



June 24, 2010

Decision on Voluntary Compliance Undertaking

**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”**

DECISION

Overview

1. The issue for the Vice-Chairperson's¹ consideration is whether the Voluntary Compliance Undertaking (VCU) submitted by Teva Neuroscience (Teva) on April 9th, 2010 for the medicine Copaxone should be approved pursuant to the *Patent Act* (Act). Having received written submissions from the parties on the appropriateness of the VCU and having carefully considered the matter the Vice-Chairperson has concluded that the VCU should not be accepted. This conclusion is not a determination that would preclude Teva from advancing whatever position they wish at a hearing.

Background

2. On May 8, 2006 the Board issued a Notice of Hearing in the Copaxone matter. Evidence was submitted followed by oral arguments before a Hearing Panel (the First Panel). In its February 25 and May 12, 2008 decisions, the First Panel determined that the price of Copaxone was excessive and ordered Teva to reimburse excess revenues through a payment to the Government of Canada. Teva successfully judicially reviewed the First Panel's decision. On November 12, 2009, in deciding to order a rehearing Justice Hughes remarked at paragraph 76:²

“The matter will be returned to the Board for redetermination preferably by a different panel if sufficient members can be provided for that purpose.”

3. Accordingly the matter was remitted and the current Panel (the Second Panel) was struck to hear the matter. Counsel to Teva and Board Staff were so informed on February 4, 2010.

¹ Pursuant to subsection 93(3) of the *Patent Act*, if the office of the Chairperson is vacant, the Vice-Chairperson has all the powers and functions of the Chairperson during the vacancy.

² *Teva Neuroscience G.P.-S.E.N.C. v. Canada (Attorney General)* (2009 FC 1155)



4. On April 9, 2010, Teva submitted a VCU for consideration by the Chairperson of the Board. Board Staff objected, arguing, among other things, that the VCU ought to be determined by the Second Panel.

5. After receiving and considering written submissions as to whether the VCU should be considered by the Second Panel or the Chairperson, the Panel decided that it would refer the VCU to the Chairperson and issued reasons on May 9th, 2010.

6. On May 18, 2010 the term of the Chairperson expired. Although a new Chairperson has not yet been appointed, subsection 93(3) of the Act provides that the Vice-Chairperson has all the powers and functions of the Chairperson during the vacancy, and as such the Vice-Chairperson considered the appropriateness of the VCU.

The issue

7. Does the VCU submitted by Teva meet the objectives of the *Patent Act*?

Analysis

8. A VCU, consistent with the Guidelines, can be submitted at any time and may be approved by the Chairperson or, if the VCU is submitted after the issuance of a Notice of Hearing, by the Hearing Panel. In deciding whether to accept a VCU, the Chairperson, or Hearing Panel, is guided by section 83 of the Act. The Chairperson is not authorized to negotiate the terms of the VCU, instead the Chairperson is to consider the VCU as submitted, taking into account the position of the parties.

9. Most often a VCU is the product of negotiation between the parties and is submitted as a joint position. This is hardly surprising as the VCU process is meant to be an alternative to a hearing, essentially a compromise between the parties, although that is not a pre-requisite. Indeed, the Chair does not receive evidence, nor does the Chair conduct a hearing to determine the appropriateness of the VCU.

10. In this case the VCU does not represent a joint position. Board Staff takes the position that the VCU is not consistent with the objectives of the Act.

11. It is important to consider the context of this case. This is a matter that has already been litigated at first instance and was the subject of review and has now been remanded for determination in accordance with Justice Hughes' ruling. Mr. Justice Hughes ruled that the matter be determined by a newly constituted panel keeping in mind all the factors set out in section 83 of the Act.

12. There are two considerations arising from the position of the parties which commend the result reached on this submission. First, the parties are quite far apart in their positions. Second, given that difference it is impossible to consider or resolve the issue without there being a full hearing on the matter.³ It is important to recall that the Guidelines preclude any negotiation with the parties.⁴ Accordingly, the Vice-Chairperson found that she is not in a position to adequately determine the appropriateness of this VCU.

13. Moreover, given the history of this matter and Justice Hughes' direction that the matter be redetermined by a differently constituted panel, and absent an agreement between the parties, his direction ought to be complied with, namely there ought to be a hearing in this matter.

14. As set out above, this conclusion is not meant to preclude the parties from taking whatever position they wish on the hearing of this matter. As well, the Second Panel is not bound by the Vice-Chairperson's decision.

Conclusion

15. The Vice-Chairperson declined the VCU and noted that the redetermination of this case by the Second Panel is scheduled to be held October 4 and 5, 2010.

16. The Vice-Chairperson thanks Counsel for their submissions.

Vice-Chairperson: Mary Catherine Lindberg

Board Counsel: Anil Kapoor

Original signed by
Sylvie Dupont
Secretary of the Board

³ This does not mean the recalling of evidence unless the parties or the Panel directs but it does contemplate having the positions of the parties subjected to examination in a hearing where the panel members are able to ask questions to address their concerns and to assess the responses given.

⁴ See C15.5 of the current Guidelines (Compendium of Policies, Guidelines and Procedures – <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1206&mid=981>) as well as 7.4 of the previously in force Guidelines (Compendium of Guidelines, Policies and Procedures – <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1034&mid=803#voluntary>).