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")

NOTICE OF APPLICATION

TAKE NOTICE THAT Board Staff will bring an application before the Patented Medicine Prices Review Board (the "Board" or the "PMPRB") for hearing on a day to be determined by the Board.

THE APPLICATION IS FOR:

1. An Order requiring the Respondent, Apotex Inc. ("Apotex"), to disclose to Board Staff whether the Respondent,
    a. is entitled to the benefit of any patents as the patent owner, or is 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; and
    b. where the medicine has been or is being sold in Canada by the Respondent or for which the Respondent has received a Notice of Compliance.
2. An Order pursuant to subsection 81(1) of the *Act* requiring the Respondent to provide to Board Staff the information referred to in section 80 of the *Act* and in section 3 of the *Patented Medicines Regulations, 1994* ("the *Regulations*"), in respect of any medicines sold in Canada by the Respondent or for which the Respondent has received a Notice of Compliance, for which the Respondent is a

"patentee of an invention pertaining to [the] medicine", other than Apo-Salvent (PMPRB Form 1).

3. An Order pursuant to subsection 81(1) of the *Act* requiring the Respondent to provide to Board Staff the information referred to in section 80 of the *Act* and in sections 4 of the *Patented Medicines Regulations, 1994* (the "*Regulations*"), in respect of any medicines sold in Canada by the Respondent for which the Respondent is a "patentee of an invention pertaining to [the] medicine", other than Apo-Salvent (PMPRB Form 2).

4. An Order pursuant to subsection 88(1) of the *Act* requiring the Respondent to provide to Board Staff the information referred to in section 88 of the *Act* and in section 5 of the *Regulations*, including the identity of any licensees in Canada of Apotex, the 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 (PMPRB Form 3).

THE GROUNDS FOR THE APPLICATION ARE:

A. Disclosure and Reporting of Information on the Identity and Price of any Medicines Sold in Canada by the Respondent as a Patentee of an Invention Pertaining to a Medicine

Legislative and Regulatory Framework

1. Subsection 79(1) of the *Act* defines a "patentee" as the person entitled to the benefit of the patent and includes any other person entitled to exercise any rights in relation to that patent.

2. The definition of "patentee" includes not only a patent owner but anyone entitled to exercise any rights in relation to a patent such as under a licensing agreement or through some form of consent with the patent owner.

3. Subsection 79(2) of the *Act* provides that a patent for "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 the medicine.

4. There is no requirement that the patent actually be used for the medicine or the preparation or production of the medicine.

5. Board Staff submits that the PMPRB has jurisdiction with respect to the pricing of any of the Respondent's medicines in Canada if:

    a. the Respondent is a patentee pursuant to subsection 79(1) of the *Act*;

    b. in respect of an invention pertaining to the medicine, pursuant to subsection 79(2) of the *Act*; and

    c. Apotex is selling or has sold the medicine in any market in Canada.

6. Paragraph 80(1)(a) of the *Act* and subsection 3(1) of the *Regulations* require a patentee of an invention pertaining to a medicine who is selling or has sold the medicine in any market in Canada to report to the PMPRB prescribed information identifying the medicine (PMPRB Form 1). Pursuant to subsection 3(2) of the *Regulations*, the prescribed information must be reported if (1) a Notice of Compliance has been issued in respect of the medicine or (2) if the medicine is being offered for sale in Canada. Pursuant to subsection 3(3) of the *Regulations*, the prescribed information must be provided within the earlier of (1) 30 days after the

date on which the first Notice of Compliance is issued in respect of the medicine or (2) 30 days after the date on which the medicine is first offered for sale in Canada.

7. Paragraph 80(1)(b) of the *Act* and subsection 4(1) of the *Regulations* require a patentee of an invention pertaining to a medicine who is selling or has sold the medicine in any market in Canada to report to the PMPRB prescribed information identifying the medicine and concerning the price of the medicine (PMPRB Form 2). Pursuant to subsections 4(2) and 4(3) of the *Regulations*, this information must be reported within 30 days after the 30-day period following the date of first sale in Canada of the medicine, in respect of this period, and within 30 days after each six month period commencing on January 1 and July 1 of each year, in respect of each of these periods.

Communications between Board Staff and Apotex

8. On February 27, 2007, Board Staff informed Apotex that Board Staff had discovered a number of patents owned by Apotex Pharmachem Inc. that pertain to some of Apotex's generic medicines, which are sold in Canada. Board Staff advised Apotex that as patented drug products sold in Canada, these generic medicines are under the jurisdiction of the PMPRB and therefore Apotex is required to file information identifying these medicines and concerning the prices of these medicines, pursuant to sections 3 and 4 of the *Regulations*.

9. On March 5, 2007, Apotex advised Board Staff that Apotex Pharmachem Inc. and Apotex are separate legal entities and that Apotex does not make use of any of the patents discovered by Board Staff in the sourcing and manufacturing of its finished product.

10. On March 26, 2007, Board Staff informed Apotex that pursuant to section 79 of the *Act*, the definition of a "patentee" falling under the PMPRB's jurisdiction is much wider in scope than the simple inclusion of the patent holder. Board Staff advised Apotex that if Apotex is entitled to exercise any rights in relation to any patents held by Apotex Pharmachem Inc. and/or any other patentee, Apotex would be considered a "patentee". Board Staff also noted that a "patent pertains" to a medicine if it is intended or capable of being used for medicine or for the preparation or production of medicine and there is no requirement that the patents actually be used in the production of medicine. Therefore, Board Staff informed Apotex that whether Apotex is actually using any of these patents in the sourcing and manufacturing of its finished product is not determinative of the issue. Board Staff requested that Apotex advise Board Staff as to whether it is entitled to the benefit of any patents owned by Apotex Pharmachem Inc., including those listed in Board Staff's letter dated February 27, 2007 and additional Canadian Patents found on Apotex Pharmachem Inc.'s website and/or patents owned by any other patentee. Board Staff also requested that Apotex provide Board Staff with a list of any medicines sold in Canada by Apotex that fall under the jurisdiction of the PMPRB in light of the definitions of "patentee" and "patent pertains", and file information on the identity and prices of these medicines pursuant to the *Regulations*.

B. Reporting of Information on the Identity of Licensees and Revenues and Research and Development Expenditures

Legislative and Regulatory Framework

11. The Respondent is a licensee of the Canadian Patent 2,004,598 (the "'598 patent"), which pertains to its medicine, Apo-Salvent, and is a "patentee in respect of an invention pertaining to a medicine" pursuant to section 79 of the *Act*.

12. The Respondent began selling Apo-Salvent in Canada on October 1, 2002, following the issuance of the '598 patent, and continues to sell the said patented medicine in Canada. As such the Respondent falls under the jurisdiction of the PMPRB.

13. Subsection 88(1) of the *Act* and subsection 5(1) of the *Regulations* require the patentee of an invention pertaining to a medicine, who is selling or has sold the medicine in any market in Canada, to report to the PMPRB prescribed information concerning the identity of any licensees in Canada of the patentee, the revenues from sales in Canada by the patentee or its licensees, and expenditures toward the costs of research and development ("R&D") in Canada carried out by or on behalf of the patentee, for all of the patentee's medicines (PMPRB Form 3). Pursuant to subsection 5(2) of the *Regulations*, this information must be reported for each calendar year and must be submitted within 60 days after the end of each calendar year.

14. The Respondent has, to date, in contravention to its statutory obligations, refused and/or failed to report the revenues from sales in Canada by it or its Canadian licensees and expenditures on R&D carried out in Canada by or on behalf of the

Respondent, with respect to all of its medicines for each of the calendar years 2002, 2003, 2004, 2005 and 2006.

15. As a result of the Respondent's failure to provide the said information, the Board is unable to report the revenues and R&D expenditures as per its statutory mandate.

Communications between Board Staff and Apotex

16. On August 18, 2006, counsel for Apotex informed Board Staff that Apotex does not dispute the assertion of jurisdiction by the PMPRB regarding Apo-Salvent (the '598 patent), of which Apotex is a licensee.

17. On September 27, 2006, Board Staff informed Apotex that it was in failure to file revenues and R&D expenditures in Canada for all its medicines for each year since the date of first sale of Apo-Salvent, pursuant to subsection 88(1) of the *Act* and the *Regulations*, and requested that Apotex provide this information

18. On October 5, 2006, counsel for Apotex outlined Apotex's position that as a generic pharmaceutical manufacturer, its revenues and R&D expenditures are not properly reportable to the PMPRB as a significant amount of this information is unrelated to the '598 patent. Apotex noted that the bulk of its revenues are earned from pharmaceuticals that do not contain patented medicines and it has not conducted any R&D on Apo-Salvent.

19. On December 6, 2006, Board Staff informed counsel for Apotex that the requirement to file the said information is determined by whether the manufacturer is a "patentee of an invention pertaining to a medicine" and not by whether the manufacturer is labeled as a "brand-name" or a "generic" pharmaceutical manufacturer. As Apotex is a licensee of the '598 patent which pertains to its

product, Apo-Salvent, Apotex is a "patentee of an invention pertaining to a medicine". Board Staff requested that Apotex reconsider its refusal to file the said information. Board Staff also advised that if Apotex had not conducted any R&D in Canada, it should simply report nil expenditure.

20. On April 23, 2007, Board Staff informed Apotex that that it was still in failure to file revenues and R&D expenditures in Canada for all its medicines and if it did not file the required information within a further time period provided, the matter would be referred to the Board.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of the Application:

1. Affidavit(s) evidence in support of its application, together with exhibits;
2. Written Submissions; and
3. Such further or other documentary evidence as Counsel may advise and the Board may permit.

THE BOARD STAFF WISHES TO USE the English language at the hearing of this application.

DATED at Ottawa this 27th day of December, 2007.

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