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 Teva Neuroscience G.P.-S.E.N.C., (the "Respondent") and the medicine "Copaxone"

STATEMENT OF ALLEGATIONS OF BOARD STAFF

INTRODUCTION

1. This Statement of Allegations results from an investigation by Board Staff into the price of Copaxone 20mg/1.0 mL syringe, a patented medicine sold in Canada by Teva Neuroscience G.P.-S.E.N.C. ("Teva") in the form of a 20 mg/1.0 mL solution in a pre-filled syringe for subcutaneous injection (DIN 02245619).

THE MEDICINE

2. Copaxone 20 mg/1.0 mL syringe is a new formulation of an existing compound (glatiramer acetate) indicated for use in ambulatory patients with Relapsing-Remitting Multiple Sclerosis to reduce the frequency of relapses. **(Attachment 1)**. Copaxone is classified as L03AX in the Anatomical Therapeutic Chemical ("ATC") Classification System, known as: "Antineoplastic and Immunomodulating Agents; Immunostimulants; Cytokines and immunomodulators; Other cytokines and immunomodulators." It is the 3rd entry in this 4th level ATC class to be introduced in Canada.

3. Health Canada issued a Notice of Compliance for Copaxone 20mg/1.0 mL syringe on March 20, 2002 **(Attachment 2)**. Teva began selling Copaxone 20mg/1.0 mL syringe in Canada on May 15, 2002.

THE PATENT

4. Canadian Patent No. 2,191,088 ("the '088 Patent") pertains to Copaxone 20mg/1.0 mL syringe **(Attachment 3)**. This patent was granted to Yeda Research and Development Co., Ltd., Israel, on September 28, 2004 and will expire on May 23, 2015.

5. Teva is, for the purposes of the Patented Medicine Prices Review Board ("PMPRB"), considered the Canadian patentee.

THE REGULATORY FILINGS

6. Following the issuance of the '088 Patent in September 2004, Teva filed, in accordance with the *Patented Medicines Regulations, 1994* ("Regulations"), its price and sales information for Copaxone 20mg/1.0 mL syringe on October 27, 2004, for the period May 15, 2002 to June 30, 2004. Teva has since continued to file its price and sales information for Copaxone 20mg/1.0 mL syringe as per the Regulations.

APPLICABLE GUIDELINES

Category

7. 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.

8. At the date of first sale of Copaxone 20 mg/1.0 mL syringe in Canada (May 15, 2002), Copaxone 20 mg/1.0 mL vial was also sold in Canada by Teva. Therefore, based on the above Scientific Review Procedures, following issuance of the '088 Patent, Board Staff categorized Copaxone 20 mg/1.0 mL syringe 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

9. Chapter 1 - Excessive Price Guidelines ("Guidelines") sets out the appropriate introductory price tests for a Category 1 new drug product during the benchmark period (date of first sale to the end of the six month period) and thereafter the test applicable to existing DINs as follows:

International Price Comparison Test

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.

Reasonable Relationship Test

8.3 In addition to the Guideline applicable to all patented drug products detailed in Section 7, the introductory price of a Category 1 new drug product will be presumed to be excessive if it does not bear a reasonable relationship to the average price of other DINs of the same medicine in the same or comparable dosage forms (Schedule 1) […]

CPI-Adjusted Price Test

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.

10. By letter dated July 27, 2004 Board Staff advised Teva that it had been informed that a price increase of [redacted] had been implemented for Copaxone 20mg/1.0 mL syringe (from [redacted] to [redacted] for a single syringe) effective July 1, 2004. Board Staff further advised Teva that, although no patent had yet been issued pertaining to Copaxone 20mg/1.0 mL syringe, price increases allowed by the CPI methodology would be from 2.2% to 3.3% (based on forecast CPI as published in the April 2003 NEWSletter). **(Attachment 4)**

11. By letter dated August 20, 2004 and October 27, 2004, Teva maintained that the price of Copaxone 20mg/1.0 mL syringe was not excessive. **(Attachment 5)**

12. By letter dated January 13, 2005, Board Staff advised Teva that while Board Staff was in the process of conducting the introductory price review of Copaxone 20mg/1.0 mL syringe, an investigation was nonetheless commenced into the price of Copaxone 20mg/1.0 mL syringe based on price and sales information showing a price increase of [redacted] for the regulatory reporting period July 2004 to December 2004, which appeared to exceed the Guidelines when applying the PMPRB's CPI-Adjustment Methodology. **(Attachment 6)**

13. By letters dated February 11, 2005 and September 1, 2005, Teva reiterated its position that the price of Copaxone 20 mg/1.0 mL syringe was not excessive. **(Attachment 7)**

14. By letter dated March 10, 2006 **(Attachment 8)**, Board Staff advised Teva that it had now completed its review of the introductory price of Copaxone 20mg/1.0 mL syringe and that when applying the Reasonable Relationship ("RR") test and the International Price Comparison ("IPC") test based upon Teva's regulatory filings, the introductory price of Copaxone 20mg/1.0 mL syringe was considered within the Guidelines for the introductory period May 2002 to June 2002.

15. As for subsequent reporting periods, Board Staff further advised Teva that the price of Copaxone 20mg/1.0 mL syringe continued to be within the Guidelines until June 30, 2004 following which the price of Copaxone 20mg/1.0 mL syringe was considered to be excessive as the price increase of Copaxone 20mg/1.0 mL syringe exceeded the MNE price calculated using the PMPRB's CPI-Adjustment Methodology for the periods January to December 2004 and January to December 2005:

Copaxone 20 mg/1.0 mL syringe	Price/Unit	
Reporting Period	Average Transaction Price ("ATP")	Maximum Non-Excessive Price ("MNE")
May02-Jun02	[redacted]	[redacted]
Jul02-Dec02		
Jan03-Dec03		
Jan04-Dec04		
Jan05-Dec05		

16. According to publicly available information, Teva was selling Copaxone 20mg/1.0 mL syringe at a price of $37.80 per syringe ($1,134.00 for a

kit of 30 syringes) for the period May 2004 to July 2004 and at a price of $45.36 per syringe ($1,360.80 for a kit of 30 syringes) commencing in August 2004. **(Attachment 9)**

17. Furthermore, in 2005, based on publicly available information, the price of Copaxone 20mg/1.0 mL syringe in Canada is the 4th lowest of the comparator countries listed in the Regulations, below the median international price. **(Attachment 10)**

POLICY OF EXCESSIVE PRICING

18. 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.

19. It is the position of Board Staff that Teva has engaged in a policy of selling Copaxone 20mg/1.0 mL syringe at an excessive price. Teva has been selling Copaxone 20mg/1.0 mL syringe in Canada since July 2004 at a price per syringe which Teva knew or ought to have known exceeded the MNE price calculated in accordance with the PMPRB's CPI-Adjustment Methodology. To date, Teva has failed and/or refused to lower the price of Copaxone 20mg/1.0 mL syringe to comply with the Guidelines.

OTHER

20. 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.

21. 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 Copaxone 20mg/1.0 mL syringe 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

22. It is respectfully submitted that there are grounds for the Board to conclude, pursuant to section 83 of the *Patent Act*, that Teva is selling or has sold the medicine known as Copaxone 20mg/1.0 mL syringe in any market in Canada at a price which is or was excessive.

23. Board Staff seeks the issuance of an Order as against Teva, the terms of which would be as follows:

a) The maximum non-excessive price of Copaxone 20mg/1.0 mL syringe in Canada for the period January 1, 2004 to December 31, 2006 inclusive shall be as follows:

Copaxone 20 mg/1.0 mL syringe	Price/Unit
Reporting Period	MNE
Jan04-Dec04	[redacted]
Jan05-Dec05	[redacted]
Jan06-Dec06	[redacted]

b) The maximum non-excessive price of Copaxone 20mg/1.0 mL syringe in Canada in future years shall be calculated in accordance with the Guidelines.

c) In accordance with subsection 83(1) of the *Patent Act*, Teva shall cause the maximum price at which it sells Copaxone 20mg/1.0 mL syringe 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), Teva shall offset twice the amount of excess revenues estimated to have been derived by Teva from the sale of Copaxone 20mg/1.0 mL syringe at an excessive price from July 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 December 31, 2005, Teva 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 January 1, 2006 to the date on which the price reduction referred to in paragraph c) comes into effect, Teva 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 Teva from the sale of Copaxone 20mg/1.0 mL syringe 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) Teva 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 Copaxone 20mg/1.0 mL syringe sold and either the average price per syringe or the net revenue from sales of Copaxone 20mg/1.0 mL syringe in Canada, in the same form as required by subsection 4(1) of the Regulations for the period January 1, 2006 to the date on which the price reduction referred to in paragraph c) comes into effect.

Dated at Ottawa this 10th day of April 2006.

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LIST OF ATTACHMENTS

Attachment 1	Product monograph for Copaxone 20mg/1.0 mL syringe dated August 28, 1997 (revised March 7, 2002)
Attachment 2	Notice of Compliance for Copaxone 20mg/1.0 mL syringe - March 20, 2002
Attachment 3	Canadian Patent No. 2,191,088 granted September 28, 2004
Attachment 4	Letter dated July 27, 2004 from Board Staff to Teva Neuroscience G.P.-S.E.N.C.
Attachment 5	Letters dated August 20, 2004 and October 27, 2004 (without enclosures) from Teva Neuroscience G.P.-S.E.N.C. to Board Staff
Attachment 6	Letter dated January 13, 2005 from Board Staff to Teva Neuroscience G.P.-S.E.N.C.
Attachment 7	Letters dated February 11, 2005 and September 1, 2005 from Teva Neuroscience G.P.-S.E.N.C. to Board Staff
Attachment 8	Letter dated March 10, 2006 from Board Staff to Teva Neuroscience G.P.-S.E.N.C.
Attachment 9	McKesson Canada Ontario Pharmacy Price Listing May-July 2004; August-October 2004; November-January 2005; February-April 2006
Attachment 10	Copaxone 20 mg/1.0 mL syringe- International Prices
Attachment 11	Copaxone 20 mg/1.0 mL syringe - Calculation of Excess Revenues