May 27, 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. (the "Respondent") and the medicine "ratio-Salbutamol HFA"

DECISION

Introduction

1. These reasons pertain to a decision of the Patented Medicine Prices Review Board ("the Board") following a hearing into whether ratiopharm Inc. ("ratiopharm"), under sections 83 and 85 of the *Patent Act* (the "*Act*"), is selling or has sold the medicine known as ratio-Salbutamol HFA ("ratio HFA") in any market in Canada at a price that, in the opinion of the Board is, or was, excessive and, if so, what order, if any, should be made (the "Proceeding").

The Medicine

2. ratio HFA is an authorized generic version of the medicine manufactured, marketed and sold in Canada by GlaxoSmithKline Inc. ("GSK") under the brand name Ventolin HFA. Ventolin HFA and ratio HFA are taken to relieve asthma, chronic bronchitis and related symptoms. ratio HFA is essentially Ventolin HFA with the same chemical composition, strength, dosage form and delivery mechanism. It differs only in labeling, packaging, and product monograph. Ventolin HFA and ratio HFA are bronchodilators whereby approximately 200 doses of the active ingredient salbutamol sulphate is delivered through a pressurized canister referred to as a metered dose (aerosol) inhaler ("MDI") in doses of 100 micrograms.

3. Both Ventolin HFA and ratio HFA are manufactured, packaged, and labeled by GSK. ratio HFA was sold by GSK to ratiopharm, an arm's length company, in final packaged and labeled form for sale in Canada by ratiopharm, from the latter half of 2002 until the end of 2009, pursuant to a series of licensing/supply agreements (the "Agreements") between GSK and ratiopharm. The Agreements were not renewed at their expiry at the end of 2009 and ratio HFA was no longer sold by ratiopharm in Canada by the end of January 2010.

The Proceeding

4. The Proceeding before a panel of the Board (the "Panel") was commenced by the issuance of a Notice of Hearing by the Chairman of the Board on July 18, 2008, after his review of a Statement of Allegations dated July 8, 2008 prepared by the staff of the Board ("Board Staff") alleging that ratiopharm was selling and had sold ratio HFA in Canada at excessive prices, contrary to sections 83 and 85 of the *Act*.

5. Before hearing Board Staff and ratiopharm (collectively the "Parties") on the merits in the Proceeding, the Panel heard the Parties on preliminary matters at a pre-hearing conference on October 27, 2008. The Panel also heard the Parties and GSK on July 8, 9 and 10, 2009 on two preliminary motions brought by Board Staff (the "Preliminary Motions") and at a further pre-hearing session on November 2, 2009.

6. In the first Preliminary Motion, Board Staff sought an order from the Panel to add GSK as a party to the Proceeding, to require GSK to file with the Board the price at which GSK has sold or is selling ratio HFA to ratiopharm, and to provide to the Board certain information with respect to the sale of ratio HFA to ratiopharm since 2001.

7. In the second Preliminary Motion, Board Staff sought an order requiring ratiopharm to permit Welch LLP ("Welch"), an accounting and consulting firm, to inspect ratiopharm's books and accounts in respect of the purchase and sale of ratio HFA and to provide to the Board certain information and documents related to such purchase and sale.

8. On August 14, 2009, the Panel denied the motion to add GSK as a party to the Proceeding but issued a *subpoena* to GSK requiring the production of information to the Board in respect of all sales of ratio HFA to ratiopharm since 2001, including quantities and prices charged with respect to such sales.

9. With regard to the second Preliminary Motion, the Panel issued on August 14, 2009: (i) an order requiring ratiopharm to provide certain information and documents to the Board; and (ii) an inspection order (the "Inspection Order") permitting Welch, on behalf of Board Staff, to conduct an on-site inspection at ratiopharm's offices and to perform an audit of ratiopharm's transactions in respect of the purchase and sale of ratio HFA in Canada for certain sample periods. The Inspection Order required ratiopharm to provide access to Welch to all books, records, documents, accounts and other forms of records necessary to

verify the amounts claimed by ratiopharm in respect of benefits given or other costs of selling ratio HFA in the sample periods and to take all reasonable steps to direct Welch to any document, record or information from which Welch could ascertain the benefits given and other costs incurred by ratiopharm in respect of its sales of ratio HFA in the sample periods. In issuing the Inspection Order, the Panel relied in part on the sworn evidence of Ms. Shari Saracino, Vice-President of Sales and Marketing at ratiopharm, that the benefits and costs of selling products, including rebates related thereto, are tracked and recorded by ratiopharm by product and by customer.

10. On January 25 and 26, 2010 and April 12 to 15, 2010, the Panel heard the evidence and arguments of the Parties on the merits in the Proceeding. Parties filed extensive and detailed written final arguments and replies thereto on April 30, 2010 and May 14, 2010 respectively.

The Issues

11. Based on the submissions of the Parties and the Panel's review of the record, the Panel has identified the following issues to be determined:

    I. Whether sections 79 to 103 of the *Act* are constitutional;

    II. Whether ratiopharm is a patentee, under sections 79 to 85 of the *Act*, with respect to the sale of ratio HFA in any market in Canada between 2002 and 2010;

    III. Whether ratiopharm, to the extent that it is a patentee, is selling or has sold ratio HFA in any market in Canada at an excessive price, contrary to sections 83 and 85 of the *Act*;

    IV. Whether, in determining the price at which ratiopharm is selling or has sold ratio HFA in any market in Canada, the Panel can take into account any rebates or discounts given by ratiopharm in respect of such sales and reported to the Board pursuant to section 4 of the *Patented Medicines Regulations* (the *"Regulations"*); and

    V. What order, if any, should be made by the Panel with respect to the sale of ratio HFA by ratiopharm in Canada.

Discussion and Determinations

I. Whether Sections 79 to 103 of the *Act* are Constitutional

a. The Argument

12. ratiopharm submits that sections 79 to 103 of the *Act*, which establish the Board and grant it certain powers with respect to the excessive pricing of patented medicines, are not supported by any federal head of power in the *Constitution Act, 1867* (the *"Constitution"*) and are *ultra vires* the power of Parliament. Specifically, ratiopharm argues that the Board's mandate under the *Act* consists of pure price regulation, a matter of provincial jurisdiction, property and civil rights, pursuant to subsection 92(13), and not a matter of federal jurisdiction, patents of invention and discovery, pursuant to subsection 91(22).

b. Conclusion

13. The Board's mandate and purpose in the *Act* is the monitoring of the price of patented medicines to ensure that prices charged by pharmaceutical companies for such medicines do not rise to unacceptable levels and the protection of Canadian consumers from the excessive pricing of such medicines. The Panel is satisfied that case law has affirmed that this mandate and purpose are consistent with subsection 91(22) of the Constitution: see for example, *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, [1997] 1 F.C. 32 ("*ICN*") approving *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485 (Man. Q. B.); affd. (1992), 96 D.L.R. (4th) 606 (Man. C.A.) ("*Manitoba Seniors*"). In *Manitoba Seniors*, the Manitoba Court of Appeal affirmed the decision of Dureault, J. of the Manitoba Queen Bench that the fact that sections of the *Act* may have an effect upon matters within provincial jurisdiction, in this case property and civil rights, is of no consequence.

14. Hughes, J. of the Federal Court in *Teva Neuroscience G.P. – S.E.N.C. v. Attorney General of Canada*, 2009 F.C. 1155 noted, at paragraph 71:

71. The constitutional jurisdiction of the Board has not been the subject of judicial consideration since the Manitoba decision. I do note that the late Justice Cullen of this Court did incorporate the entirety of Justice Dureault's reasons reflecting the historic review of the *Patent Act* and the Board in his reasons in *ICN Pharmaceuticals Inc. v. Canada* (*Patented Medicine Prices Review Board*) (1996), 66 C.P.R. (3rd) 46.

II. Whether ratiopharm is a patentee under sections 79 to 85 of the *Act* with respect to the sale of ratio HFA in any market in Canada between 2002 and 2010.

a. The relevant legislative provisions

15. For the purposes of sections 80 to 103 of the *Act*, a patentee is defined in subsection 79(1) as follows:

> 79.(1) "patentee", in respect of an invention pertaining to a medicine, means the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a licence continued by subsection 11(1) of the *Patent Act Amendment Act*, 1992, that other person in respect of those rights.

16. Subsection 79(2) of the *Act* provides that, for the purposes of subsection (1) and sections 80 to 103, "an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine."

17. Sections 80 and 81 of the *Act* require a patentee or former patentee of an invention pertaining to a medicine, as required by and in accordance with the *Regulations*, or in accordance with a Board order, to provide to the Board certain information and documents respecting the medicine, including the price at which the medicine is being sold or has been sold in any market in Canada.

18. The powers of the Board to make findings of excessive pricing under section 83 of the *Act* are also granted with respect to a patentee of an invention pertaining to a medicine.

19. Reviewing the provisions relating to the Board's jurisdiction under the *Act* in *ICN*, the Federal Court of Appeal, at paragraph 47, established three conditions precedent for the Board to acquire jurisdiction under section 83 of the *Act*: (i) the party before it must be a patentee of an invention; (ii) the patentee's invention must pertain to a medicine; and (iii) the patentee must be selling the medicine in any market in Canada.

20. There is no dispute between the Parties that ratio HFA is a medicine, and would be, if the Board had jurisdiction in relation to the sale of ratio HFA by ratiopharm, a Category 1 drug product within the Board's Compendium of Guidelines, Policies and Procedures-pre-2010 (the "Guidelines"). As described in the Guidelines, it is a new Drug Identification Number ("DIN") of an existing or comparable dosage form of an existing medicine, Ventolin HFA. A new DIN was assigned to ratio HFA in 2001 by Health Canada under the *Food and Drug Regulations.* There is also no dispute between the Parties that ratio HFA was sold in Canada by ratiopharm under a Notice of Compliance ("NOC") issued by Health Canada to ratiopharm on July 16, 2002, pursuant to those *Regulations*.

21. Neither do the Parties dispute that two Canadian patents, Nos. 2,125,665 and 2,125,667 (the "Patents"), granted to Glaxo Group Ltd., UK and licensed to GSK, pertain to an invention for the production of Ventolin HFA and ratio HFA within the meaning of subsection 79(2) of the *Act*. The Patents cover formulations of salbutamol sulfate with a hydrofluoroalkane propellant used to form an aerosol for inhalation.

22. ratiopharm's witness, Mr. Kent Major, Vice-President of Research and Development and Regulatory Affairs at ratiopharm, acknowledged during his sworn testimony that, in September 2001, in order to obtain an NOC from Health Canada for the sale of ratio HFA by ratiopharm, he had listed on the relevant Health Canada form signed by him (Form V: Declaration Re: Patent List) one of the Patents, with its expiry date of 2012, as applicable to ratio HFA, and had indicated on that Form that ratiopharm had obtained consent from the Patent owner "to the making, constructing using or selling of [ratio HFA] in Canada".

23. Mr. Major's testimony was that ratiopharm had introduced ratio HFA in Canada in 2002 and sold it in markets in Canada from September 2002 until the end of January 2010.

24. ratiopharm argues, however, that it is not a patentee within the meaning of section 79 of the *Act* with regard to the sale of ratio HFA because any patent that pertains to ratio HFA is owned exclusively by GSK and all rights, interest and title in and to the Patents and the invention they document and protect are the exclusive rights, interests and title of GSK, to the complete exclusion of ratiopharm. ratiopharm emphasizes that it has never held any patent for ratio HFA.

b. The Agreements

25. As part of the arrangement under which ratiopharm sold ratio HFA, ratiopharm took title to ratio HFA from GSK for resale in Canada at a price per MDI agreed to by the parties pursuant to the Agreements which were amended and restated over time. In essence, the Agreements grant to ratiopharm an exclusive licence to promote, market, and sell ratio HFA in Canada. Under the Agreements, ratiopharm assumed the responsibility for all activities related to the resale of ratio HFA, including pricing. The Agreements expressly prohibit ratiopharm from sub-licensing the rights granted in the Agreements and expressly reserve to GSK ownership in its intellectual property, including the Patents.

26. In ratiopharm's submission, since GSK did not transfer, assign or license any rights of use or exploitation or any interest in patent rights or any licence in patents owned exclusively by GSK, ratiopharm has no entitlement to any right or interest in the Patents, express or implied, and is not entitled to the benefit of the Patents pertaining to GSK's ratio HFA invention other than the right to market and sell ratio HFA. Therefore, ratiopharm argues, the Board has no jurisdiction under the *Act* in relation to the sale of ratio HFA in Canada by ratiopharm.

27. Board Staff takes the position that:

    (a) under section 42 of the *Act*, the exclusive rights associated with the grant of a patent include the right to use the invention or to sell the invention to be used;
    (b) by permitting ratiopharm to market and sell ratio HFA in Canada under its own brand name, GSK granted ratiopharm a right the exercise of which, absent such permission, would have infringed the Patents; and
    (c) this results in ratiopharm exercising a right in relation to a patent pertaining to ratio HFA within the meaning of subsection 79(1) of the *Act* and, accordingly, qualifies ratiopharm as a patentee in respect of the sale of ratio HFA.

28. Section 42 of the *Act* provides as follows:

> 42. Every patent granted under this *Act* shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this *Act*, grant to the patentee's legal representative for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.

c. The "ex-factory price" Issue

29. ratiopharm argued that the Board might have jurisdiction over GSK, the manufacturer of ratio HFA, with regard to GSK's ex-factory sales of ratio HFA to ratiopharm, but not over ratiopharm's resale of ratio HFA pursuant to the Agreements. In ratiopharm's view, there cannot be two patentees, each with a different ex-factory, or factory gate price, or manufacturer's price of a medicine for the same unit in the same sales and distribution chain. ratiopharm relies on *Pfizer Canada Inc. v. Attorney General of Canada* 2009 FC 719 ("*Pfizer*") to conclude that the Board's jurisdiction is limited to the first sale in the supply or distribution chain, in this case the sale of ratio HFA by GSK to ratiopharm for resale by ratiopharm to wholesalers, pharmacies, hospitals, or others.

30. Subparagraph 4(1)(*f*)(ii) of the *Regulations* requires patentees to file, as part of the information related to a patented medicine required to be filed by paragraph 80(1)(*b*) of the *Act*, the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold by a patentee to each class of customer in each province and territory. "Ex-factory price" is not defined in the *Regulations*.

31. In the Board's Patentee's Guide to Reporting (the "Guide"), "ex-factory price" is defined in part as follows:

> Ex-factory price: The price established for the first sale … of the product "at arm's length" to distributors, wholesalers, hospitals, pharmacies, etc… The ex-factory price is generally the "list price" for medicines …

32. The Board thus identified in the Guide as the "ex-factory price" the point at which patented medicines are sold to distributors, wholesalers, hospitals or pharmacies, as distinct from retail sales. If the Board is to carry out its statutory mandate as determined in *ICN* with consistency, it must be responsive, in establishing the price over which it has jurisdiction, to different sales, distribution, commercial and marketing arrangements, such as those applicable to ratiopharm where ratiopharm purchases ratio HFA from GSK, the manufacturer, and resells it at a price that it determines to distributors and pharmacies for sale to customers.

33. Moreover, the Panel notes that *Pfizer* did not address or determine who, in any specific circumstances such as those in the case before the Panel, can be considered to be the patentee for the purposes of sections 83 and 85 of the *Act*. Neither did *Pfizer* address or determine therefore what is, under such specific circumstances, the "publicly available ex-factory price" for the purpose of subparagraph 4(1)(*f*)(ii) of the *Regulations* or the "first" or "list" price of the medicine at issue.

d. The meaning of "patentee" for the purposes of sections 80 to 85 of the *Act*

34. The issue of whether ratiopharm is a patentee with respect to the sale of ratio HFA requires the Panel to determine whether ratiopharm can be characterized as "any other person entitled to exercise any rights" in relation to a patent pertaining to ratio HFA within subsection 79(1) of the *Act* at the time of the sale of ratio HFA in Canada by that other person.

35. It is a well established principle of statutory interpretation that "the words of an *Act* are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the *Act*, the object of the *Act*, and the intention of Parliament." The Supreme Court agreed in *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27 ("*Rizzo*") with this basic principle enunciated by Elmer Driedger in *Construction of Statutes* (2nd ed. 1983) and it has been generally applied by the courts since.

36. In *Shire Biochem Inc. v Attorney General of Canada*, 2007 FC 1316, Russell, J., relying on *Rizzo* and on the provisions of the *Interpretation Act*, considered that the interpretation of the jurisdiction conferred on the Board by statute requires a purposive analysis and as fair, large and liberal a construction of the words of the statute as will best ensure the attainment of the objective of the statute, in accordance with the relevant jurisprudence.

37. In *Celgene Corp. v. Canada (Attorney General)*, 2011 SCCI ("*Celgene*"), the Supreme Court agreed with the Board and the Federal Court of Appeal that, in interpreting disputed words in the *Act*, the legislative context and the purpose of the statute must be considered. It agreed with the Court below that the meaning of the words "sold in any market in Canada" in sections 80(1)(*b*), 83(1) and 85 of the *Act* cannot be given a meaning strictly in accordance with commercial law principles. The words must yield to an interpretation that best meets the overriding purpose of the statute.

38. Abella, J., speaking for the full Court in *Celgene*, agreed that the purpose of the *Act* was, as affirmed in *ICN*, consumer protection, and that the mandate of the Board was to ensure that Canadians have access to patented medicines that are reasonably priced. An interpretation by the Board of its mandate under disputed provisions of the *Act* consistent with its consumer protection purpose should not be disturbed and therefore, the Supreme Court held in *Celgene*, the Board's jurisdiction extends to a patented medicine shipped from the United States to doctors in Canada and paid in the United States in U.S. dollars as a medicine "sold in any market in Canada".

39. In addressing the meaning of "patentee" in section 79 of the *Act*, both the Board and the Federal Court have taken a purposive approach. In PMPRB-99-D6-NICODERM (August 8, 2000), a panel of the Board considered whether Hoechst Marion Roussel Canada Inc. ("HMRC"), selling Nicoderm in Canada pursuant to a Licensing Agreement between its parent and the holder of the relevant Canadian patents, was itself a patentee for the purpose of section 83 of the *Act.* The panel concluded as follows:

> The definition of "patentee" for the purposes of the Board's jurisdiction is expressly broadened by section 79(1) of the *Act* to include not only the person entitled for the time being to the benefit of the patent but also any person entitled to exercise rights in relation to the patent. Needless to say, this expansion of the definition of patentee is necessary for the Board to fulfil its mandate. The Board must be able to prevent excessive pricing of medicines by persons taking advantage of the patent regime established by the *Act*, whether or not they are actually the holder of a patent or patents pertaining to the medicine.

40. In *Hoechst Marion Roussel Canada Inc. v. Canada*, [2005] F.C.J. No. 1928, at paragraph 128, Heneghan, J. agreed that, while the patents at issue were actually held by a party other than HMRC under a License Agreement between the patent holder and HMRC's parent, HMRC was authorized to exercise in Canada the rights held by its parent under that Agreement and HMRC thus was within section 79 of the *Act* with respect to those patents.

41. Turning to the situation before us and considering the words of the *Act* and the mandate and purpose of the Board, the Panel notes that subsection 79(1) of the *Act* does not, on its face, encompass only a person who owns a patent in respect of an invention pertaining to a medicine and does not require that a person be entitled to exercise all rights in relation to a patent in order to fall within the definition of patentee for the purposes of sections 80 to 103 of the *Act*. Since subsection 79(1) expressly includes as a patentee any other person entitled to exercise any rights in relation to a patent, it is incumbent on the Panel to assign a meaning to those words that is consonant with the discharge of the Board's statutory mandate.

42. The Agreements gave ratiopharm the exclusive right to set the price of and to sell ratio HFA and to obtain the necessary regulatory approvals to do so. Absent the licence granted, these acts would have violated rights held exclusively by GSK pursuant to section 42 of the *Act*. There can be no doubt that these rights are "in relation to" the patent held by GSK.

43. In the Panel's view, were it to accept ratiopharm's position that the jurisdiction of the Board could be avoided through the supply under contract of a patented medicine at one negotiated price to another party for resale in any market in Canada at a different price set by that second party, while the first party retains ownership in its intellectual property apart from the right to market and sell, the Board's jurisdiction would be severely undermined and the attainment of the objective of the *Act* enunciated in *ICN* in effect rendered nugatory with regard to the patented medicine involved. This would allow the simple insertion of a commercial entity such as ratiopharm in the distribution chain in a manner that would cause the Board to lose the ability to review the pricing of the medicine, without any rationale for this result. Provided that the sale by the patent holder was at a non-excessive price, the distributor who is given the right to resell the patented medicine would be able to sell to pharmacies or other consumers at an unregulated price, thereby completely defeating the Board's mandate.

44. For these reasons the Panel believes that there is a sound basis for the interpretation of section 79 of the *Act* in a manner that captures entities in the position of ratiopharm: not only does the plain meaning of the words in section 79 capture ratiopharm selling ratio HFA under an agreement with GSK as a person entitled to exercise rights in relation to the Patents, but the purposive interpretation of the *Act* requires such a conclusion in order for the Board to carry out its statutory mandate.

e. Conclusion

45. The Panel concludes that, for the reasons enunciated, ratiopharm is a patentee under sections 79 to 85 of the *Act* with respect to the sale of ratio HFA in any market in Canada, and that, as a patentee, it had the sole responsibility to ensure that the price at which it sold ratio HFA in any market in Canada was not excessive under sections 83 and 85 of the *Act*.

46. The Panel is of the view that, although GSK may hold title to the Patents related to ratio HFA, in the circumstances of this case, and in accord with the purposive construction of the words "selling [a] medicine in any market in Canada" in section 83 of the *Act*, GSK is not the patentee of ratio HFA for the purpose of that section. GSK is not, in the Panel's view, in the circumstances of the case before it, the party responsible for ensuring that the price paid by Canadian consumers for ratio HFA is set at a non-excessive level, as required by the *Act.* ratiopharm is.

47. The Panel notes further that, by virtue of subsection 4(5) of the *Regulations*, as a patentee who sells a patented medicine to another patentee, GSK is exempt from filing the price and sales information for ratio HFA required by section 80 of the *Act*, and section 4 of the *Regulations*, including the publicly available ex-factory price at which ratio HFA was sold.

III. Whether ratiopharm has sold ratio HFA in any market in Canada at an excessive price, contrary to sections 83 and 85 of the *Act*.

a. The Board's jurisdiction over excessive pricing

48. Section 83 of the *Act* confers on the Board the power to find that a patentee of an invention pertaining to a medicine is selling or has sold the medicine in a market in Canada at a price that, in its opinion, is excessive and, upon such a finding, to issue remedial orders to offset the amount of excess revenues estimated by the Board to have been derived by the patentee from such sale. The Board can

make an order, *inter alia*, that a payment be made to Her Majesty in right of Canada of an amount specified in the order.

49. Subsections 85(1) and (2) of the *Act* set out the factors to be taken into consideration by the Board in making a determination under section 83, to the extent that information on these factors is available to the Board. They are as follows:

> 85.(1) (*a*) the prices at which the medicine has been sold in the relevant market;
> (*b*) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
> (*c*) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
> (*d*) changes in the Consumer Price Index; and
> (*e*) such other factors as may be specified in any regulations made for the purposes of this subsection.
>
> 85.(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:
> (*a*) the costs of making and marketing the medicine; and
> (*b*) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

50. The Panel must therefore determine whether or not the price of a patented medicine sold in Canada is, or was, excessive, by comparing the price of the medicine in Canada to the price at which comparable medicines are sold in Canada, by comparing the price at which the medicine is sold in other countries specified in the *Regulations* and the price at which comparable medicines are sold in those countries, and by taking into account changes in the Consumer Price Index ("CPI").

b. Filing requirements under the *Act*

51. The Board's ability to fulfil its mandate under sections 83 and 85 of the *Act* to monitor the prices of patented medicines and make remedial orders in response to incidences of excessive pricing is dependent on a system of self-reporting. Under paragraph 80(1)(*b*), of the *Act*, patentees must, as required by and in accordance with the *Regulations,* provide to the Board for stated periods, *inter alia*, price and sales data for the patented medicines they sell in Canada.

52. Subparagraphs 4(1)(*f*)(i) and (ii) of the *Regulations* provide in part as follows:

> 4(1)(*f*) For the purposes of paragraphs 80(1)(*b*) and (2)(*b*) of the *Act*, information identifying the medicine and concerning the price of the medicine shall indicate:
>
> (i) the quantity of the medicine sold in final dosage form and either the average price per package or the net revenue from sales in respect of each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory,
>
> (ii) the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory.

53. For the purposes of subparagraph 4(1)(*f*)(i) of the *Regulations*, subsection 4(4) provides that:

> 4(4)(*a*) in calculating the average price per package of medicine, the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after any deduction of the federal sales tax shall be used; and
>
> 4(4)(*b*) in calculating the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue after any reduction in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of federal sales taxes shall be used.

This information is included in Form 2 Filing implementing section 4 of the *Regulations*. Form 2 Filings allow the Board to calculate the net average transaction price ("ATP") per dose of a patented medicine sold by a patentee during six-months periods, on the basis of net revenues and total units sold, as required by section 4 of the *Regulations*.

c. ratiopharm's Form 2 Filings for ratio HFA

54. Although ratiopharm sold ratio HFA in Canada beginning in September 2002, it did not file any information in respect of the sale of ratio HFA until requested to do so by Board Staff. On September 29, 2006, ratiopharm filed Form 2 Filing information for ratio HFA for the period July 2, 2002 to June 30, 2006 and continued to file such information for subsequent periods (the "Initial Form 2 Filings"). In the Initial Form 2 Filings, the net revenues derived from the sale of ratio HFA were calculated by deducting from gross revenues amounts paid as (i) fees for product distribution; (ii) prompt pay discounts; and (iii) product returns.

55. On March 30, 2009, approximately eight months after the issuance of the Notice of Hearing regarding ratio HFA, ratiopharm filed revisions to its Initial Form 2 Filings for the period July 2, 2002 to December 31, 2008 (the "Revised Form 2 Filings"). ratiopharm stated that these revisions were due to an oversight in the calculation of average prices in the Initial Form 2 Filings. In recalculating the net revenues derived from the sale of ratio HFA, ratiopharm made further deductions: it deducted from gross revenues, as rebates: (i) amounts paid to pharmacies referred to as continuing education ("CE") payments; (ii) performance enhancement program ("PEP") payments – collectively "Professional Allowances"; (iii) prompt pay discounts; and (iv) amounts related to product returns. ratiopharm removed as rebates the fees for product distribution previously included. The result of the revisions is a significant reduction in ratiopharm's ATP for ratio HFA during these periods, amounting to tens of millions of dollars. The revised ATPs for ratio HFA in the 2003-2007 period range from 11% to 26% lower than the ATPs based on the Initial Form 2 Filings for those years.

d. The role of the Board's Guidelines in determinations of excessive pricing

56. A decision of the Board under subsection 83(1) of the *Act* is discretionary in that the Board is required to formulate an opinion whether a medicine is sold or has been sold in any market in Canada at an excessive price. In formulating such an opinion, the Board is required to take into consideration the factors enumerated

in subsection 85(1) and no others, unless the Board is unable to make a decision on those factors and thus needs to consider the factors set out in subsection 85(2) of the *Act*. Subsection 85(1), however, provides only basic factors and limited guidance to the Board in determining excessive pricing.

57. The Board's Guidelines are intended to implement subsection 85(1) of the *Act* by providing parameters and information on how the Board, in the normal course, will assess the factors in subsection 85(1) to make a determination of excessive pricing. The Guidelines were issued by the Board after consultation with its stakeholders and are periodically updated after further consultations. Pursuant to subsection 96(4) of the *Act*, the Guidelines are not binding on the Board or on any patentee. However, they provide detailed and comprehensive guidance and predictability to patentees, as well as transparency and consistency in the discharge of the Board's mandate.

58. As recently as December 21, 2009, in PMPRB-07-D5 Quadracel and Pentacel ("*Quadracel*"), a panel of the Board emphasized that it has been recognized by all prior panels of the Board, and by the Federal Court, that a panel, when considering whether a medicine is being sold or has been sold at an excessive price, can give due consideration to the Board's Guidelines.

59. In *ICN Pharmaceuticals, Inc. v. Canada* (*Patented Medicine Prices Review Board)*, [1996] F.C.J. No. 1112 (FC-TD), Rothstein, J., then a Federal Court Justice, considered whether the Board acted without jurisdiction in taking into consideration its Guidelines in deciding whether Virazole had been sold at an excessive price, given that such Guidelines are not an enumerated factor in subsection 85(1) of the *Act*. He stated, at paragraph 6:

> 6. The applicants say the Board could not have regard to its Guidelines under subsection 85(1) as the Guidelines are not an enumerated factor in the subsection. However, each factor listed in subsection 85(1) is not an abstract concept that would be useful in a vacuum. The Board is obviously required to consider the factors in subsection 85(1) according to some rationale, approach or methodology. The rationale, approach or methodology may be ad hoc or may be derived from the Board's Guidelines. That it had regard to the Guidelines for rationale, approach or methodology did not take the Board outside of the scope of subsection 85(1)[2].

Rothstein, J. specified in note 2 of paragraph 6 of his judgment that, had the Board treated the Guidelines as binding, it may well have erred, in light of subsection 96(4) of the *Act*.

60. A Board panel must thus be satisfied that the Guidelines provide for an appropriate implementation of subsection 85(1) of the *Act* in a case before it. The panel's conclusions in that regard will be informed by the evidence and argument of the parties, with the initial onus resting on the staff of the Board to satisfy the panel, in light of the factors set out in subsection 85(1), of the appropriateness of applying the Guidelines*,* and to convince the panel that the price of a medicine is excessive, on a balance of probabilities: see, for example, *Leo Pharma Inc. v. Canada (Attorney General)* 2007 FC 306, at paragraph 27 ("*Leo Pharma*").

61. It was made equally clear in *Quadracel* that a panel can depart from the Board's Guidelines when it is satisfied that it is appropriate to do so, based on the evidence, in reaching a conclusion on excessive pricing. The panel's determinations must be based on a balanced consideration of the factors in the *Act* taken together and after due consideration of the appropriateness of the Board's reliance on the pricing tests set out in the Guidelines and on the presumption of excessive pricing flowing from them in the case before it.

62. It was the testimony of Ms. Ginette Tognet, Director of Regulatory Affairs and Outreach Branch of the Board and responsible for conducting the price review of patented medicines, that the allegations of excessive pricing by Board Staff with regard to the sale of ratio HFA by ratiopharm are based on analyses that are consistent with the pricing and other tests set out in the Board's Guidelines. However, despite the presumptive effect of the analysis conducted in accordance with the Guidelines, Board Staff presented evidence and arguments for the Panel's consideration during the Proceeding concerning: the appropriateness of applying the Guidelines in the circumstances of this case; the weight to be given to any particular factor in subsection 85(1); and the appropriateness of a departure from the applicability of the Guidelines as advocated by ratiopharm. Board Staff did not simply rely on the existence of the Guidelines, but adduced evidence and made argument to the effect that the Guidelines provided an appropriate implementation of subsection 85(1) of the *Act* in the particular circumstances of the case before the Panel.

e. The pricing of ratio HFA by ratiopharm

63. When ratiopharm began to sell ratio HFA in Canada in September 2002, there were four salbutamol MDIs containing a chlorofluorocarbon ("CFC") propellant available:

i. Ventolin CFC, at a list price of $12.27 per MDI, in the market in Canada since 1972, well before the establishment of the Board in 1987;

ii. ratio-Salbutamol;

iii. Apo-Salvent; and

iv. Novo-Salmol, at list prices of $4.64 per MDI.

Airomir, a salbutamol CFC-free MDI introduced in Canada in 1998, was also available at a list price of $4.65 per MDI.

64. As a result of a Canadian government ban of the use of CFC in MDIs, CFC-containing MDIs were no longer sold in Canada after December 31, 2002. Apo-Salvent, an authorized generic version of Airomir, was an additional CFC-free MDI made available in 2002. The list price of ratio HFA and CFC-free Apo-Salvent was set at $4.64 per MDI and Airomir soon reduced its list price from $4.65 to $4.64 per MDI. Ventolin HFA was also introduced in Canada by GSK in 2002, at the same list price per MDI as Ventolin CFC.

65. The list price of ratio HFA, Airomir, and CFC-free Apo-Salvent remained the same until November 2004 when ratiopharm, then holding approximately 75% of the Canadian market for salbutamol MDIs, raised the list price of ratio HFA by 67% to $7.73 per MDI. There had been no increase in Canadian prices of comparable medicines prior to this price increase. International prices had generally declined or been stable since 2002. In the weeks following the increase in the price of ratio HFA, the list prices of Airomir and CFC-free Apo-Salvent were also raised to $7.73 per MDI. In October 2009, GSK advised the Board of the expiry of the Agreements and of the reduction of the list price of Ventolin HFA to $6.50 per MDI to obtain provincial formulary listings. ratio HFA's list price was reduced to $6.50 per MDI in November 2009 until ratiopharm's stock of ratio HFA was liquidated by the end of January 2010. The list price of Airomir was substantially reduced following a voluntary compliance undertaking ("VCU") with the Board in April 2007. CFC-free Apo-Salvent is currently the subject of an excessive price proceeding before the Board.

f. Board Staff's application of the Guidelines pricing tests

66. When a patented medicine is introduced to the market in Canada, the maximum non-excessive price ("MNE") of the medicine is determined by the staff of the Board based on either the price of comparable medicines, i.e. medicines in the same therapeutic class, or on the international prices of the medicine – median or

the highest – as sold in the seven countries specified in the *Regulations*. The price of the new medicine at introduction will be presumed by the staff of the Board not to be excessive under the Board's Guidelines if it is sold at or below the MNE thus established. In subsequent years, the yearly MNE is determined by the ATP of a previous year, grown by the CPI factors (if the patentee elects to so increase the price of the medicine) according to the Board's CPI-Adjustment Methodology, subject always to the price of the medicine not being the highest price of the medicine in the seven stipulated countries. The ATP of the medicine for a given year will be presumed not to be excessive if it is at or below its MNE for that year.

67. Under the Board's Guidelines, no further pricing test is required to make a determination of excessive pricing once the MNE of a medicine at introduction is established. However, in light of the position of ratiopharm on the appropriateness of relying on this test in the case of its sale of ratio HFA, Board Staff conducted further pricing tests in preparation for this Proceeding. Tests were conducted for the post-introductory period and until 2009, based on the price of comparable medicines sold in Canada and in the countries specified in the *Regulations*. The calculations of net revenues for ratio HFA, with CE and PEP rebates, could only cover to the end of the 2008 reporting periods in light of the Form 2 Filing information provided by ratiopharm at that time. Some information was updated during the Proceeding.

i) Determining comparability

68. As suggested by the Board's Guidelines, the comparable medicines used by Board Staff to establish the introductory MNE of a Category 1 medicine and to conduct price tests under subsection 85(1) of the *Act* are determined pursuant to a scientific review designed to identify medicines that are clinically equivalent in addressing the approved condition for which they are used, and having comparable dosage form and strength. These criteria establish the therapeutic class of the medicine for the purposes of paragraphs 85(1)(*b*) and (*c*) of the *Act*. The Human Drug Advisory Panel ("HDAP"), an independent panel of scientists who advise Board Staff on these matters, recommended that the therapeutic class of ratio HFA include Airomir and the CFC versions of Ventolin, Apo-Salvent, ratio-Salbutamol, and Novo-Salmol. Board Staff used these medicines for the pricing tests at the introduction of ratio HFA in 2002. Board Staff noted that Ventolin was not used for the price test that established the benchmark MNE of ratio HFA because it was subject to investigation for excessive pricing at the time, although it was later found to be non-excessive as of 2003. The Board's practice is not to use a medicine under investigation as a price comparator since it is neither consistent nor logical to establish the MNE of a medicine by reference

to the price of a medicine that may, itself, be excessively priced. (See PMPRB-99-D10-Nicoderm-Merits (April 9, 2010)).

69. The appropriate comparators to ratio HFA sold in Canada and in the countries specified in the *Regulations* for assessing the price of ratio HFA after the introductory period were found by Board Staff to be Ventolin HFA after 2003, Airomir, and CFC-free Apo-Salvent and, in six of the seven countries specified in the *Regulations* Ventolin HFA, and in Germany, Ventolin HFA and ratio HFA.

70. ratiopharm sought to expand the therapeutic class of comparators of ratio HFA used for these pricing comparisons. Ms. Joan McCormick, a consultant at Brogan Inc., now IMS Brogan, but not a medical expert, pharmacist or scientist, gave evidence to that effect. Her evidence was contrary to that given on behalf of Board Staff by Dr. Adil S. Virani, Assistant Professor of Pharmaceutical Sciences at the University of British Columbia, Director of Pharmacy Sciences at the Fraser Health Authority and a member of the HDAP. Dr. Virani testified that it is not necessary to compare ratio HFA to further medicines, given the existence of the drug products with the same dosage form of the same active ingredient as those of ratio HFA. Dr. Virani's evidence was that salbutamol MDIs constitute the appropriate class of comparators for ratio HFA, "the best apples to apples comparison". The evidence of Dr. Tom Kovesi, a pediatric respirologist, was that the additional medicines that Ms. McCormick sought to add as comparators to ratio HFA for pricing comparisons are not, in fact, clinically equivalent to ratio HFA.

71. The Panel is satisfied, on the basis of the evidence, that the correct comparators were used by Board Staff to establish the non-excessive price of ratio HFA at introduction and in the period 2002 to 2009.

ii) The introductory price of ratio HFA and paragraphs 85(1)(a) and (b) of the Act

72. By reference to publicly available prices of the comparators to ratio HFA in Canada, Board Staff found the price of ratio HFA during the introductory period to have been non-excessive when assessed according to the test set out in the Board's Guidelines. The Therapeutic Class Comparison Test in the Guidelines provides that the price of the medicine at introduction will be presumed not to be excessive by Board Staff if it is no higher than the price of its highest comparator. The introductory price of ratio HFA was lower than the highest price of comparable drugs sold in Canada.

73. The ATP of ratio HFA in the period after introduction was calculated by Board Staff with the deduction of only the prompt pay discounts and returns filed by ratiopharm in its Initial Form 2 Filings and then, when ratiopharm filed the Revised Form 2 Filings, with the added deduction of the CE and PEP rebates recorded in the Revised Form 2 Filings. Board Staff found ratio HFA's ATP to be non-excessive in both cases until after the list price of ratio HFA was raised to $7.73 per MDI in November 2004. It is common ground between the Parties that, absent a departure by the Panel from the Board Guidelines' pricing methodology, the price of ratio HFA, on the basis of both the original and revised Form 2 information, is excessive after 2004. The only issue is the quantum of the excess revenues. These are essentially cut in half if all rebates that ratiopharm claims in the Revised Form 2 Filings, rather than only prompt pay discount and returns in the Initial Form 2 Filings, are taken into account.

74. Since 2005, the public price of ratio HFA and its ATP, without the deduction of CE and PEP rebates, were higher than the Canadian public prices of comparable medicines not considered to be excessive, including the public price of Ventolin HFA which trended downward after 2002. The public price of ratio HFA, without the deduction of CE and PEP rebates, was also higher than the CPI-adjusted VCU price of Airomir. With the full deduction of CE and PEP, ratio HFA's ATP remained below the price of Ventolin HFA. The public price of Apo-Salvent was not relied upon as a comparator for the price tests however as it is the subject of an investigation for excessive pricing.

75. ratiopharm objected to the fact that Board Staff used, as the list price of Ventolin HFA for the price tests conducted for the period 2003 to 2009, the average price of sales of Ventolin HFA by GSK to hospitals and to community pharmacies. ratiopharm referred to this average price as a "mixed market price" which, in its view, is a variable or shifting price at which Ventolin HFA is not in effect sold in any market. ratiopharm indicated that the proportion of sales of Ventolin HFA by GSK to hospitals at one price and to community pharmacies at another price varies over time and the price of Ventolin HFA to hospitals can be as low as 25% of the price of Ventolin HFA to community pharmacies. Therefore, in its view, using an average for the price of Ventolin HFA has the effect of keeping the price of Ventolin HFA to pharmacies lower than it should be for the purpose of a comparison with the list price of ratio HFA, to ratiopharm's detriment. ratiopharm argued that the price of ratio HFA should be compared only to the IMS Health Inc., now IMS Brogan ("IMS") price of Ventolin HFA to pharmacies which, it claims, contrary to Board Staff's tests, has remained above the price of ratio HFA.

76. Ms. Tognet referred to the public price used for Ventolin HFA as an average public price as collected by IMS in the ordinary course on the basis of total sales and total number of units sold, rather than the 'constructed' price claimed by ratiopharm. She emphasized that this approach for determining average price is consistently applied by the Board, most recently in its investigation of the comparable medicine, Airomir.

iii) Paragraph 85(1)(c) of the Act

77. An International Price Comparison Test ("IPC") and an International Therapeutic Class Comparison Test ("ITCC") were also conducted by Board Staff in preparation for the Proceeding, in the manner described in (though not in these circumstances required by) the Board's Guidelines and using publicly available ex-factory prices of ratio HFA and of comparable medicines in the seven countries specified in the *Regulations*. In accordance with the Guidelines, under the IPC test, the price of a patented medicine sold in Canada will be presumed by Board Staff not to be excessive if it is not the highest of the international prices of the medicine in the comparator countries identified in the *Regulations.* Under the ITCC test, primary weight is given to the median of the international prices. At introduction, the price of ratio HFA in Canada was less than the highest ex-factory price of Ventolin HFA and of ratio HFA in the seven countries listed in the *Regulations.* Neither did ratio HFA's introductory price exceed the international median of the ITCC test.

78. However, since 2004, allowing the deduction of the CE and PEP amounts claimed by ratiopharm, the ATP of ratio HFA exceeded the median international price ("MIP") of ratio HFA in 2005, 2007 and 2008. Without such deduction, ratio HFA's ATP was higher than the MIP of ratio HFA in each year from since 2004, although ratio HFA's price was not the highest price in the comparator countries.

iv) Paragraph 85(1)(e) of the Act

79. Board Staff found that, in each year since 2005, the price of ratio HFA has exceeded substantially its MNE adjusted for CPI in accordance with the three-year banking methodology set out in the Board's Guidelines*,* even if its ATP is calculated with the deduction of the CE and PEP amounts claimed by ratiopharm.

80. ratiopharm objected to the application by Board Staff of the methodology established in the Board's Guidelines for CPI adjustments in assessing the price of ratio HFA after introduction. Its objection was based in large part on the argument that, in 2002, when the benchmark MNE of ratio HFA was set, ratiopharm could have, within the pricing tests in the Board's Guidelines, introduced ratio HFA to the market at the $9.02 per MDI public price of Ventolin HFA, based on IMS data, rather than at the "arbitrarily low" price of $4.64 per MDI.

81. ratiopharm argued that it introduced ratio HFA in 2002 at an artificially low price that did not reflect its costs of acquisition from GSK, in response to the government's expectation, when the use of the CFC propellant in MDIs was banned, that the use of another propellant not be the cause of price increases for MDIs. Dr. Richard Schwindt, an expert economist, testified on behalf of Board Staff regarding the appropriateness of using ratio HFA's introductory price as the benchmark to calculate subsequent price increases. He was of the view that the evidence indicates that the price constraint on ratiopharm for ratio HFA at introduction was likely the presence of CFC-free Airomir in the market at a list price of $4.65 per MDI, at parity with the competing CFC MDIs, and of CFC-free Apo-Salvent at $4.64 per MDI and that, effectively, ratio HFA was introduced in a price competitive market in 2002 that informed its pricing strategy at the time. The introductory price of ratio HFA thus was not arbitrarily or artificially low, but rather calculated on the basis of the market conditions prevailing at the time of introduction.

82. Dr. Schwindt's expert opinion was that the Board's CPI-adjustment methodology in the Board's Guidelines, which permits a limit of a three-year "bank" of price increases, reflects the desirability of avoiding excessive changes in the price of a medicine in a given period, changes which would be at the expense of price stability and predictability for consumers and contrary to the *Act's* objective. Dr. Ronald J. Corvari, Director of the Policy and Economic Branch of the Board until 2008, testified that sudden and significant price increases was one of the major concerns of the Board during the extensive stakeholder consultations that led to the 1994 changes in the CPI-adjustment methodology in the Board's Guidelines. The Guidelines allow a patentee to increase the price of its medicine in line with increases in CPI, and provide some flexibility in that regard by allowing a patentee to "bank" increases for a limited period, but prevent sudden significant price increases by limiting that banking of price increases to the three most recent years of CPI.

83. Board Staff submitted in argument that, given its submissions on the application of the Board's Guidelines to the evidence before the Panel, the Panel should find that the price of ratio HFA has been excessive since 2004. It argued however that, in light of the very magnitude of the price increase of 67% effected by ratiopharm for ratio HFA in 2004, at a time when there was no change in the price of Airomir or CFC-free Apo-Salvent, the price of Ventolin HFA was decreasing and prices for comparable medicines in foreign countries were stable or decreasing, the Panel should, in its discretion, give greater weight to the CPI factor in this case.

84. The Panel considers that the Board's CPI-adjustment methodology constitutes an important protection from sudden and significant price increases. It is intended to moderate the extent to which a patentee may increase the price of a medicine from year to year. The Panel concludes that it should be given considerable weight in this case, where the price of a widely-used patented medicine was increased suddenly and significantly in 2004 in circumstances that, in the Panel's view, did not warrant such an increase. The Panel accepts the appropriateness of applying the CPI-adjustment methodology in the manner contemplated by the Board's Guidelines and in line with ratio HFA's MNE at introduction.

v) Paragraph 85(1)(e) of the Act

85. No other factor to be taken into consideration by the Panel for the purposes of subsection 85(1) determinations has been specified in the *Regulations*.

vi) Subsection 85(2) of the Act

86. In accordance with subsection 85(2) of the *Act*, the Panel need only take into consideration the factors set out therein if it is unable to determine whether the medicine under review is being or has been sold at an excessive price after taking into consideration the factors referred to in subsection 85(1).

87. ratiopharm introduced evidence with regard to the costs of acquisition of ratio HFA and with regard to the costs of making and marketing ratio HFA prepared by Cole Valuation Partners Limited ("Cole Partners"). Board Staff, for its part, submitted that it is neither necessary nor appropriate for the Panel to consider subsection 85(2) factors in the circumstances of this case since its evidence was that, since 2004, under all the factors identified in subsection 85(1) of the *Act*, implemented in accordance with the Board's Guidelines, only when the full amounts of the CE and PEP claimed by ratiopharm are deducted to determine the ATP of ratio HFA is the price of ratio HFA lower than the price of Ventolin

HFA. If the price of ratio HFA is compared to the CPI-adjusted VCU price of Airomir, to international prices and to the price resulting from the application of the Guidelines' CPI methodology, even with the full amounts of the CE and PEP claimed by ratiopharm, the price of ratio HFA has been excessive since 2004.

88. The Panel considers that it is in a position to reach a decision in this case on the basis of the subsection 85(1) factors. Moreover, ratiopharm, as the reseller of ratio HFA, has no evidence of the material costs of making ratio HFA nor has it such information within its knowledge or control.

vii) The existence of market power

89. ratiopharm also argued that its price for ratio HFA could not be considered excessive since it did not enjoy monopoly power or even market power in the sale of ratio HFA in any market in Canada. The Panel notes that it was made clear by the Federal Court of Appeal in *ICN* that the existence of market power is not a pre-condition to the Board's exercise of its jurisdiction, nor is it relevant to that exercise.

g. Conclusion

90. Based on Board Staff evidence, the Panel has determined that it is appropriate to apply the tests set out in the Board's Guidelines in this case. It is also satisfied that the price tests conducted by Board Staff allow it to weigh all the factors to be considered under subsection 85(1) of the *Act* in the case before it. However, the Panel's final conclusions on the issue of excessive pricing under section 83 of the *Act* require it to determine first whether and, if so, which rebates claimed by ratiopharm can be taken into account in establishing whether ratiopharm has sold ratio HFA at an excessive price contrary to the *Act*.

IV. Whether, in determining the price at which ratiopharm is selling or has sold ratio HFA in any market in Canada, the Panel can take into account any rebate or discount given by ratiopharm in respect of such sale and reported to the Board pursuant to section 4 of the *Regulations.*

a. The indirect sales and distribution of ratio HFA

91. During the Proceeding, Ms. Saracino described what ratiopharm refers to as an indirect distribution model of ratio HFA almost exclusively to pharmacies for eventual resale to consumers. Under this model, ratiopharm sells ratio HFA, with few exceptions, to what she characterized as 'distributors', consisting of

wholesalers and ‘distribution centres’, for resale to pharmacies. Distribution centres include the distribution arms of large pharmacy groups and buying groups of a number of unaffiliated pharmacies and potentially hospitals who have banded together for purchasing. Wholesalers and distribution centres make up ratiopharm’s corporate accounts, a few individual pharmacies its retail accounts. Witnesses for ratiopharm estimated the number of ratiopharm’s corporate accounts for the sale of ratio HFA to be in the range of ten to twelve.

92. Ms. Saracino’s testimony was that wholesalers and distribution centres purchase ratio HFA from ratiopharm at the list price and sell ratio HFA to pharmacies at that same list price and on terms of payment they negotiate and enforce independently of ratiopharm. Wholesalers and distribution centres are paid a fee by ratiopharm for what Ms. Saracino characterized as their distribution services. They also generally benefit from prompt pay discounts and handle the return to ratiopharm of ratio HFA product recalled, damaged or beyond expiry date and for which they issue a credit to retailers and then receive an associated credit from ratiopharm. Distributors distribute ratio HFA at the price they paid ratiopharm for the product, with no mark-up. This model avoids the need for ratiopharm to own and operate its own system of distribution to retailers or to follow up with delinquent accounts.

93. It was Ms. Saracino’s view that in this indirect business model, distributors do not sell ratio HFA or market it but that it is their distribution services they sell.

94. Ms. Saracino explained that the quantities of ratio HFA that individual pharmacies are forecast to purchase through wholesalers and distribution centres are estimates made by those pharmacies for varying forward-looking periods. These estimates generate the supply need. The percentages to be applied to the total sales of ratio HFA by pharmacies to determine Professional Allowances, CE payments in the case of corporate accounts and PEP payments in the case of retail accounts, are also agreed upon on a going-forward basis. CE and PEP payments are made by ratiopharm directly to individual pharmacies or the regional corporate head offices of banner pharmacies, not to the latter’s distribution arm, according to the level of sales anticipated and the rebate percentage agreed to. Those payments are later validated and reconciled by ratiopharm with the help of data purchased from IMS. The payments made are adjusted in the next sales period, as and when required. Ms. Saracino therefore identified the pharmacy as ratiopharm’s “ultimate customer” in the sales and distribution chain since it is the pharmacy that really creates demand.

b. ratiopharm's Revised Form 2 Filings

95. The deductions claimed for the sale of ratio HFA by ratiopharm in its Revised Form 2 Filings, whether for prompt pay discounts, returns or CE and PEP rebates, consist largely of estimates. All deductions are attributed to ratio HFA sales *pro rata* on the basis of the sales volume of ratio HFA as a percentage of total company sales reported in ratiopharm's accounting records and audited financial statements for all products sold by ratiopharm. The deductions filed are allocated to ratio HFA as a percentage of the company-wide deductions recorded by ratiopharm for all products.

96. The Panel notes that ratiopharm is on record as estimating that it has a portfolio of some 250 products for sale in Canada in a wide variety of dosage forms and therapeutic classes, and that, in the few documents filed by ratiopharm, the percentage used for CE and PEP rebates varies from 0% to 70% and specifically for ratio HFA, between 20% and 40%. Ms. Saracino testified that, for ratio HFA, the percentage applied in a given case could potentially be as low as 0%.

97. From the very outset of the review by the Board of the price at which ratiopharm was selling and had sold ratio HFA, Board Staff expressed to ratiopharm its concerns that the information it was providing to the Board in its Revised Form 2 Filings was not sufficient to enable the Board to confirm that the rebates and expenses claimed by ratiopharm in respect of the sale of ratio HFA were incurred for and properly related to the sale of ratio HFA. The Panel shared these concerns, and this led to the issuance of the Inspection Order by the Panel.

98. A significant portion of the Proceeding involved discussion of 1) whether the Panel needs product- specific documentation to verify the amounts claimed by ratiopharm as rebates in order to ensure that they are incurred, properly supported and directly related to the sales of ratio HFA; and 2) the adequacy of the supporting documentation provided by ratiopharm with regard to the rebates claimed by ratiopharm in respect of ratio HFA. In the Panel's view, as further outlined below, the debate raises questions regarding the *bona fides* of ratiopharm as a party in the Proceeding and the credibility of some of its witnesses.

99. The sworn testimony of Mr. Richard Monk, a certified management accountant with Welch, was that the on-site inspection ordered by the Panel in the Inspection Order, and conducted by Welch, and the documentation provided by ratiopharm during the inspection, did not yield the ratio HFA-specific information required to conclude that the deductions claimed by ratiopharm in its Revised Form 2 Filings were incurred specifically on account of ratio HFA or are otherwise properly

attributable to sales of ratio HFA. This information was not available to Welch or produced to the Board despite the sworn testimony of Ms. Saracino at the hearing of the Preliminary Motions that ratiopharm tracks and records the payment of discounts and rebates on a product-specific basis and that such product-specific documentation is maintained by ratiopharm.

100. During the on-site inspection, in addition to the provision of internal budgets, forecasts, estimates and audited financial statements, ratiopharm agreed to Welch sending a letter to a sample of sixteen pharmacies chosen in concert with ratiopharm, in an attempt to obtain third party confirmation of the percentage applied to sales of ratio HFA for the payment of CE and PEP rebates. Five responses were received. Two pharmacies confirmed the average rate used by ratiopharm, two indicated a different rate and one response was a refusal to provide any information.

101. Long after the on-site inspection ordered by the Panel, which lasted some thirteen days between October 6 and 30, 2009, and after the reply evidence of Welch in the Proceeding had been filed on January 6, 2010, ratiopharm produced examples of information of the type that, Mr. Monk testified at the Proceeding, would have been helpful had it been made available to Welch during the inspection process, but was not. It includes two product-specific CE agreements between ratiopharm and pharmacies, two product-specific CE-related invoices, one example of an internal product-specific sales data reconciliation related to rebates and a limited number of examples of purchase orders and proof of rebate-related payments. Mr. Monk considered in his testimony that this very type of product-specific information for all sales of ratio HFA is necessary to meet the requirements of the Panel in the Inspection Order and for any reliable conclusion to be drawn with respect to the connection between CE and PEP rebates and ratio HFA.

102. During the Proceeding, Ms. Saracino testified, as she had at the hearing of the Preliminary Motions, that ratiopharm retains product-specific information and supporting documentation for sales, as well as reconciliations supporting the payment of all CE and PEP amounts, by customer and by product, and that ratiopharm also tracks and documents returns and prompt pay discounts on a product-specific basis. This information and documentation was not made available to Welch or, other than the few examples tendered, filed with the Board.

103. The Panel notes that, of the seven ratiopharm witnesses who gave testimony during the Proceeding, not one claimed to have direct knowledge of the information used to generate the Revised Form 2 Filings, or to know who was responsible for their preparation. This is despite the fact that the Revised Form 2 Filings were certified to be true and correct by a ratiopharm representative and that the Revised Form 2 Filings were submitted by a representative of ratiopharm who attended most of the Proceeding, but did not testify, and who, according to Mr. Major, reports to Ms. Saracino. The inexplicable vacuum of data and the failure of any ratiopharm witness to speak directly to the significant revisions made to ratiopharm's pricing information made it impossible for the Panel to assess the integrity of the rebate information and therefore to give it any weight in this Proceeding. It should be noted that this is a separate matter from the interpretive question of whether *Pfizer* precludes the consideration of the rebates. This is an evidentiary matter: there is an unexplained failure by ratiopharm to file credible information about the rebates that the Board requires in order to calculate the ATP of ratio HFA – information that ratiopharm's witness swore that ratiopharm possesses.

c. The Debate

104. Mr. Monk and Mr. Andrew Milner, a chartered accountant with Welch, repeatedly recognized in cross-examination by ratiopharm counsel during the Proceeding that there is evidence that ratiopharm has paid out significant amounts in rebates across all the products it sells. These witnesses, however, cast the appropriate question as being whether there was sufficient evidence before the Panel connecting these payments to the ratio HFA product itself so that they could be legitimately used in reducing its net price.

105. Mr. Monk's expert opinion was that, in order to support claims for rebates for past transactions, at a minimum, ratiopharm should have provided: third party confirmation for CE and PEP percentage rates and sales data reconciliation information in respect of ratio HFA; documentation with respect to the terms and conditions of all amounts paid in respect of ratio HFA; and internal reconciliations supporting the payment of CE and PEP rebates given for ratio HFA. Only with this type of accurate ratio HFA-specific information can the Board, in his expert view, properly calculate the ATP and make other pricing calculations with respect to a medicine.

106. Dr. Ramy Elitzur, professor of financial analysis, gave expert evidence on behalf of ratiopharm as to whether the deductions claimed by ratiopharm in respect of ratio HFA and the documentation used by ratiopharm to calculate them are reasonable in the circumstances. In his expert opinion, from a management

accounting perspective, the test should be whether the rebates claimed are reasonably attributable to ratio HFA in the context of ratiopharm's business realities. It suffices, in his view, if disbursements are accurately tracked by ratiopharm in its books and records and reflected in its audited financial statements. He opined that it is reasonable to calculate Professional Allowances for ratio HFA based on the average Professional Allowances paid across all products.

107. Professor Elitzur expressed the view that management accounting posits specific guidelines and factors to be taken into account, including not only financial accounting and auditing standards and effective control procedures but also certain criteria such as business realities and situational relevance related to a specific business context. He would not, however, relate his analysis to a regulatory context or to whether information useful for business needs, internal management accounting and decision-making is necessarily sufficient to verify compliance with regulatory requirements. He stated that this was not part of the mandate given to him, although the questions for which his opinion was sought by ratiopharm had included a request to relate his comments "to the matter involving ratiopharm and the PMPRB in respect of ratio-Salbutamol HFA."

108. Mr. Scott Davidson, a chartered accountant and specialist in investigative and forensic accounting and Mr. Larry Andrade, a chartered accountant, both with Cole Partners, commented on the report filed by Welch following the on-site inspection and gave opinion evidence on behalf of ratiopharm similar to Professor Elitzur's with regard to the adequacy of the supporting information filed by ratiopharm with respect to rebates. Their view was that a "reasonably attributable" test is adequate, in light of the absence of established specific Board standards, guidelines and policies, in the Board's Guidelines, the Guide or elsewhere, with respect to the information and documentation to be filed in support of rebates claimed pursuant to the *Regulations*. They acknowledged that their evidence was prepared without independent verification of the accuracy of the information provided to them by ratiopharm.

d. Conclusion

109. Paragraph 80(1)(*b*) of the *Act* specifies the information that must be provided to the Board by a patentee of a medicine, in accordance with the *Regulations*, respecting the price at which the medicine is being sold or has been sold in any market in Canada. For the purposes of paragraph 80(1)(*b*), the information required by subparagraph 4(1)(*f*)(i) of the *Regulations* is the average price of and net revenue from sales of the medicine and, pursuant to paragraph 4(4)(*a*),

rebates with respect to the specific medicine at issue must be taken into account ("le" médicament in the French-language version).

110. In the reasons for its decision leading to the Inspection Order, Decision: PMPRB-08-D2-ratio-Salbutamol ratio HFA – Preliminary Motions (May 22, 2009), at paragraph 29, the Panel emphasized that there is a responsibility on a party subject to ongoing statutory regulation to produce, as required by the regulator in the legitimate exercise of its jurisdiction, the information that it requires for the purpose in a form reasonably capable of permitting that exercise. At paragraph 30, the Panel concluded that the information required in the Inspection Order is necessary for the making of an informed decision in the case before it and in the circumstances surrounding it. Those circumstances include the very substantial increase in ratiopharm's list price for ratio HFA in 2004, the magnitude of its 2009 revisions in its Revised Form 2 Filings for ratio HFA for a number of years, the size and nature of the rebate amounts deducted from its gross revenues in respect of ratio HFA for many years and the impossibility of verifying, in respect of ratio HFA, ratiopharm's pricing and cost information using external sources.

111. The Panel remains of the view that a patentee, in reporting the average price at which a patented medicine is being sold or has been sold, or the net revenue from its sale, is required to file supporting documentation of any rebate claimed in respect of the medicine and that is clearly, directly and verifiably related to the medicine involved. The Panel concludes that, on the basis of its Form 2 Filings and the evidence in the Proceeding, ratiopharm has not met this requirement in respect of the sale of ratio HFA, despite sworn testimony that it has such evidence, and the issuance of a Panel order to produce it. ratiopharm has failed throughout to respond to repeated requests by Board Staff and by the Panel, even during the Proceeding, for information that would allow the Panel to determine the specific pricing issue before it. ratiopharm had a number of opportunities to make available and/or submit the evidence that its representative swore that it had with respect to both the originally claimed and then substantially revised rebate claims, but ratiopharm failed to do so.

112. The Panel concludes that it cannot, in the circumstances, take into account any of the rebates claimed by ratiopharm in respect of the sale of ratio HFA in determining the price at which ratiopharm has sold ratio HFA for the periods involved and whether the price of that specific medicine was excessive contrary to the *Act*.

113. This conclusion is consistent not only with the provisions of the *Act* and the *Regulations,* the filing requirements for the proper discharge of the Board's mandate under sections 83 and 85 of the *Act* and reasonable realities in a regulatory environment but also, as testified by Ms. Tognet, with the type of information filed in support of deductions claimed by patentees in other proceedings before the Board.

114. Subsection 4(4) of the *Regulations* requires the Board to determine the actual price of a medicine after the reductions or rebates set out in that paragraph. Patentees thus have the obligation to keep the records required to support the reductions and rebates attributable to that medicine and to file them with the Board. A panel of the Board must determine their adequacy after reasonable requests for further production for the purpose of applying subsection 4(4) and has the discretion not to consider rebates which are not, in its view, specifically supported by the evidence provided.

e. The applicability of the *Pfizer* judgment

115. Both Board Staff and ratiopharm raised the applicability of *Pfizer* to the issue of the rebates, discounts, refunds and other deductions to be considered by the Panel pursuant to paragraph 4(4)(*a*) of the *Regulations* in calculating the average price of ratio HFA.

116. At issue in *Pfizer* was a Board Stakeholder Communiqué issued on August 18, 2008 (the "Communiqué"). The Communiqué required patentees to include henceforth, as part of their reporting of the net price of a patented medicine pursuant to subparagraph 4(1)(*f*)(i) and paragraph 4(4)(*a*) of the *Regulations,* all rebates, discounts, refunds and other deductions, including payments made to a province as consideration for the province's agreement to list the medicine on the provincial formulary at a specified price.

117. The applicants in *Pfizer* sought judicial review of the Communiqué, on the ground that the Board's jurisdiction is limited to reviewing prices associated with sales of patented medicines made at the factory gate and does not extend to transactions involving third parties that may take place further downstream in the supply chain.

118. In *Pfizer,* Mactavish, J. held that the Board did not have jurisdiction to enforce the requirement that patentees include, as part of the reporting of the net prices of their patented medicines, pursuant to subparagraph 4(1)(*f*)(i) and subsection 4(4) of the *Regulations*, payments made to a province in respect of those medicines, on the ground that such payments are made to third parties.

119. Since *Pfizer* was issued, interpreting the scope of the decision beyond the specific question that was raised in the judicial review proceedings has caused the Board and patentees considerable difficulty.

120. Board Staff takes the position that broad language is used in *Pfizer* that has the impact of excluding payments made by patentees to third parties who are not, in the words of *Pfizer,* a customer of the patentees contemplated by subparagraph 4(1)(*f*)(i) of the *Regulations,* from being taken into account for the purpose of establishing the net price at which a patented medicine is being sold, or has been sold. This would have the effect of excluding from the ATP of ratio HFA, as a matter of law, all of the rebates claimed by ratiopharm. The Panel agrees that there is support for this interpretation in the decision. Both the opening paragraphs of *Pfizer*, as well as the order*,* provide that subparagraph 4(1)(*f*)(i) and paragraph 4(4)(*a*) of the *Regulations* do not authorize the Board to require the reporting of rebates or payments made to third parties by the manufacturers of patented medicines. This is stated to be the central issue in the decision. Even had the question been framed more narrowly, the underlying rationale provided by Mactavish, J. to exclude the payments to the provinces relies upon an interpretation of the legislation that is consistent with commercial law applicable to the sale of goods and is in turn dependent on limiting the scope of reporting to the relationship of privity between a buyer and a seller. Given the rationale used in *Pfizer*, based on the technical private law meaning of "customer", it is difficult to apply *Pfizer* to exclude third party payments to a public party such as the government while ignoring the applicability of *Pfizer* in the private chain of distribution that would fall squarely within the traditional purview of the retail sale of goods.

121. The position of ratiopharm is that *Pfizer* can be read more narrowly. Again, there is support for this position in the decision. The specific question before the Court in *Pfizer* was, as indicated, whether payments to the provinces under expenditure limitations agreements related to the price of patented medicines must be reported under subparagraph 4(1)(*f*)(ii) and subsection 4(4) of the *Regulations*. Furthermore, in *Pfizer*, Mactavish, J. supported the decision in *Leo Pharma*. In *Leo Pharma*, the Court determined that the free distribution of a patented medicine by a patentee to doctors for their patients must be considered, pursuant to the *Regulations*, in establishing the average net price of the medicine. Support for *Leo Pharma* is not consistent with an expansive exclusion of all third party transactions in the calculation of the net price of a medicine.

122. It should also be noted that ratiopharm made a further argument in passing to the effect that *Pfizer* can be read as providing patentees with the discretion to include or exclude payments made to third parties. However, this argument was not pressed very hard before us and for the reasons set out below, the Panel does not accept this argument.

123. Since *Pfizer* was decided, the Supreme Court of Canada has provided further guidance to the Board in matters requiring statutory interpretation. *Celgene* supported the decision of the Board to reject the technical commercial law definition of the words "sold" and "selling" in the *Patent Act* when guided to do so based upon the purpose and legislative history of the *Act* and consumer protection as the Board's mandate recognized by the courts. Furthermore, the Supreme Court of Canada stated in *Celgene* that, when the Board interprets its enabling legislation, it should be accorded deference and only if the Board's decision is unreasonable should it be set aside.

124. In *Pfizer*, the Court had before it an executive Board decision and therefore a limited record and no detailed evidentiary documentation and argument as are developed in a hearing with regard to the operations common to the pharmaceutical industry in the distribution of patented medicines. The business reality of the pharmaceutical industry is one that operates by providing rebates and other payments throughout a chain of distribution. Such business realities must be taken into consideration by the Board if it is to review the true price at which patented medicines are provided to Canadians, in accordance with its statutory mandate, and if it is to give effect to subsection 4(4) of the *Regulations* which remains in force.

125. Guided by the consumer protection goals of its mandate, the Panel is of the view that if it were required to do so, it would conclude that the interpretation of subparagraph 4(1)(*f*)(i) and paragraph 4(4)(*a*) of the *Regulations* set out in the Communiqué is the appropriate one except, given the decision in *Pfizer*, which is binding on the Board, as regards the payments that were at issue in *Pfizer*; i.e. payments to the provinces. In this case then, had the Panel determined that the pricing information filed with respect to ratio HFA was substantively sufficient and credible, it could have deducted payments made by ratiopharm as rebates. However, in light of the Panel's conclusion with regard to the inadequacy of the evidence provided in this regard in the Proceeding, and the resulting inappropriateness of considering rebates in its findings in the circumstances of the sale of ratio HFA by ratiopharm, the Panel need not finally assess the scope of *Pfizer* at this time.

V. What order, if any, should be made by the Panel with respect to the sale of ratio HFA by ratiopharm in Canada.

126. The Panel is satisfied that the evidence and argument of the Parties establish that the Board Guidelines provide for an appropriate implementation of subsection 85(1) of the *Act* in this case and accordingly it is of the view that excessive revenues arising from sales of ratio HFA should be calculated on the basis of the tests provided in the Board's Guidelines which indicate that ratio HFA was excessively priced by ratiopharm from the time of the 2004 price increase until sales ceased in 2010. In particular, the Panel finds that excessive revenues should be calculated using the CPI methodology following the establishment of an MNE for ratio HFA at the time of its introduction to the market in 2002.

127. The Panel reached this conclusion after hearing evidence that, even when using the various pricing tests in the Guidelines independently of CPI adjustments throughout the period from 2002 to 2008, there was compelling evidence that the price of ratio HFA was excessive within the terms of subsection 85(1) of the *Act* during that period.

128. Under subsection 85(1) of the *Act*, the price of a medicine can be excessive in two separate ways: (i) relative to the prices of comparable medicines; and (ii) relative to its own price in prior periods. The Board's Guidelines take the factor stipulated in paragraph 85(1)(*a*), the price of the medicine in Canada, and consider that price relative to the two comparative factors stipulated in paragraphs 85(1)(*b*) and (*c*), the prices of domestic comparators and the international prices of the medicine itself, and the temporal factor in paragraph 85(1)(*d*), changes in the CPI during the time that the medicine is marketed in Canada. The Guidelines as they existed during the relevant periods did not account for tests based on the international prices of comparators, but a panel of the Board in a review hearing will weigh that factor in its consideration of whether or not the price of the medicine is or has been excessive, as was done in this case.

129. The Guidelines combine the three factors by which subsection 85(1) of the *Act* instructs the Board to assess the price of a medicine in Canada by (i) establishing an initial non-excessive price for a medicine by reference to the prices of comparable medicines; and (ii) establishing its non-excessive price in subsequent periods by reference to increases in the CPI. Accordingly, the application of the Guidelines results in all of the factors in subsection 85(1) being considered and weighed in the analysis of whether or not ratio HFA has been excessively priced. In this case, Board Staff went on to confirm that this

conclusion from the Guidelines, which is based on CPI increases after initial comparative tests, is supported by supplemental testing of the price of ratio HFA throughout the period of its sale in Canada using all of the comparative factors in subsection 85(1) repeatedly for all reporting periods.

130. The Panel therefore orders that the MNE for ratio HFA sold by ratiopharm for the period September 2002 to January 2010, and the amount to be paid to the Crown by ratiopharm for excessive revenues derived from such sale, pursuant to paragraph 83(2)(*c*) the *Act*, be determined in accordance with this decision, based on ratio HFA's MNE at introduction, as adjusted for CPI in accordance with the methodology set out in the Board's Guidelines, but without taking into account any reduction of the ATP of ratio HFA for rebates, whether for prompt pay, returns, CE or PEP payments. The Panel requires that Board Staff present to it, within 30 days of this decision, on or before June 27, 2011, a draft order that implements the terms of this decision.

Board Members: Dr. Brien Benoit
Anne Warner La Forest

Board Counsel: Gordon Cameron
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

Original signed by

Sylvie Dupont
Secretary of the Board