PATENTED MEDICINE PRICES REVIEW BOARD

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

AND IN THE MATTER OF Apotex Inc., (the "Respondent") and the medicine "Apo-Salvent CFC Free" ("Apo-Salvent")

NOTICE OF MOTION

Board Staff will make a motion to a Panel of the Patented Medicine Prices Review Board (the "Board") to discontinue this excessive-pricing proceeding (the "Apo-Salvent Matter").

Background to this Motion

The Apo-Salvent Matter

1. By way of background, in a Notice of Hearing dated July 8, 2008, the Board announced that it would hold a hearing into allegations of excessive pricing by Board Staff in respect of Apo-Salvent CFC Free ("Apo-Salvent") as set out in Board Staff's June 17, 2008 Statement of Allegations. The Statement of Allegations sought, inter alia, a declaration that the Respondent, Apotex Inc. ("Apotex") sold Apo-Salvent at an excessive price, an order setting the maximum non-excessive price of Apo-Salvent in Canada and an order requiring Apotex to take certain steps as a result of any excess revenue finding, including payment of the excess revenues to Her Majesty in right of Canada.

2. In its August 18, 2008 Response, Apotex took the position that, to the extent that the Patent Act (the "Act") grants authority to the Patented Medicine Prices Review Board ("PMPRB") to regulate the prices of "generic" medicines sold in a competitive market, the Act was ultra vires

the authority of Parliament under the Constitution Act, 1867. Apotex also denied selling Apo-Salvent at an excessive price.[1]

3. The parties are in agreement that Canadian Patent No. 2,004,598, which subsequently expired December 5, 2009, pertained to Apo-Salvent. Apo-Salvent is a bronchodilator used to treat asthma, chronic bronchitis and related symptoms.

The Apotex Matter

4. Prior to the Notice of Hearing in the Apo-Salvent Matter, on December 27, 2007, Board Staff commenced a failure-to-file proceeding (the "Apotex Matter") by way of a Notice of Application to the Board. The Notice of Application sought an order requiring Apotex to report information to the PMPRB pursuant to the reporting requirements in the Act and the Patented Medicines Regulations (the "Regulations"). More specifically, Board Staff sought an order, inter alia, requiring Apotex to:

a. disclose whether Apotex was entitled to the benefit of any patents as the patent owner, or was entitled to exercise any rights in relation to any patents, in respect of an invention intended or capable of being used for a medicine or for the preparation or production of a medicine;

b. disclose where the medicine has been or is being sold in Canada by the Apotex or for which Apotex had received a Notice of Compliance;

[1] Board Staff's Reply was submitted on September 8, 2008.

c. provide the information referred to in s. 80 of the Act and in ss. 3 and 4 of the Regulations in respect of any medicines sold in Canada by the Apotex for which Apotex was a patentee of an invention pertaining to the medicine, other than Apo-Salvent[2];

d. provide the information referred to in s. 88 of the Act and s. 5 of the Regulations, including revenues from sales in Canada by Apotex or its licensees, and expenditures on research and development in Canada carried out by or on behalf of Apotex, in respect of all of the Respondent's medicines, including Apo-Salvent.

5. Board Staff's Notice of Application took the position that the PMPRB had jurisdiction with respect to the pricing of any of Apotex's medicines sold in Canada to the extent Apotex was a patentee pursuant to subsection 79(1) of the Act in respect of an invention pertaining to the medicine pursuant to subsection 79(2) of the Act. Board Staff further asserted that the requirement to file information applied regardless of whether the medicine was described as a "brand name" or a "generic".[3] Board Staff identified as issues, whether Apotex was a patentee in respect of patents held by a related entity, Apotex Pharmachem Inc.[4], and whether Apotex should be required to file its sales and research and development information for all its medicines sold in Canada.

[2] Apotex had previously accepted the jurisdiction of the PMPRB in respect of Apo-Salvent, and had filed the requisite information in accordance with ss. 3 and 4 of the *Regulations*.
[3] Apotex filed a Response to Board Staff's Notice of Application on April 4, 2008. Board Staff filed a Reply to Apotex's Response to the Notice of Application on April 21, 2008.
[4] On October 27, 2008, the Board granted leave for Board Staff to amend the Application to add Apotex Pharmachem Inc. ("Pharmachem") and another Apotex Technologies Inc. ("Technologies") as Respondents. On March 27, 2009, Board Staff filed its amended Notice of Application adding Pharmachem and Technologies as Respondents to the Apotex matter, and adding allegations related to them.

6. In its response, Apotex claimed that Board Staff was attempting to assert jurisdiction in a manner ultra vires the authority of Parliament under the Constitution Act, 1867. Apotex further denied that it was a "patentee" under 79(1) of the Act, other than with respect to Apo-Salvent. In addition, Apotex denied that it was required to file sales and research and development information for all its medicines sold in Canada.

7. On October 2, 2008, Apotex brought a motion to consolidate the Apotex and Apo-Salvent Matters, which the Board declined to grant.[5]

Canada (Attorney General) v. Sandoz Inc; Canada (Attorney General) v. Ratiopharm Inc,

8. While the proceedings in the Apotex and Apo-Salvent Matters were still pending, the Board issued three decisions which are highly relevant to this motion:

a. PMPRB-08-D3-ratiopharm (the "ratiopharm Matter")[6],

b. PMPRB-08-D3-ratio-Salbutamol HFA (the "ratio-Salbutamol Matter")[7], and

c. PMPRB-10-D2-SANDOZ (the "Sandoz Matter").[8]

9. The ratio-Salbutamol Matter focused on a medicine that, like Apo-Salvent, is a bronchodilator used to treat asthma, chronic bronchitis and related symptoms[9]. The jurisdictional issues in the ratio-Salbutamol Matter closely mirrored those in the Apo-Salvent Matter, notably, in respect of the constitutionality of applying the PMPRB's excessive pricing

[5] October 27, 2008 Decision: PMPRB-08-D1-Apotex – Preliminary Motions.
[6] May 27, 2011 Decision: PMPRB-08-D3-ratio-Salbutamol HFA – Merits.
[7] June 30, 2011 Decision: PMPRB-08-D3-ratiopharm – Merits.
[8] August 1, 2012 Decision: PMPRB-10-D2-SANDOZ – Merits.
[9] May 27, 2011 Decision: PMPRB-08-D3-ratio-Salbutamol HFA – Merits paras 2 and 63-71

regime to medicines sold by generic pharmaceutical companies. Indeed, ratio-Salbutamol HFA ratiopharm Inc. ("ratiopharm") was granted leave to intervene in the Apo-Salvent Matter on the issue of the interpretation of the Act and the scope of the PMPRB's jurisdiction[10]. The Board ultimately concluded that the provisions were constitutional, and ordered ratiopharm to pay excess revenues.

10. In the ratiopharm Matter, Board Staff sought an order from the Board requiring ratiopharm to file the information and documents set out in sections 80, 81, 88 of the Act, and sections 3, 4, and 5 of the Regulations. As in the Apotex Matter, ratiopharm disputed that it was a patentee under subsection 79(1) of the Act with respect to patents owned by other entities, and was required to report its research and development expenditures. Ultimately, the Board concluded ratiopharm was, indeed, a patentee in respect of certain medicines at issue in the proceeding, and was obliged to report its research and development expenditures under section 88 of the Act.

11. In the Sandoz Matter, much like in the Apotex Matter and the ratiopharm Matter, Board Staff sought an order requiring Sandoz Canada Inc. ("Sandoz") to file the information and documents set out in section 80, 81, 88 of the Act, and sections 3, 4, and 5 of the Regulations. The jurisdictional issues in the Sandoz Matter included whether Sandoz was a patentee within the meaning of subsection 79(1) of the Act, such that it has reporting obligations with respect to its sales of patented medicines where the patents were held by other entities, and also whether the PMPRB scheme could constitutionally apply to medicines sold by generic pharmaceutical

[10] October 27, 2008 Decision: PMPRB-08-D1-APO-SALVENT – Application for Leave to intervene by ratiopharm inc.

companies. The Board concluded that Sandoz was a patentee and that the impugned provisions of the Act were not unconstitutional in respect of generic pharmaceutical companies.[11]

12. All three of the above-referenced decisions of the Board were the subject of applications for judicial review brought by the respondents before the Federal Court and argued together.

Apotex, Apo-Salvent Matters held in abeyance pending judicial review/appeal proceedings

13. A case conference was held between the parties and the Board on September 26, 2011, during which counsel for Apotex suggested that the Apotex and Apo-Salvent Matters be held in abeyance pending Federal Court proceedings in respect of ratiopharm Inc. and the medicine ratio-Salbutamol HFA.

14. On May 27, 2014, the Federal Court rendered a decision in the ratiopharm case, *Ratiopharm Inc. v. Canada (Attorney General)*, 2014 FC 502, and in *Sandoz Canada Inc. v. Canada (Attorney General)*, 2014 FC 501.

15. Both decisions were appealed and heard together before the Federal Court of Appeal.

16. The Federal Court of Appeal's decision in Canada *(Attorney General) v. Sandoz Inc; Canada (Attorney General) v. Ratiopharm Inc, 2015 FCA 249* ("*Sandoz/Ratiopharm* FCA") was released on November 6, 2015. In that decision, the Federal Court of Appeal:

[11] The Apotex Matter, the Apo-Salvent Matter, the Sandoz Matter, the ratiopharm Matter and the ratio-Salbutamol Matter were all commenced prior to the adoption of the current Policy on Generic Medicines.

a. Upheld the Board's findings in respect of the application of the "generic pharmaceutical industry" not being conducive to defining legal rights under the Act and Regulations;

b. Upheld the Board's findings concerning the ability of a pharmaceutical company to qualify as a patentee by virtue of an implied license, despite not being the owner of the patent;

c. Upheld the constitutionality of the PMPRB pricing and reporting scheme in respect of generic pharmaceutical companies.

17. On December 2, 2015, Board Staff wrote to the Board to inquire into the status of the Apotex and Apo-Salvent matters. In a December 7, 2015 letter in response, the Board informed the parties that both the Apotex and Apo-Salvent matters would be held in abeyance until the expiry of all available appeal routes.

18. The application for leave to appeal the *Sandoz/Ratiopharm* FCA decision to the Supreme Court of Canada was discontinued on September 8, 2016.

Grounds for discontinuance of this proceeding

19. While the Patented Medicine Prices Review Board Rules of Practice (the "Rules") do not expressly address the discontinuance of a proceeding, Rule 5.02 of the Rules provides that any procedural matter not provided for in the Act, the Regulations or the Rules which arises in any proceeding may be dealt with in any manner that the Board Panel directs in order to ensure the fair and expeditious conduct of any proceeding. Section 97 of the Act provides that all

proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit.

20. As set out above, this proceeding was commenced by Notice of Hearing nearly ten years ago, and did not proceed beyond the pleading's stage. No documents were exchanged between the parties, and no evidence on the merits was filed.

21. In light of the *Sandoz/Ratiopharm* FCA decision referenced above, Board Staff's position is that there is no significant and novel legal issue for the Board to decide in the Apo-Salvent Matter. The scope of the "patentee" definition under the Act, as it relates to generic pharmaceutical companies, and the obligations of those companies to provide information to the PMPRB, have been clearly laid out by the Federal Court of Appeal, and the constitutional applicability of the PMPRB's excessive pricing scheme as applied to generic drug companies has been upheld.

22. Additionally, the '598 patent at issue in this proceeding expired nearly 8 years ago on December 5, 2009. Board Staff's understanding is that, during the period when it was marketed, Apo-Salvent comprised a relatively small percentage of the Canadian market for salbutamol inhalers (approximately 15% or less).[12]

23. Accordingly, given these highly unique circumstances, it would not be in the public interest, and would not be an appropriate use of the Board's time and resources, to further pursue this excessive pricing proceeding.

[12] Decision dated May 27, 2011 (PMPRB-08-D3-ratio-Salbutamol HFA – Merits) at paras 64-65.

24. Board Staff believes that it should be possible for this motion to be dealt with in writing, and invites further direction from the Board on process or other issues.

DATED at Ottawa, this 22nd day of June, 2017.

Original signature redacted

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