February 25, 2008 **Decision: PMPRB-06-D2-COPAXONE**

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"

Introduction

1. On May 8, 2006, the Chairperson of the Board issued a Notice of Hearing to enquire into the price of the medicine Copaxone[1], which is distributed in Canada by the Respondent Teva Neuroscience GP-SENC ("Teva"). Teva holds a patent pertaining to Copaxone and is thus subject to the price regulation provisions of the *Patent Act* (the "Act"). Public hearings were held and evidence was presented by the Staff of the Board ("Board Staff") and by Teva over the course of three days and the proceedings were concluded by two days' of oral argument.

2. The Board is mandated by the Act to ensure that the price of Copaxone, a patent medicine, is or was not sold at an excessive price in Canada. In carrying out its function, the Board's determination of whether or not a price is excessive must be based upon the factors stipulated in section 85 of the Act. At a hearing, Board Staff has the onus of establishing, to the Board's satisfaction, that the medicine in question is or has been excessively priced, in accordance with the factors set out in section 85.

Facts

3. Copaxone was initially introduced in Canada in vial form. The medicine is used in the treatment of patients with multiple sclerosis ("MS") to reduce the frequency of relapses. Although the first sale was not made until September, 1997, Teva applied for a patent for Copaxone in 1995. On November 30, 1995, the patent pertaining to a new formulation of the active ingredient of Copaxone (glatiramer acetate) was laid open.

[1] In the style of cause the medicine is listed as "Copaxone". Under section **C.** of the Notice of Hearing – **Grounds for the Proposed Orders and the Material Facts** – the medicine subject to the hearing is described as: "Copaxone is a 20mg/1.0mL solution in a pre-filled syringe for subcutaneous injection (DIN 2245619)."

4. At or about the time of the first sale in September 1997, Board Staff became aware that Copaxone was on the market when Teva asked Board Staff for a scientific review of the vial, with a view to determining its likely categorization and the acceptability of its price, which on introduction was $36.00 for a one-day vial dosage of 20 mg/1.0 mL.

5. On November 5, 1997, Board Staff advised Teva that since its price was below that of the only competitor product then on the market, Betaseron – the vial price of which had been approved by the Board under a voluntary compliance undertaking ("VCU") in 1995 at $44.51 per day – Copaxone's price was, in all probability, non-excessive. However, since no patent had issued, it was explained by Board Staff that Copaxone was not yet under the Board's jurisdiction.

6. Between 1997 and 2002, Teva made significant changes to Copaxone's mode of delivery (see paragraphs 21 and 22, *infra*). By 2002, the most common form of delivery had become a syringe, although the multi-dose vial was then still on the market.[2] Health Canada issued a Notice of Compliance ("NOC") for the Copaxone syringe on March 20, 2002. Teva began selling the syringe on May 15, 2002 and the patent for the syringe was issued on September 28, 2004.[3] Although the patent was issued to Teva's parent company in Israel, it is agreed that Teva is considered the Canadian patentee.

7. On October 27, 2004, in response to Board Staff's request and in accordance with the *Patented Medicines Regulations, 1994* ("Regulations"), Teva filed its price and sales information for both the vial (from the second period of 1997 to the end of the second period of 2003) and for the syringe (for the first period of 2002 to the end of the first period of 2004). The Respondent has continued to make the required filings since then.[4]

8. On or about July 27, 2004, prior to the issuance of the patent, Teva advised Board Staff that effective July 1, 2004, it had implemented a 20% increase in the price of the syringe, raising it from $36.00 to $43.20, still the lowest priced

[2] The sale of Copaxone, in the vial form, in Canada was discontinued in July 2004.

[3] This patent, Canadian Patent No. 2,191,088, is the only patent that issued. We received no further information with respect to the status of any other patent application relating to Copaxone.

[4] At the date of first sale of Copaxone 20mg/1.0mL syringe in Canada (May 15, 2002), the vial was still being sold in Canada by Teva. Therefore, based on the above Scientific Review Procedures, following issuance of the '088 Patent, Board Staff categorized Copaxone 20mg/1.0mL 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. This assertion was not contested by the Respondent.

medicine in its therapeutic class. Board Staff replied that although no patent had yet issued, the 20% increase would appear to be contrary to the CPI methodology set out in the Board's Excessive Price Guidelines (Guidelines) which, based on published CPI forecasts from Statistics Canada, would be in the 2.2%-3.3% range for that year.

9. Upon receipt of this information, Board Staff conducted its normal inquiries. In due course, it advised Teva that based on its investigation, the introductory price of the syringe, $36.00, was within the Guidelines for the introductory period May 2002 to June 2002. That remained the case until the price was increased to $43.20 on July 1, 2004, following which Board Staff advised Teva that the syringe price was excessive under the CPI methodology contained in the Guidelines. Teva was supplied with Board Staff's calculation of the maximum non-excessive prices ("MNEs") for the period January 2003 through December 2005.

10. Teva advised Board Staff that it disagreed with Board Staff's conclusion that the price of Copaxone syringe, post-July 2004, was excessive. Discussions ensued, but no agreement was reached. Accordingly, the Chairperson of the Board issued a notice of hearing on May 8, 2006, and the hearing, involving considerable oral and documentary evidence, proceeded before this hearing panel ("Panel"), with the final submissions being made by Board Staff on June 27, 2007 and by Teva on August 13, 2007.

Submissions

Board Staff

11. Counsel contended that the Board's decision on whether a price is excessive under subsection 85(1) is discretionary. However, it must be based on a consideration of *all* of the factors enumerated in subsection 85(1) and, if necessary, subsection 85(2). The weight to be given to each of the factors in section 85 is within the discretion and judgment of the Board, so long as all of the factors "are taken into consideration".

12. Counsel stated that while Copaxone syringe may offer some improvements over Betaseron, the evidence fails to establish that the improvement is substantial and that Copaxone is therefore properly characterized as a Category 1 medicine.[5]

[5] See s. 3.1 of the Guidelines "Category 1 – A new DIN of an existing or comparable 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.

13. Acting in accordance with the Guidelines, Board Staff established the introductory price of the syringe in May, 2002, $36.00, as the benchmark price for the purpose of calculating allowable future price increases. As will later be seen, Teva contends that in their communications, Board Staff suggested that the benchmark price would be established much closer to the time that the patent issued. This assertion is denied by Board Staff (see paragraph 19, *infra*).

14. Board Staff counsel reviewed the way in which the Guidelines dealing with CPI increases originally had been formulated and applied since the Board's creation in 1987. Briefly stated, from 1987 to 1994, the Guidelines permitted unrestricted banking of CPI increases. A patentee could wait an unlimited number of years before taking any price increase and then be permitted to take the full cumulative CPI increase at one time. In 1992, concerned about the impact on consumers of significant banked increases being implemented in a single year, the Board consulted stakeholders with a view to establishing a different CPI methodology in its Guidelines.

15. The CPI formula was changed in 1994. Under the revised CPI-Adjustment Methodology, the maximum allowable annual percentage increase in a DIN's price is equal to the lesser of (a) the cumulative percentage change in CPI since the benchmark year to a maximum of three years back, and (b) 1.5 times the current year forecast change in CPI. Accordingly, under the current Guidelines methodology, if the patentee takes the full CPI increase in each year of a rolling three-year period, the patentee has reached the maximum allowable CPI increase for that three-year period. On the other hand, if less than the allowable CPI increase has been taken, the "banked" CPI not taken over that three-year period can be taken so long as it does not exceed 1.5 times the change in CPI in the current year: i.e., the year in which the increase is being taken.

16. Board Staff counsel's argument for applying the current CPI methodology set out in the Guidelines was essentially two-fold. First, it was contended that the methodology provides effective and highly desirable protection to consumers against sudden one-time price increases in substantial and potentially unaffordable levels. Second, to permit Teva to justify its 20% increase on the basis that its product still remains the lowest priced drug in its therapeutic class, domestically and internationally, would establish a precedent that would create unmanageable administrative difficulties for Board Staff in its monitoring of other patentees who might attempt to exceed the current CPI methodology restrictions. Board Staff's contention was that in each such case, it would be necessary to exhaustively review and either confirm or redefine the appropriate comparators in the relevant therapeutic class, and determine their current product prices, both domestically and internationally. The extra time and resources needed to do this would, it was argued, be virtually incalculable.

17. Board Staff counsel also sought to support the current CPI methodology on the basis of statements made by the Minister responsible (Minister of Consumer and Corporate Affairs) during the Parliamentary debates in 1986, over twenty years ago, when the Act was amended to permit the review of excessive pricing of patented medicines.

18. Counsel urged that in assessing Teva's assertion that it is entitled to exceed the CPI methodology in the current Guidelines, the Panel should give no weight to the alleged attention, time, care and costs associated with Teva's patient care programs, or to the improvements and refinements said to have been made to the manner in which Copaxone is administered. It was contended that these issues are not – or not sufficiently – quantified in terms of costs and that, in any event, it appeared that many had been undertaken by and for Teva's international business, and could not be isolated for attribution, in any reliable way, to its Canadian operations.

19. Board Staff rejected the suggestion that it had represented to Teva, expressly or by implication, that its introductory benchmark price would be deferred until a time much closer to the date the patent was issued – i.e., until some time after the price increase on July 1, 2004. Counsel contended that as a result of discussions and correspondence as early as 1997, Teva knew, or ought to have known, the significance of the Guidelines, both with respect to the setting of the benchmark price and the CPI methodology limitations on subsequent price increases. Counsel cited the evidence of Dr. Weir, an economist, whose supposition was that Teva's pricing strategy was deliberately planned in the hope that it could maximize revenues and profits before the Board's restrictive Guidelines on post-benchmark pricing became operative. Since the scheme, according to counsel, was a deliberate policy to evade the Board's restrictions on excessive pricing, he urged the Panel to exercise its discretion under subsection 83(4) of the Act and order Teva to pay twice the amount of excess revenues it received as a result of its excessive pricing practices.

Patentee's Submissions

20. Counsel for Teva reviewed, in considerable detail, the programs and policies that the Teva had instituted since 1997 to enhance its patient care programs, referring in particular to Teva Canada's General Manager, Jon Congelton's descriptions of specially-designed initiatives like *Shared Solutions*, *MS Watch* and the *Copaxone Assistance Program*. For the purposes of this decision, the details of these programs need not be described. Suffice it to say that it was argued that all were of significant benefit to Copaxone users and involved considerable costs to the patentee, both in capital expenditures and the devotion of human resources to their design and implementation, all done without

increases to the price of the medicine.

21. Similar emphasis was placed by counsel on product changes for the benefit of MS patients over the 7-year period 1997-2004, also carried out with no costs to the consumers, while the price of the medicine remained constant. The original vial, according to the evidence, required a complicated administration protocol, involving 18 steps to ensure that the medicine was mixed and administered safely. This was a difficult task, with substantial risks of product wastage and accompanying patient anxiety, especially for those MS patients with manual dexterity impairment. Accordingly, the Company's initial response was to provide two additional *free* dosages with each monthly kit to compensate for inadvertent spillage.

22. Then, in 1998, Teva introduced a new Mixjet vial adaptor – a plastic device facilitating withdrawal of the solution from the vial, again with no change in price to the consumer. That same year it provided a new mechanism, the Autojet, which allowed injection from the vial with the pushing of a single button, again with no price increase. And finally, in 2002, the most significant improvement was introduced, namely the pre-filled syringe, again at no extra cost. All these improvements, extending over a 7-year period, it was argued, warranted the one-time price increase of 20% in July 2004.

23. Throughout the period under consideration, the price of Copaxone has remained lower than its competitor products in Canada and has always been at or near the bottom of the price charged for Copaxone in the comparator countries named in Schedule 1 of the Regulations under the Act. Although there was only one other medicine, Betaseron, in the same therapeutic class in 1997, when Copaxone was first sold, there have since been three additional products introduced on the market in the same therapeutic class: Avonex and two formulations of Rebif (22 MCG/0 mL) and Rebif (44 MCG/0 mL). Copaxone has always been the lowest priced product in its therapeutic class both before and after the 20% price increase in 2004.

24. Reference has already been made to Teva's argument that it was "misled" by Board Staff's alleged representation that the product's benchmark price should be set nearer to the time the product became patented and further, that no or insufficient mention was made of limitations on subsequent price increases because of the Guidelines' CPI methodology.

25. Counsel argues that Board Staff's position distorts and in fact violates the provisions of section 85 of the Act. It is agreed, even with the 20% price increase, that Copaxone's price meets the tests set out in paragraphs 85(1)(a), (b) and (c). However, the Board is mandated to consider as well "changes in the

Consumer Price Index", the factor stipulated in paragraph (d). By arguing that Teva has violated paragraph (d) alone, Board Staff is effectively contending that *no weight whatsoever* should be given to its compliance with paragraphs (a), (b) or (c). It is asserted that this violates the mandate given to the Board under subsection 85(1), which *requires* the Board to take into consideration *all* of the factors listed in (a), (b), (c) and (d). Implicit in this argument is that if no weight is given to a factor, it necessarily follows that it has not been taken into consideration.

26. Moreover, in purporting to define what the Board may or may not consider in assessing "changes in the Consumer Price Index" by an interpretation definition in the Guidelines, Board Staff is usurping the function of Parliament. A hearing panel cannot be limited above and beyond the constraints that Parliament has imposed in considering how and to what extent it applies CPI considerations to a determination of "excessive pricing". If there is any doubt about this proposition, according to counsel, it is made clear by statements made in Parliament – both the Senate and the House of Commons – during the debate on the legislation. To use the language of counsel, the Board cannot issue *de facto* law disguised as Guidelines. Under sections 91 and 92 of the *Constitution Act, 1987*, it is clear that Parliament, not an agency created by an act of Parliament, is the sole source of lawmaking. If the Guidelines, as is argued to be the case here, conflict with the section 85 factors, they are null and void and can have no application in a section 85 determination.

27. Counsel acknowledged that if the Panel is to consider the patient care programs and product improvements which, according to Teva, justified Copaxone's price increase in 2004, it must do so pursuant to the provisions of section 85. It was contended that we are entitled to do so under either (or both) paragraph 85(2)(a) or paragraph 85(1)(a).

28. Under paragraph 85(2)(a), where the Panel is unable to determine whether the price of the medicine is excessive after considering the factors in subsection 85(1), it may take into account the costs of making and marketing the medicine. Counsel argued that the patient care and assistance programs and product improvements referred to in paragraphs 20 through 22, *supra*, necessarily involved making and marketing costs that justify the price increase implemented by Teva in July 2004.

29. Alternatively, counsel argues that subsection 85(1)(a), properly construed, must be held to cover issues other than those raised in paragraphs 85(1)(b) and (c). Since the prices referred to in (a) will necessarily be considered under (b) and (c), (a) would otherwise be duplicative and redundant, a conclusion which would be inconsistent with the principle that Parliament intends to give each provision a

separate and distinct purpose. Hence we are urged to use paragraph 85(1)(a) to support our consideration of the factors referred to in paragraphs 20 through 22, *supra*: namely, the fact that the price has been held constant for many years; the improved patient care services; the substantial advances in medicine delivery techniques; and the other factors referred to by counsel.

30. It was contended that in the *Adderall XR* decision[6], the Board properly identified the purpose of section 85, namely to control or restrain potential abuse of market power by a patentee arising from the exclusivity granted under its patent. This is the extent of the Board's power and if it were to consider any other factor than this specific type of abuse of market power in determining whether the medicine's price is excessive, it would be engaging in price regulation beyond the Board's jurisdiction and the purposes of the Act.

31. The same principle, it was argued, applies in considering the constitutional constraints on the Board's jurisdiction. Pure price regulation divorced from concern about abuse of patent power, according to counsel, would fall outside the Act. In the absence of a national emergency or some other head of power, such as the need to roll back prices that are the product of patent abuse, neither the federal government nor its agencies have the constitutional power to engage in pure price regulation.

32. Counsel then alluded to the negative effects that would flow from a finding that Teva had in the circumstances of this case, engaged in excessive pricing. Such a finding, he contended, would encourage patentees to introduce prices at the highest levels permitted under the Guidelines. It would also induce companies to introduce their medicines in the first instance in countries other than Canada in order to establish higher international comparisons. Further, it would indicate that there is a benefit given to the first medicine on the market, as was done in the case of Betaseron, which was priced high internationally and then had its domestic price approved by the Board under a VCU. It was pointed out that under the existing CPI methodology, price increases within the methodology's formula need not be justified by any increase in costs or provision of the types of improvements that have been introduced by Teva in the case of Copaxone. The existing CPI methodology, if inflexibly followed, will inevitably force patentees to take their annual CPI increases, whether or not they can be justified on cost or other grounds. And fewer investments will be made in product development or service enhancement if their costs exceed the increases permitted under the existing CPI methodology set out in the Guidelines.

[6] PMPRB-06-D1-ADDERALL XR, December 15, 2006

33. On the other hand, according to counsel, a finding that the price in this instance is *not* excessive would create positive incentives. For example, new products would be introduced at lower prices if the patentees were not disadvantaged by the setting of an introductory benchmark price that reflects market conditions and product characteristics that may no longer be relevant. Patentees would be encouraged to engage in product and service enhancements if they could see that these would be recognized in the allowance of reasonable price increases, unrestricted by the imposition of an inflexible CPI ceiling.

Conclusion

34. This is the first case that the Board has been called upon to rule on an issue that relates to the meaning and effect of paragraph 85(1)(d) and the CPI-Adjustment Methodology as set out in Schedule 4 of the Guidelines. The Panel is fortunate to have had able and exhaustive submissions from all counsel on this important matter. We turn now to the key propositions advanced by the parties.

35. It is agreed that the Panel's decision is discretionary as to whether or not the price of the medicine is excessive. However, such a determination must be based on *all* factors enumerated in subsection 85(1) and further that if, after taking into consideration all of those factors, we are unable to make a judgement, then we may consider the factors enumerated in subsection (2).

36. It is agreed that the Copaxone syringe is properly characterized as a Category 1 drug. It is not a medicine that provides a breakthrough or substantial improvement (Category 2) or the new DIN of a non-comparable dosage form of an existing medicine or the first DIN of a new chemical entity (Category 3).

37. Having considered the testimony as well as the written communications between the parties, the Panel is satisfied that Board Staff did not mislead the Respondent or misrepresent the manner in which the Guidelines are routinely applied in categorizing drug products, establishing benchmark prices for drugs, or in applying the Guidelines' CPI Methodology to increases in drug prices following introduction.

38. The Panel sees no reason to disagree with Board Staff's application of the Guidelines in establishing the introductory price of the Copaxone syringe as of May 2002 at $36.00, characterizing it as the benchmark price. The Panel notes, however, that the price of the syringe in 2002 was the same price as the vial when it was introduced into the market in 1997. The evidence also establishes that both the vial and the syringe have the same active ingredient; both are used for the same disease (MS); both the vial and syringe are injectable drugs, administered daily, and both have comparable dosages. Therefore, in

determining any allowable increases, the Panel has determined that it is appropriate to use the benchmark year of the vial formulation of Copaxone, being 1997 when the vial was introduced into the market, for the purposes of considering any CPI increases since 1997 up until 2004.

39. The CPI Methodology contained in the Guidelines is the central issue in this case. The Panel agrees with the Respondent that its discretion cannot be restricted or curtailed by the provisions of the current CPI methodology *if* the Panel determines that there are factors, within the ambit of section 85, which support a departure from that methodology. However, in making any determination as to excessive pricing, the Panel wishes to emphasize that it does not agree with the Respondent's assertion that subsection 85(1) requires equal weight to be given to each of subparagraphs (a), (b), (c) and (d); rather, while each must be considered by the Board, the weight to be assigned to each is a matter within the Board's sole discretion.

40. The unique situation is that Copaxone, in both forms of delivery, has always been the lowest priced drug in its therapeutic class. When introduced, there was only one other drug in the class, Betaseron, and its price was found by the Board to be non-excessive when the Board approved a VCU, establishing the Betaseron price at a level approximately 25% higher than the introductory price of Copaxone. Later, three other drugs in the same therapeutic class came into the market – Avonex and two versions of Rebif – and all carry prices significantly higher than Copaxone. The only issue, therefore, is the permissible increase to the price of Copaxone in 2004, and whether it must be strictly limited in accordance with the terms of the current CPI Methodology in the Guidelines.

41. For the most part, the Guidelines deal with matters of definition and process and the ways in which the comparison measurements mandated by paragraphs 85(1)(a), (b) and (c) should be carried out to avoid a presumption that a given price is excessive. For these purposes, as counsel for the Respondent freely admits, they are helpful in assisting patentees in establishing non-excessive introductory prices. The CPI methodology, in contrast, qualifies and refines the language of paragraphs 85(1)(d) by defining precisely how patentees must, in all cases, apply the CPI measurement factor in dealing with price increases following the establishment of the medicine's benchmark price. Whether this is tantamount to legislation by an administrative tribunal improperly purporting to exercise legislative powers that are within the exclusive jurisdiction of Parliament, as argued by the Respondent, is not necessary for us to decide. However, as the Act stipulates, the Guidelines are not binding on the Board in its adjudicative role, and it remains for this Panel to determine whether, on the unique facts of this particular case, how the CPI factor should be applied in determining whether the price increase in dispute was justified.

42. As the Respondent points out, the Board's previous jurisprudence deals with its understanding of the reasons for its establishment by Parliament. In the *Adderall XR* case, which dealt with jurisdiction in the pre-patent, laid open period, the Board stated, *inter alia*, "There is a quite obvious connection between *the market power associated with the statutory monopoly granted by patents and the price control provisions of the Patent Act.*" (emphasis added). However, the Federal Court of Appeal has dealt with whether or not the Board can or should go beyond pricing and determine whether or not the patentee has abused the market power conferred upon it by its patent: see *ICN Pharmaceuticals, Inc. v. Canada (Patented Medicine Prices Review Board)*." [1996] F.C.J. No. 1065, where the Court stated "In my opinion, subsection 83(1) of the Act is concerned only with the existence of a related patent and not its potential or actual effect on the ability of potential competitors to enter a market, *or for that matter the ability of patent holders to exercise market power.*" (emphasis added)

    The Board agrees with this conclusion, namely that the Act is drafted so as to regulate abuse of presumed market power of monopolies based only on price considerations. There is no need to go behind price factors to show an abuse of market power. The Respondent disagrees with this proposition, and contends that absent specific evidence of patent abuse, the Board does not have jurisdiction and if it purports to simply make a finding of excessive pricing, it is engaging in pure price regulation, a matter that falls outside any federal head of power. In light of the ICN case, and having considered other authorities, including *Manitoba Society of Seniors Inc. v. Canada (A.G.)*[7] and *Smith Klein & French Laboratories Ltd. v. Attorney General of Canada*[8], the Panel concludes that the jurisprudence by which it is bound establishes that Parliament is entitled to enact legislation, including laws intended to mitigate potential abuse from the exclusivity of patents, *by a scheme based on prices of medicines without the need to consider actual abuse in the case of any specific medicine.*

43. The Respondent argues that since subsection 85(1) of the Act refers solely to *excessive* prices, we should concern ourselves only with a given medicine's price *level*. The Panel does not agree. The reference in paragraph 85(1)(d) clearly enables the Board to take into account the quantum of incremental increases in prices based on their relationship to CPI level changes. The Panel's determination of whether or not a price increase is excessive will of necessity start from the factor in paragraph 85(1)(d) concerning the relevant CPI Index in

[7] Manitoba Society of Seniors Inc. v. Canada (A.G.) (1992) 95 D.L.R. (4th) 506 (Man. C.A.)

[8] Smith, Kline & French Ltd. et al. v. A.G. Canada, [1986] 1 F.C. 274 (F.C.T.D.); appeal dismissed [1987] 2 F.C. 359 (F.C.A.); leave to appeal refused (S.C.C., April 9, 1987)

accordance with the Guidelines, but ultimately be based on the Panel's assessment of its relationship, if any, to other factors in subsection 85(1).

44. The only relevant issue remaining is whether the one-time increase in 2004 justifies a conclusion that the "medicine is being or has been sold at an excessive price", within the meaning of and in accordance with all the factors listed section 85 of the Act.

45. The Board confirms its comments made above whereby it allocates the greatest weight to the CPI factor in paragraph 85(1)(d) in situations concerning increases in prices of existing medicines. The Board agrees however, that fact situations involving price increases similar to the circumstances of Copaxone in this matter cross a threshold where the CPI factor should not be the sole determinant of whether a price increase is excessive. In other words, the Board is prepared to recognize that the factors in paragraphs 85(1)(b) and (c) should apply to situations involving an increase in the price of a medicine that was and remains the lowest in a group of medicines of its therapeutic class in order to moderate the determination of excessiveness of price based on the Guidelines' CPI methodology.

46. The Panel is prepared to adopt this interpretation of the Act because it is of the view that at some point the price of a medicine relative to that of the other medicines in its class, which are the measures referred to in paragraphs 85(1)(b) and (c), can be so low that it flies in the face of common sense to conclude that the medicine is excessively priced merely because the increase exceeds the CPI. The Panel recognizes that the determination of the point at which price differentials between medicines will impact on issues of price increases is not easy to formulate. In all the circumstances, the Panel considers that a reasonable threshold for the application of paragraphs 85(1)(b) and (c) factors is crossed in the situation presented by Copaxone, when after an increase in the price of a medicine it remains the lowest priced in a group of medicines in its therapeutic class. In these exceptional circumstances, the Panel is prepared to conclude that the patentee may increase the price of its medicine in an amount in excess of the Guidelines, subject to certain limitations described below.

47. In the alternative, even were the Panel's conclusion based upon subsection 85 (1) factors for some reason found not to be conclusive, having considered the evidence and submissions, and weighing all of the factors outlined in paragraphs 85(1)(a), (b), (c) and (d), the Panel would nevertheless conclude that it is unable to determine whether the medicine is being or has been sold in Canada at an excessive price and would invoke paragraph 85(2)(a) of the Act.

48. The Panel is cognizant that this is the first time that the Board is required to address excessive pricing issues based on paragraph 85(2)(a) factors and that the Guidelines provide no guidance on this issue. Paragraph 85(2)(a) refers to "the costs of making and marketing the medicine". Obviously costs are regularly incurred by patentees in the making and marketing of medicines. Thus, it is only in exceptional circumstances that the Board is prepared to consider costs of this nature under this provision. It must normally be something which demonstrates that the costs incurred in making or marketing the medicine are so exceptional or provide such an obvious benefit to users that the Board is entitled to rely on this provision. In addition, because the circumstances before the Panel concern whether an increase in the price of Copaxone above the CPI should be considered excessive, the Panel must normally be satisfied that these costs were incurred after the benchmark price of the medicine was established and that it is reasonable to take them into consideration in the matters of price increases in medicines.

49. After due consideration, the Panel concludes that the only costs referred to in this matter that it is prepared to consider under paragraph 85(2)(a) are those in relation to the successive improvements in the delivery of the medicine made between 1997 and 2002. While there was no evidence showing that these delivery improvements affected the therapeutic value of the medicine, the Panel is satisfied that the "cost of making … the medicine" in paragraph 85(2)(a) is not limited to costs that improve the therapeutic value of the medicine. The Panel considers the improvements to have significantly benefited users of Copaxone, particularly for patients with MS whose personal coordination limitations make improvements in the delivery of their medicines of considerable importance to them. Paragraph 85(2)(a) includes reference to marketing costs which is indicative that a wide range of costs are to be considered under this provision and not just those related to the therapeutic value of medicines. The Board is also of the opinion that where benefit is demonstrated, it is appropriate to consider the costs incurred in making the delivery mechanisms and other necessary components of medicine as part of the costs of making a medicine, as those words are used in paragraph 85(2)(a).

50. The Respondent did not provide any objective data on the costs incurred in making the improvements to the delivery mechanisms of Copaxone. Nor did it attempt to attribute these costs to Canada, as opposed to those incurred in other countries where its affiliates carry on business. Instead, it relies upon the obvious conclusions that such improvements in the delivery mechanisms involve very substantial investments in research and manufacturing and that it is reasonable to attribute a portion of those costs to Canada where the medicine is sold.

51. Because the increase in prices that Panel is considering herein are in the realm of the magnitude of CPI increases that Teva could have taken after 1997, but chose not to implement, there is less concern about the need to demonstrate a direct relationship between the costs incurred to improve the delivery mechanisms and the increase in the price of Copaxone. To some extent, it is generally recognized that yearly increases in prices up to the CPI are intended to reflect the increasing cost of medicines. Not having increased its price, there is no issue of the Respondent taking these costs twice.

52. While the Panel would have preferred to have more concrete evidence as to the precise expenditures incurred by the Respondent, for these purposes the Panel is satisfied that substantial costs were incurred which should properly be attributed to the Canadian operations of Teva. In the circumstances the improvement initiatives undertaken involved sufficient additional costs to Teva Canada to justify an increased price in the medicine that is not considered excessive.

53. In coming to this conclusion, the Panel has taken note of the fact, as previously stated, that the only increase in the medicine's price since its introduction in Canada was the 20% increase in July, 2004. It remains the lowest-priced medicine in its therapeutic class in Canada, and one of the lowest-priced medicines in its class among the comparator countries referred to in the Regulations under the Act. The Panel emphasizes in particular that there were, at the time of the price increase, four products in the therapeutic class. No inference can be drawn, therefore, that there were as any lack of real price choice for MS therapy medicines of this sort.

54. There are three other issues deserving of comment. First the Panel is mindful of the administrative difficulties to which counsel for Board Staff alluded, as set out in paragraph 16, *supra*. The fear is that in permitting the departure from the current CPI methodology, other patentees will attempt to follow the Teva route, causing Board Staff untold difficulties in making new therapeutic class comparisons, with all the attendant problems of identifying the appropriate parties, products and prices to be compared. To this the Panel says that the facts of this case – including in particular the fact that Copaxone, throughout, has had the lowest price in its therapeutic class; the existence of four higher-priced products in the class; and the costs associated with product improvements – severely restrict its precedential application.

55. The second issue relates to the Parliamentary debates and their significance in determining what was intended by the CPI factor in paragraph 85(1)(d) of the final version of the 1987 amendments to the *Patent Act*. As a matter of statutory interpretation, we are reluctant, based on our understanding of the law, to resort

to what was said in legislative debates, unless the meaning of the particular provision in question is patently ambiguous. However, to the extent that the debates are a permissible aid to interpretation, we are of the view, from the relevant excerpts to which we were referred, that the government and Parliament did not intend to restrict the Board, in its application of the CPI factor, in a way that would make the price increase which our decision permits, a violation of paragraph 85(1)(d). More than that we need not say.

56. The final matter relates to the Respondent's argument that the Guidelines are a mere tripwire for Board Staff to alert itself to the need for an investigation into possible excessive pricing. We disagree. In fact, counsel for the Respondent, as we have observed in paragraph 41 *supra*, modifies or arguably abandons that argument when he says that the Guidelines serve a useful purpose in aiding patentees in setting their introductory prices in such a way as to prevent them being presumed to be excessive. Thus, while the statute makes it abundantly clear that the Guidelines are not binding on the Board, we wish to affirm that they are, and will remain, of utmost importance in the continued fair and impartial administration of the Act by the Board's expert and dedicated Staff.

57. In light of all the factors enumerated in section 85 of the Act, we have concluded that the magnitude of the price increase, and its one-time impact on consumers, resulted in the medicine being sold at an excessive price on and after July 1, 2004. However, for the reasons set out in paragraphs 45 through 53, the Panel finds that an increase above that permitted by the current Guidelines' CPI Methodology is justified. We therefore direct that the only price increase to be permitted for reasons of increases in the CPI or for any other reasons are as follows:

a) A phased increase in the price of the medicine will be permitted in an amount equal to the CPI increase from the date of the first sale of Copaxone, in vial form in 1997, until the date the increase in the syringe form of the medicine was implemented by the Respondent on July 1, 2004. The information in our possession from Statistics Canada, which is in the public domain, is that the CPI increased by 15.9% over this period. However, to ensure accuracy, we direct that the parties confer with a view to reaching an agreement on the CPI increase over that period.

b) In the interests of protecting the consumer against excessive prices and to lessen the impact of a sudden, one-time price increase, the permitted increase, calculated in accordance with the above formula, shall be implemented in three equal phases: one-third on July 1, 2004, one-third on July 1, 2005 and one-third on July 1, 2006. The Panel further directs the parties to confer to determine the prices permitted on each of those

three dates in accordance with the permissible CPI increase established under a) above and, having done so, to then calculate the total amount of the excess revenues received by Teva to date in accordance with that calculation.

58. The amount of the excess revenues determined pursuant to paragraph 49 payable to Her Majesty In Right of Canada shall be set out in a draft Order to be prepared by the parties and shall be submitted to the Secretary of the Board on or before March 25, 2008, for the Panel's review. If no agreement on the terms of the draft Order is reached by the parties, on or before March 25, 2008, or if in the Panel's view the draft Order does not comply with the Panel's directions, as set out in paragraph 49, the Panel will draft and issue the appropriate final Order.

59. The Panel has concluded that the Respondent has not engaged in a *policy* of selling the medicine at an excessive price, and therefore no Order will be issued pursuant to subsection 83(4) of the Act.

60. The Panel retains jurisdiction to entertain any requests by the parties, or either of them, for clarification of its decision, so long as any response to a requested clarification does not entail a substantive amendment to the Panel's decision.

Board Members:	Dr. Brien Benoit Mary Catherine Lindberg Tim Armstrong
Board Counsel:	Peter Annis

Appearances:

For Board Staff:	Guy Pratte Nadia Effendi
For the Respondent:	David Stratas Brad Elberg Trevor Guy

Sylvie Dupont
Secretary of the Board