order for the inspection of real or personal property. Board Staff also points to case law where, in circumstances where it appears necessary for the determination of an issue before them, superior courts have issued orders for inspection and the removal of documents, with appropriate safeguards.

27. The Panel is satisfied that, pursuant to its powers under the Act, in particular in paragraph 81 (1)(c) and subsection 96 (1), it has the power to order an on-site inspection, as necessary for the production of required information. In its view, it is essential that the Board remain the judge of what production and information

are necessary to ensure that it has a complete record and a full understanding of the issues at play in a proceeding. The test of the proper exercise of its discretion in this regard must be the relevance of the information sought to the discharge of its legislated pricing mandate, in light of the circumstances of each case, including the evidence filed and the issues raised. The test cannot be, as suggested by ratiopharm, the volume or quantity of the evidence filed or the particular evidence a party intends to rely on at a hearing.

28. The Panel agrees that section 4 of the Regulations, unlike the enforcement powers in the *Income Tax Act*, is a reporting regulation. It cannot be used to restrict or limit the plain wording of the Act itself, particularly paragraph 81 (1)(c) which empowers the Board, by order, to require a patentee to provide the Board with information and documents respecting such matters related to its jurisdiction over a patentee as it may require. Neither can section 4 of the Regulations be used to carve out any of the powers conferred on the Board by subsection 96 (1) of the Act with respect to the production and inspection of documents and other matters necessary or proper for the due exercise of its excessive pricing authority under the Act.

29. The Panel considers as well that, contrary to ratiopharm's submissions, there is an onus on a party subject to ongoing regulation to be prepared to produce, as required by the regulator in the legitimate exercise of its jurisdiction, the information that the regulator may require in a form reasonably capable of permitting that exercise.

30. The Panel concludes that the information sought by Board Staff in the Inspection Order and the Production Order is necessary as part of the record of the Pricing Proceeding. It is necessary for the making of an informed decision in the particular circumstances at hand, in part ratiopharm's reliance on its cost of acquisition of HFA, the very substantial increase in ratiopharm's list price for HFA in 2004, the magnitude of its 2009 revisions to ratiopharm's Form 2 filings for HFA for a number of years, the magnitude and nature of the rebate amounts deducted by ratiopharm from its gross revenues in respect of HFA, for many years and the impossibility of verifying, in respect of HFA, ratiopharm's pricing and cost information using external sources.

31. Considering the history of the Pricing Proceeding, the Panel is not persuaded that the material listed in the Inspection Order can be obtained in an effective and efficient manner by requesting further production. An inspection order, in the Panel's view, is more likely to ensure, in the circumstances, a timely and thorough filing of the information required without repeated iterations and interlocutory processes. An inspection order is more likely, it has concluded, to ensure that the Pricing Proceeding is dealt with as expeditiously as the circumstances and considerations of fairness to all parties permit, as required by subsection 97 (1) of the Act.

32. Accordingly and for all the reasons set out above, the Board will issue, in respect of Board Staff's second motion, both an inspection order and a production order substantially as sought by the Board Staff.

Board Members: Dr. Brien Benoit
Anne Warner La Forest

Board Counsel: Andrée Wylie

Appearances

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

Original signed by

Sylvie Dupont
Secretary of the Board

Subpoena issued to GlaxoSmithKline Inc., August 14, 2009
Inspection and Production Order issued to ratiopharm Inc., August 14, 2009