May 12, 2008

Decision: PMPRB-06-D3-COPAXONE - Board Order

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

At the conclusion of its decision and reasons in this matter dated February 25, 2008 (the "Decision"), this hearing panel of the Board (the "Panel") requested that the parties draft an order that would implement the Decision. The parties were unable to agree on the terms of the order.

The Respondent provided written submissions concerning the terms of the order to the Panel on April 4, 2008. Board Staff provided its submissions on the terms of the order on April 10, 2008. On April 22, 2008, the Respondent made submissions in response to those of Board Staff, and in reference to the Board's April 10, 2008 decision in the proceeding concerning the medicine Adderall XR. Board Staff responded to those submissions on April 24, 2008. On April 25, 2008, the Respondent filed further submissions responding to those of Board Staff.

By means of this thorough exchange of submissions, the Panel considers the parties to have made their positions on the terms of the order very clear. The Panel has attached the order (the "Order") that will issue in respect of its decision of February 25, 2008. In the following paragraphs, the Panel provides its reasons for the terms of the Order, and, to the extent that the submissions of the parties indicated that they required clarification of the terms of the Decision, these reasons provide the clarification contemplated by paragraph 60 of the Decision. The Decision is final and no part of these reasons alters the substance of the Decision.

Maximum Non-excessive ("MNE") Price of Copaxone

While the Panel agrees with Board Staff that section 83 of the *Patent Act* (the "Act") empowers the Board to stipulate the price at which the Respondent may sell Copaxone in the future, the Panel does not consider it appropriate to do so in this case.

The Board, in its past decisions, has made a number of references to the role of the Board's "Compendium of Guidelines, Policies and Procedures" (the "Guidelines").

The Decision does not suggest that the Guidelines will not be applicable to the price of Copaxone in the future, and the Panel does not consider it appropriate for the Order to address that issue.

Permitted price increases

In paragraph 57 of the Decision, the Panel stated:

> 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…

The Panel then indicated that the price of Copaxone would be permitted to increase at rates above those permitted by the Consumer Price Index ("CPI") methodology in the Guidelines, for the years 2004, 2005 and 2006. These increases were expressly stated to be the only increases permitted on account of CPI, or for any other reason, for those years.

The Respondent, in its April 22, 2008 submission on the terms of the Order, took the position that the decision of the Board in the proceeding pertaining to the medicine Adderall XR – released on April 10, 2008 – should permit both the increases described in the Decision, and increases for 2005-2006 on account of changes in the CPI during those years. The Respondent argued that the price increases permitted by the Decision were referable to CPI increases from 1997-2004, and that further allowance should be made for subsequent increases in the CPI.

The Panel disagrees with the submissions of the Respondent on this point. The increases permitted by the Decision for 2004-2006 were greater than, and in lieu of (not in addition to) the CPI increases that would have been permitted by the Guidelines for those years. Though the permitted price increases were based on all of the facts of the case, including the fact that the Respondent did not increase the price of Copaxone from 1997-2003 despite increases in the CPI, the permitted price increases were not increases for 1997-2003, but for 2004-2006.

On a separate point, to give effect to the Decision, the MNE price of Copaxone for 2007 should be unchanged from the 2006 MNE price.

With regard the Adderall XR decision, that decision is not binding on this Panel, but in any event, the Panel does not consider the substantive of this Decision to be inconsistent with the Adderall XR decision. The panels in the two proceedings found different ways to reach a fair and reasonable conclusion based on the circumstances of the particular cases.

Accordingly, the Order reflects the conclusion of the Panel that the MNE price of Copaxone, as determined by the findings in the Decision, was $37.8960 for 2004, $39.7920 for 2005, and $41.6880 for 2006 and 2007.

Off-setting excessive revenues

For the reasons set out in the Decision, the Panel has significantly reduced the amount of excessive revenues that the Respondent would be required to offset, relative to the amount that is determined by the Guidelines. The Respondent has argued that its sales of Copaxone in 2006 and 2007, at prices below the MNE prices permitted by the Decision, should offset its sales of Copaxone during 2004 and 2005 at prices above the MNE prices permitted by the Decision.

The consequence of the Respondent's argument would be that the Respondent would not only have a reduced obligation towards excessive revenues, but to have no such obligation at all. The Panel does not consider this position to result in the proper implementation of the Decision.

The Guidelines provide for the calculation of the average transaction price at which a medicine is sold on an annual basis.[1] The Guidelines do not permit a patentee to charge excessive revenues in one or several years and then offset those revenues of its own accord by reducing (or not increasing) the price of the medicine in subsequent years. Indeed, such an approach would seriously impair, if not defeat, the Board's mandate. While the Guidelines permit price-averaging within a calendar year, the Panel believes that this is the reasonable time limit on price-averaging. Beyond such averaging, excessive revenues (other than *de minimus* revenues that do not warrant an investigation by Board Staff) should only be capable of being offset by compliance with an order of the Board. The Panel considers these terms in the Guidelines to be an appropriate implementation of the terms of the Act, and that the Order is reflective of this.

[1] The Respondent, in its submissions, refers to Schedule 5 of the Guidelines, where year-over-year price adjustments are recommended to adjust for *de minimus* excessive revenues that fall below the criteria for the initiation of an investigation. That provision of the Guidelines is not pertinent to this matter.

Accordingly, the Panel concludes that, in implementing the Decision, the terms of the Order should require the offsetting of the cumulative excessive revenues received by the Respondent in 2004 and 2005 by a payment to the Crown in the amount of $2,417,223.29. This amount will represent the excess revenues received by the Respondent for the period from the introduction of Copaxone in Canada to the end of 2007.

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

Board Counsel: Peter Annis

Sylvie Dupont
Secretary of the Board