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 ratiopharm Inc. (the "Respondent")

NOTICE OF APPLICATION

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

THE APPLICATION IS FOR AN ORDER pursuant to sections 81 and 88 of the *Patent Act* (the "*Act*") requiring the Respondent, ratiopharm Inc. ("ratiopharm"), to provide the Board with the information and documents referred to in sections 80, 81 and 88 of the *Act* and in sections 3, 4 and 5 of the *Patented Medicines Regulations* (the "*Regulations*"), on the terms set out in Appendix 1.

THE GROUNDS FOR THE MOTION ARE:

Legislative and Regulatory Framework

1. Under subsection 79(1) of the *Act,* a "patentee" in respect of an invention pertaining to a medicine refers to the person for the time being entitled to the benefit of a patent, including any person entitled to exercise any rights in relation to that patent. The "patentee" definition is not confined to the patent owner, but includes anyone entitled to exercise any rights in relation to a patent, for example, through a licensing agreement or consent from the patent owner.

2. In subsection 79(2) of the *Act*, an invention is deemed to pertain to a medicine if the invention is intended or capable of being used for medicine or for the production of medicine. The *Act* does not require that the patent actually be used for the medicine or for production of the medicine.

3. The *Act* and the *Regulations* impose the following reporting requirements on patentees and former patentees:

   a. Paragraphs 80(1)(a) and 80(2)(a) of the *Act* and section 3 of the *Regulations* require patentees and former patentees to provide to the PMPRB prescribed information identifying the medicine (PMPRB Form 1). Pursuant to subsections 3(2) and 3(3) of the *Regulations*, the prescribed information must be provided (i) either if a notice of compliance has been issued with respect to the medicine, or if the medicine is being offered for sale in Canada; and (ii) seven days after the first notice of compliance is issued in respect of the medicine or after the medicine is first offered for sale in Canada, whichever occurs first.

   b. Paragraphs 80(1)(b) and 80(2)(b) of the *Act* and section 4 of the *Regulations* require patentees and former patentees to provide to the PMPRB prescribed information identifying the medicine and concerning the price of the medicine (PMPRB Form 2). Pursuant to subsection 4(2), this information must be provided, for the date of first sale in Canada, within 30 days after that date, and subsequently after each six month period commencing on January and July 1 of each year.

   c. Subsection 88(1) of the *Act* and section 5 of the *Regulations* require patentees to report to the PMPRB prescribed information concerning the identity of any licensee in Canada and the revenues and research and development expenditures of the patentee (PMPRB Form 3). This information must be provided within 60 days after the end of each calendar year, in respect of the preceding calendar year.

4. Pursuant to paragraphs 81(1)(a) and (b) of the *Act*, the Board has the authority to require a patentee or former patentee of an invention pertaining to a medicine to provide the Board with information and documents respecting, among other things, the identify of the medicine (PMPRB Form 1) and the price at which the medicine is being or has been sold in any market in Canada and elsewhere (PMPRB Form 2). Pursuant to subsection 88(1) of the *Act*, the Board may require a patentee to provide the Board with information and documents respecting the identity of any licensee in Canada and the revenues and research and development expenditures of the patentee (PMPRB Form 3).

5. In addition, the Board has the authority pursuant to paragraph 81(1)(c) of the *Act* to require a patentee of former patentee of an invention pertaining to a medicine to provide the Board with information and documents respecting other related matters as the Board may require.

The Patented Medicines

6. By agreement with GlaxoSmithKline Inc. or a related company ("GSK"), ratiopharm is entitled to exercise rights in relation to patents pertaining to the medicine ratio-Salbutamol, a bronchodilator used for the treatment of asthma, chronic bronchitis, and other breathing disorders. ratiopharm is selling ratio-Salbutamol in any market in Canada. The date of first sale in Canada was July 1, 2002.

7. ratiopharm is also a licensee under Canadian patent No. 1,075,228 (the " '218 Patent"), issued on April 8, 1980 to Syntex (U.S.A.) LLC, pertaining to the medicine ratio-Flunisolide, which ratiopharm is selling in any market in Canada. ratio-Flunisolide, a nasal spray used to treat rhinitis (inflammation of the nasal passages, eyelids, and throat), was first sold in any market in Canada on June 15, 1993.

8. Board Staff also understands that ratiopharm has agreements with GSK pursuant to which ratiopharm has sold and/or is selling the patented medicines ratio-Paroxetine and ratio-Fluticasone in any market in Canada.

9. ratio-Fluticasone is a nasal spray that is indicated for the treatment of seasonal allergic rhinitis including hay fever, and perennial rhinitis poorly responsive to conventional treatment. In patients with allergic rhinitis, it is also used for the management of associated sinus pain and pressure. ratio-Paroxetine is an oral anti-depressant used in the treatment of major depressive disorder, obsessive-compulsive disorder, panic order, social phobia, generalized anxiety disorder and posttraumatic stress disorder.

Summary of Board Staff's Position

10. Board Staff's position is that the PMPRB has jurisdiction with respect to ratiopharm because:
    a. ratiopharm is a patentee within the meaning of subsection 79(1) of the Act;
    b. in respect of inventions pertaining to a medicine; and
    c. ratiopharm has sold or is selling patented medicines in any market in Canada.

11. Subsection 88(1) of the *Act* and section 5 of the *Regulations* require all patentees, including ratiopharm, to provide the Board with the following information:
    a. revenue from sales of medicine in Canada, and
    b. research and development expenditures relating to medicine.

12. The obligation to file such information exists with respect to "medicine," not merely patented medicines.

13. Board Staff's position is that the PMPRB has jurisdiction with respect to the pricing of any patented medicines sold in any market in Canada by ratiopharm, including

patented medicines sold pursuant to agreements with patent holders, as is the case with ratio-Fluticasone and ratio-Paroxetine.

ratiopharm's Failure to File

14. As further described below, ratiopharm has filed certain prescribed information, but has failed to file other prescribed information as required by the *Act* and the *Regulations*. In particular:

    a. ratiopharm has only filed certain Form 3 information for the years 2002 to 2006 (total gross revenues), and has failed to specify its medical research and development expenditures as required by paragraph 5(1)(d) of the *Regulations*.

    b. ratiopharm has failed to meet its reporting requirements under the *Act* and the *Regulations* in respect of ratio-Fluticasone and ratio-Paroxetine.

Correspondence Between Board Staff and ratiopharm

15. On March 4, 2008, Board Staff advised ratiopharm that it had failed to file its Form 3 information for 2007.

16. In a follow-up letter dated March 18, 2008, Board Staff explained that ratiopharm falls under the definition of "patentee" with respect to its sales in Canada of two of its products, ratio-Salbutamol and ratio-Flunisolide, and must accordingly file the Form 3 information. Board Staff emphasized that the requirement to file the Form 3 information is not determined by a manufacturer's status as a generic or brand-name pharmaceutical manufacturer. Board Staff explained that this information is needed for the PMPRB to fulfill its statutory reporting mandate.

17. On April 28, 2008, Board Staff informed ratiopharm that they were aware that GSK has licensing agreements with ratiopharm for three drug products (salbutamol, paroxetine and fluticasone). Based on the information that was then being filed by ratiopharm, only two drug products were being reported, namely, ratio-Flunisolide

and ratio-Salbutamol. Board Staff advised that, if ratiopharm is selling the medicines ratio-Paroxetine and ratio-Fluticasone in Canada, it is in failure to file the information required by the *Regulations*. Board Staff requested that ratiopharm file its Form 1 information with respect to these two medicines by May 5, 2008, and its Form 2 information, by May 12, 2008. These filing deadlines were subsequently extended until June 27, 2008. Board Staff further noted that if ratiopharm sells any other patented drug products in Canada under any other licensing arrangement, it is obligated to identify these medicines and file the required information forthwith.

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

1. Affidavit(s) to be filed in support of the Application, together with exhibits; and
2. Such further or other documentary evidence as Counsel may advise and the Board may allow.

Dated at Ottawa this 15 day of July, 2008.

Original signed by

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APPENDIX 1

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")

Within 30 days of the date of this Order, ratiopharm shall provide to the Board in accordance with paragraphs 81(1)(a) and (b) and subsection 88(1) of the *Patent Act* (the "*Act*"):

1. the prescribed information identifying the medicines ratio-Fluticasone and ratio-Paroxetine in accordance with section 3 of the *Patented Medicines Regulations* (the "*Regulations*").

2. the prescribed information identifying all other patented medicines that ratiopharm sells in any market in Canada under licence from a patent holder, in accordance with section 3 of the *Regulations*.

3. the prescribed information identifying each medicine referred to in paragraphs 1 and 2 and concerning the price of each such medicine in accordance with section 4 of the *Regulations*, for each six month-period since the date of first sale in Canada until the present.

4. the prescribed information concerning the revenues and research and development expenditures of ratiopharm in accordance with section 5 of the *Regulations*, for each calendar year since the date of first sale of each patented medicine sold by ratiopharm in any market in Canada. Such information is to include:

a. the total gross revenues from all sales in Canada during the year by ratiopharm of medicine for human and veterinary use and the total revenues received from all licensees from the sale in Canada of medicine for human and veterinary use; and
b. a summary of all expenditures made during the year by ratiopharm towards the cost of research and development relating to medicine for human or veterinary use carried out in Canada by or on behalf of ratiopharm.

Within 30 days of the date of this Order, ratiopharm shall provide to the Board in accordance with paragraph 81(1)(c) of the *Act* a copy of any and all agreements between ratiopharm and a patent holder pursuant to which ratiopharm is entitled to exercise rights in Canada in relation to one or more patents pertaining to a medicine that ratiopharm has sold or is selling in any market in Canada.