**ABRIDGED**

**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 Canada Innovation G.P.-S.E.N.C., (the "Respondent") and the medicine "Copaxone"**

# AMENDED 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 Canada Innovation G.P. – S.E.N.C., formerly 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)**. Its 4th level in the Anatomical Therapeutic Chemical ("ATC") Classification System is L03AX13 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.

**FACTORS SET OUT IN SUBSECTION 85 (1) OF THE *PATENT ACT***

7. Subsection 85(1) of the *Patent Act* (the "Act") sets out the factors the Board shall take into consideration in determining whether a medicine is being or has been sold at an excessive price in any market in Canada:

> In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (a) the prices at which the medicine has been sold in the relevant market;
>
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
>
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
>
> (d) changes in the Consumer Price Index; and
>
> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.

8. To date, no additional factors have been prescribed pursuant to paragraph 85(1)(e).

9. Board Staff submits that it is appropriate in the case at bar for the Board to give due consideration to its *Compendium of Guidelines, Policies and Procedures* (the "Guidelines") to establish an approach and methodology in applying the factors set out in subsection 85(1) of the Act to determine if Copaxone is being or has been sold at an excessive price in Canada.

## APPLICABLE GUIDELINES

### Category

10. 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.

11. 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

12. 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.

13. By letter dated July 27, 2004 Board Staff advised Teva that it had been informed that a price increase of 20% had been implemented for Copaxone 20mg/1.0 mL syringe (from $36.00 to $43.20 for a single syringe) effective July 1, 2004. Board Staff further advised Teva that, although no patent had yet 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)**

14. 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)**

15. 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 20% 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)**

16. 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)**

**PRICE AT WHICH THE MEDICINE HAS BEEN SOLD IN CANADA AND CHANGES IN THE CONSUMER PRICE INDEX (CPI)**

17. 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.

18. 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 beginning January to December 2004 and for all subsequent periods:

| Copaxone 20 mg/1.0 mL syringe | Price/Unit | |
|---|---|---|
| Reporting Period | Average Transaction Price ("ATP") | Maximum Non-Excessive Price ("MNE") |
| May02-Jun02 | $36.0000 | $36.0000 |
| Jul02-Dec02 | $36.0000 | $36.0000 |
| Jan03-Dec03 | $36.0000 | $37.0080 |
| Jan04-Dec04 | $38.6038 | $36.9720 |
| Jan05-Dec05 | $40.9029 | $38.1921 |
| Jan06-Dec06 | $41.0145 | $38.2320 |
| Jan07-Dec07 | | $39.3752 |
| Jan08-Dec08 | | $40.7128 |
| Jan09-Dec09 | | $40.1054 |
| Jan10-Dec10 | | $41.1471 |
| Jan11-Dec11 | | $42.7892 |
| Jan12-Dec12 | | $42.6320 |

19. According to publicly available information, Teva was selling Copaxone 20mg/1.0 mL syringe at a price of $1,134.00 for a kit of 30 syringes ($37.80 per syringe) for the period May 2004 to July 2004 and at a price of $45.36 per syringe commencing in August 2004. **(Attachment 9)**

## PRICES AT WHICH THE MEDICINE HAS BEEN SOLD IN COUNTRIES OTHER THAN CANADA

20. Board Staff has considered the publicly available prices at which Copaxone has been sold in the comparator countries listed in Schedule 1 to the Regulations from 2002 to 2012. The publicly available prices, as filed by Teva and as verified by Board Staff, at which Copaxone has been sold in the comparator countries are found in **Attachment 10.**

## PRICES AT WHICH OTHER MEDICINES IN THE SAME THERAPEUTIC CLASS HAVE BEEN SOLD IN COUNTRIES OTHER THAN CANADA

21. Board Staff has also considered the international prices of the comparator medicine, Copaxone vial, by conducting an International Therapeutic Class Comparison ("ITCC") for the comparator countries listed in the Regulations using the straight class approach and the ratio approach. The results of the ITCC tests for Copaxone at introduction and for subsequent periods are found in **Attachment 10.**

## OTHER

22. 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.

23. 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

24. 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.

25. 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, 2012 inclusive shall be as follows:

| Copaxone 20 mg/1.0 mL syringe | Price/Unit |
|---|---|
| Reporting Period | MNE |
| Jan04-Dec04 | $36.9720 |
| Jan05-Dec05 | $38.1921 |
| Jan06-Dec06 | $38.2320 |
| Jan07-Dec07 | $39.3752 |
| Jan08-Dec08 | $40.7128 |
| Jan09-Dec09 | $40.1054 |
| Jan10-Dec10 | $41.1471 |
| Jan11-Dec11 | $42.7892 |
| Jan12-Dec12 | $42.6320 |

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(2) of the *Patent Act*, Teva shall offset 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, 2012, 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 the amount set out in **Attachment 11**; and

ii) With respect to the period from January 1, 2013 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 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, 2013 to the date on which the price reduction referred to in paragraph c) comes into effect.

Dated at Ottawa this 24th day of June 2013.

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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 and International Therapeutic Class Comparison |
| Attachment 11 | Copaxone 20 mg/1.0 mL syringe - Calculation of Excess Revenues and Reasonable Relationship Test |