December 21, 2009 **Decision: PMPRB-07-D5-QUADRACEL and PENTACEL - Merits**

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

I. *Introduction*
(a) This proceeding

1. The mandate of the Patented Medicine Prices Review Board (the "Board"), as established by the patented medicines provisions of the *Patent Act* (the "Act"), is to ensure that prices at which patentees sell their patented medicines in Canada are not excessive.

2. This proceeding before a panel of the Board was commenced by the issuance of a Notice of Hearing on March 27, 2007. The Notice of Hearing was issued when, after reviewing a Statement of Allegations dated March 15, 2007, prepared by the staff of the Board ("Board Staff"), the Chairperson of the Board determined that it was in the public interest that a panel of the Board (the "Panel") inquire into the pricing of the medicines Quadracel and Pentacel. Quadracel and Pentacel are marketed in Canada by the Respondent, sanofi pasteur Limited ("sanofi pasteur" or the "Respondent").

3. Quadracel and Pentacel have been sold in Canada since June 1997. They are combination or multi-component vaccines; that is, they combine, in single doses, antigens to protect against four (Quadracel) and five (Pentacel) different diseases. Quadracel is intended to protect young children against diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio). Pentacel is sold in the form of a reconstituted product for injection with Quadracel and contains a fifth vaccine that protects against diseases in young children (such as bacterial meningitis and other serious infections) associated with *Haemophilus influenzae* type b (Hib).

4. The hearing portion of this proceeding could not commence until various preliminary matters were dealt with, including an application for intervention, a pre-hearing conference and an application for judicial review. The Panel then heard evidence and argument over the course of 5 days during the months of June and November 2008 and January 2009. During this period, Board Staff presented the evidence of two non-expert and two expert witnesses; sanofi pasteur presented the evidence of three non-expert and two expert witnesses. Both parties presented oral and written final arguments.

(b) The allegations of excessive pricing

5. In the Statement of Allegations, Board Staff alleged that sanofi-pasteur sold Quadracel and Pentacel at prices that were excessive, within the meaning of the patented medicines provisions of the Act as implemented by the Board's *Compendium of Guidelines, Policies and Procedures* (the "Guidelines"). Board Staff alleged that Quadracel was sold at excessive prices from 2002-2006 and that Pentacel was sold at excessive prices from 2002-2007.

6. The primary basis for the allegations of Board Staff that the prices of Quadracel and Pentacel were excessive during the 2002-2007 timeframe, was that the prices of these medicines increased by amounts that were greater than the amounts permitted by the provisions of the Guidelines that are intended to implement paragraph 85(1)(d) of the Act. Paragraph 85(1)(d) of the Act requires that the Board, when determining whether a medicine has been sold at an excessive price, consider changes in the consumer price index ("CPI").

7. As explained in further detail below, the Guidelines are intended to implement paragraph 85(1)(d) by stipulating that, with allowance for some flexibility from year to year, the prices of patented medicines generally will be considered not to be excessive if, having been introduced to a market in Canada at non-excessive prices, those prices do not increase from one year to the next by more than increases in the CPI.

8. The main focus of the Respondent's arguments was not that Board Staff incorrectly applied the Guidelines when coming to the conclusion that Quadracel and Pentacel were sold at excessive prices. Rather, the Respondent argued that the Guidelines do not properly implement subsection 85(1) of the Act with respect to the pricing of vaccines (as opposed to other types of medicines) or, more narrowly, with respect to the particular vaccines Quadracel and Pentacel and the circumstances in which Quadracel and Pentacel were sold by the Respondent during the relevant periods.

9. The Respondent also advocated an alternative method (to that adopted by Board Staff) of comparing the prices of Quadracel and Pentacel to other similar medicines for the determination of whether or not Quadracel and Pentacel were sold at excessive prices in relation to the prices of comparable medicines. As noted, Quadracel and Pentacel combine, in single doses, antigens to protect against four (Quadracel) and five (Pentacel) different diseases. Board Staff presented evidence that the appropriate comparator medicines were other similar multi-component vaccines. The Respondent argued that these other vaccines were based on older technology, and that the appropriate price comparisons should be between the prices of (more modern) Quadracel and Pentacel, on the one hand, and the combined prices of the (similarly more modern) separate vaccines for the multiple diseases protected-against by Quadracel and Pentacel.

10. The disagreement between Board Staff and the Respondent concerning the pricing of Pentacel is complicated by the fact that, towards the end of the period under review and afterwards, the Respondent replaced the supply of Pentacel in Canada with a newer vaccine, Pediacel. Board Staff argued that, inasmuch as Pediacel was a new medicine, sales of that medicine were not relevant to the determination of whether or not Pentacel had been sold at excessive prices. The Respondent, on the other hand, argued that Pediacel is so similar to Pentacel that the pricing of Pentacel and Pediacel should be assessed on the basis they are the same medicine. As detailed below, the determination of this issue is argued by the Respondent to have an impact on the quantification of any excessive revenues that might have been earned by the Respondent.

II. *Analysis of the issues*

(a) The Board's Guidelines

(i) Role and Onus

11. Section 96 of the Act permits the Board, in consultation with various interested parties, to issue non-binding guidelines with respect to matters, such as the excessive pricing of patented medicines, within its jurisdiction. Subsections 96(4)-(6) provide as follows:

> *Guidelines*
>
> (4) Subject to subsection (5), the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any patentee.

Consultation

(5) Before the Board issues any guidelines, it shall consult with the Minister, the provincial ministers of the Crown responsible for health and such representatives of consumer groups and representatives of the pharmaceutical industry as the Minister may designate for the purpose.

Non-application of Statutory Instruments Act

(6) The *Statutory Instruments Act* does not apply to guidelines issued under subsection (4).

12. The Board was established in 1987. Following the requisite consultations, the Board issued guidelines in the form of notices to stakeholders published in the Board's periodic newsletter. In 1994, these guidelines were consolidated in the Board's "*Compendium of Guidelines, Policies and Procedures*", which has been updated through clarifications in the Board's periodic newsletter and amendments implemented through the Board's Notice and Comment process. This compendium was last consolidated in 2003.

13. Panels of the Board have had occasion to comment on the role of the Guidelines in pricing hearings such as the current proceeding. Subsection 85(1) of the Act provides only very basic guidance to the Board as to the factors that are to be considered in determining whether the price of a patented medicine is excessive. The Guidelines, however, provide detailed guidance and predictability to patentees and all parties concerned with the Board's mandate. It has been uniformly recognized by prior panels and the Federal Court that panels of the Board, when considering whether a medicine has been sold at an excessive price, should give due regard to the Guidelines.

14. However, it has also been uniformly acknowledged that the Guidelines are not binding on the Board or any panel conducting a price review hearing. Past hearing panels of the Board have departed from the Guidelines when it has been considered appropriate to do so.

15. During the hearing, the parties also debated the appropriateness of earlier pronouncements by panels of the Board to the effect that the onus on Board Staff to establish that a medicine has been sold at excessive prices includes an onus to satisfy the hearing panel that the Guidelines provide an appropriate basis for that conclusion. Board Staff argued (against these earlier findings) that a medicine should be presumed by a hearing panel to have been excessively priced if the application of the Guidelines so indicates, unless the patentee can

convince the panel that the Guidelines are not appropriate in the particular circumstances of the medicine under review.

16. The Panel is of the view that, in a price review hearing, the hearing panel must determine whether the medicine under review has been excessively priced within the meaning of the Act alone. In coming to that conclusion due weight should be given to the Guidelines, but ultimately the determination of the panel is a conclusion under the Act. Accordingly, if the panel relies on the provisions of the Guidelines to reach a conclusion on excessive pricing within the meaning of the Act, the panel must be satisfied that the Guidelines provide an appropriate implementation of the Act specifically in relation to the pricing of the medicine under review. The panel may reach that conclusion as the result of evidence and argument presented by the parties, or the panel's own expertise, or a combination of the two.

17. In a pricing hearing, Board Staff will almost invariably rely on the provisions of the Guidelines to establish that a medicine has been excessively priced. If Board Staff relies on the Guidelines for this purpose and the panel hearing the matter is not convinced that the Guidelines provide an appropriate implementation of the provisions of the Act, Board Staff's case will fail. Accordingly, Board Staff will doubtless encourage the panel to give due weight to the Guidelines, given their provenance and their salutary role in assisting the Board in administering its mandate, including their importance in providing transparency and consistency for patentees. But the panel must still assess whether or not the Guidelines appropriately implement the Act in the case before it. Thus, unless Board Staff is content to leave the assessment of the appropriateness of the Guidelines to the panel's own deliberations, Board Staff should present evidence and/or argument on the appropriateness of the Guidelines for the specific case before a hearing panel.

18. This Panel did not rely on any presumption that the Guidelines provide an appropriate implementation of the Act in relation to the pricing of Quadracel and Pentacel. Despite its position on the presumptive effect of the Guidelines, Board Staff also presented evidence and argument concerning the appropriateness of and weight to be given to the Guidelines, together with evidence and argument concerning what Board Staff alleged to be the inappropriateness of the departures from the Guidelines advocated by the Respondent.

19. As noted below, the Panel has found that the Guidelines are generally appropriate for the application of the provisions of the Act to the pricing of Quadracel and Pentacel, but that certain departures from the Guidelines are necessary to properly implement the Act through the order to be issued by the

Panel. The Panel wishes to note that, while it will refer in this decision to specific paragraphs of subsection 85(1) and the provisions of the Guidelines that implement those paragraphs, the Panel's decision is based on a balanced consideration of all of the factors in subsection 85(1) taken together.

(ii) The manner in which the Guidelines determine excessive pricing

20. The Guidelines are comprehensive and sometimes complex, and it is not necessary to provide a précis of all of the provisions of the Guidelines here, given that only parts of the Guidelines are potentially relevant to the determination of whether Quadracel and Pentacel were sold at excessive prices.

21. When a medicine is introduced to a market in Canada, the Guidelines use several tests to establish a price "ceiling" for the wholesale price of the medicine; that is, the price at (or below) which the Board will presume the price of the medicine not to be excessive. This price is referred to as the "maximum non-excessive price" or "MNE"[1] of the medicine. Described summarily, the MNE of a medicine is established at the time the medicine is introduced to the market by reference to the price of the medicine in certain specified countries or the price of comparable medicines in Canada and in other countries.

22. Once the MNE of a medicine is established, the price of the medicine will be presumed not to be excessive if it is sold at or below the lower of (1) at the time of introduction, the MNE then established; and (2) in subsequent years, the average price of the medicine in prior years, with allowance for price increases in line with the CPI. As a medicine is marketed from year to year, its MNE will rise in accordance with the annual price increases for the medicine, provided that those increases are in line with increases in the CPI, as calculated by the methodology described in the Guidelines.

23. The Act and the *Patented Medicines Regulations* (the "Regulations") require patentees of patented medicines to report the average prices at which the medicines are being sold. Board Staff use this information to generate an "Average Transaction Price" or "ATP". Provided that the ATP remains at or below the MNE, the patentee will be presumed to be in compliance with the Act and, barring special circumstances, no action will be taken by Board Staff to bring the pricing of the medicine to the attention of the Chairperson of the Board.

[1] The more accurate expression would be "MNE price", but the more compact "MNE" has come to be used to mean "MNE price".

24. If, however, the ATP exceeds the MNE, Board Staff will initiate an investigation and contact the patentee. If the matter is not resolved between Board Staff and the patentee, Board Staff will bring the matter to the attention of the Chairperson of the Board and the Chairperson will decide whether it is in the public interest to initiate a public proceeding to determine the matters raised by Board Staff and the patentee.

(iii) The CPI-Adjustment Methodology in the Guidelines

25. The Guidelines, implementing paragraph 85(1)(d) of the Act, provide as follows in relation to price increases and the CPI:

> 6.5 The measurement of change in the Consumer Price Index (CPI) over a specified period is used to compare the average transaction price of a drug product with the CPI-adjusted price of the product. The calculation of the CPI-adjusted price is described in Schedule 4.

26. Schedule 4 of the Guidelines provides detailed definitions and calculations for the "CPI-Adjustment Methodology". In a general sense, the CPI-Adjustment Methodology allows a patentee to increase the price of a patented medicine in line with CPI increases over a rolling three year period, falling behind or catching up with those increases over the rolling three year periods, provided that the increase in any one year is not greater than 1.5 times the forecast CPI increase for that year.

27. For the reasons discussed below, it is relevant to note at this point that this CPI-Adjustment Methodology in the Guidelines has been used by the Board since 1994. From some point after the creation of the Board in 1987 until 1994, a different CPI methodology was used. After a review by the Board, that earlier methodology was abandoned in favour of the current CPI-Adjustment Methodology.

28. It was common ground between the parties that the price increases of Quadracel and Pentacel exceeded those that would have been allowed by the CPI-Adjustment Methodology currently in the Guidelines. For the reasons detailed in its evidence and final argument, the Respondent argued that the CPI-Adjustment Methodology in the Guidelines is not appropriate for the pricing of vaccines or, in particular, the pricing of Quadracel and Pentacel during the relevant periods. The Respondent argued for the application of the pre-1994 approach to CPI-related MNE increases, and, as discussed below, for a number of ancillary departures from the Guidelines in relation to the issue of whether or not Quadracel and Pentacel was sold at excessive prices during the periods in issue.

(b) The sales and pricing of Quadracel and Pentacel

(i) Position of the Parties

29. The Respondent advanced detailed arguments regarding the unique nature of vaccines (relative to other medicines under the Board's jurisdiction) and the particular circumstances surrounding the market for, and sales of, the vaccines Quadracel and Pentacel. The Respondent argued that these factors supported variances from the Guidelines for these medicines. The Panel, having reviewed and carefully considered the Respondent's evidence and helpfully comprehensive written and oral submissions on these issues, will outline, rather than repeat them, here.

30. The Respondent's position may be briefly, albeit not comprehensively, summarized as follows:
    a. Vaccines are unique among the medicines under the Board's jurisdiction, in that they require a more costly level of research and development than other medicines, and produce substantially greater benefits for the population and the health care system (through prevention rather than amelioration or cure) than other medicines;
    b. As a result of the foregoing factors, security of demand is more important for producers of vaccines than for producers of other medicines under the Board's jurisdiction, and security of supply is more important for purchasers of vaccines than for purchasers of other medicines under the Board's jurisdiction; and
    c. Vaccines such as Quadracel and Pentacel are not marketed or sold in the same manner as other medicines, but rather are sold primarily pursuant to long-term contracts with the federal and provincial governments, who are sophisticated purchasers with significant bargaining power, potentially requiring less intervention by the Board. This type of arrangement also reflects the value that manufacturers and purchasers place on security of supply and demand.

31. The Respondent argued generally that all of these factors are essential to understanding the pricing and price increase clauses negotiated between the governments and Respondents with respect to Quadracel and Pentacel. Taking into account the differences between vaccines and other medicines under the Board's jurisdiction, and considering the circumstances in which Quadracel and Pentacel were sold in Canada during the period in issue, the Respondent argued that the provisions of the Guidelines that might be applicable to other medicines under the Board's jurisdiction, should not be applied to Quadracel and Pentacel. The Guidelines, the Respondent argued, do not – for the sales of the vaccines

Quadracel and Pentacel during the relevant periods – properly reflect the factors listed in subsection 85(1) of the Act.

32. In particular, and while not derogating from the position (with which the Panel agrees) that the Board must assess the pricing of Quadracel and Pentacel in light of all of the factors in subsection 85(1) of the Act, the Respondent argues that the CPI-Adjustment Methodology in the Guidelines is not an appropriate methodology for the implementation of paragraph 85(1)(d) of the Act for the pricing of Quadracel and Pentacel. Rather, it is argued that the Panel should use a CPI-adjustment methodology that is based on the CPI-adjustment methodology that was used by the Board until 1994.

33. The Respondent presented its evidence on this point primarily through its expert witnesses Dr. Melvyn Fuss and Mr. Alan Martyszenko. Dr. Fuss is an economist and Mr. Martyszenko is a chartered accountant. These witnesses gave evidence that it was not clear that the current CPI-Adjustment Methodology is better than the pre-1994 methodology, and in some circumstances the current CPI-Adjustment Methodology can be inefficient and inequitable. Furthermore, they said, the pre-1994 methodology was preferable for the pricing of Quadracel and Pentacel in particular.

34. The primary feature of the pre-1994 CPI methodology that the Respondent argued was more equitable and resulted in superior allocative efficiency in respect of Quadracel and Pentacel was the ability of the patentee, under the pre-1994 CPI methodology, to "bank" CPI increases by not increasing the price of the medicine to the extent of the CPI increase in a given year or years, and then make a cumulative price increase reflective of the "banked" CPI increases in some future year or years.

35. Board Staff also presented an expert witness on this issue, Dr. Richard Schwindt, an economist. Board Staff argued that there were good reasons that the CPI-Adjustment Methodology was adopted by the Board in 1994 and no reason to revert, for Quadracel and Pentacel, to a methodology that the Board determined in 1994 to be flawed. Indeed, Board Staff argued that the very flaw in the pre-1994 methodology was that banking of CPI increases allowed large sudden price increases that were contrary to paragraph 85(1)(d) of the Act.

(ii) Analysis and conclusions regarding the CPI Adjustment Methodology

36. The CPI-Adjustment Methodology is not mandated by the Act and is not binding on this or any other panel of the Board. It is, however, an element of the

Guidelines that was adopted, and then revised, by the Board in 1994 after considerable stakeholder consultation and deliberation by the Board.

37. This provenance of the CPI-Adjustment Methodology, and the stability and predictability that the CPI-Adjustment Methodology and other Guidelines provide to patentees, cause the Panel to give them due weight when determining whether it is appropriate to apply the CPI-Adjustment Methodology to the pricing of Quadracel and Pentacel. The ultimate question, however, is whether the CPI-Adjustment Methodology is, for the determination of whether there was excessive pricing in sales of Quadracel and Pentacel, the appropriate way to implement paragraph 85(1)(d) of the Act. The Panel believes that, subject to an appropriate departure as discussed below, it is.

38. From its inception, the Board has been of the view that, broadly speaking, there are three ways in which the price of a medicine can be considered to be excessive in accordance with the factors listed in subsection 85(1) of the Act:
    a. at introduction, in relation to the prices of comparable medicines sold in Canada or abroad;
    b. after introduction, in relation to the price of the medicine in Canada in previous years; and
    c. at all times, in relation to the price of the medicine itself sold in certain comparable international markets.

39. The second factor is reflected in the "CPI-Adjustment Methodology" in the Guidelines. The CPI-Adjustment Methodology moderates the extent to which a patentee may increase the price of its medicine from year to year by tying such increases approximately (that is, over rolling three year periods) to increases in the CPI. This provides a balanced approach under which patentees have some flexibility as to whether and when to increase the price of a medicine. By the same measure, customers are protected from sudden significant increases in the prices of the medicines.

40. "Banking" of CPI increases as advocated by the Respondent for Quadracel and Pentacel, would remove the protection from sudden and significant price increases in patented medicines when the patentee uses the "banked" CPI increases. The Respondent defended this approach for Quadracel and Pentacel, insofar as it could have this impact on purchasers, on the grounds that the purchasers of those vaccines were primarily governments who did not require protection from price increases that were out of line with CPI increases. The Respondent also noted that the contracts in question contained specified (and thus predictable) price increases which, even if greater than increases that would be allowed by the CPI-Adjustment Methodology in the Guidelines, were

acceptable for government purchasers. The Panel was not persuaded by either argument.

41. First, the evidence established that there were material sales of Quadracel and Pentacel and other vaccines to purchasers who were not governments or otherwise large and sophisticated purchasers. Also, some of the smaller provincial government purchasers could not be said to have the sophistication and/or bargaining power of the larger provinces and the federal government. While these sales might constitute a relatively small portion of the total sales of the vaccines, they are still significant to the purchasers in question.

42. Second, the Panel was satisfied by the evidence presented by Board Staff, including that of Dr. Schwindt and Mr. Henry Kreker (a government purchasing representative), to the effect that governments do not have materially greater market power than many other purchasers who are protected by the Board's statutory mandate, and that in all events the Board should not attempt to inquire into the market power of specific purchasers.

43. Dr. Schwindt provided expert evidence with respect to the appropriateness of the CPI-Adjustment Methodology in the Guidelines. He also provided an opinion to the effect that the position of the Respondent, regarding the market power of the purchasers of vaccines, was not supportable. Dr. Schwindt was not able to say that the Respondent's position was incorrect, but rather that it would require a large amount of data and study for one to be able to come to a conclusion as to whether the study was reliable or not. He noted that the Respondent had not undertaken the requisite study and the Board would not be in a position to do so if and when patentees made the argument that a given purchaser or purchasers had market power.

44. The Panel is of the view that it would be inappropriate for the Board to assess the market power of purchasers of patented medicines. In its first price review decision,[2] a decision upheld by both the Federal Court and the Federal Court of Appeal, the panel hearing the case noted that, while the Board's jurisdiction was premised on the potential for a patentee to exercise market power, it was not necessary or appropriate for the Board (nor was the Board able) to inquire into the existence of actual market power in order to exercise its jurisdiction.

45. By the same token, the Panel does not consider it necessary or appropriate for the Board (or this Panel in relation to Quadracel and Pentacel) to inquire into whether the purchasers of certain patented medicines do or do not have market

[2] In the matter of ICN Pharmaceuticals Inc. and the medicine Virazole

power despite the monopoly held by the patentee. None of the provisions of the Act require or entitle the Board to inquire into these issues, and the Board is not equipped to do so.

46. Board Staff's second witness on this topic, Mr. Kreker, was the person in charge of the directorate at Public Works and Government Services Canada ("PWGSC") that was responsible for the purchasing of drugs and vaccines in 2007 (when PWGSC took over such purchases for all but two of the provinces and territories) and who signed the 2007 contracts for the purchase of Quadracel and Pentacel. For a number of years Mr. Kreker was responsible for all federal government purchases of vaccines and drugs, involving many negotiations and contracts amounting to hundreds of millions of dollars. Mr. Kreker's evidence established to the Panel's satisfaction that in a non-competitive procurement for vaccines, the federal government typically will be a price-taker. The Board cannot know whether some or all future vaccine purchases will be competitive or sole-sourced.

47. However, for the reasons noted, the evidence of both parties on this topic was not influential in the Panel's decision, as the Panel agrees with the proposition that it is not possible or appropriate for the Board to inquire into the presence or absence of the market power of patentees with respect to their patented medicines. The Act instructs the Board to prevent excessive pricing of a medicine where a patent pertains to that medicine. The Board has never considered the factors delineated in subsection 85(1) of the Act to include the relative market power that the patent has conferred on the patentee, and this Panel agrees with that position.

48. While the Respondent framed all of the features of vaccine development and marketing, including the largely sophisticated customer base, to be elements of the price at which the medicine is sold in Canada (paragraph 85(1)(a)), the Panel disagrees. Paragraph 85(1)(a) requires the Board to establish a means of determining the price at which a patented medicine is or has been sold in Canada. As described below, the Guidelines set out a methodology for implementing paragraph 85(1)(a). Paragraph 85(1)(a) does not instruct the Board to engage in an open inquiry into the excessiveness (or not) of the price of the medicine on the basis of the factors (unique to vaccine production and marketing) suggested by the Respondent. Rather, having established the price at which the medicine is or has been sold in Canada in accordance with paragraph 85(1)(a), the Board is instructed by the balance of subsection 85(1) to consider whether that price is or was excessive in accordance with the factors listed therein.

49. Board Staff challenged the Respondent's proposition that vaccines were unique among medicines under the Board's jurisdiction, and the Panel agrees with Board Staff (for the reasons outlined at paragraph 5 of their written submissions) that it is not reasonable to attempt to carve out separate categories of medicines when, in fact, the allegedly unique features of vaccines are or could be true of present or future categories of medicines, or would be pertinent only in an inquiry under subsection 85(2) of the Act. The salient feature of all medicines under the Board's jurisdiction is that a patent pertains to them. That having been established with respect to a given medicine, subsection 85(1), and if necessary subsection 85(2), instruct the Board as to the factors to consider when determining whether the price of that medicine is or has been excessive.

50. Despite the Respondent's evidence concerning the costs of developing and marketing vaccines, the Respondent did not suggest that the Board was unable to determine whether the prices of Quadracel and Pentacel were excessive by applying the factors in subsection 85(1), such that resort should be had to the factors described in subsection 85(2): the costs of making and marketing the medicines. Neither was evidence led on the application of subsection 85(2).

51. Finally, regarding the Respondent's argument that the price increases in question, even if greater than increases that would be allowed by the CPI-Adjustment Methodology in the Guidelines, were agreed to by contract, the Panel notes that patentees and their customers may not "contract-out" of the provisions of subsection 85(1) of the Act, as that subsection is implemented by the Guidelines or hearing panels of the Board. That said, and as discussed below, the Panel finds that in the unique circumstances of this case the MNEs of Quadracel and Pentacel should not be affected by the discounts given to Ontario when that province entered into a five-year contract to purchase Quadracel and Pentacel.

52. Accordingly, subject to the variation in the CPI-Adjustment Methodology to adjust the MNE of Quadracel and Pentacel in a manner that ignores the discounts given to Ontario, the Panel is satisfied that the CPI-Adjustment Methodology generally is the most appropriate way to implement paragraph 85(1)(d) of the Act for the establishment of the MNEs for Quadracel and Pentacel. The Panel also concludes that paragraph 85(1)(a) does not permit an inquiry into the price at which Quadracel and Pentacel were sold based on the unique aspects of the development and marketing of vaccines, nor that such considerations would be persuasive in this case if permitted under any part of subsection 85(1).

(iii) Off-setting excessive revenues with sales below the MNE

53. The Respondent, assisted by the evidence of Mr. Martyszenko, proposed that revenues from the sale of Quadracel and Pentacel at prices that exceeded its MNE in a given year should be offset by sales during other years at prices that were below the MNEs of Quadracel and Pentacel.

54. The Guidelines, implementing paragraph 85(1)(a) of the Act, allow for price averaging on an annual basis. In other words, within each calendar year, the price of the medicine in Canada is determined by price averaging that results in sales above the MNE being averaged with sales below the MNE. Patentees report average prices for the January-June and July-December periods, and these two periods are themselves averaged to determine the annual average transaction price. This gives patentees a reasonable level of flexibility without exposing purchasers, on average over the course of the year, to increases beyond those in line with annual CPI increases. The patentees of virtually all of the medicines under the Board's jurisdiction operate within these bounds.

55. The Panel believes that the Board would not be fulfilling its mandate to protect consumers from excessive prices of patented medicines if it allowed patentees to average price excesses and prices below the MNE over periods of time greater than one year, and especially over periods of time chosen by the patentee. Such an approach would allow a patentee to charge excessive prices for a period of years without regulation by the Board, with the patentee relying on lower prices in a subsequent period chosen by the patentee to avoid sanction for the excessive prices. There would be no protection for consumers during the periods that the patentee chose to charge excessive prices. The later reduction in prices cannot be presumed, or even expected, to remedy the potential harm done during the period of excessive pricing. This is true whether or not the customer base remains the same throughout the two periods, because the effect of the excessive prices on the purchasing decisions made by the customer base will likely be a matter for speculation only.

56. The Respondent noted a prior occasion on which the Respondent was permitted by Board Staff to offset a small amount of excess revenue in one year by price reductions in a subsequent year. Two panels of the Board in other proceedings (regarding the medicines Nicoderm and Copaxone) have disapproved of price averaging outside of individual calendar years, and, for the reasons stated by those panels and in this decision, this Panel concurs in that disapproval.

57. The Guidelines provide that Board Staff will not initiate an investigation of excessive pricing if the quantum of excess revenues is at a *de minimus* level, the

excess pricing was inadvertent, and the patentee reverses the excess in the following year. This latitude is not a departure from the overall structure of the Guidelines, which is to limit price averaging to reporting periods in a calendar year. The Panel finds that this approach in the Guidelines is appropriate and was well understood by the Respondent, which approached Board Staff when it realized it was outside its bounds.

(iv) Reporting of returns

58. The Respondent, again supported by the evidence of Mr. Martyszenko, argued that adjustments should be made to the ATP of Quadracel and Pentacel to reflect more accurately the impact of returned goods (that is, by matching the returns to the period in which the returned medicine was sold). In final argument the Respondent noted that this issue did not have a substantive impact on the outcome of the excessive revenue calculations.

59. The Panel appreciates the logic of Dr. Martyszenko's approach to matching the pricing impact of returned goods to the period during which the returned goods were sold. However, the Panel agrees with Board Staff that the Guidelines, in requiring reporting of returns during the reporting period in which the returns were received, is (1) sufficiently accurate and (2) has the great advantages of predictability and simplicity, in that reported prices need not be re-reported and retroactively revised, with the concomitant requirement to revisit the question of whether the price for the earlier period was, as a result of the subsequent filing, excessive or not.

(v) Conclusions regarding departures from the Guidelines concerning the CPI-Adjustment Methodology, off-setting of excessive revenues and reporting of returns

60. For the reasons outlined above, and subject to the qualifications later in these reasons:
    a. the Panel accepts the appropriateness of applying the CPI-Adjustment Methodology in the manner contemplated by the Guidelines, without the alterations proposed by the Respondent;
    b. other than the annual price averaging provided for in the Guidelines, the Panel does not accept any price averaging methodology by which excessive revenues are off-set by the notional amounts by which sales of a medicine were made at prices below its MNE; and
    c. the Panel believes that returns should be reported in the reporting period during which they are received, regardless of the period during which the sale of the medicines occurred.

(c) Comparing the prices of Quadracel and Pentacel to the prices of vaccines containing the constituent antigens in Quadracel and Pentacel

(i) The Positions of the Parties

61. As noted above, the manner in which the MNEs of Quadracel and Pentacel were established was, in accordance with the Guidelines, by comparison to the prices of comparable medicines that were being sold in Canada at the time that Quadracel and Pentacel were first marketed in Canada. These provisions of the Guidelines, among others, are intended to implement paragraph 85(1)(b) of the Act. Once those MNEs are established, subsequent price increases are subject to prior years' ATPs and the CPI-Adjustment Methodology.

62. The Respondent argued that this initial comparison was of somewhat limited current relevance because the initial comparators were whole-cell vaccines, soon replaced on the market with acellular vaccines such as Quadracel and Pentacel. The Respondent advocated an alternative approach. The Respondent argued that the prices of Quadracel and Pentacel, which contain antigens to protect against four and five diseases, respectively, in single vaccines, should be compared to the prices of multiple vaccines containing the same antigens but in uncombined or less combined forms.

63. For example, the Respondent notes that Pentacel contains antigens to protect against diphtheria, pertussis, tetanus, polio and diseases associated with Hib. Accordingly, the Respondent suggests, it is appropriate, when establishing a price comparison with comparable medicines, to look to the total of the prices of:
    a. the vaccine Adacel, which protects against diphtheria, pertussis, tetanus;
    b. the vaccine IPV, which protects against polio; and
    c. the vaccine Act HIB, which protects against Hib.

64. The Respondent proposes such comparisons on both a domestic and international basis (the latter in respect of paragraph 85(1)(c) of the Act. In this manner, the Respondent argues, the Board can conclude that, on consideration of paragraphs 85(1)(a)-(c) of the Act, the prices of Quadracel and Pentacel were not excessive.

65. Board Staff disagreed with this approach, and, in the alternative, offered what it believed to be more appropriate combinations of vaccines with which to compare Quadracel and Pentacel.

(ii) Conclusions of the Panel regarding the appropriate comparator medicines for Quadracel and Pentacel

66. The Panel supports the approach (taken in the Guidelines) of comparing the price of a new medicine at the time of its introduction in Canada with the prices, where available, of comparable medicines. Where there are no comparable medicines, the price-cap of the new medicine is established by the median international price of the medicine.

67. At the time that Quadracel and Pentacel were introduced to the Canadian market, the Human Drug Advisory Committee ("HDAP"), giving advice to the Board, sought to establish whether there were comparable medicines and if so, which medicines were the appropriate comparators for Quadracel and Pentacel. The HDAP concluded that the appropriate comparators were cellular vaccines that protected against the same diseases as Quadracel and Pentacel. The Panel agrees with this conclusion.

68. The Panel accepts the definition in the Guidelines of medicines that are in the "same therapeutic class" as the medicine under review, which definition focuses on the concept of clinical equivalence. Acknowledging the difference between cellular and acellular vaccines, the Panel agrees with the conclusion of the HDAP that the comparator cellular vaccines identified by the HDAP were in the same therapeutic class as Quadracel and Pentacel, as supported by the scientific evidence relied on by the HDAP. The Panel has concluded that the cellular comparator vaccines identified by the HDAP and used by Board Staff to establish the MNEs of Quadracel and Pentacel are much closer and more appropriate comparators than the combinations of individual acellular vaccines proposed by either the Respondent or Board Staff, the comparisons (to Quadracel and Pentacel) for which there is little or no scientific evidence.

69. In conclusion, the Panel believes that the approach adopted in the Guidelines for the establishment of an MNE at the time a medicine is introduced by reference to the prices of comparable medicines is correct, and that the correct comparator medicines were used by Board Staff in establishing the initial MNEs of Quadracel and Pentacel. This approach resulted in the appropriate implementation of paragraphs 85(1)(a)-(c) of the Act.

(d) Exceptions to the Guidelines

70. There are two remaining questions for the Panel. The first is whether the discount given to Ontario in the first five year contract (1997-2002), and which (by lowering the MNE of Quadracel and Pentacel) generated a substantial portion of the alleged excess revenues, should be the subject of an exception (or exceptions) to the CPI-Adjustment Methodology. The second is whether the provisions of the Guidelines that require each medicine identified by a new Drug Identification Number to be treated as a new medicine (regardless of its relation to a precursor medicine) should be applied to Pediacel, the medicine with which the Respondent replaced Pentacel in Canada.

71. On these questions the Panel supports the positions taken by the Respondent, albeit, in the case of the first question, in a more limited fashion than the Respondent advocated, and in the case of the second question, in a manner that is moot for this proceeding given the Panel's conclusions on averaging beyond calendar years.

(i) Pricing in the Ontario contract

72. In 1997, when sanofi pasteur introduced Quadracel and Pentacel to the Canadian market, it entered into a five-year contract with Ontario. This contract included price discounts in years 4 and 5. Despite these reductions, the evidence of the Respondent was that Ontario understood (though not in a binding way) that, when the 1997 contract was renewed, the pricing of Quadracel and Pentacel would revert to the undiscounted levels that applied in years 1-3 of the 1997 contract, as adjusted for inflation. All of the provinces were offered this pricing structure if they entered into five-year contracts, but only Ontario contracted on this basis.

73. Pursuant to the Guidelines, the MNE in a given year is not a direct function of the MNE in the prior year, but rather of the ATP of the medicine in the prior year. In other words, the MNE in year 6 is based on what the patentee actually charged in year 5, regardless of the MNE in year 5.

74. Accordingly, the price discounts given to Ontario in years 4 and 5 of the 1997 contract reduced the MNEs of Quadracel and Pentacel, with the result that, if the Guidelines are applied, the prices of Quadracel and Pentacel after the expiry of the Ontario contract exceeded their MNEs. The evidence of the Respondent was that it understood that, when it renewed the 1997 contract, it would be at price levels that exceeded the MNEs of Quadracel and Pentacel.

75. Generally speaking, the Panel understands and agrees with the rationale behind the use, in the Guidelines, of the ATP (rather than the MNE) of a medicine in a given year for the establishment of the MNE for the following year. However, the Panel is also mindful of the fact that there are some circumstances in which the Board should consider encouraging patentees (or at least removing disincentives from patentees) to provide benefits to purchasers, without the patentees being prejudiced by reductions in their MNEs.

76. In the unique circumstances of this case, including the fact that all provinces were offered the discount arrangement that was accepted by Ontario, the Panel believes that relatively less weight should be put on paragraph 85(1)(d) of the Act with respect to this arrangement with Ontario. Accordingly, sanofi-pasteur, for the purposes of calculating any excessive revenues in relation to sales of Quadracel and Pentacel, should be deemed not to have given Ontario the discounts in years 4 and 5 of the 1997 contract. In other words, the ATP of Quadracel and Pentacel should be deemed to be based on the prices at which those medicines would have been sold without the applicable discounts, and the MNE of Quadracel and Pentacel should be calculated accordingly. This will eliminate any excessive revenues that would otherwise be generated by the discounts in question.

(ii) Pediacel

77. In 2007, sanofi pasteur replaced Pentacel in the Canadian market with Pediacel. Pediacel is identical to Pentacel except that it is in fully liquid form; that is, there is no need for the person giving the vaccine to reconstitute (mix together) the Hib vaccine and Quadracel. Other than the packaging and the name, which of course would vary from Pentacel, the only difference in the product monographs of the two medicines is that the dosage for Pedicel is different. The different dosage, of course, results from the fact that in Pediacel, the Hib vaccine is already fully combined with Quadracel.

78. Given that purchasers of Pentacel accept Pediacel as a substitute for Pentacel under ongoing contracts, it is reasonable to conclude that the purchasers of Pentacel (Canada and the provinces) considered Pediacel to be an equivalent vaccine to Pentacel, doubtless with advantages in its simpler delivery format.

79. However, because Pediacel was a new medicine in the eyes of Health Canada, it required a new Drug Identification Number (DIN). As with the regulation of medicines in Canada generally, the Board's Guidelines treat each DIN as a separate medicine. The consequence of this was that Board Staff, implementing

the Guidelines, considered it appropriate to treat Pediacel as a new medicine requiring a new price comparison and its own MNE.

80. The Panel appreciates the need for clear rules and the resulting predictability in the Guidelines. There are times, however – and the Panel believes that this is one of them – when simplicity and predictability can result in rules that create unfair results. The Panel agrees that, in virtually all cases, the emergence of a new DIN for a patented medicine will appropriately engage the price review tests contained in the Guidelines for new medicines. In this case, however, where the new medicine was identical to the prior medicine in all material respects and different from it only in an immaterial way, and where most of the sales of the new medicine were under continuing contracts for the prior medicine, the Panel believes that an exception can be made: Pediacel can be deemed to have inherited the MNE of Pentacel.

81. Given that the Panel does not agree that sales of either Pentacel or Pediacel at levels below the MNE of Pentacel should offset prior excessive revenues, this acceptance of the position of the Respondent does not affect the outcome of this proceeding, but it may be important to the Respondent in its sales of Pediacel in the future.

(e) Policy of Selling at an Excessive Price

82. Finally, Board Staff initially requested that the Panel conclude that the Respondent engaged in a policy of selling Quadracel and Pentacel and excessive prices, and that as a result, pursuant to subsection 83(4) of the Act, the Panel should impose a remedy that requires the Respondent to take measures that have an impact that exceeds the excessive revenues received by the Respondent. The basis of Board Staff's position was that the Respondent knew the MNEs of Quadracel and Pentacel and entered into long term contracts that the Respondent knew would or could result in prices for Quadracel and Pentacel that exceeded their MNEs.

83. While there was some discussion of this issue during the hearing, Board Staff did not develop its position or seek a remedy based on sanofi-pasteur having engaged in a policy of excessive pricing. Accordingly, the Panel does not consider it appropriate to make a finding on the point in this case.

III. *Remedy*

84. The Panel considers that the most appropriate remedy in this case, given the stability of the customer base for Quadracel and Pentacel, is that the Respondent

reduce the price at which it sells Quadracel and Pentacel (to any customers) during the term of the Respondent's current contract with the Government of Canada, to a level that offsets the excessive revenues that were earned by the Respondent, as determined by the conclusions in this decision. That is to say, the calculation of excessive revenues for the sales of Quadracel and Pentacel should be undertaken on the basis advocated by Board Staff, but with the ATP and MNE of Quadracel and Pentacel calculated as if the Ontario discounts had not occurred.

IV. *Conclusion*

85. The Panel requests that Board Staff and the Respondent present the Panel with a draft order that implements the terms of this decision. The Board expects the parties to submit a proposed order on or before February 3, 2010. The Panel remains seized with this matter and is willing to assist the parties in the event that the terms of the draft order cannot be agreed upon.

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Anne Warner La Forest

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Appearances

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Original signed by

Sylvie Dupont
Secretary of the Board