JANSSEN-ORTHO

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"

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VOLUNTARY COMPLIANCE UNDERTAKING

Product Summary

1. Evra is the brand name of a medicine known generically as norelgestromine/ethinyl estradiol. Evra is a patented medicine sold in Canada by Janssen-Ortho Inc. ("Janssen-Ortho"). Janssen-Ortho is a wholly-owned subsidiary of Johnson & Johnson Corporation of the US.
2. Health Canada issued a Notice of Compliance ("NOC") for the sale of Evra for the prevention of pregnancy in women who elect to use hormonal contraceptives on August 20, 2002 (DIN 02246340). Janssen-Ortho began selling Evra pursuant to Health Canada's regulatory approval on October 23, 2002.
3. Evra is a contraceptive transdermal system. It is supplied in packages of 3 patches representing a 28-day cycle. Each patch contains 150mcg/20mcg of the active ingredients.
4. Evra is manufactured by Ortho-McNeil Pharmaceutical Inc. in the United States which holds the patent pertaining to Evra in Canada and in other countries, including the countries listed in the *Patented Medicines Regulations, 1994*, i.e., France, Germany, Italy, Sweden, Switzerland, UK and US ("the Regulations Countries"). Janssen-Ortho has the exclusive rights to sell Evra in Canada and is the patentee for purposes of the Patented Medicine Prices Review Board ("PMPRB" or "the Board").

Application of the Excessive Price Guidelines

Position of Board Staff

5. Board Staff advised Janssen-Ortho that, following an investigation pursuant to the policies of the Board, Board Staff concluded that the price of Evra exceeded the Excessive Price Guidelines. Based on the recommendations of the PMPRB's Human Drug Advisory Panel ("HDAP"), the policies of the Board, and the price and sales information supplied by Evra pursuant to the Regulations, Board Staff concluded that the price of Evra exceeded the Guidelines at the time it was introduced in Canada in October 2002 because it exceeded the highest price in the therapeutic class of comparable medicines by more than 90%.
6. More specifically, the average transaction price for Evra exceeded the maximum non-excessive (MNE) price of $4.2133 per patch in 2002 and, as a result, Janssen-Ortho received excess revenues from the sale of Evra in Canada.
7. In 2002 Evra was only sold in the United States. In the introductory period October to December 2002 the price of Evra in Canada did not exceed the price in the United States, but did exceed the median of international prices in 2003 and 2004.
8. As a result of Board Staff's investigation, the Board commenced these proceedings by issuing a Notice of Hearing on December 23, 2004 to determine, among other things, if the price of Evra is or was excessive under the *Patent Act*.
9. By applying the CPI-adjustment provisions of the Guidelines, it is Board Staff's position that the MNE price of Evra in 2005 is $4.4703.

Position of Janssen-Ortho

10. When it introduced Evra in 2002, Janssen-Ortho established a price which it believed would be within the PMPRB's Guidelines given Evra's different dosage form and delivery system. Janssen-Ortho is of the view that these elements should be considered in the introductory price review of Evra in

accordance with the Guidelines and the *Patent Act and that based on such consideration the introductory price of Evra was not excessive.*

Terms of the Undertaking

11. This Voluntary Compliance Undertaking ("VCU") is being made for purposes of resolving the issues raised in the proceedings commenced by the Notice of Hearing, and as a result of settlement discussions with Board Staff. This VCU constitutes no admission by Janssen-Ortho that the price of Evra in Canada is now, or was at any time since the date of the first sale of the medicine, excessive for purposes of the *Patent Act*.

12. Janssen-Ortho agrees for purposes of the negotiated compromise to undertake the following:

    a) The list price of Evra shall be reduced from $8.33 to $4.67 per patch effective on or before March 1, 2005

    b) The average transaction price (ATP) for purposes of the Guidelines shall be reduced so that it does not exceed the MNE price calculated by Board Staff of $4.4703 per patch for the remainder of 2005;

    c) The maximum non-excessive price in future years shall be calculated in accordance with the Guidelines based on the benchmark price of $4.2133 per patch in 2002; and

    d) The price of Evra shall not exceed the Guidelines in all future years during which it is under the Board's jurisdiction.

13. In addition, Janssen-Ortho undertakes to offset the amount by which the revenues from the sale of Evra in Canada exceeded revenues based on the MNE calculated by Board Staff by making a payment to Her Majesty the Queen in Right of Canada in the amount of $1,359,263.67 for the period from its first sale to the end of June 2004 no later than 30 days after the acceptance of this VCU by the Board.

14. Janssen-Ortho estimates that excess revenues for the reporting period July 1, 2004 to December 31, 2004 is approximately $2 million. The

precise amount is to be calculated once Janssen-Ortho's regulatory price and sales is filed and processed.

15. Furthermore, Janssen-Ortho undertakes to offset the amount calculated in accordance with paragraph 14 above in respect of the reporting period July 1, 2004 to December 31, 2004 by reducing the price of one of the company's patented medicines in 2005. In the event that the full amount of these excess revenues is not offset by December 31, 2005, Janssen-Ortho undertakes to offset such amount by making a further payment to Her Majesty the Queen in Right of Canada by January 31, 2006.

16. All the details of the offset described in paragraph 15 above will be made public by the Board no later than the end of February 2005.

17. Janssen-Ortho shall, within 30 days of acceptance by the Board, advise its existing customers of the price reduction set out in this VCU and provide a reference to the PMPRB website for the complete text of the VCU. Janssen-Ortho shall provide copies of such notifications to the Board forthwith.

Signature:

Gary J. Pruden
President,
Janssen-Ortho Inc.

Date: 2/8/05