November 28, 2008

Decision: PMPRB-08-D1-ratio-Salbutamol HFA - Preliminary Motions

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

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

1. A Notice of Hearing was issued on July 18, 2008 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 we refer to the proceeding pursuant to the Notice of Hearing as the "Pricing Proceeding".

2. In another proceeding, Board Staff are seeking orders requiring ratiopharm to report information to the Board pursuant to the reporting requirements in the Act and the *Patented Medicines Regulations* (the "Regulations"). For convenience, we will refer to this second proceeding as the "Filing Application".

3. Board Staff and ratiopharm have each brought preliminary motions in the Pricing Proceeding. The Panel heard the motions on October 27, 2008. These are the reasons of the Panel on the preliminary motions.

A. The Respondent's Motion

4. In ratiopharm's motion it is seeking (1) a confidentiality order; (2) a change in the schedule of events; and (3) an order compelling Board Staff to provide production of documents and particulars.

5. Counsel advised the Panel at the outset of the hearing that they had resolved the first two matters. Therefore, argument was heard on the third aspect of ratiopharm's motion only, as set out in paragraph (e) of its Notice of Motion.

6. In effect, ratiopharm seeks disclosure of the contents of Board Staff's internal file and a range of additional documents pertaining to other asthma inhaler medicines, as well as any documents that Board Staff delivered to the Board Chair for the purposes of assessing what action, if any, should be taken after the investigation. In its materials filed on the motion, Board Staff states that the only communication or report fitting this description is the report from Board Staff to the Chair with respect to whether a notice of hearing should issue.

7. In his submissions, Counsel for ratiopharm, Mr. Duchesne, noted that the items listed in subparagraphs (i) though (xv) of paragraph (e) of ratiopharm's Notice of Motion comprise documents and information that may have been reviewed or considered by Board Staff, which may be detrimental to Board Staff's case and which would not otherwise be disclosed in the usual course. In Mr. Duchesne's submission, production of these documents and information is necessary for fairness, because otherwise ratiopharm will not be in possession of all relevant documents, and will not be in possession of documents that could be helpful to its case. Such production, he argued, is akin to the examination for discovery process in a civil court action.

8. In resisting the motion for disclosure, Board Staff rely on the decision of the Federal Court of Appeal in *Ciba-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*.[1] In that case, Ciba-Geigy brought an application for judicial review to the Federal Court (Trial Division) of an order of the Board dismissing Ciba-Geigy's request for disclosure and production of all documents relating to the matters in issue in an upcoming hearing to determine whether Ciba-Geigy was selling the medicine Habitrol at an excessive price. McKeown J. dismissed the application for judicial review.

9. The Federal Court of Appeal, *per* MacGuigan J.A., dismissed Ciba-Geigy's appeal. The court recognized that while "there are extremely serious economic consequences for a successful patentee to a s. 83 hearing, and a possible effect on a corporation's reputation in the market place", fairness in the context of the Board's role and objectives did not mandate disclosure of the documents sought.

10. Mr. Duchesne seeks to distinguish *Ciba-Geigy* based on the amount of disclosure that had taken place in that case before the Notice of Hearing was issued. He asserts that in the present case, such disclosure has not occurred.

[1] [1994] 3 F.C. 425 (T.D.); aff'd [1994] F.C.J. No. 884 (F.C.A.).

11. With respect to ratiopharm's argument that it is entitled to disclosure of Board Staff's internal file and the report from Board Staff to the Chair, the Panel does not accept that the present proceedings should be, or can be, distinguished from *Ciba-Geigy* on the basis put forward by ratiopharm. The principled basis on which McKeown J. dismissed Ciba-Geigy's action can be summarized by the following passage from his reasons, which was endorsed by the Court of Appeal in its reasons at para. 5:

> The Board is supposed to proceed efficiently and to protect the interest of the public. This requires, *inter alia*, that a hearing shall not be unduly prolonged. Certainly, the subject of an excess price hearing is entitled to know the case against it, but it should not be permitted to obtain all the evidence which has come into the possession of the Board in carrying out its regulatory functions in the public interest on the sole ground that it may be relevant to the matter at hand. The Board's function is not to obtain information solely for investigative purposes; its primary role is to monitor prices. [...] Law and policy require that some leeway be given an administrative tribunal with economic regulatory functions, if, in pursuing its mandate, the tribunal is required by necessity to receive confidential information. It is not intended that proceedings before these tribunals be as adversarial as proceedings before a court. To require the Board to disclose all possibly relevant information gathered while fulfilling its regulatory obligations would unduly impede its work from an administrative viewpoint. Fairness is always a matter of balancing diverse interests. I find that fairness does not require the disclosure of the fruits of the investigation in this matter.

12. The disclosure standard set out by the Supreme Court of Canada in *R. v. Stinchcombe* does not apply to proceedings before the Board: *Ciba-Geigy* (FCA) at para. 8. Nor do the principles for documentary discovery present in the adversarial context of a civil action, apply to an excessive price hearing. What is required from a fairness perspective is that ratiopharm know the case it has to meet.

13. The Notice of Hearing and Board Staff's Statement of Allegations have provided information to ratiopharm about the allegations against it. At the hearing of the motion, Board Staff noted that prior to the hearing in the Pricing Proceeding, ratiopharm will be provided with affidavits of all expert witnesses on whose evidence Board Staff will rely. Board Staff stated that it will also pre-file copies of all documents that it intends to rely on at the Pricing Proceeding. Therefore, ratiopharm will know the case it has to meet before commencement of the hearing. To the extent that Board Staff will be relying on any alleged facts or information, Board Staff represented at the hearing of the motion that it will disclose them to ratiopharm before the hearing in the Pricing Proceeding. On the basis that the disclosure outlined above will take place, the Panel has concluded that ratiopharm

does not have a right to the documents and information requested by ratiopharm in sub-paragraphs (ii) through (xv) of paragraph (e) in its Notice of Motion.

14. With respect to the report by Board Staff to the Chair, the Panel will not be relying on this report. As noted by the court in *Hoechst Marion Roussel Canada v. Canada (Attorney General)*[2], when the Chair receives Board Staff's report, he does so for the sole purpose of determining whether it is in the public interest to hold a hearing. In that context, he only considers whether the allegations, if proven to be true, would establish a *prima facie* case of excessive pricing. The report does not come before the Panel, which will base its decision in the Pricing Proceeding solely on the evidence placed and tested before it. Accordingly, there is no prejudice to ratiopharm because it does not have access to Board Staff's report to the Chair.

15. ratiopharm's motion is accordingly dismissed.

B. Board Staff's Motion

16. Board Staff contend that since 2004, ratiopharm has sold or is selling HFA in Canada at a price per dose that exceeded or exceeds the maximum non-excessive (MNE) price.

17. In its motion, Board Staff seek four types of information: (1) confirmation whether ratiopharm is a licensee of GlaxoSmithKline Inc. ("GSK") and a patentee; (2) identification of the patents that pertain to HFA; (3) the public ex-factory price for each dosage form, strength and package size in which HFA was sold to each class of customer in each country set out in the Schedule to the Regulations, as required by subparagraph 4(1)(f)(iii) of the Regulations; and (4) a copy of the agreement between ratiopharm and GSK pursuant to which ratiopharm began selling HFA in Canada.

18. Counsel for Board Staff, Mr. Wilson, said he would defer his request for an order that ratiopharm confirm whether it is a patent holder, a person holding a license or any other person referred to in the definition of patentee in subsection 79(1) of the Act. Therefore, the Panel need only consider Board Staff's other three requests for information set out above.

19. Board Staff state that although ratiopharm has filed its Form 1 information with Board Staff, it has failed to identify the patents that pertain to HFA. Board Staff say this information will be relevant to the Board's determination of whether ratiopharm is a patentee within the meaning of subsection 79(1) of the Act.

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[2] [2003] F.C. 1343.

20. Pursuant to s. 96 of the Act, the Board has all the powers, rights and privileges as are vested in a superior court with respect to, among other things, the production and inspection of documents.

21. In its response to the statement of allegations, ratiopharm pleads that it does not manufacture HFA "but rather acquires it under a supply agreement" with GSK. ratiopharm has put the nature of its agreement with GSK squarely before the Panel in the Pricing Proceeding. Mr. Duchesne stated that his client does not know what the patent numbers are and that his client would have to obtain this information from GSK. He also stated that the agreement between ratiopharm and GSK is in the nature of a supply agreement. However, no evidence was filed on these issues.

22. Board Staff filed evidence that GSK has advised Board Staff that ratiopharm is a licensee of GSK with respect to HFA.[3] ratiopharm filed no evidence to contradict this evidence.

23. Board Staff say the public ex-factory prices are relevant to the Board's determination of whether ratiopharm has sold or is selling HFA in any market in Canada at a price that was or is excessive. Board Staff assert that the Panel is required to take into account the factors listed in subsection 85(1) in determining whether the price of the medicine is or was excessive. Included in these factors are the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada.

24. The Panel agrees with Board Staff that the agreement between GSK and ratiopharm and the identification of the patents that pertain to HFA will be relevant to the matters before the Board in the Pricing Proceeding. The publicly available ex-factory prices are also relevant. The fact that ratiopharm is challenging the jurisdiction of the Board does not strip the Panel of its powers under s. 96 of the Act to order production of documents.

25. The Panel does not accept the distinction that counsel for ratiopharm has attempted to make in characterizing the exercise of Board powers under s. 96 of the Act as an exercise of its adjudicative powers. The Panel is not yet in a position to adjudicate the matter of whether HFA is being or has been sold at a excessive price. The Panel will not see the documentation ordered unless Board Staff intends to rely on it at the hearing.

[3] Affidavit of Ginette Tognet sworn September 22, 2008, paragraph 5.

26. The Panel therefore orders ratiopharm to produce a copy of all agreements between it and GSK that pertain to HFA, and documentation establishing the patent numbers of each invention pertaining to HFA, the date on which each patent was granted and the date on which each patent will expire. If the patent documentation is not obtainable from ratiopharm's own records, it is to make best efforts to obtain it from GSK. If ratiopharm is unable to obtain such documentation, ratiopharm is to file a document with the Secretary to the Board detailing the efforts it has made and the outcome of those efforts. ratiopharm is also to supply documentation evidencing the publicly available ex-factory prices for each dosage form, strength and package size in which HFA was sold to each class of customer set out in the Schedule to the Regulations.

27. The Panel will expect the documentation to be delivered by December 19, 2008.

C. Consolidation of the Pricing Proceeding and the Application

28. The parties have jointly submitted that the Pricing Proceeding and the Filing Application be joined and that the Board hear both matters concurrently.

29. The Panel recently rejected a similar request by Apotex Inc. ("Apotex").[4] The Apotex proceedings, which concerned a pricing hearing for Apo-Salvent and an application by Board Staff requiring Apotex to report information to the Board, are similar to the two proceedings concerning ratiopharm. In rejecting Apotex's motion to consolidate the two proceedings, the Board noted that the two proceedings involved different topics, had different procedures and were on separate and different timelines. Although the last is not a factor in the present case, the other two factors are. Therefore, as in the Apotex proceedings, the Panel here finds that consolidation of the Pricing Proceeding and the Application is not practical or legally sound.

30. Board Staff and the Respondent agree that the original date set for the hearing in the Pricing Proceeding, January 12, 2009, does not provide sufficient time for the parties to prepare. The Panel directs the parties to confer with the Secretary who will set dates for Filing Application and the Pricing Proceeding. Assuming that the Filing Application will be heard first, the Panel may be able to incorporate the record of evidence and argument, to the extent that it is relevant to the Pricing Proceeding, from the Filing Application.

[4] Decision: PMPRB-08-D1-APOTEX, October 27, 2008.

Board Members:	Dr. Brien Benoit Anne Warner La Forest
Board Counsel:	Nancy Brooks

Appearances

Board Staff:	David Wilson, Counsel Anne Tardif, Counsel
For the Respondent:	Gavin MacKenzie, Counsel Benoit Duchesne, Counsel Judith Parisien, Counsel

Original signed by

Sylvie Dupont
Secretary of the Board