Decision: PMPRB-07-D1-QUADRACEL and PENTACEL
Application for leave to intervene by GlaxoSmithKline Inc.

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"

Introduction

1. This proceeding concerns the pricing by sanofi-pasteur Limited ("sanofi pasteur") of the medicines Quadracel and Pentacel, vaccines used for the immunization of infants against diphtheria, tetanus, whooping cough, polio and *haemophilus influenzae type b* disease (the "medicines").

2. The Statement of Allegations produced by Board Staff in this proceeding alleges that sanofi pasteur sold, and engaged in a policy of selling, the Medicines at excessive prices during the period 2002-2006.

3. GlaxoSmithKline Inc. ("GSK") has sought intervener status in this proceeding. GSK brought a motion for such status, sanofi pasteur filed submissions opposing the motion, and GSK filed responding submissions.

Positions of the parties

4. GSK notes that it and sanofi pasteur are the only two suppliers of quadravalent and pentavalent vaccines in Canada. GSK argues that, as the only other supplier of these vaccines than sanofi pasteur, it has a significant interest in pricing "irregularities" in sales by sanofi pasteur of the Medicines.

5. GSK also takes the position that, with its experience and expertise in what is alleged to be a unique market for these vaccines, it could provide the Board with relevant information concerning that market, the manner in which that market is and was served by sanofi pasteur and GSK, and the remedy that would be appropriate, given that market, if the Board were to find that sanofi pasteur had sold the Medicines at excessive prices.

6. In its reply submissions, GSK also urged the Board to conclude that the Board's mandate to protect consumers from excessive prices of patented medicines includes ensuring that its decisions promote, and do not dissuade, competition in the marketplace. GSK suggested that there could be a link between the allegedly excessive prices charged by sanofi pasteur in the 2002-2006 period and the price that sanofi pasteur bid for the contract to sell vaccines to Canada from 2007 forward, and that this link could involve anti-competitive conduct by sanofi pasteur.

7. sanofi pasteur has submitted that GSK has not identified any legitimate interest in the proceeding, or any contribution that GSK could make to the hearing that would be useful to the Board. sanofi pasteur argues that GSK is seeking intervener status because GSK is a competitor of sanofi pasteur with respect to the Medicines and is trying to use this proceeding as a way to achieve a competitive advantage over, or impose a competitive disadvantage on, sanofi pasteur.

General Analysis

8. Rule 19 of the (proposed) *Patented Medicine Prices Review Board Rules* provides that the Board may grant leave to intervene to a party that "has an interest in the subject-matter" of the proceeding.

An excessive price hearing before a panel of the Board involves a dispute between Board Staff and a patentee about whether the patentee is, or has been, selling the medicine in question at an excessive price. Jurisdictional issues sometimes also arise in an excessive price hearing.

9. In the course of an excessive price hearing, the Board determines the maximum non-excessive price of the medicine and whether the patentee is or has been selling the medicine in any market above that price. If a finding of excessive pricing is made, the Board has the authority to order the patentee to take such measures as will offset the excessive revenues that have been earned, such as a payment to the Crown or a reduction in the price of the medicine.

10. In an excessive price hearing, Board Staff prosecutes the case by establishing that the price of the medicine exceeds or exceeded the Board's Excessive Price Guidelines, that the Guidelines properly implement the relevant provisions of the *Patent Act,* and, where jurisdiction is in issue, that the Board has jurisdiction. The patentee has an obvious interest in the case and a statutory right to make representations rebutting the allegations of Board Staff.

11. It can be noted that the *Patent Act* provides, in subsection 86(2), that the Minister of Health and the provincial health ministers have a right to notice of, and to intervene in, excessive price hearings.

12. As a general matter, and consistent with past practice at the Board, the Board would expect that other persons with an interest in the Board's hearings, in the sense contemplated by Rule 19, would be in one of the following three categories:

1. Persons who, in one manner or another, will bear some or all of the cost burden of the medicine in question, or the cost burden of other medicines where the prices of such medicines could be affected by the outcome of the proceeding;
2. Patentees, the maximum non-excessive prices of whose medicines will be affected by the specific outcome of the proceeding, or by the establishment of a point of principle pertaining the non-excessive pricing of medicines or the Board's jurisdiction; or
3. Organizations representing persons in the two previous categories.

13. In addition, where a proposed intervener does not have a material and direct interest in the outcome of the proceeding in question, the Board would also require that an applicant for intervener status demonstrate the ability to contribute, to the proceeding, some element of evidence that was expected by the Board to be unique, or otherwise to be usefully supplementary to the evidence and argument expected to be adduced by Board Staff, the patentee of the medicine in question, or another person that is granted intervener status.

14. It must be noted that Board Staff will generally represent the interests of persons who bear the cost burden of medicines under review, and patentees, by advocating their own interests, will typically represent interests that are not unique to them or to the particular medicine under review. Perhaps as importantly, the Board is aware of the impact of each of its decisions on persons other than those appearing before it in any given proceeding, and takes the interests of those persons into account whether or not they are independently represented in a proceeding.

16. None of these factors removes the right of appropriate persons to be interveners in the Board's proceedings, or detracts from the important role that interveners can play in the Board's proceedings. However, those factors, and the Board's statutory obligation pursuant to subsection 97(1) of the *Patent Act* to conduct its proceedings as expeditiously as the circumstances and considerations of fairness permit, and the Board's need to control its process, do bear on the discretion that the Board will exercise when deciding, in a particular case, whether a person is an appropriate intervener in a proceeding.

The jurisprudence

17. sanofi pasteur placed reliance on a number of cases in which the Federal Courts made relatively restrictive pronouncements on the circumstances in which persons should be permitted to intervene, typically in judicial review applications.

GSK argued that this jurisprudence pertained to litigation that constituted "private disputes" or "disputes between private parties", and was inapplicable to the proceedings of the Board. The panel does not agree that applications for judicial review of tribunal decisions or ministerial conduct in the Federal Courts constitute private disputes, and takes some guidance from the discussions of intervener status in this jurisprudence.

18. However, the Board also notes the cases cited by GSK to the effect that the scope for intervention in a tribunal hearing can be broader than in a court proceeding. The Board would note that this is true of the Board's proceedings given the polycentric nature of the interests that are likely to be given consideration in an excessive price hearing.

GSK's application to intervene

19. It is the view of the panel that GSK has not established any grounds on which it has an interest in the outcome of the proceeding that warrants GSK's status as an intervener. The panel has also concluded that GSK could not assist the Board with the matters in issue in this proceeding by the contribution of evidence or insight that is not expected to be provided by the parties to the proceeding.

20. Also, the panel does not believe that the Board has a mandate to consider whether the price of a medicine under its jurisdiction has been or will be, for competitive purposes, set by the patentee at a level that is somehow unfairly high or low relative to the price of a medicine competing in the same market, or to otherwise inquire into the fairness of the competitive strategy of one patentee relative to another. The *Patent Act* and the Board's Excessive Pricing Guidelines deal with the prices of medicines for the exclusive purpose of ensuring that those prices are not excessive. The Board's statutory mandate does not include setting maximum prices of medicines, or taking remedial measures against patentees, to foster competition, nor to inquire into whether the prices of medicines are, or have been, somehow unfair as a matter of competition policy.

21. The panel was able to reach its decision on GSK's application without reliance on the submissions of sanofi pasteur concerning the motives of GSK in seeking intervener status in this proceeding. The mere fact that GSK is a competitor of sanofi pasteur, and that GSK would pursue its own interests if it were granted intervener status, does not disentitle GSK from being an intervener in this proceeding. Indeed, the intervention of Janssen-Ortho in the ongoing proceeding before the Board concerning Shire BioChem's medicine Adderall XR is an example of a direct competitor demonstrating an interest in a proceeding that warranted intervener status. The maximum non-excessive prices of the two companies' competing medicines were arguably logically linked. However, in the case of GSK, the Board sees no similar or analogous interest in the instant proceeding.

Conclusion

22. For the foregoing reasons, the application of GSK to intervene in this proceeding is dismissed.

Board Members: Dr. Brien G. Benoit
Anne Warner La Forest
Anthony Boardman

Board Counsel: Gordon Cameron

Original signed by

Sylvie Dupont
Secretary of the Board

July 26, 2007