July 21, 2008

Decision: PMPRB-99-D8-NICODERM - Continuation of the Hearing

IN THE MATTER OF the *Patent Act* R.S. 1985, c. P-4, as amended by R.S. 1985, c. 33 (3rd Supp.), and as further amended by S.C. 1993, c. 2

AND IN THE MATTER OF Hoechst Marion Roussel Canada Inc. (Respondent) and the medicine Nicoderm

1. The Panel has considered carefully the oral submissions of the parties in support of the Joint Submission dated August 26, 2006.

2. The Panel is not persuaded that the resolution proposed in the Joint Submission is appropriate.

3. A central premise of the Joint Submission is that sales of Nicoderm below its maximum non-excessive price (MNE) during the period from and after 1998 should be deemed to off-set excessive revenues alleged to have been earned from 1995, when the Board acquired jurisdiction over the pricing of Nicoderm, until 1997.

4. The Panel is not satisfied that this premise is consistent with the Guidelines, which appear to contemplate the off-setting of excessive revenues only by compliance with a Board order or voluntary compliance undertaking. For the reasons described in the Panel's letter of March 14, 2007, there is arguably a sound basis for this approach.

5. The Panel is not bound by the Guidelines, but, given the apparent inconsistency of a central premise of the Joint Submission with the Guidelines, the Panel does not consider it appropriate to rely on that premise as a reason to conclude the proceeding without a hearing. The premise and any related positions will, of course, remain open for argument if the Panel concludes that excessive revenues have been earned and the issue of the appropriate remedy is before the Panel.

6. The Panel finds support for this conclusion in the recent decision of a differently constituted panel in the proceeding pertaining to the medicine Copaxone.

7. In its main decision on the merits, the panel had allowed the patentee to increase the price of Copaxone at a rate that exceeded the CPI methodology in the Guidelines.

8. However, when it came to drafting the order to implement the decision, the patentee also sought to use pricing below the MNE in more recent years to offset excessive revenues from earlier years (which excessive revenues existed even with the higher-than-CPI increases allowed by the Panel). The panel issued a decision on this point, in which it said:

> 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.

9. The Panel is not bound by this decision, either for the purpose of deciding whether or not to conclude this proceeding now, or in deciding the appropriate remedy should there be a finding of excessive revenues in this proceeding. However, the decision does support the decision of the Panel to proceed with the hearing in this matter.

10. The parties provided various other reasons why it would not be in the public interest to continue this proceeding, mostly related to the passage of time and the intervening events. The Panel is not persuaded that any of these reasons, or all of them taken together, warrant discontinuance of the proceeding.

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[1] PMPRB-06-D3-COPAXONE, May 12, 2008, p. 3. 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.

11. Accordingly, parties are instructed to continue with the proceeding according to the following schedule:

i)	Evidence of Board Staff:	September 27, 2008
ii)	Evidence of the Respondent:	October 25, 2008
iii)	Reply evidence of Board Staff:	November 15, 2008
iv)	Pre-hearing conference:	November 21, 2008
v)	Hearing	Date to be determined week of August 18, 2008

Board Members: Dr. Robert G. Elgie
Réal Sureau
Anthony Boardman
Ingrid Sketris

Board Counsel: Gordon Cameron

Appearances

For Board Staff: Nadia Effendi, Counsel

For the Respondent:
Martin Mason, Counsel

Original signed by

Sylvie Dupont
Secretary of the Board