PATENTED MEDICINE PRICES REVIEW BOARD

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

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris"

REASONS FOR DECISION

(Motion to Strike Expert Evidence
Heard on March 18, 2016)

1. On March 18, 2016, the panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**Board**") seized with this proceeding heard a motion brought by Alexion Pharmaceuticals Inc. ("**Alexion**" or the "**Respondent**") to strike certain parts of the expert evidence filed by Board Staff on February 16, 2016.

2. Alexion seeks the following relief:

i. An order striking the Expert Report of Sumanth Addanki (the "**Addanki Report**") in its entirety;

ii. An order striking all of or at least section 6 of the "Opinion With Regard to the Use of External Reference Pricing in the Determination of Excessive Patented Medicine Prices: the Case of Soliris" by Richard Schwindt (the "**Schwindt Report**");

iii. An order striking out documents, and references to documents, relating to IMS Midas data found in Tabs 75, 76, 77 and 82 of Board Staff's Disclosure List of Documents and referred to in the Schwindt Report (the "**IMS Data**"); or

iv. In the alternative, an order postponing the hearing of this matter to permit Alexion an adequate opportunity to respond to the expert evidence of Board Staff.

3. For the reasons that follow, the motion is dismissed without prejudice to Alexion's right to challenge both the admissibility and the weight to be assigned to any of the expert evidence at the hearing on the merits. The Panel also recognizes that the Respondent may require additional time beyond the 30 days that Alexion has already received to date to prepare responding expert reports. The Panel has made the following amendments to the Order Regarding Scheduling issued on December 7, 2015 (the "**Scheduling Order**")[1]:

i. Alexion shall serve and file responding expert reports on or before April 18, 2016;

ii. Board Staff shall serve and file any reply expert reports on or before May 13, 2016; and

iii. The remainder of the schedule as set out in the Scheduling Order, including the hearing dates, shall remain as previously established.

Background

4. Soliris (eculizumab) 10mg/mL ("**Soliris**") is indicated for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH), a rare and life-threatening blood disorder that is characterized by complement-mediated hemolysis (the destruction of red blood cells).

[1] Scheduling Order of the Board (December 7, 2015): http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/BoardSchedulingOrderDecember72015.pdf.

5. Soliris is also approved as a treatment for patients with atypical hemolytic uremic syndrome (aHUS), a rare and life-threatening genetic disorder characterized by "complement-mediated thrombotic microangiopathy" or TMA (blood clots in small vessels).

6. Soliris is sold in Canada by the Respondent, Alexion. Board Staff has determined that the Respondent is selling Soliris at a price that is excessive and seeks an Order under section 83 of the *Patent Act*[2] requiring Alexion to, *inter alia*, discontinue the sale of Soliris at a price that is alleged to be excessive and to offset the allegedly excess revenues that Alexion has generated from prior sales of Soliris.

7. On January 22, 2015, the Board issued a Notice of Hearing to require a public hearing with respect to Board Staff's allegations of excessive pricing of Soliris.

8. The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, the Respondent is selling or has sold Soliris in any market in Canada at a price that, in the Board's opinion, is or was excessive, and if so, what order, if any, should be made.

9. In a motion heard on September 16, 2015, Alexion raised allegations of conflicts of interest and reasonable apprehensions of bias on the part of a number of the individual counsel involved in this proceeding and the Chairperson of the Board. The Panel dismissed this motion in a decision dated October 5, 2015.[3]

10. At a pre-hearing conference held on October 28, 2015, the Panel heard five motions relating to procedural issues in respect of this proceeding. The Panel's decision with reasons with respect to each motion was issued on November 24, 2015.[4]

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2 RSC, 1985, c P-4.

3 Board Decision – *Respondent's Motion Relating to Conflicts of Interest* (October 5, 2015): http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/MotionRelatingtoConflictsofInterest-October5thdecision-Final.pdf.

4 Board Decision – *Various Motions Related to Procedural Matters* (November 24, 2015): http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/SOLIRIS-PMPRBNovember24th2015decision.pdf.

11. The Panel also issued a Scheduling Order on consent of the parties on December 7, 2015, which set out the schedule for the remaining steps until the hearing, including the filing of expert reports. Board Staff filed its expert reports in accordance with this schedule on February 16, 2016.

12. Alexion served a Notice of Motion dated February 26, 2016 seeking to strike certain parts of Board Staff's expert evidence. At a conference call in respect of this motion held on March 4, 2016, the Panel, with mutual consent of the parties and pending the hearing and decision of this motion, extended the deadline for Alexion to file its expert reports to March 31, 2016.

13. At a hearing held on March 18, 2016, the Panel heard Alexion's motion to strike the expert evidence and issues this decision, based on the reasons that follow.

Relevant Facts

i. Pleadings

14. The purpose of the proceeding between Alexion and Board Staff is to determine whether, under sections 83 and 85 of the *Patent Act*, Alexion is selling or has sold Soliris in any market in Canada at a price that, in the Board's opinion, is or was excessive, and if so, what order, if any, should be made.

15. Evidence tendered by the parties must be relevant to the matters at issue in this proceeding. The pleadings are the starting point for the determination of the matters at issue in this proceeding.

16. In its Statement of Allegations, Board Staff states, in part, as follows:

> 15. In accordance with the 2010 Compendium of Guidelines, Policies and Procedures ("**2010 Guidelines**"), and the Highest International Price Comparison ("**HIPC**") test, Board Staff compared the National Average Transaction Price ("**N-ATP**") to the publicly available list prices of Soliris sold in the comparator countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States) listed in the Schedule of the Patented Medicines Regulations (the "**Regulations**").

…

22. Subsection 85(1) of the Act sets out the factors the Board shall take into consideration in determining whether a medicine is being or has been sold at an excessive price in any market in Canada...

…

25. Although the 2010 Guidelines are not binding on the Board, Board Staff submits that it is appropriate in this case for the Board to apply the approach and methodology set out in these 2010 Guidelines when applying the factors set out in subsection 85(1) of the Act to determine whether Soliris is being or has been sold at an excessive price in any market in Canada.

…

27. Board Staff submits that when applying the factors under subsection 85(1) of the Act, there are grounds for the Board to conclude, pursuant to section 83 of the Act, that Alexion is selling or has sold the medicine known as Soliris in any market in Canada at a price that is or was excessive.

28. Board Staff reserves the right to make such other allegations and submissions and to introduce such other documents as Board Staff may advise and the Board may permit.[5]

17. Alexion in its Amended Response dated July 17, 2015, states, in part:

10. …Alexion still believes from the particulars delivered in response to the Particulars Order that it is only fluctuations in the international exchange rates that made the Canadian ex-factory price appear to have increased relative to some reference countries when applying the international price test in the Guidelines.

11. …The Act requires the Board to take into account price factors in s. 85(1), and to reach a reasonable determination, based on all of these factors, whether a price is "excessive".

…

13. The Allegations demonstrate the absurdity of applying the Guidelines in this case. Board Staff reach the arbitrary, impractical, and logically untenable position that a Canadian ex-factory price that did not change from the time the medicine was first sold in Canada and did not change in comparator countries (other than price increases in the U.S., went from

[5] Board Staff Statement of Allegations (January 15, 2015).

being "non-excessive" to "excessive" based on the value of foreign currency fluctuations.

36. Board Staff's application of the HIPC test contains many inconsistencies and is an unreliable basis for making any finding of excessive pricing against Alexion…

18. In its Amended Reply dated September 1, 2015, Board Staff further alleges:

5. …Board Staff determined that Alexion's introductory price of Soliris exceeded the median international price among the comparator countries; however, the excess revenues Alexion generated did not meet the criteria for continuing the investigation. These criteria were established to allow Board Staff to allocate its resources to investigations as efficiently as possible. In deciding not to pursue the investigation, Board Staff did not therefore deem the introductory price of Soliris to be "non-excessive".

6. …Board Staff has not alleged that the price of Soliris is excessive due to changes in exchange rates. Board Staff submits that based on the factors under subsection 85(1) of the Act, the Regulations and the Board's Guidelines, Alexion has been selling Soliris to Canadians at an excessive price since 2012. Board Staff further submits that its application of the factors, the Regulations and the Board's Guidelines in this case is appropriate and reasonable.

7. Additionally, Alexion has failed to justify its excessive price under subsection 85(2) of the Act. In any event, there appears to be no justification for Alexion's excessive price based on costs or other factors.

8. …Board Staff's position is and always has been that the price of Soliris is excessive under the Act. Alexion's "belief" as to Board's Staff's "apparent conclusions" is irrelevant as the only relevant issue in this proceeding is whether the price of Soliris has been excessive under the Act. In this regard, Alexion misunderstands the purpose of an investigation into excessive pricing and how that differs from a proceeding before the Board in the context of a hearing. Board Staff's interpretation of the Guidelines and the Regulations are not binding on the Board during a hearing. The hearing is a fresh opportunity for the Board to determine whether a medicine's price is excessive under the Act.

19. In its Surreply dated December 4, 2015, Alexion further states:

5. Apart from allegations in the Statement of Allegations relating to the Highest International Price Comparison (HIPC) test under Schedule 6 of the Guidelines, Board Staff have provided no details of how (i.e., in what

> way or ways) the price of Soliris violates "factors ... under subsection 85(1)" or any factor under subsection 85(2)(b) of the Act.
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> 6. The absence of any specificity concerning existing factors under subsection 85(1) and Board Staffs failure to identify any factor at all under 85(2)(b) mean Alexion does not, and cannot, know the case it has to meet other than the application of the HIPC test mentioned in the Statement of Allegations.

20. In support of its allegations, Board Staff served on February 16, 2016 the Addanki Report and the Schwindt Report, which the Respondent is moving to strike, along with the IMS Data referenced in the Schwindt Report.

a) The Addanki Report

21. Dr. Sumanth Addanki is an economist and a Senior Vice President at National Economic Research Associates, Inc., and holds a Ph.D. degree in economics. The Addanki Report, provides an opinion on the following two questions:

i. What economic measures, tests and considerations should be considered to be appropriate to the question of whether the price of Soliris in Canada is or has ever been excessive under s. 85 of the *Patent Act*; and

ii. Whether the application of the economic measures, test and considerations in Question 1 indicates that the price of Soliris in Canada is or has ever been excessive.

22. In preparing his report, Dr. Addanki was asked by Board Staff to ignore the existence of the *PMPRB Compendium of Policies, Guidelines and Procedures* (the "**Guidelines**") and focus only on the *Patent Act* in addressing the questions above.

23. The following is an overview of the findings in the Addanki Report:

> 9. Based on the information available to me and my economic analysis to date, I have concluded that Section 85(1) of the Patent Act lists a variety of economic considerations that may help inform the analysis of whether a given price is excessive. These considerations relate in one fashion or another to comparing the price at issue with relevant yardsticks, which, in turn, need to be chosen with careful attention to the specific economic circumstances of the patented drug whose price is at issue.

> 10. While I understand that the ultimate determination of whether or not a given price is excessive lies within the purview of the PMPRB, my economic analysis of Soliris's pricing in Canada in light of the economic considerations provided for in the Patent Act indicates that Soliris's price may, in fact, be excessive.[6]

b) The Schwindt Report

24. Dr. Richard Schwindt is an economist and a professor, and holds A.M. and Ph.D. degrees in economics.

25. The Schwindt Report provides an opinion, from an economic perspective, on several issues regarding the use of external reference pricing ("**ERP**") to set ceilings on prices of patented drugs. External reference pricing, also called international reference pricing in the literature, involves a comparison between the prices in other jurisdictions to prices and price changes domestically.

26. In particular, the Schwindt Report evaluates Alexion's allegation that the current methodology, as set out in the Guidelines is inappropriate for its product Soliris, and concludes that the ERP system as set out in the Guidelines is reasonable and provides a measure of predictability for patentees and other stakeholders.

27. IMS Data is provided by IMS Health, a private global information and technology services company. The Schwindt Report references IMS Data as follows: "the analysis in this report uses prices for the reference countries (France, Germany, Italy, Switzerland, Sweden, the United Kingdom and the United States) as reported and revised by Alexion in accordance with the PMPRB *Guidelines*... I understand that these are not the prices used by Board Staff in its calculations of excessive prices and excess revenues. Using prices determined by application of Board Staff's 2012 to 2014 Methodology or prices derived from IMS MIDAS data would not materially change my findings."

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[6] Addanki Expert Report at 9-10.

ii. Pre-Hearing Conferences

28. Rule 8(1) of the *Patented Medicine Prices Review Board Rules of Practice and Procedure* (the "**PMPRB Rules**")[7] provides that expert witness evidence is not admissible in a proceeding before the Board in respect of any issue unless the issue has been raised in the pleadings or in a pre-hearing conference order. Thus, in addition to the pleadings, issues raised in the various pre-hearing conferences in this proceeding and subsequently issued orders in respect of those pre-hearing conferences are relevant facts to the current motion.

29. At a pre-hearing conference held on October 28, 2015, the Panel heard five motions relating to procedural issues in respect of this proceeding. The Panel's decision with reasons with respect to each motion was issued on November 24, 2015.[8]

30. In its analysis as set out in paragraphs 75 to 79 of this decision, this Panel stated: "Section 85 contemplates the potential of a dual-stage review by the Panel consisting of an initial examination of the factors listed in subsection 85(1) and where necessary, an examination of the additional factors listed in subsection 85(2)… the Panel should receive evidence and submissions regarding the factors listed in both subsections 85(1) and 85(2), to the extent relied upon by either party. Where a party submits evidence relating to the factors listed in subsection 85(2), the Panel will not have regard to such evidence unless it is unable to decide this matter based on a consideration of the factors listed in subsection 85(1) alone… Clearly, evidence regarding both subsections 85(1) and 85(2) of the *Patent Act* is admissible in this proceeding… [t]he Panel therefore anticipates that the parties will make representations and adduce evidence with respect to the factors listed in subsections 85(1) and 85(2) of the *Patent Act*."

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7 SOR/2012-247.

8 Board Decision – *Various Motions Related to Procedural Matters* (Novermber 24, 2015): http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/SOLIRIS-PMPRBNovember24th2015decision.pdf.

Submissions of the Parties

a) The Addanki Report

31. Alexion submits that the Addanki Report is irrelevant and will complicate and expand the proceeding, resulting in a waste of time and costs for the Panel and the parties. Alexion alleges that the issues addressed by Dr. Addanki have not been raised in the pleadings, as required under Rule 8(1) and that Board Staff is, through the Addanki Report, attempting to amend its pleadings and raise entirely new allegations and issues.

32. According to Alexion, there "are only two excessive price 'issues' raised by Board Staff in the Statement of Allegations: (1) that Alexion 'has been selling Soliris in Canada at the highest international price among the comparator countries.' (2) that Alexion has been selling Soliris 'at a price in Canada that is appreciably higher than in the United States.'"[9] Alexion submits that there is no reference whatsoever in the Statement of Allegations to any other factor in s. 85(1), in particular to comparators or "therapeutic classes", whether in relation to 85(1)(b) or (c). Alexion submits that when "measured against the pleadings, it becomes apparent that the issues addressed in the Addanki Opinion were not 'raised in the pleadings' as required by Rule 8(1)."[10]

33. Alexion takes specific issue with the approach adopted by Dr. Addanki to the consideration of products that fall within the same "economic class" as part of the consideration of the therapeutic class for Soliris:

> 19. When Alexion introduced Soliris on the Canadian market in 2009, it complied with the Guidelines and procedures of the Board, including the scientific review procedures of HDAP. The approach of the Board, and the courts, to interpreting "other medicines in the same therapeutic class" in ss. 85 (1)(b) and (c) consistently refers to therapeutic, pharmacologic, and chemical methods of classification described in the Guidelines and not to any "economic" classification as proposed by Dr. Addanki. Dr. Addanki's

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9 Alexion Reply Submissions dated March 16, 2016 at 6.

10 *Ibid* at 17.

> expert opinion based on a purported "economic" class of products is therefore irrelevant under Rule 8(1).
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> 20. As much as it is irrelevant, any acceptance of Dr. Addanki's purported "economic" class of products is equally prejudicial and violates fundamental fairness. Classification of medicines based on economic factors like those identified by Dr. Addanki have never been part of the Guidelines, practices, procedures, or jurisprudence of the Board. In no way could Alexion (or any other manufacturer) have known, until delivery of the Addanki opinion at this late stage of this proceeding, that a determination of "excessive" pricing could be reached by such an approach. Yet Board Staff seeks to penalize Alexion under this entirely novel reading of the words "therapeutic class."
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> …
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> 27. The Addanki Opinion, which deliberately disregards the Guidelines at Board Staff counsel's request, is not only irrelevant, it directly contradicts the case Board Staff pleaded, which itself relies on the Guidelines for the proposed interpretation of s. 85(1)(c). While the Panel may depart from the Guidelines in interpreting s. 85(1) of the *Act,* Board Staff cannot depart from their own pleadings to allege a self-contradictory case.[11]

34. Board Staff submits that the Addanki Report is relevant. Board Staff state that Dr. Addanki provided his opinion from an economic perspective on various economic tests to determine whether Soliris is, or has ever been, excessively priced under s. 85 of the *Patent Act*.

35. According to Board Staff, given that the Guidelines are not binding on the Board and in light of Alexion's allegation that it would be "absurd" to apply the Guidelines in the present case, Dr. Addanki's economic analysis was made without regard to the Guidelines. Board Staff submits that the Guidelines are not the law and the Board's decision on whether a medicine is excessively priced must be guided by the *Patent Act* and the factors enumerated therein. Board Staff states that it is for this reason that Dr. Addanki's economic analysis focuses on the factors in the *Patent Act* rather than the Guidelines.

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[11] *Ibid.*

36. Board Staff submits that the Addanki Report looks at a "variety of economic considerations that may help inform the analysis" of whether the price of Soliris is excessive using an economic analysis of the various factors set out in s. 85 in the specific circumstances of the supply of Soliris.

37. Board Staff further submits that the Addanki Report does not offer an opinion on the scientific meaning of the words "therapeutic class" and "Alexion's argument that the Addanki Report uses the term 'therapeutic class' in a manner that is different than how it is used in the Guidelines or in other decisions of the Board, is not a basis for a finding that the report is not admissible. Alexion will obviously have the ability at the hearing on the merits to challenge the assumptions used in the Addanki Report and to disagree with the opinions and conclusions contained therein."[12]

b) The Schwindt Report

38. Alexion also submits that the Schwindt Report is not relevant as it addresses the concept of ERP. According to Alexion, ERP is not mentioned by Board Staff in the Allegations or the Amended Reply at all. Alexion does not object to the HIPC test specifically, or to the ERP concept generally. To the extent the Schwindt Report addresses ERP, Alexion argues that it raises a "straw man" issue because Alexion has never pled, or argued, that the ERP system was unreasonable. However, Alexion also submits that to the extent it deals with ERP issues, the Schwindt Report is irrelevant to the case as pleaded and should be struck.

39. Alexion submits that the first paragraph of the Schwindt Report explains in clear terms that he was asked to provide an "evaluation of Alexion's allegations" in the Amended Response. Alexion also submits that section 6 of the Schwindt Report asserts that Professor Schwint engages in an evaluation of the parties' legal positions and allegations, and that an expert may not provide what is, in essence, a legal assessment of the arguments of a party. Alexion states that is axiomatic that expert evidence that is directly argumentative on legal issues is neither relevant nor admissible.

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[12] Board Staff Written Submissions at 74.

40. Board Staff submits that section 6 of the Schwindt Report is responsive to paragraphs 15 to 27 of Alexion's Response which appear under the heading "Economic Analysis," and that the Schwindt Report is directly responsive to the economic analysis contained in these paragraphs, specifically the following:

a) Alexion's assertion in paragraph 17 of its Response that the term "price" is used by economists in different ways and that in real terms the price of Soliris has declined;

b) Alexion's assertion in paragraph 19 that economic agencies charged with making international price comparisons do not utilize the methods used by Board Staff since it results in errors;

c) Alexion's assertion in paragraph 20 that it is being placed in the position it finds itself as a result of the world's central bankers or other vagaries that cause international currency fluctuations;

d) Alexion's assertion in paragraphs 21 – 23 that it cannot be said that the price of Soliris has increased in Canada since patented drugs fall into a category described by economists as "non-traded goods";

e) Alexion's assertion in paragraph 26 that Board Staff's position expropriates revenues from Alexion based on foreign currency fluctuation and leaves Alexion to deal with the burden of a weak Canadian dollar and does nothing to protect purchasers; and

f) Alexion's assertion in paragraph 24 of its Response that the analysis done by Board Staff in this case does not make "economic sense" and leads to "perverse results".[13]

c) The IMS Data

41. Alexion submits that the IMS Data is irrelevant because the pleaded case refers exclusively to publicly available data used to make price comparisons and the IMS Data is private information purchased by Board Staff.

42. As noted above, the Schwindt Report refers to the IMS Data to indicate that "[u]sing prices determined by application of Board Staff's 2012 to 2014 Methodology or prices derived from IMS MIDAS data would not materially change [Professor

[13] Board Staff Written Submissions at 42 - 43.

Schwindt's] findings"[14]. Alexion is seeking to strike this reference and documents in Tabs 75, 76, 77 and 82 of Board Staff's Disclosure List of Documents.

43. Alexion submits that the HIPC test involves a comparison of "publicly available" prices. Alexion notes that the Statement of Allegations refers only to "publicly available" prices and any other non-public sources of pricing data, like the proposed IMS Data, are clearly irrelevant to the pleaded issues. Alexion submits that the IMS Data is also hearsay that can only be introduced through a proper witness who can explain how the data are collected and attest to the veracity of the data. Alexion also argues that the IMS Data is incomplete because it does not include Canadian information.[15]

44. Board Staff submits that an expert is entitled to rely upon hearsay evidence in forming their opinion. Further, s. 85 of the *Patent Act* does not require a Panel to only examine "publicly available prices". A Panel may consider prices from other sources and IMS data is routinely relied upon by Board Staff and has been considered by hearing panels in other cases.[16]

d) Timing of Admissibility Determination

45. Board Staff submits that the admissibility of expert evidence should be considered in the context of a full hearing in order that the decision-maker may have regard to all potential issues and evidence to be relied upon. Board Staff submits that a determination of admissibility at this stage is premature and refers the Panel to several cases in support of this submission, including, *Merck & Co. Inc. v. Canada (Minister of Health)* ("***Merck***"),[17] *Association des Crabiers Acadiens v. Canada (Attorney General)* ("***Crabiers Acadiens***"),[18] *Harrop v. Harrop* ("***Harrop***"),[19] *Ivetic v. State Farm Mutual*

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14 Schwindt Report, Appendix 2.

15 Alexion's Reply at 52 - 54.

16 Board Staff Written Submissions at 86 – 91.

17 2003 FC 1242 (CanLII).

18 2005 FC 1191 (CanLII).

19 2010 ONCA 390 (CanLII).

Automobile Insurance Co. ("***Ivetic***"),[20] and *White Burgess Langille Inman v. Abbott and Halliburton Co.* ("***White Burgess***").[21]

46. Alexion disagrees and submits that the cases referenced by Board Staff in support of the position that an admissibility determination is premature are distinguishable in the circumstances of this case. Alexion submits that in this case, "the 'issues' have all been established by the pleadings" and that "Board Staff are now attempting to introduce new issues that have not been pled by either party via the impugned opinions". Alexion therefore submits no additional context beyond the pleadings is needed to determine admissibility at this stage.[22]

47. Alexion also notes that in contrast with civil cases, where concerns are raised about interlocutory motions and trial proceedings before different adjudicators, proceedings before this Board are generally heard by the same panel from start to finish.[23]

48. Alexion directs the Panel to various cases, including *GlaxoSmithKline Inc. v. Apotex Inc.*[24] and submits that delaying the admissibility determination will cause it prejudice because it will be required to respond, at great cost, to issues that: (a) are irrelevant to pleaded matters before the Panel; (b) will unduly prolong the proceeding; and (c) confuse the issues to be addressed before the Board.[25]

e) Compliance with Rule 8(3) of the PMPRB Rules

49. Alexion also submits that Board Staff's expert evidence was defective because it did not include the affidavits required under Rule 8(3)(a) of the PMPRB Rules. Board Staff concedes that at the time the expert reports were filed, the requisite affidavits were

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20 2016 CarswellOnt 2671 (SCJ).

21 [2015] 2 SCR 182.

22 Alexion Reply at 31.

23 *Ibid* at 34.

24 (2003) FC 920.

25 Alexion Reply at 48.

not submitted. Board Staff subsequently filed affidavits from Dr. Addanki and Professor Schwindt with its written submissions on March 14, 2016.

50. However, Alexion continues to challenge the sufficiency of the affidavits filed by Board Staff on the basis that they do not comply with the requirements set out in Rule 8(3). Specifically, Alexion asserts at paragraph 55 of its Reply:

> Alexion's primary arguments relate to the admissibility of the expert reports under Rule 8(1) because the reports are not relevant to pleaded issues. Alexion also submits that the so-called "affidavits" delivered by Board Staff following commencement of this motion, did not comply with Rule 8(3). The "supporting" affidavit under the Rule (and required by the Scheduling Order) "must" address each requirement in the list under Rule 8(3)(a) either independently, or by reference to where each requirement is addressed in the report. Had there been compliance with the Rule in this case by Board Staff, readers of the supporting affidavit would become acquainted immediately with the Rule 8(3) criteria. In this case, the perfunctory affidavits filed by Board Staff fail to provide the reader with the information required in Rule 8(3). It is not clear whether the required information is addressed in the reports, or even whether the requirements in Rule 8(3) have been satisfied at all. Compliance with the Rule would also have assisted the Panel, and Alexion, in addressing admissibility under Rule 8(1).

Relevant Legislation

51. Rule 8 of the PMPRB Rules provides:

> 8(1) Expert witness evidence is not admissible in a proceeding before the Board in respect of any issue unless the issue has been raised in the pleadings or in a pre-hearing conference order or the expert witness evidence is called for the purpose of rebutting the evidence of an expert witness introduced by another party.
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> (2) More than two expert witnesses may not be called by a party, per issue, without leave of the Board.
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> (3) Every party who, in a proceeding before the Board, intends to introduce evidence given by an expert witness must

(a) file with the Secretary and serve on each of the parties in accordance with the Board's schedule of events, an expert witness report that is supported by an affidavit and that must include

(i) a statement of the issues addressed in the report,

(ii) a description of the qualifications of the expert with respect to those issues,

(iii) the expert's curriculum vitae attached to the report as a schedule,

(iv) the facts and assumptions on which the opinions in the report are based,

(v) a summary of the opinions expressed,

(vi) in the case of a report provided in response to another expert's report, an indication of the points of agreement and of disagreement with the other expert's opinions,

(vii) the reasons supporting each opinion expressed,

(viii) any literature or other documents specifically relied on in support of the opinions expressed,

(ix) a summary of the methodology on which the expert has relied;

(b) file with the Secretary and serve on each of the parties a signed Expert Witness Declaration in Form 1 set out in the schedule; and

(c) ensure that the expert witness is available for examination and cross-examination at the hearing.

(4) Examination in chief of any expert witness may not, without the Board's consent, exceed 90 minutes.

52. Sections 85(1) and (2) of the *Patent Act* provide:

> 85(1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (a) the prices at which the medicine has been sold in the relevant market;
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> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
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> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
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> (d) changes in the Consumer Price Index; and
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> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.
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> (2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:
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> (a) the costs of making and marketing the medicine; and
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> (b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

Analysis

53. Alexion submits that all or portions of the expert reports filed by Board Staff should be struck on the basis that they are irrelevant as the issues they address are not explicitly raised in the pleadings. Alexion refers the Panel to Rule 8(1) of the PMPRB Rules which provides that expert evidence "is not admissible in a proceeding before the

Board in respect of any issue unless the issue has been raised in the pleadings or in a pre-hearing conference". Further, Alexion takes the position that the reports are inadmissible because they go to the ultimate legal issue in dispute between the parties.

54. One of the consistent issues raised in the interlocutory motions to date is the proper scope of the current proceeding before the Board. According to Alexion, the Statement of Allegations is confined to two issues: (1) the allegation that Alexion has been selling Soliris in Canada at the highest international price among the comparator countries; and (2) that Alexion has been selling Soliris at a price in Canada that is appreciably higher than in the United States. Alexion submits that there is no reference whatsoever in the Statement of Allegations to any other factor in s. 85(1), in particular to comparators or "therapeutic classes", or other references to the factors in 85(1)(b) or (c) of the *Patent Act*.

55. Board Staff disagrees and contends that it has consistently adopted the position that an application of all of the factors set out in section 85 of the *Patent Act* demonstrates that Soliris is being or has been sold at an excessive price in Canada. Board Staff submits that its case is not confined to any given factor, such as a consideration of the highest international price among comparator countries as set out in subsection 85(1)(c).[26]

56. The Panel agrees with Alexion that in many respects, the Statement of Allegations filed by Board Staff lacks the level of particularity with respect to the specific allegations addressed in the expert reports that may have been preferable in the circumstances. However, the Statement of Allegations does contain a number of express references to the fact that Board Staff's allegations are not limited to any single factor under section 85, such as 85(1)(c), but involves a consideration of all of the factors set out in section 85.

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[26] Board Staff's Written Representations in response to Alexion's Motion for Particulars, dated June 5, 2015, at 34(f).

57. The Panel agrees with the position of Board Staff that the hearing is a fresh opportunity for the Panel to determine whether the price of Soliris is excessive. The Panel also agrees with Board Staff that the Guidelines are not binding on the Panel. This does not mean that the Panel will disregard the Guidelines in its determination, but ultimately, the Panel is bound to consider the factors outlined in sections 85(1) and (2) of the *Patent Act* in making a determination of whether the price for Soliris is excessive.

58. To the extent that any doubt remained on these issues, the Panel addressed the scope of the proceeding in reasons issued on November 24, 2015 regarding a number of procedural motions. In that decision, the Panel held that "evidence regarding both subsections 85(1) and 85(2) of the *Patent Act* is admissible in this proceeding" and that the "Panel therefore anticipates that the parties will make representations and adduce evidence with respect to the factors listed in subsections 85(1) and 85(2) of the *Patent Act*".

59. On this basis, expert or other evidence relating to any of the factors outlined in section 85 of the *Patent Act* is relevant to the matters at issue in this proceeding.

60. In the Panel's view, the primary issue to be determined is whether the decision to determine the admissibility of the expert reports should be made at this stage of the proceeding. Based on the discussion below, the Panel is of the view that the admissibility and weight to be assigned to the expert reports should be decided at the hearing on the merits in the context of the full evidentiary record.

a) Timing of Admissibility Determination

61. The Panel has broad discretion with respect to the admissibility of evidence as set out in Rule 6(1)(a) of the PMPRB Rules: "In relation to any proceeding, the Board may receive any evidence that it considers appropriate".

62. Although this Panel is not strictly bound by the decisions of Canadian courts which deal with other statutes, or civil cases, the Panel has considered case law for guiding principles on this issue to arrive at its decision.

63. Expert evidence should only be struck at this stage of the proceeding if it is *prima facie* irrelevant to the issues in dispute. There are various Canadian cases which stand for the proposition that a determination of admissibility should be made at this stage only in the "rarest of cases" where there is a risk of irreparable prejudice.

64. In *Merck*,[27] the applicant sought an order striking out all or part of affidavits, many of which were expert affidavits, in the context of a proceeding under the *Patented Medicines (Notice of Compliance) Regulations*. The Court agreed with the following principle from previous decisions, at paragraph 3:

> Nonetheless, I would emphasize that motions to strike all or parts of affidavits are not to become routine at any level of this Court. This is especially the case where the question is one of relevancy. Only in exceptional cases where prejudice is demonstrated and the evidence is obviously irrelevant will such motions be justified.

65. This reasoning is consistent with the decision of the Ontario Court of Appeal in *Harrop*, where the Court notes that judges should generally refrain from exercising jurisdiction to strike out expert evidence in advance of the hearing on the merits, except in very exceptional circumstances.

66. The decision to determine admissibility at this stage is a discretionary one. In deciding a motion to strike two expert affidavits filed by the plaintiffs in support of their application for a class action certification, the Court in *Andersen v. St. Jude Medical Inc.* noted: "[i]n civil cases, the court will often be entitled to admit evidence conditionally and a decision whether to deal with questions relating to the admissibility of the contents of affidavits in advance on a motion to strike, or to defer the question to the hearing of the motion or application for which the evidence is tendered, must, I believe, lie in the court's discretion."[28]

67. In the Panel's view and as discussed above, Board Staff's expert evidence is not obviously irrelevant and these are not exceptional circumstances which warrant the

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[27] This case was reversed on other grounds, 2003 FC 1511.

[28] [2002] OJ No 4478, at 17.

striking of the expert evidence. Board Staff's evidence relates broadly to section 85 of the *Patent Act*. The evidence addresses the reasonability of the Guidelines, or in the alternative, presents a different economic interpretation of the factors outlined in section 85(1) of the *Patent Act*.

68. Alexion seeks to distinguish the cases relied upon by Board Staff on the basis that many of the considerations for deferring the admissibility determination relate to circumstances where there is a different judge hearing the interlocutory motion than the judge presiding over the trial.

69. In *Ivetic*, the plaintiff brought a motion to exclude expert evidence proposed by the defendant, which was dismissed. The judge hearing the motion was also the same judge that had been assigned to preside over the trial and held:

> 10 In the present case, although I have been assigned by the Regional Senior Justice to preside over the trial, the trial has not commenced. The plaintiff's motion is interlocutory in nature. Accordingly, the same policy considerations, identified by the Court of Appeal in *Harrop* and applied in *Forbes*, as pointing to the question being determined at trial, apply to this case.
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> 11 Based upon a careful review of the plaintiff's position as set forth in her extensive Factum and augmented by her counsel's oral submissions, I am not satisfied that this is one of the "rarest of cases" which would justify making a ruling on the admissibility of expert evidence on an interlocutory motion prior to trial. Although I have been assigned as the trial judge, it is not beyond the realm of possibility that circumstances may prevent me from presiding over the trial. Moreover, the issues raised by the plaintiff in her motion represent "a smaller part of a larger whole" (as termed by Justice Ratushny), such that the questions of the admissibility and scope of the defence expert medical evidence should be determined in the larger context of the evidence at trial.

70. The issues raised by Alexion also represent a "smaller part of a larger whole". It does not follow that because the pleadings do not explicitly address the points raised in the expert reports filed by Board Staff, that the evidence in issue is irrelevant and inadmissible.

71. The issues in this proceeding are complex. Board Staff alleges that it is not bound by the Guidelines but a direct application of the Guidelines results in a finding that the price of Soliris is excessive under sections 83 and 85 of the *Patent Act*. Alexion disputes this finding and takes issue with the application of the Guidelines in this case.

72. As noted above, the Schwindt Report address the use of external reference pricing (ERP) to set ceilings on prices of patented drugs and evaluates Alexion's allegation that the current methodology, as set out in the Guidelines is inappropriate for its product Soliris.

73. The Addanki Opinion addresses the following two questions:

i. What economic measures, tests and considerations should be considered to be appropriate to the question of whether the price of Soliris in Canada is or has ever been excessive under s. 85 of the *Patent Act*; and

ii. Whether the application of the economic measures, test and considerations in Question 1 indicates that the price of Soliris in Canada is or has ever been excessive.

74. These expert reports are not "obviously irrelevant" to the issues between the parties. In the view of the Panel, it would be premature to strike these reports at this stage of the proceeding. The admissibility of the reports and the weight to be assigned to their content is better left to the hearing on the merits of the proceedings, in the context of the full evidentiary record.

75. Based on the reasons above, the Panel is of the view that the admissibility of expert evidence should be considered in the context of the full hearing. This determination is without prejudice to Alexion's right to challenge both the admissibility and the weight to be assigned to the expert reports at the hearing on the merits. The panel is aware of the test for admissibility of expert evidence as set out by the Supreme Court of Canada in *R v Mohan*[29] and subsequent decisions, but because of its decision to defer the issue of admissibility and weight to the hearing on the merits, the Panel, as in *Ivetic*, "decline[s] to go further in carrying out an analysis of the [Respondent's']

[29] [1994] 2 SCR, as clarified in *R v J-LJ*, [2000] 2 SCR and *WBLI v Abbott and Haliburton*, [2015] 2 SCR.

detailed position with respect to the admissibility and scope of the… expert evidence so as not to prejudice the consideration of these matters at trial."[30]

76. Further, with respect to the reference to IMS Data in the Schwindt Report, the Panel notes that there is ample support in case law for the proposition that expert reports may be based on hearsay or second-hand evidence; see, for example: *R v Lavallee*[31] and *Mazur v Lucas*.[32] The Panel also notes that there is no limitation in section 85 of the *Patent Act* and in the Regulations which restrict or prohibit the consideration by the Panel of private pricing information, such as IMS Data. The IMS Data is not obviously irrelevant to the issues in dispute between the parties and any weight to be given to this evidence should be considered in the context of the full hearing and with the benefit of the full evidentiary record.

77. Alexion also submits that Board Staff's expert evidence seeks to address the ultimate legal issue before the Panel and should be struck on that basis. The Panel notes that the main concern which the "ultimate issue rule" seeks to address is that an expert should not usurp the function of the trier of facts. The Supreme Court of Canada in *R v Burns* noted "[w]hile care must be taken to ensure that the judge or jury, and not the expert, makes the final decisions on all issues in the case, it has long been accepted that expert evidence on matters of fact should not be excluded simply because it suggests answers to issues which are at the core of the dispute before the court."[33]

78. The fact that an expert report may touch on the ultimate legal issue is thus not sufficient grounds to strike the evidence. Canadian appellate courts have noted that

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30 *Ivetic*, at 12.

31 1990 Canlll 95 (SCC).

32 2010 BCCA 473 (BCCA).

33 1994 CanLII 127 (SCC), [1994] 1 SCR 656 at 666.

"one may conclude that there is no general rule that opinion evidence on the ultimate issue must be rejected"[34]. This Panel is aware of its role in this proceeding as the trier of facts. In fact, the Addanki Report explicitly acknowledges that "the ultimate determination of whether or not a given price is excessive lies within the purview of the PMPRB".

b) Compliance with Rule 8(3) of the PMPRB Rules

79. The Panel will also deal briefly Alexion's argument that the expert evidence is not in compliance with Rule 8(3) of the PMPRB Rules.

80. The Panel agrees with Alexion that when Board Staff filed its expert reports, they were defective in form because they did not include the necessary affidavits as required in Rule 8(3). Board Staff has since filed affidavits attaching the previously filed expert reports.

81. Alexion submits that the expert reports are still defective and that it is the affidavit which must include all of the necessary components set out in Rule 8(3) "either independently, or by reference to where each requirement is addressed in the report. Alexion states that had there been compliance with the Rule in this case by Board Staff readers of the supporting affidavit would become acquainted immediately with the Rule 8(3) criteria."

82. The Panel is satisfied that the filed affidavits satisfy the substantive elements of Rule 8(3). Both expert reports provide a statement of the issues addressed in the report, a description of the qualifications of the expert, the *curriculum vitae* for each expert, a summary of the opinion, references to the literature and other documents relied upon in support of the opinions expressed and a description of the methodologies applied by the experts.

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[34] *Parker v. Saskatchewan Hospital Association (c.o.b. Saskatchewan Association of Health Organizations)*, 2001 SKCA 60 (CanLII) at 179.

83. Alternatively, to the extent that the expert reports do not comply with Rule 8(3), such noncompliance would be a defect of form only. The Panel has broad discretion with respect to matters of form and procedure. Rule 6(1)(e) provides that the Panel may decide any question of procedure, and Rule 5(3) provides that for "the purpose of ensuring the fair and expeditious conduct of any proceeding, the Board may vary, supplement or dispense with any requirement set out in these Rules."

c) Extension of Time to File Responding Reports

84. The original deadline for Alexion to file its responding expert reports, as set out in the Scheduling Order issued on consent, was March 16, 2016. At a conference call in respect of this motion held on March 4, 2016, the Panel, with mutual consent of the parties and pending the hearing and decision of this motion, extended the deadline for Alexion to file its expert reports to March 31, 2016.

85. Notwithstanding the Panel's decision to defer the issue of admissibility of, and weight to be assigned to, expert evidence to the hearing on the merits, the Panel recognizes however that given the nature of the points raised in Board Staff's expert reports, Alexion should be granted additional time to file its responding expert reports. Board Staff advised at the hearing that it would consent to an extension of the deadline for Alexion to file its expert reports by an additional 30 days.

86. Such an extension will not require any change to the hearing dates established for this matter. The Panel therefore grants the Respondent an additional 30 days to file responding expert reports, extending the original deadline to April 18, 2016.

Conclusion and Order

87. Based on the foregoing reasons, the Panel makes the following Orders:

(a) Alexion's motion is dismissed, without prejudice to Alexion's right to challenge both the admissibility and the weight to be assigned to any of the expert evidence at the hearing on the merits;

(b) Alexion shall serve and file responding expert reports on or before April 18, 2016;

(c) Board Staff shall serve and file any reply expert reports on or before May 13, 2016; and

(d) The remainder of the schedule, including the hearing dates, shall remain as previously established in the Scheduling Order issued by the Panel on December 7, 2015.

Dated at Ottawa, this 29th day of March, 2016.

Original signed by Dr. Mitchell Levine

Signed on behalf of the Panel by Dr. Mitchell Levine

Panel Members:
Dr. Mitchell Levine
Carolyn Kobernick
Normand Tremblay