



February 14, 2014

Decision: PMPRB-13-D1-COPAXONE Redetermination 2013
- 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"
REDETERMINATION 2013**

ORDER

This Order pertains to a decision of the Patented Medicine Prices Review Board ("the Board") following a hearing initiated on May 8, 2006 with the issuance of a Notice of Hearing, to determine whether Teva Neuroscience G.P. – S.E.N.C., now Teva Canada Innovation ("Teva"), under sections 83 and 85 of the *Patent Act* (the "Act"), is selling or has sold the medicine known as Copaxone Syringe, Drug Identification Number ("DIN") 02245619 ("Copaxone Syringe") in any market in Canada at a price that, in the opinion of the Board is, or was, excessive and, if so, what order, if any, should be made.

The procedural history of this matter is detailed in the Board's February 23, 2012 decision on the 2010 redetermination of this case.¹

On January 31, 2014, Teva and Board Staff filed a Joint Submission proposing a Voluntary Compliance Undertaking ("VCU") by which it proposed to resolve all issues raised in these proceedings. On February 13, 2014, Teva and Board Staff filed a Supplementary Joint Submission at the Board's request to clarify the methodology applied by the parties to appropriately balance the subsection 85(1) factors of the Act and determine a payment by way of VCU, specifically how the methodology set out in paragraph 11 of the Joint Submission yielded the proposed payment set out in paragraph 12 of the Submission.

The Board has decided to accept Teva's VCU as proposed by the parties, effective as of the date of this Order.

The Board Members underscore that the acceptance of the attached VCU is premised on the specific and unique facts presented in this case. The Board Members also underscore that the parties accept the approach and methodology set out in the Board's February 23, 2012 decision.

¹ <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1611&mp=254>

The acceptance of this VCU is not to be interpreted as recognition of any policy change in how the Board's Guidelines are to be interpreted.

Accordingly, by Order of this Board the proceeding of redetermination which was commenced in May 2013 is hereby concluded.

Board Members: Normand Tremblay
 Mary Catherine Lindberg

Board Counsel: Anil K. Kapoor



Sylvie Dupont
Secretary of the Board