SEVERED VERSION

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 3M Canada Company, (the "Respondent") and the medicine "Airomir"

STATEMENT OF ALLEGATIONS OF BOARD STAFF

INTRODUCTION

1. This Statement of Allegations results from an investigation by Board Staff into the price of Airomir Aerosol Inhaler ("Airomir") (DIN 02232570), a patented medicine sold in Canada by 3M Canada Company ("3M Canada").

THE MEDICINE

2. Airomir is a new formulation of an existing compound (salbutamol sulphate) indicated for the symptomatic relief and prevention of bronchospasm due to bronchial asthma, chronic bronchitis and other chronic bronchopulmonary disorders and for the prevention of exercise-induced asthma. **(Attachment 1)** Its 4th level in the Anatomical Therapeutic Chemical (ATC) Classification System is R03AC known as "Anti-Asthmatics".

3. Health Canada issued a Notice of Compliance for Airomir on August 20, 1997. **(Attachment 2)**

THE PATENTS

4. Canadian Patents No. 2,098,727 and No. 2,161,632 pertain to Airomir. **(Attachment 3)** These patents were granted to Minnesota Mining and Manufacturing Company, US on June 29, 1999 and August 10, 1999 and will expire on December 20, 2011 and April 15, 2014 respectively.

5. Canadian Patent No. 2,004,598 also pertains to Airomir. **(Attachment 4)** This patent was granted to Riker Laboratories, Inc., US on November 7, 2000 and will expire on December 5, 2009.

6. 3M Canada is, for the purposes of the Patented Medicine Prices Review Board ("PMPRB"), considered the Canadian patentee.

REGULATORY FILINGS

7. 3M Canada filed price and sales information on January 31, 2000 for the July to December 1999 regulatory filing period. 3M Canada has since continued to file its price and sales information for Airomir as per the *Patented Medicines Regulations, 1994* ("the Regulations").

APPLICABLE GUIDELINES

Category

8. Section 3 of Chapter 3- Scientific Review Procedures ("Scientific Review Procedures") provides the following guidance with respect to determining categorization for a new drug product:

   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.

9. Based on the above Scientific Review Procedures, Board Staff categorized Airomir as a Category 1 new drug product as it represents a new DIN of another dosage form of an existing medicine that is comparable to the existing dosage form.

The Maximum Non-Excessive Price for Airomir at Introduction

10. By letter dated April 18, 2000, Board Staff advised 3M Canada that based on the Reasonable Relationship ("RR") Test and the International Price

Comparison ("IPC") Test, the introductory price of Airomir per 0.1 mg/dose ("per dose") was within the Excessive Price Guidelines ("Guidelines") for the introductory period July 1999 to December 1999. **(Attachment 5)**

The Maximum Non-Excessive Price of an Existing Drug Product

11. The Guidelines also set out the appropriate price tests for an existing drug product as follows:

> 7.1 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*.
>
> 9.1 In addition to the Guideline applicable to all patented drug products detailed in Section 7, the price of an existing DIN will be presumed to be excessive if it exceeds the benchmark price of the DIN adjusted for the cumulative change in the Consumer Price Index (CPI) from the benchmark period to the pricing period under review (CPI-adjusted price). Schedule 4 provides detailed definitions and examples of the PMPRB's CPI-adjustment methodology.
>
> 9.2 Regardless of the above, and in addition to the Guideline applicable to all patented drug products detailed in Section 7, one-year price increases in the current pricing period may not exceed 1.5 times the forecast change in the annual CPI. In periods of high inflation (over 10%), the limit will be five percentage points more than the forecast change in the CPI.

12. Commencing in 2000, Board Staff reviewed the price of Airomir by applying the IPC Test and the PMPRB's CPI-adjustment methodology and the price of Airomir remained within the Guidelines until December 31, 2003:

Airomir	Price/Unit	
Reporting Period	Average Transaction Price ("ATP")	MNE
Jul99-Dec99	$ [redacted]	$ [redacted]
Jan00-Dec00	$ [redacted]	$ [redacted]
Jan01-Dec01	$ [redacted]	$ [redacted]
Jan02-Dec02	$ [redacted]	$ [redacted]
Jan03-Dec03	$ [redacted]	$ [redacted]

13. By letter dated October 27, 2004 Board Staff advised 3M Canada that for the period January 2004 to June 2004 it had accumulated excess revenues for Airomir and that 3M Canada should undertake the necessary measures in future periods to reduce the excessive revenues to zero. **(Attachment 6)**

14. By letter dated January 27, 2005, 3M Canada informed Board Staff that it had increased the price for Airomir as of November 2004. **(Attachment 7)**

15. According to publicly available information, 3M Canada was selling Airomir at a price of $4.65 per inhaler ($0.0232 per dose) in 2004 and at a price of $7.74 per inhaler ($0.0387 per dose) in 2005. **(Attachment 8)**

16. By letter dated May 12, 2005, Board Staff informed 3M Canada that for the period January 1, 2004 to December 31, 2004 the ATP of $[redacted] for Airomir exceeded the MNE price of $[redacted] per dose by [redacted]%. As a result Board Staff advised 3M Canada that an investigation was commenced into the price of Airomir. **(Attachment 9)**

17. By letters dated June 10, 2005 and August 2, 2005, 3M Canada maintained its position that the price of Airomir was not excessive. **(Attachment 10)**

18. By letters dated September 8, 2005 and November 8, 2005, Board Staff advised 3M Canada that it had completed its investigation and that the price of Airomir continued to be excessive as the price increase of Airomir exceeded the amount calculated using the PMPRB's CPI-adjustment methodology. **(Attachment 11)** Based on publicly available information in 2005, the price of Airomir in Canada is the 2nd highest of the comparator countries listed in the Regulations and exceeds the median of the international prices. **(Attachment 12)**

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 former patentee from the sale of the medicine at an excessive price.

20. It is the position of Board Staff that 3M Canada has engaged in a policy of selling Airomir at an excessive price. 3M Canada has been selling Airomir in Canada since November 2004 at a price per dose which 3M Canada knew or ought to have known exceeded the MNE price calculated in accordance with the PMPRB's CPI-Adjustment Methodology. To date, 3M Canada has failed and/or refused to lower the price of Airomir 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 Airomir should be held in public and, subject to the 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 3M Canada is selling or has sold the medicine known as Airomir in any market in Canada at a price which is or was excessive.

24. Board Staff seeks the issuance of an Order as against 3M Canada, the terms of which would be as follows:

a) The maximum non-excessive price of Airomir in Canada for the period January 1, 2004 to December 31, 2006 inclusive shall be as follows:

Airomir	Price/Unit
Reporting Period	MNE
Jan04-Dec04	$ [redacted]
Jan05-Dec05	$ [redacted]
Jan06-Dec06	$ [redacted]

b) The maximum non-excessive price of Airomir in Canada in future years shall be calculated in accordance with the Guidelines.

c) In accordance with subsection 83(1) of the *Patent Act*, 3M Canada shall cause the maximum price at which it sells Airomir 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 *Patent Act*, and in lieu of an order under subsection 83(2), 3M Canada shall offset twice the amount of excess revenues estimated to have been derived by 3M Canada from the sale of Airomir at an excessive price from January 1, 2004 until the date on which the price reduction referred to in paragraph c) above comes into effect:

   i) With respect to the period from January 1, 2004 to June 30, 2005, 3M Canada 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 13**; and

   ii) With respect to the period from July 1, 2005 to the date on which the price reduction referred to in paragraph c) comes into effect, 3M Canada 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 3M Canada from the sale of Airomir 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) 3M Canada shall, within 30 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 decrease;

   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 Airomir sold and either the average price per inhaler or the net revenue from sales of Airomir in Canada, in the same

form as required by subsection 4(1) of the Regulations for the period July 1, 2005 to the date on which the price reduction referred to in paragraph c) comes into effect.

Dated at Ottawa this 6th day of February 2006.

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LIST OF ATTACHMENTS

Attachment 1	Product monograph for Airomir
Attachment 2	Notice of Compliance for Airomir- August 20, 1997
Attachment 3	Canadian Patent No. 2,098,727 granted June 29, 1999 and Canadian Patent No. 2,161, 632 granted August 10, 1999
Attachment 4	Canadian Patent No. 2,004,598 granted November 7, 2000
Attachment 5	Letter dated April 18, 2000 from Board Staff to 3M Canada Company
Attachment 6	Letter dated October 27, 2004 from Board Staff to 3M Canada Company
Attachment 7	Letter dated January 27, 2005 from 3M Canada Company to Board Staff
Attachment 8	Pharmaceutical Product Reference Price Listing (2004 and 2005) for Airomir
Attachment 9	Letter dated May 12, 2005 from Board Staff to 3M Canada Company
Attachment 10	Letters dated June 10, 2005 and August 2, 2005 from 3M Canada Company to Board Staff
Attachment 11	Letters dated September 8, 2005 and November 8, 2005 from Board Staff to 3M Canada Company
Attachment 12	Airomir - International Prices
Attachment 13	Airomir - Calculation of Excess Revenues