Conseil d'examen du prix des médicaments brevetés

Decision: PMPRB-07-D3-QUADRACEL and PENTACEL
Motion for an Order for Particulars

## IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF sanofi pasteur Limited (the "Respondent") and the medicines "Quadracel and Pentacel"

This is the decision of the Panel on the motion by the "Respondent for an order for particulars of Board Staff's allegation that the Respondent engaged in a policy of excessive pricing in relation to its sales of Quadracel and Pentacel. The Respondent's motion sought, in the alternative, an order striking the allegation of excessive pricing from the Statement of Allegations.

## **Decision**

The Panel has considered the written and oral submissions of the Respondent and Board Staff, and for the following reasons, dismisses the Respondent's motion.

- 1. The Panel has reviewed the Statement of Allegations, the Response thereto of the Respondent, and the Reply of Board Staff to the Response. Board Staff has stated that it has set out all of the material facts now known to it in its pleadings. Briefly put, the allegation of Board Staff is that the Respondent sold Quadracel and Pentacel at prices that the Respondent knew to be in excess of the maximum non-excessive price (MNE) established by the application of the Guidelines.
- 2. The Panel accepts that Board Staff has disclosed all of the material facts now known to Board Staff in support of its allegation of a policy of excessive pricing. It is a straightforward allegation that relies on relatively few material facts. The law and policy issues that arise from the allegation could be complex, but the allegation itself is not.
- 3. The Respondent, argues in the alternative that, if these are the only material facts that are or can be alleged by Board Staff, the allegation is deficient, in that such facts could never support a finding of a policy of excessive pricing. The Respondent argues that a patentee's knowing departure from the MNE established by the application of the Guidelines, by itself, could not constitute a policy of excessive pricing. This argument is premised on the fact that the Guidelines are not binding on the Board and there has been no finding by the Board that the pricing of Quadracel and Pentacel was excessive within the terms of the Guidelines or the *Patent Act*.

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In consequence, the Respondent argues, if knowing departure from the Guidelines is the only allegation that is or can be made by Board Staff, the allegation that the Respondent engaged in a policy of excessive pricing should be struck from the Statement of Allegations.

- 4. Board Staff acknowledge that the Guidelines are not binding on the Board, but reply that, if the Guidelines are held by this panel to correctly implement section 85 of the *Patent Act* as it pertains to this proceeding, past sales of Quadracel and Pentacel, that the Respondent knew to be in excess of the MNEs for those medicines, could be found by the Board to constitute sales pursuant to a policy of excessive pricing. In support of this position, Board Staff argue that, if the Respondent's position were correct, a policy of excessive pricing could only be found where a patentee sold a medicine at a price that had already been found by the Board to be excessive. Board Staff argues that this interpretation of the *Patent Act* is untenable.
- 5. The Panel considers this latter debate to be a matter for final argument after the hearing of this proceeding and thus declines to strike the allegation of excessive pricing from the Statement of Allegations.

## Conclusion

6. Accordingly, the motion of the Respondent is dismissed.

Board Members: Dr. Brien G. Benoit

Anne Warner La Forest Anthony Boardman

Board Counsel: Gordon Cameron

Nancy Brooks

Sylvie Dupont Secretary of the Board

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November 16, 2007