June 30, 2011

Decision: PMPRB-08-D3-ratiopharm - Merits

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

AND IN THE MATTER OF ratiopharm Inc. ("ratiopharm")

BOARD ORDER

The Panel hereby orders that:

1. ratiopharm Inc. ("ratiopharm") shall, within 90 days of the date of this Order, on or before October 3, 2011, file with the Board:

    a. all of the prescribed Form 1 information in accordance with section 3 of the *Patented Medicines Regulations, 1994* (the "Regulations") for each of the medicines listed below and in respect of each of the Drug Information Numbers (DINs) listed for each medicine (the "Form 1 Information"):

        i. ratio-OMEPRAZOLE:
            1. DIN 02260867 (20mg/tab)

        ii. ratio-KETOROLAC:
            1. DIN 02247461 (0.5% liquid)

        iii. ratio-BRIMONIDINE:
            1. DIN 02243026 (0.2% liquid)

        iv. ratio-PAROXETINE:
            1. DIN 2027887 (10mg/tab)
            2. DIN 1940481 (20mg/tab)
            3. DIN 1940473 (30mg/tab)

        v. ratio-CEFUROXIME:
            1. DIN 02242656 (250mg/tab)
            2. DIN 02242657 (500mg/tab)

        vi. ratio-LAMOTRIGINE:
            1. DIN 02246963 (l50mg/tab)
            2. 02243352 (25 mg/tab)
            3. 02243353 (100 mg/tab)

vii. ratio-ACYCLOVIR:
   1. DIN 02078627 (200mg/tab)
   2. DIN 02078635; (400 mg/tab)
   3. DIN 02078651 (800 mg/tab)

viii. ratio-RAMIPRIL:
   1. DIN 02287692 (125 mg/cap)
   2. DIN 02287706 (2.5 mg/cap)
   3. DIN 02287714 (5 mg/cap)
   4. DIN 02287722 (10mg/cap)

ix. ratio-DILTIAZEM
   1. DIN 02229781 (120 mg/cap)
   2. DIN 02229782 (180 mg/cap)
   3. DIN 02229783 (240 mg/cap)
   4. DIN 02229784 (300mg/cap)

x. ratio-SIMVASTATIN:
   1. DIN 02247067 (5mg/tab)
   2. DIN 02247068 (10mg/tab)
   3. DIN 02247069 (29mg/tab
   4. DIN 02247070 (40mg/tab)
   5. DIN 02247071 (80mg/tab)

xi. ratio-SERTRALINE
   1. DIN 02245787 (25mg/cap)
   2. DIN 02245788 (50mg/cap)
   3. DIN 02245789 (100mg/cap)

xii. ratio-QUETIAPINE:
   1. DIN 02311704 (25mg/tab)
   2. DIN 02311712 (100mg/tab)
   3. DIN 02311747 (200mg/tab)
   4. DIN 02311755 (300mg/tab)

b. in respect of the medicines referred to in this paragraph 1, all of the prescribed Form 2 information (the "Form 2 Information") identifying and concerning the price of each medicine, in accordance with section 4 of the Regulations, for each six month-period from the date of the first sale of the medicine in Canada to the present and thereafter in accordance with the *Patent Act* (the "*Act*") the Regulations and any applicable instructions in the Board's Compendium of Policies, Guidelines and Procedures; and

c. the prescribed information concerning the revenue and research and development expenditures of ratiopharm in accordance with the *Act* and section 5 of the Regulations*,* for each calendar year since the date of the first sale of any patented medicine sold by ratiopharm in any market in Canada, including any of the medicines listed in this paragraph 1, and thereafter for any year during which ratiopharm is a patentee in accordance with the terms of the *Act*.

2. ratiopharm shall, within 90 days of the date of this Order, on or before October 3, 2011, in respect of each of the medicines ratio-FENOFIBRATE MC [DIN: 02250039] and ratio-TAMSULOSIN [DIN: 02294265] file with the Board either:
   a. the prescribed Form 1 Information and Form 2 Information referred to above in paragraphs 1(a) and 1(b); or
   b. a written report in the following form, with the stipulated information and attachments, which information and attachments will be privileged information pursuant to section 87 of the *Act*:

[Letterhead of ratiopharm Inc.]

1. This report relates to [specify medicine and DIN] (the “Medicine”) and the inquiries made by ratiopharm to [the supplier to ratiopharm] (the "Supplier") with respect to the Medicine.

2. On [specify date], ratiopharm submitted an inquiry in writing to the Supplier with respect to the Medicine:

   a. requesting that the Supplier inform ratiopharm as to whether any patents pertain or did pertain to the Medicine or its brand name equivalent;
   b. requesting the dates on which the patent(s) was/were laid open and expire or expired;
   c. informing the Supplier that the inquiry is being made pursuant to an Order of the Patented Medicine Prices Review Board;
   d. requesting a response from the Supplier in writing; and
   e. informing the Supplier that the information will be filed with the Board and will be privileged information pursuant to section 87 of the *Patent Act.*

3. Copies of ratiopharm’s inquiry to the Supplier and any response or responses from the Supplier are attached.

4. To the extent that the Supplier provided information in response to the inquiry, ratiopharm believes that the information provided by the Supplier is complete and accurate.

5. To the extent that the Supplier did not respond or the response was incomplete, ratiopharm has made reasonable efforts to obtain the information that was sought in the inquiry to the Supplier from other sources and was able to obtain the following information: [as applicable].

6. Copies of all agreements and amendments to same between ratiopharm and the Supplier in force from the date of the first sale of the Medicine by ratiopharm in Canada to the date of this report are attached to this report.

   Name of ratiopharm representative:

   Position:

   Date:

   _____
   Signature

3. The parties may at any time seek directions from the Panel regarding any matters with respect to this Order.

Board Members: Dr. Brien G. Benoit
Anne Warner La Forest

Board Counsel: Gordon Cameron

Sylvie Dupont
Secretary of the Board