May 6, 2010

Decision: PMPRB-2010-D1-Copaxone
- Determination of VCU

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

Overview

1. On April 9, 2010, Teva submitted a Voluntary Compliance Undertaking (VCU) for consideration by the Chairperson. Teva was advised that as a Hearing Panel in this matter has been struck, the normal course, pursuant to the Board's Guidelines, is to have the Panel consider the VCU. Notwithstanding this advice, Teva maintained its position that this VCU should be considered by the Chairperson. Board Staff objected to having the Chairperson consider the VCU and argued, instead, that the Panel should consider the VCU. Given this dispute, the Panel directed that the parties submit written submissions on the issue. The Panel has not been made privy to the contents of the VCU.

2. This preliminary issues are as follows:

First, does the Panel have the jurisdiction to have the VCU considered by the Chairperson; and

Second, if such jurisdiction exists, should the Panel exercise its discretion to grant Teva's request.

3. For the reasons that follow, the Panel has concluded that it has the jurisdiction to have the VCU referred to the Chairperson and, in the particular and unusual circumstances of this case, the Panel accedes to Teva's request.

Background

4. On May 8, 2006 the Board issued a Notice of Hearing. Evidence was submitted followed by oral arguments before a Hearing Panel (the First Panel), comprised of three members. In its February 25 and May 12, 2008 decisions, the First Panel ordered that Teva 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:

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

5. 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.

Analysis

6. In deciding whether there is jurisdiction to entertain Teva's request it is important to understand that the authority of the Second Panel to hear this case is derived from ss. 83(6) of the *Patent Act* (the Act). This subsection provides a hearing panel with the authority to manage hearings and devise procedures for the orderly determination of hearings, keeping in mind the requirements of fairness and natural justice. Further, the Chairperson has the authority under ss. 93(2) of the Act to assign members of the Board to sit at hearings and to preside over hearings or other proceedings (emphasis added).

7. The Act does not explicitly refer to a VCU. The provisions relating to a VCU are set out in the Guidelines. Importantly, the submission of a VCU is not an admission on the part of a patentee that the price of the drug product is or was excessive. In this sense it is akin to an offer to settle. Customarily the VCU is the result of an agreement between Board Staff and the patentee. C.15 of the Guidelines sets out the procedure to be followed when a VCU is submitted and provides at C.15.4 that it is the "policy of the Board that only the Chairperson (or, if the VCU is submitted after the issuance of a Notice of Hearing, the Board Hearing Panel) may approve the VCU" (emphasis added).

8. It is this provision that, as a matter of policy, requires that a VCU be determined by the hearing panel. The Guidelines, however, are not binding upon the Panel, and there may be unusual circumstances where, despite the issuance of a Notice of Hearing, it is not appropriate to have a VCU determined by the hearing panel.

9. Both parties advance the same argument in opposition to each other. They each argue that the other's proposal would create a reasonable apprehension of bias. For the Board Staff the argument is that since the Chairperson was part of the First Panel, there is a reasonable apprehension of bias were he to preside over the VCU. For Teva, the argument is that should the VCU not be accepted, the Second Panel will be tainted and be unable to decide the case on the merits.

10. The consideration of this problem must be undertaken within the context of this particular matter. In normal circumstances, were a panel to review and then reject a VCU, it would be possible to establish a new panel to hear the matter if necessary. The reality is that there are only five potential hearing panel members, three of whom were on the First Panel and two of whom are designated for the Second Panel. There are thus no other members who can determine either the VCU or preside over the hearing.

11. Understanding that the VCU process is not a hearing and represents a proceeding in which the parties submit written submissions (most often jointly) to support the VCU in accordance with C.15, it is a fundamentally different proceeding than a hearing. As well, Justice Hughes recognized the challenges of differently populating a panel from the First Panel when he ruled that it is *preferable* that the redetermination be by a different panel. Justice Hughes clearly appreciated that it may well be impossible to have a differently constituted panel consider this matter.

12. This supports the proposition that it is not *necessary* that the decision maker, be it on the hearing panel or determining the VCU, be one who has not been involved in the previous hearing.

13. Therefore the question becomes whether it is better to have the VCU determined by someone who has knowledge derived from the First Panel or is it better to have the Second Panel acquire knowledge of the matter under the auspices of considering the VCU and then be in the position of hearing the matter on its merits, having rejected the VCU.

14. In this Panel's view, it is vitally important to preserve a panel that has no knowledge of the matter to determine the merits afresh should a hearing be necessary. If this Panel were to consider the VCU that would not be possible.

15. Given that the VCU is typically a settlement proposal[1] and is not a hearing on the merits, the Panel is confident that the Chairperson will be able to evaluate the merits of the VCU impartially and fairly. At a minimum this approach preserves a panel for hearing that will have no difficulty giving a "thorough reconsideration of the matter without considering that it is in any way bound to arrive at the same result."[2]

[1] In this instance, the VCU proposed by Teva without agreement of the Board Staff.

[2] 2009 FC 1155 at para76 per Hughes J.

Conclusion

16. Having considered the submissions of Counsel, the relevant statutory provisions as well as the Guidelines, the Panel refers the VCU to the Chairperson for consideration. As indicated above, the circumstances here are unusual for at least two reasons; first, there simply are not enough members to have all aspects of this case be determined by someone who has had no prior involvement, and second, the VCU is rarely contested as it is usually put forward jointly. Both of these circumstances militate in favour of having the Chairperson determine the issue. This result is exceptional and should be regarded as such.

17. The parties, if they wish, are to file written submissions in support of their positions on the VCU on or before May 13, 2010. These submissions will be provided to the Chairperson who will then consider the VCU, the Panel will not be provided with either the submissions or the VCU.

18. The Panel thanks Counsel for their submissions.

Panel Members: Anne Warner La Forest
Anthony Boardman

Counsel: Anil Kapoor

Original signed by

Sylvie Dupont
Secretary of the Board