June 14, 2012 **Decision: PMPRB-07-D6-QUADRACEL and PENTACEL - Reconsideration of Remedy**

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"

DECISION

Introduction

1. These reasons relate to a decision by this Panel in the matter of the pricing by the patentee sanofi pasteur Limited ("sanofi pasteur") of the vaccines Quadracel and Pentacel (the "Board's Decision") [1] specifically with regard to the Board's remedy. The Board's Decision was reviewed by the Federal Court and in the Court's decision (the "Review Decision")[2] the reasons for the Board's Decision were found to be lacking in clarity and completeness. The matter was remitted by the Court to the Board for reconsideration.

2. The Board sought the views of the parties on the implications of the Review Decision and then received submissions from the parties on the Panel's reconsideration of the matter. The Panel is of the view that the Review Decision requires the Panel to consider the questions posed by the Court in the Review Decision and provide reasons, based on the evidence that it heard in the original proceeding, that answer the questions posed by the Court and explain the Panel's position on the matters queried in the Review Decision with clarity and completeness. The Panel believes that it can do this with relative concision and has attempted to do so in these reasons.

Discussion

3. The difficulties that the Court had with the Board's Decision arose from the failure of this Panel to explain clearly and fully why it rejected sanofi pasteur's argument that excessive revenues earned by sanofi pasteur from sales of Quadracel and Pentacel

[1] PMPRB-07-D5-Quadracel-Pentacel,dated December 21, 2009
[2] Federal Court decision – 2011 FC 859

pre-2007 should be reduced or eliminated[3] by sales of those medicines in 2007 and following years at prices that were below the maximum non-excessive prices ("MNE prices") of the medicines. The Panel agrees with the Court that this point is not addressed well in the reasons in the Board's Decision.

4. The Panel, as with any panel in an excessive pricing hearing, had (among all of the matters before it) two broad issues to decide: (1) were excessive revenues earned as a result of sales of the medicines at excessive prices; and (2) if so, what is the appropriate order for the Board to make for those excessive revenues to be offset: a payment by the patentee to Her Majesty the Queen in Right of Canada, a reduction in the prices of the medicines, or a reduction in the price of some other patented medicine sold by the patentee.

5. The first issue necessarily raises questions of quantification. There can be a number of questions related to how the MNE price of the medicine in question should be determined, but once that issue has been decided, a hearing panel typically can perform a relatively straightforward calculation that generates the difference between the maximum revenues that ought to have been earned and the revenues that actually were earned: barring other particular issues, these are the excessive revenues.

6. A particular issue that arose in this and two prior cases is whether, in quantifying excessive revenues, foregone revenues from sales of the medicine below its MNE price in a given year should reduce or eliminate excessive revenues earned from sales above the MNE price in another year. This Panel and the two prior panels of the Board (referred to in the Board's Decision) considered this to be inappropriate in the cases before them. This is discussed further below.

7. The second issue – the manner in which the excessive revenues should be offset by an order of the Board – does not necessarily raise questions of quantification. Subsection 83(2) of the *Patent Act* (the "Act") provides that the Board, having found that a patentee has sold a medicine at an excessive price, may order the patentee to do one or more of three things (as described in paragraphs 83(2)(a)-(c)) "as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price."

8. In other words, once the Board has estimated the quantum of the excessive revenues, its order normally should offset those revenues through one or more of the mechanisms described in paragraphs 83(2)(a)-(c), and the question at that stage of the analysis is which offsetting method(s) is or are the most appropriate (payment to the Crown or reduction in future prices).

[3] The Panel will not use the expression 'offset' "offset", as used in the Panel Decision, in order to reduce the risk of confusion with the use of the term "offset" in subsection 83(2) of the *Patent Act*, where the term pertains to orders of the Board.

9. The Panel notes that subsection 83(2) uses the word “may”, and the Panel does not go so far as to say that the Board would not have jurisdiction to decline to make an order or to make an order that would not fully offset excessive revenues that had been calculated. However, absent reasons to do otherwise, the order should fully offset the excessive revenues that were calculated by the panel.

10. The Panel believes that, absent special circumstances, none of which the Panel considers to arise in this case, a panel’s remedial choices once excessive revenues have been quantified are choices among the methods of offsetting the revenues, not an exercise of deciding whether there are reasons not to make a remedial order or to adjust the dollar amount in the order. In civil litigation, damages are a “remedy” and their quantification is part of the court’s remedial effort, but that is not the case with the Board’s jurisdiction under section 83 of the Act. A finding by the Board that a certain quantity of excessive revenues was earned establishes, absent special circumstances, the patentee’s obligation to offset those excessive revenues; the remedial issue for the Board is how that offsetting should take place.

11. The Board considers this to be a more logical approach, and one more consistent with the structure and language of section 83 of the Act, than to calculate excessive revenues (absent consideration of mitigating sales below the MNE price) and then decide whether a remedy is warranted given evidence of sales that arguably reduced or eliminated excessive revenues. In any event, provided that due consideration is given to the patentee’s position on whether there were sales at prices that reduced or eliminated excessive revenues, the issue can be dealt with fairly wherever in the course of the Board’s analysis it is addressed.

12. In this case there were two reasons why the Panel believed that, in determining whether there were excessive revenues, and quantifying them if there were, the foregone revenues from sales below the MNE price should not reduce or eliminate the excessive revenues from sales above the MNE price.

13. First, the Panel was of the view that the Government of Canada should have had the benefit of the MNE price for its purchases during the years before 2007 and the benefit of the lower (below MNE) price that it obtained (as a result of the competition it held) for purchases in subsequent years. The Government was entitled to the protection of the Board’s pricing mandate prior to 2007 and it was entitled to obtain a lower price from and after 2007 by introducing competition as part of its procurement strategy. The Government would not obtain both of these benefits if the foregone revenues from sales at a competitive price were used to reduce or eliminate the restoration to the Government of excessive revenues from paid during prior years’ sales at an excessive price.

14. Second, the Board's pricing guidelines (the "Guidelines") set out the parameters within which the reduction of excessive revenues can take place: sales within a calendar year. The Guidelines are not binding on any panel of the Board. However, they provide certainty and predictability for patentees. The Panel considered the appropriateness of the price-averaging parameters in the Guidelines and concluded that they were an appropriate implementation of the Act generally and in this case, though they might not be in every case. This is because a period of one year for price-averaging strikes a reasonable balance between (1) allowing patentees some flexibility and the ability to correct for unexpected revenues; and (2) preventing patentees from charging excessive prices at will and reducing or eliminating the resulting excessive revenues at some time of their choosing in the indefinite future. The Board's consumer protection mandate can accommodate the former, but would be frustrated if patentees were permitted to do the latter.

15. The Panel heard and considered carefully sanofi pasteur's arguments to the effect that sales below the MNE price in this case eliminated the excessive revenues from sales above the MNE price. Evidence and argument on the point occupied an appreciable portion of the hearing. The Panel concluded that the evidence established that sanofi pasteur's bid price in the procurement was exclusively the consequence of the competitive procurement. As such it was a benefit to which the Government was entitled and sales at that price should not reduce another benefit to which the government was entitled – the compensation for excessive prices paid before 2007.

16. At paragraph 64 of the Review Decision the Court queries whether the Panel was of the view that there is no action that a patentee could take outside of a VCU or a Board order to reduce or eliminate excessive revenues. As indicated in paragraph 14, the Panel is not of that view. However, the circumstances of this case do not call for an exception to the parameters for price-averaging set out in the Guidelines.

17. In paragraphs 68 and 69 of the Review Decision, the Court queried the Board's observations in paragraph 55 of the Board's Decision about mitigating excessive revenues. In paragraph 55 of the Board Decision, the Panel was not directing its comments to the facts of this case, but to the general reason that price averaging outside of the annual averaging allowed by the Guidelines is inappropriate. The Panel believes that on the facts of this case the salient point is that the evidence established that the lower price at which the Government purchased the medicines post-2006 was a benefit arising from its competitive procurement process that should not reduce the benefit of the restoration of excessive price revenues paid pre-2007.

18. On sanofi pasteur's approach, the Government would have to forego a significant portion of this benefit by having the benefit reduce the Government's entitlement to the restoration of the excessive price revenues it paid pre-2007. The Panel does not consider sanofi pasteur's approach to be reasonable or supported by the evidence.

Conclusion

19. For the reasons above the Panel considers that its Order dated March 16, 2010, was the appropriate remedy by which the excessive revenues earned by sanofi pasteur should be offset. When the Court remitted this matter to the Board for reconsideration, the Court declared that Order to be a nullity. Accordingly the Panel considers it appropriate to issue a replacement order, supported by the Board's Decision and these additional reasons on reconsideration of the matter. A copy of that Order is annexed to these reasons.

Board Members:	Dr. Brien Benoit Anthony Boardman Anne Warner La Forest
Board Counsel:	Gordon Cameron

Appearances

Board Staff:	David Migicovsky, Counsel
For the Respondent:	Sandra Forbes, Counsel

Original signed by

Sylvie Dupont
Secretary of the Board