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 Janssen-Ortho Inc., (the "Respondent") and the medicine "Evra"

STATEMENT OF ALLEGATIONS OF BOARD STAFF

INTRODUCTION

1. This Statement of Allegations results from an investigation by Board Staff into the price of Evra (norelgestromin/ethinyl estradiol) 150 mcg / 20 mcg per patch (DIN 02246340), a patented medicine sold in Canada by Janssen-Ortho Inc. ("Janssen-Ortho"). According to publicly-available information in 2004, Janssen-Ortho sells Evra at a price of $8.33 per patch. **(Attachment 1)**

THE MEDICINE

2. Evra (norelgestromin/ethinyl estradiol) is a transdermal contraceptive patch indicated for the prevention of pregnancy in women who elect to use hormonal contraceptives. **(Attachment 2)** Its Anatomical, Therapeutic, Chemical (ATC) System classification is G03AA13. It is a new active substance and the 7th entry in its 4th level ATC class to be introduced in Canada.

3. Health Canada issued a Notice of Compliance for Evra on August 20, 2002. **(Attachment 3)**

4. Janssen-Ortho began selling Evra in Canada on October 23, 2002.

THE PATENT

5. Canadian Patents 2,065,311 and 2,222,133 pertain to Evra. **(Attachment 4)** These patents were granted to Ortho-McNeil Pharmaceutical Inc. on January 11, 2000 and December 24, 2002 and will expire on August 22, 2010 and June 6, 2016 respectively. Janssen-Ortho is, for purposes of the Patented Medicine Prices Review Board (PMPRB), considered as the Canadian patentee.

6. Canadian Patent Applications 2,478,206 and 2,478,336 pertain to Evra. These patent applications filed by Janssen Pharmaceutica N.V. were both laid open for public inspection on September 25, 2003, and are still pending. **(Attachment 5)**

7. In accordance with the *Patented Medicines Regulations, 1994* ("the Regulations"), Janssen-Ortho filed price and sales information in November 2002 for the first 30 days sales.

8. Following the procedures outlined in the PMPRB's Guidelines for new medicines, Board Staff referred the medicine Evra to the Human Drug Advisory Panel ("HDAP") for its review during a meeting held on November 17, 2003. The HDAP was asked for its recommendation as to categorization and the appropriate comparable medicines and comparable dosage regimens for the comparable medicines.

APPLICABLE GUIDELINES

9. The Guidelines provide the following guidance with respect to determining categorization for a new active substance:

    3.1 A Category 1 drug product is a new DIN of an existing dosage form of an existing medicine, or a new DIN of another dosage form of the medicine that is comparable to the existing dosage form as per Schedule 7.

    3.2 A Category 2 drug product is one that provides a breakthrough or substantial improvement. It is a new DIN of a non-comparable dosage form of an existing medicine or the first DIN of a new chemical entity.

    3.3 A Category 3 drug product is a new DIN of a non-comparable dosage form of an existing medicine or the first DIN of a new chemical entity. These DINs provide moderate, little or no therapeutic advantage over comparable medicines. This group includes those new drug products that are not included in Category 2 above.

10. Based on its review of Evra, the HDAP recommended in its report dated November 17, 2003 that Evra be classified as a category 3 new medicine **(Attachment 6)**. The same category had been proposed by the patentee in its submission to Board Staff **(Attachment 7)**.

COMPARABLE MEDICINES AND DOSAGE REGIMENS

11. With respect to selection of comparable medicines, the Guidelines provide as follows:

    9.1 Comparable drug products are selected by identifying both comparable medicines and comparable dosage forms.

    9.2 Comparable medicines are clinically equivalent in addressing the approved indication that is anticipated to be the primary use of the new drug product under review. The PMPRB refers to the World Health Organization (WHO) Drug Utilization Research Group's Anatomical Therapeutic Chemical Classification System (ATC) as the starting point for the selection of comparable medicines.

    9.3 Comparable medicines will typically be those identified under the ATC classification system at the sub-class level above the single chemical substance. This will normally be the fourth sub-class level. If the appropriate comparable medicines are not identified at this level, then the PMPRB may choose from the next higher sub-class or another sub-class. In some instances, it may be appropriate to select from the fifth or single chemical substance level. Selection criteria will include the indication and therapeutic use, and could include other factors such as mode of action, spectrum of activity or chemical family.

    9.4 The PMPRB may omit from the comparison a chemical substance or a drug product of the same ATC therapeutic class as the drug product under review if, in the panels' or staff's opinion, it is not clinically equivalent or is unsuitable for comparison. For example, drug products with primary uses other than to address the indication anticipated to be the primary use of the drug product under review may be omitted from the comparison. Similarly, the PMPRB may choose to add products from other ATC classes if they are clinically equivalent for the appropriate indication to the drug product under review.

12. Based on the scientific information available to the HDAP at the time of its review, the HDAP recommended that the appropriate comparable medicines were oral contraceptives. **(Attachment 6)**

THE MAXIMUM NON-EXCESSIVE PRICE

13. The Guidelines set out the appropriate price test for a category 3 new drug product as follows:

> 8.5 In addition to the Guideline applicable to all patented drug products detailed in Section 7, the introductory price of a Category 3 new drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products based on a Therapeutic Class Comparison Test (Schedule 2).
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> 8.6 When it is inappropriate or impossible to conduct a Therapeutic Class Comparison Test, Board Staff will give primary weight to the median of the international prices identified in an International Price Comparison Test (Schedule 3) to determine if the introductory price of the new DIN is excessive.

14. Subsection 7.1 of the Guidelines (Chapter 1, Excessive Price Guidelines) further provides that:

> The price of a new or existing patented drug product will be presumed to be excessive if it exceeds the prices of the same medicine sold in all countries listed in the Regulations. These prices will be determined using the International Price Comparison Test described in *Schedule 3*.

15. As per the Guidelines, Board Staff conducted a Therapeutic Class Comparison ("TCC") test and an International Price Comparison ("IPC") test. The results of the TCC test indicated that the introductory price exceeded the maximum non-excessive ("MNE") price of $4.2133 per patch by more than 90% in 2002.

16. By letter dated March 23, 2004, Board Staff advised Janssen-Ortho of the commencement of an investigation into the introductory price of Evra. **(Attachment 8)**

17. By letter dated April 28, 2004, Janssen-Ortho replied to Board Staff's investigation letter maintaining its position that the price of Evra was not excessive. **(Attachment 9)**

18. Following its review of Janssen-Ortho's submission, Board Staff advised Janssen-Ortho by letter dated November 5, 2004 that it had completed its investigation and that the price of Evra continued to be excessive. **(Attachment 10)** In fact, based on publicly-available information in 2004,

the price of Evra in Canada of $8.3333 per patch is the second highest of the comparator countries listed in the Regulations and exceeds the Median International Price of $4.5848 per patch. **(Attachment 11)**

POLICY OF EXCESSIVE PRICING

19. Subsection 83(4) of the *Patent Act* provides that:

> "Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will in the Board's opinion offset not more than twice the amount of the excess revenues estimated by it to have been derived by the patentee or the former patentee from the sale of the medicine at an excessive price.

20. It is the position of Board Staff that Janssen-Ortho has engaged in a policy of selling Evra at an excessive price. Janssen-Ortho has been selling Evra since its introduction in Canada in October 2002 at a price per patch which Janssen-Ortho knew or ought to have known exceeded the MNE price calculated in accordance with the PMPRB's Guidelines. To date, Janssen-Ortho has failed and/or refused to lower the price of Evra to comply with the PMPRB's Guidelines.

OTHER

21. Board Staff reserves the right to make such other allegations and submissions and introduce other additional documents as Board Staff may advise and the Board may permit.

22. Pursuant to section 86 of the *Patent Act*, a hearing shall be held in public unless the Board orders otherwise. Board Staff submits that any hearing conducted by the Board into the price of Evra should be held in public and, subject to orders of the Board, all information and documents filed should form part of the public record.

ORDER REQUESTED

23. It is respectfully submitted that there are grounds for the Board to conclude pursuant to section 83 of the *Patent Act* that Janssen-Ortho is selling or has sold the medicine known as Evra in any market in Canada at a price which is or was excessive and that Janssen-Ortho further engaged in a policy of selling Evra at an excessive price.

24. Board Staff seeks the issuance of an Order as against Janssen-Ortho, the terms of which would be as follows:

a) The maximum non-excessive prices of Evra in Canada for the period October 23, 2002 to December 31, 2004 inclusive shall be the prices set out in **Attachment 11**.

b) The maximum non-excessive price of Evra in Canada in future years shall be calculated in accordance with Schedule 4 of the Guidelines;

c) In accordance with subsection 83(1) of the *Act*, Janssen-Ortho shall cause the maximum price at which it sells Evra in Canada to be reduced to the maximum non-excessive price effective on or before 30 days from the date of the Board's Order;

d) In accordance with subsection 83(4) of the *Act*, and in lieu of an order under subsection 83(2), Janssen-Ortho shall offset twice the amount of excess revenues estimated to have been derived by Janssen-Ortho from the sale of Evra at an excessive price from October 23, 2002 until the date on which the price reduction referred to in paragraph c) above comes into effect:

i) With respect to the period from October 23, 2002 to June 30, 2004, Janssen-Ortho shall pay to Her Majesty in right of Canada, within 30 days of the date of the Board's Order, an amount equal to twice the amount set out in **Attachment 11**; and

ii) With respect to the period from July 1, 2004 to the date on which the price reduction referred to in paragraph b) comes into effect, Janssen-Ortho shall pay to Her Majesty in right of Canada, a further amount equal to twice the amount of the excess revenues estimated by the Board to have been derived by Janssen-Ortho from the sale of Evra at an excessive price; and make the payment within 30 days of receipt of a notification from

the Board of its estimate of excess revenues based on the information filed in response to paragraph e) below;

e) Janssen-Ortho shall, within 60 days of the date of the Board's Order:

i) Notify federal/provincial/territorial ministers of health or their representatives and all customers of the price decrease as required by the Board's Order (a copy of which shall be included in such notifications) and the effective date of such price decreases;

ii) Submit copies of the above-noted notifications and any other notice to the Board; and

iii) Provide to the Board information concerning the quantity of Evra sold and either the average price per package or the net revenue from sales of Evra in Canada, in the same form as required by subsection 4(1) of the *Patented Medicines Regulations, 1994* for the period July 1, 2004 to the date on which the price reduction referred to in paragraph c) comes into effect.

Dated at Ottawa this 1st day of December 2004.

Johnston & Buchan, LLP
275 Slater Street, Suite 1700
Ottawa, Ontario
K1P 5H9
Tel.: (613) 236-3882
Fax: (613) 230-6423

David Wilson
E-mail: wilson@johnstonbuchan.com
Lynn Starchuk
E-mail: starchuk@johnstonbuchan.com

Counsel to Board Staff

LIST OF ATTACHMENTS

Attachment 1	Association québécoise des pharmaciens propriétaires – List price for Evra, October 2004
Attachment 2	Product Monograph for Evra, dated September 24, 2002;
Attachment 3	Notices of Compliance – Prescription Pharmaceuticals for Human Use, Jan 1 – Dec 31 2002;
Attachment 4	Canadian Patent No. 2,065,311 granted January 11, 2000 and Canadian Patent No. 2,222,133 granted December 24, 2002;
Attachment 5	Canadian Patent Application No. 2478336 and Canadian Patent Application No. 2478206;
Attachment 6	Report of the Human Drug Advisory Panel dated November 17, 2003;
Attachment 7	Submission from Janssen-Ortho to Board Staff dated February 12, 2003;
Attachment 8	Letter from Board Staff to Janssen-Ortho dated March 23, 2004;
Attachment 9	Letter from Janssen-Ortho Inc. to Board Staff dated April 28, 2004;
Attachment 10	Letter from Board Staff to Janssen-Ortho dated November 5, 2004;
Attachment 11	Evra – Calculation of Excess Revenues and International Prices.