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. ("Respondent") and the Medicine "Soliris"

WRITTEN SUBMISSIONS OF BOARD STAFF
(Alexion's Motion to Strike Expert Evidence as Inadmissible)

I. OVERVIEW

1. Soliris is one of the most expensive drugs in the world. The cost of the medicine can be up to $700,000.00 annually. Patients who are prescribed Soliris must take the medicine for the rest of their lives. Board Staff allege that Soliris is excessively priced.

2. From the very beginning of this litigation Alexion has mischaracterized the issues involved as being based solely on s. 85(1)(c) of the *Patent Act* ("the *Act*") and the application of the Highest International Price Comparison ("HIPC") test found in the Guidelines. In particular, Alexion has alleged that the price of Soliris is excessive under the Guidelines solely as a result of international currency fluctuations.

3. By a letter dated April 23, 2015 counsel for Board Staff confirmed that it did not allege that the price of Soliris was excessive because of foreign exchange rates.

Rather, it alleged that Soliris was excessively priced based on all of the factors set out in s. 85 of the *Act*.

4. The present motion by Alexion to exclude the expert evidence is yet another attempt to mischaracterize the issues involved in this matter. It is an attempt to prevent Board Staff from leading evidence and making argument on why Soliris is excessively priced having regard to all of the factors set out in s. 85(1) of the *Patent Act*, namely:

> **(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.

5. The motion ought to be dismissed. Moreover, issues relating to the admissibility of expert evidence and the weight to be assigned to same should only be determined in the context of a full hearing of this case on its merits.

II. ADMISSIBILITY OF EXPERT EVIDENCE SHOULD BE DETERMINED AT HEARING ON MERITS

6. Alexion is making this application prior to providing any of the expert or other evidence that it intends to rely upon. It is asking this Board to make an admissibility determination in a vacuum. Board Staff submits that it is only in the

context of understanding all of the evidence and issues that the Board will be in a position to determine matters of weight or reliability of the expert evidence.

7. 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.

> ***Merck & Co. Inc. v. Canada (Minister of Health)*, 2003 FC 1242 (CanLII), [Merck], rev'd on other grounds 2003 FC 1511, Board Staff's Authorities Brief, Tab 10**
> ***Association des Crabiers Acadiens v. Canada (Attorney General)*, 2005 FC 1191 (CanLII) [Crabiers Acadiens], Board Staff's Authorities Brief, Tab 5**
> ***Harrop v. Harrop*, 2010 ONCA 390 (CanLII)[Harrop],Board Staff's Brief,Tab 7**
> ***Ivetic v. State Farm Mutual Automobile Insurance Co.*, 2016 CarswellOnt 2671 (SCJ) [Ivetic], Board Staff's Authorities Brief, Tab 8**
> ***White Burgess Langille Inman v. Abbott and Halliburton Co.*, [2015] 2 SCR 182 [White], Board Staff's Authorities Brief, Tab 20**

8. In *Merck*, the applicant sought an order striking out all or part of affidavits, many of which were expert affidavits, in the context of *Patented Medicines (Notice of Compliance) Regulations*. The Court agreed with the following principle from previous case law, 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.

9. In *Crabiers Acadiens*, the respondent moved to strike out certain paragraphs of an expert affidavit. The Court refused to strike out the expert affidavit in the absence of evidence that it was abusive or would cause prejudice. At paragraph 11, the Court stated:

> For all these reasons, I consider that the admissibility of Mr. Haché's affidavit and the weight to be given to it should be left to the appreciation of the judge who hears the judicial review on the merits. That judge will have a more complete record available. For instance, that judge would be in a better position to determine whether expert evidence should be receivable on this application and what weight should be given to Mr. Haché's opinion, given that he has been closely connected with some of the applicants.

10. In *Harrop*, the Ontario Court of Appeal 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. At paragraph 2;

> In our view, the policy considerations relevant to this issue all point to the trial judge determining this question. It avoids the risk of a multiplicity of proceedings in any given case. It ensures a full context in which the decision can be made. It avoids the risk of preliminary steps being taken for purely tactical reasons.

11. In *Ivetic* a plaintiff brought a motion to exclude expert evidence proposed by the defendants. The trial judge noted that although the *Harrop* decision was determined in the context of a motion, the policy considerations outlined in that case applied to an interlocutory application to a trial judge as well, noting at paragraph 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.

12. The judge went on to hold 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."

13. In *White* the Supreme Court of Canada upheld the decision of the Nova Scotia Court of Appeal, which found that a motion judge erred by striking out the affidavit of an expert on a summary basis in the context of a claim of negligence against financial auditors of a company. The Court noted that the decision was made on a summary judgment motion where a judge may not weigh evidence, draw reasonable inferences from the evidence or settle matters of credibility. At paragraph 55 the court held as follows:

> I must say a brief word about the procedural context in which this case originates — a summary judgment motion.... It is common ground that the court hearing the motion can consider only admissible evidence. However, under the Nova Scotia jurisprudence, which is not questioned on this appeal, it is not the role of a judge hearing a summary judgment motion in Nova Scotia to weigh the evidence, draw reasonable inferences from evidence or settle matters of credibility: ... Taking these two principles together, the result in my view is this. A motions judge hearing a summary judgment application under the Nova Scotia rules must be satisfied that proposed expert evidence meets the threshold requirements for admissibility at the first step of the analysis, but should generally not engage in the second step cost-benefit analysis. That cost-benefit analysis, in anything other than the most obvious cases of inadmissibility, inevitably involves assigning weight — or at least potential weight — to the evidence.

14. The Supreme Court of Canada has therefore recognized that in order to determine whether the probative value of the proposed expert evidence is outweighed by other trial considerations it will be necessary to review and weigh the evidence within the context of the issues that arise at the hearing.

15. It is notable that in the *Sandoz* case relied upon by Alexion, the Board was not dealing with an issue of excessive prices, but was dealing with the issue of whether or not the Respondent was a patentee pursuant to the Act. It is clear that the Board had all relevant evidence prior to making the decision as to whether it

ought to rely upon certain portions of the evidence. It is also notable that the Board treated the question about this evidence as a matter of whether the evidence should ultimately be relied upon, and not whether it was admissible.

III. COMPLIANCE WITH RULE 8(1)

16. The Board's Scheduling Order directed Board Staff to file their expert reports by February 16, 2016. Board Staff complied with that requirement by serving and filing the expert reports of Professor Schwindt ("the Schwindt Report") and Dr. Addanki ("the Addanki Report") on February 16, 2016. Both of these experts have signed the necessary Expert Witness Declaration required by the Rules.

17. Professor Schwindt is a highly qualified economist who holds a Ph.D. He has published widely. He has testified as an expert before courts and tribunals, including this Board.

18. Professor Schwindt's report contains his opinion from an economic perspective regarding the use of "external reference pricing" to set ceiling prices on patented drugs[1]. In particular, Professor Schwindt provides his economic opinion on the appropriateness of the methodology set out in the Guidelines for evaluating the price of Soliris.

[1] "external reference pricing" involves the use of prices in other national jurisdictions to condition prices and price changes domestically.

19. Dr. Addanki is also a highly qualified economist who holds a Ph.D. He too has published widely. Dr. Addanki has been qualified as an expert witness in several jurisdictions.

20. 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 *Act*. Given that the Guidelines are not binding on the Board, Dr. Addanki's economic analysis was made without regard to the Guidelines.

21. On February 26, 2016, Alexion served a Notice of Motion to strike the expert reports. The motion to strike did not allege that Board Staff had not complied with Rule 8. Moreover, contrary to Rule 25, Alexion did not serve any written representations with the motion.

22. Board Staff requested that Alexion comply with the Rules and file written representations. Board Staff also requested a conference call with the hearing panel ("the Hearing Panel") to address the scheduling of the matter and the requirement for Alexion to file written representations in support of its motion.

23. On March 4, 2016 the requested conference call was held. During the conference call, for the first time, Alexion alleged that Board Staff had not complied with Rule 8 since the expert reports were not appended to affidavits.

Board Staff was surprised by the assertion since it had never been raised previously.

24. In light of Alexion's request, Board Staff has now also served an affidavit from each of its experts attaching their reports. (The affidavits contain no substantive information. The affidavits merely attach the identical reports that were previously served on February 16, 2016.)

25. It is clear that Board Staff complied with the spirit of Rule 8 by serving its expert reports on February 16, 2016. The failure to attach the report to an affidavit was at its highest, a defect in form. Rule 5(1) makes it clear that such a defect is not significant.

26. Alexion asserts in paragraph 19 of its Written Representations that Board Staff did not comply with Rule 8(3) because the affidavit accompanying the report did not include the following items:

(a) a statement of the issues;

(b) a description of the expert's qualifying with respect to those issues;

(c) the facts and assumptions on which the opinions in the report are based;

(d) a summary of the opinions expressed;

(e) the reasons supporting each opinion expressed;

(f) any literature or other documents specifically relied on in support of the opinions expressed; and

(g) a summary of the methodology on which the expert has relied.

27. Paragraph 19 of Alexion's Written Representations is deliberately misleading. It selectively leaves out some of the words used in Rule 8(3) which make it clear that it is the report must contain these matters and not the affidavits. The full text of Rule 8(3) is set out below.[2]

> **Report, declaration and availability**
> **(3)** Every party who, in a proceeding before the Board, intends to introduce evidence given by an expert witness must
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> **(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
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> **(i)** a statement of the issues addressed in the report,
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> **(ii)** a description of the qualifications of the expert with respect to those issues,
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> **(iii)** the expert's curriculum vitae attached to the report as a schedule,
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> **(iv)** the facts and assumptions on which the opinions in the report are based,
>
> **(v)** a summary of the opinions expressed,
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> **(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;

28. It is clear that when reviewed in context, the meaning of Rule 8(3)(a) is that it is the expert report that must contain the elements outlined in subsections (i) to (ix) of Rule 8(3)(a) and not the affidavit. The Addanki Report and the Schwindt Report meet all of these requirements.

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[2] We have underlined the words omitted by Alexion in paragraph 19 of its Written Representations.

IV. ISSUES RAISED IN EXPERT REPORTS ARE RELEVANT TO THE PLEADINGS

29. The test for admissibility of expert evidence is set out in Rule 8(1). It provides that expert reports must be relevant to an issue raised in the pleadings. As noted below, both expert reports clearly address issues raised in the pleadings.

(1) The Addanki Report

30. The assertion that the Addanki Report is inadmissible because it is not based on allegations in the pleadings is based upon Alexion's repeated insistence that the only issue raised in this litigation is s. 85(1)(c) of the *Act* and the application of the HIPC test. However this has never been the position of Board Staff.

31. Board Staff has consistently advised Alexion that its position is that Soliris is excessively priced based on all of the factors contained in s. 85(1). This is reflected in the pleadings, correspondence and all of the previous motions. To this end the Addanki Report contains an economic analysis of the various factors set out in s. 85 and how they apply to Soliris.

32. Alexion's assertion that it is "undisputed" that the price of Soliris was not considered excessive by Board Staff prior to 2012 is erroneous. Paragraph 14 of the Statement of Allegations asserts that the introductory price of Soliris in Canada exceeded the median of the international prices among the comparator countries, but that it did not trigger the criteria used by Board Staff for continuing the investigation. In paragraph 5 of its Amended Reply, Board Staff asserts that

Alexion deliberately priced Soliris at introduction above the ceiling price under the Guidelines. Contrary to the assertion of Alexion, Board Staff did not deem that the introductory price of Soliris was non-excessive.

33. Paragraphs 6-8 of the Amended Reply of Board Staff specifically note that Board Staff has not alleged that the price of Soliris is excessive due to changes in exchange rates. Rather, Board Staff noted that the price of Soliris was excessive based on all of the factors set out in s. 85(1) of the *Act*. Board Staff further noted that the Guidelines were not binding on the Board during a hearing and that the purpose of a hearing was a fresh opportunity for the Board to determine whether a medicine was excessively priced.

34. Alexion also objects to the Addanki Report because it disregards the Guidelines. This is a rather surprising argument by Alexion given its own assertion in paragraph 13 of its Amended Response that the Guidelines should not be applied. Paragraph 13 states "The Allegations demonstrate the absurdity of applying the Guidelines in this case."

35. Section 96(4) of the *Act* is clear – the Guidelines are not binding on the Board or on a patentee. The Guidelines are not the law and the Board's decision on whether a medicine is excessively priced must be guided by the *Act* and the factors enumerated therein. It is for this reason that Dr. Addanki's economic analysis focuses on the factors in the *Act* rather than the Guidelines.

***Teva Neuroscience G.P.-S.E.N.C. v. Canada (Attorney General), 2009* FC 1155 at para. 30, Board Staff's Authorities Brief, Tab 19**

36. The jurisprudence has established that although a hearing panel may apply the Guidelines where appropriate, it is not required to do so. Its overall duty when considering an issue of excessive pricing is to apply the provisions of the *Act*. Where it is not convinced that the Guidelines are appropriate in a particular circumstance, the Board may depart from the Guidelines, in whole or in part.

> ***PMPRB-06-D3-ADDERALL XR – Merits*, April 10, 2008 [Adderall Merits], Board Staff's Authorities Brief, Tab 11**

37. The Amended Reply filed by Board Staff specifically noted that expert evidence may be relied on to support its allegation that the price of Soliris is and has been excessive under the *Act*.

38. The Addanki Report looks at a "variety of economic considerations that may help inform the analysis" of whether or not the price of Soliris is excessive. In doing so Dr. Addanki looks at the specific economic issues surrounding the drug Soliris.

39. The Addanki Report also analyzes the disparity between the Canadian price of Soliris with the U.S. price – a fact which Dr. Addanki finds to be "striking and informative" given that Canadian prices of pharmaceuticals tend to be substantially less than in the United States, a jurisdiction which typically does not regulate prices. Dr. Addanki's analysis is relevant in light of the assertions in the Statement of Allegations that there is a significant disparity between the Canadian and U.S. price of Soliris.

40. The Addanki Report also analyzes the price of Soliris relative to other medicines that also have Orphan Drug designation. The Statement of Allegations of Board Staff specifically notes that Soliris has received Orphan Drug Designation in the United States.

41. The fact that the Addanki Report compares the price of Soliris to other Orphan Drugs that are similar from an economic perspective to Soliris is therefore directly relevant to matters raised in the pleadings.

(2) The Schwindt Report

42. Alexion asserts that section 6 of the Schwindt Report is inadmissible since it responds to legal arguments. This is incorrect. This section of the Schwindt Report is responsive to paragraphs 15-27 of Alexions Response which appears under the heading "Economic Analysis". The Schwindt Report is directly responsive to the economic analysis contained in these paragraphs.

43. The following economic issues and arguments that were raised in Alexion's Response are addressed in the Schwindt Report:

(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 word'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.

(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".

V. COURT REQUIREMENTS FOR EXPERT EVIDENCE ARE NOT APPLICABLE TO ADMINISTRATIVE TRIBUNALS

44. The powers of the Board to receive evidence are set out in Rule 6(1)(a) of the Board Rules, as follows:

> **Board powers**
> 6(1) In relation to any proceeding, the Board may
> (a) receive any evidence that is considers appropriate;

45. The Board is entitled to receive any evidence that it considers appropriate. The strict rules of evidence that are enforced in court hearings are not appropriate in the context of hearings before administrative tribunals. It is not necessary for a tribunal to qualify an expert relying on the same factors that are required by courts. Any issue with respect to the reliability of expert evidence may go to weight, not admissibility, of expert evidence in tribunal hearings.

> **Sara Blake, *Administrative Law in Canada*, 5th edition (Toronto: LexisNexis Butterworths, 2011) [Blake], Board Staff's Authorities Brief, Tab 22**
> **David Phillip Jones, N.S. deVillars, *Principles of Administrative Law*, 6th edition (Toronto: Carswell, 2014) [Jones and deVillars] at p. 318, Board Staff's Authorities Brief, Tab 21**
> ***Alberta (Workers' Compensation Board) v. Appeals Commission)*, 2005 ABCA 276 (CanLII) [Alberta WCB], Board Staff's Authorities Brief, Tab 2**
> ***Alberta (Securities Commission) v. Workum*, 2010 CarswellAlta 2478 (C.A.) [Workum], Board Staff's Authorities Brief, Tab 1**
> ***Canadian Recording Industry Association v. Society of Composers, Authors and Music Publishers of Canada*, 2010 FCA 322 (CanLII) [Cdn Recording Industry], Board Staff's Authorities Brief, Tab 6**

46. In *Blake*, the author notes at page 63:

> Relevant expert evidence is admissible. Any frailties in the facts or hypotheses upon which an opinion is based, or in the qualifications of the expert, affect the weight of the evidence but not its admissibility, but an opinion of an expert who is biased and not objective may be rejected. ... [Footnotes omitted.]

47. In *Jones and deVillars*, the authors note as follows at page 318:

> Relevant expert evidence is admissible. Before administrative tribunals, the admissibility criteria for expert evidence outlined in *R. v. Mohan* arguably does not apply. However, a consideration of the *Mohan* elements may lead to the tribunal according more or less weight to the evidence.

48. In *Alberta WCB*, the Workers' Compensation Appeals Commission had received expert evidence relating to "brain mapping" testing. On appeal, the appellant claimed that the Appeals Commission's failure to embark upon an inquiry as to the reliability or scientific validity of brain mapping and the qualifications of the expert was an error. The Alberta Court of Appeal rejected this approach, holding at paragraphs 62 and 63:

> The WCB's second argument is that the Appeals Commission erred in failing to apply the test for admission of expert evidence outlined by the Supreme Court in *R. v. Mohan*, 1994 CanLII 80 (SCC), [1994] 2 S.C.R. 9 at para. 17. ...
>
> This argument departs from established principles of administrative law. As a general rule, strict rules of evidence do not apply to administrative tribunals, unless expressly prescribed: **...**While rules relating to the inadmissibility of evidence (such as the *Mohan* test) in a court of law are generally fixed and formal, an administrative tribunal is seldom, if ever, required to apply those strict rules: *Practice and Procedure before Administrative Tribunals* at 17-11. "Tribunals are entitled to act on any material which is logically probative, even though it is not evidence in a court of law": ...

49. The Court observed that even in the absence of a specific legislative directive indicating that the usual rules of evidence do not apply, the common law has established that the normal rules of evidence do not apply in the context of a tribunal hearing.

50. In *Workum*, the Alberta Securities Commission had received the evidence of an expert without reference to the *Mohan* criteria. The Alberta Court of Appeal rejected the appellant's claim that the *Mohan* criteria should have been applied despite the fact that the laws of evidence applicable to courts did not apply to the Commission. The Court held at paragraph 83:

> On the contrary, the decision of this court in *Alberta (Workers' Compensation Board) v Appeals Commission*, 2005 ABCA 276 (CanLII), 371 AR 318, suggests that *Mohan* has no application in administrative hearings. In that case, the WCB argued that the Appeals Commission failed to properly qualify an expert and therefore his evidence should not have been used in the decision. Even though the *Workers' Compensation Act*, RSA 2000, c W-15, did not have a specific provision excepting the rules of evidence, this court found that a rule of general application was that the rules of evidence do not apply in administrative proceedings.

51. In *Cdn Recording Industry*, the appellant alleged that the Copyright Board of Canada erred in relying upon the evidence of an expert in the face of conflicting fact evidence and expert evidence to the contrary. The Federal Court of Appeal noted that, as a general proposition, the rules of evidence do not apply to tribunals, and that the guiding principle with respect to the admission of evidence, including expert evidence, in the context of an administrative tribunal was the concept of procedural fairness.

52. The Court observed that even though there was not a specific provision exempting the Board from the rules of evidence applicable in a court proceeding, the general rules did not apply. The Court held at paragraph 16:

> When a challenge to a tribunal's decision is based upon an alleged failure to comply with the rules of evidence, without a concomitant allegation that the applicant has thereby been deprived of procedural fairness, the Court should proceed with caution lest the formal argument with respect to the rules of evidence displaces the substantive principle which is procedural fairness.

53. The Court considered the issue of procedural fairness with respect to the expert report and concluded at paragraph 27:

> It is equally clear from these paragraphs that CRIA enjoyed full rights of procedural fairness with respect to this evidence: it had notice of Professor Liebowitz's report; it was given the opportunity to cross-examine Professor Liebowitz; and it was also able to call evidence to contradict aspects of the Professor's evidence. To the extent that evidentiary questions are an aspect of procedural fairness, there is no basis in procedural fairness to challenge the manner in which the Board dealt with this evidence.

54. Although the appellant alleged that the Board acted on assumptions made by the expert, the Court noted that the "assumptions" could equally be characterized as conclusions based on the established facts. The conclusions were evidence that the Board could act upon. The Court concluded on this ground of appeal at paragraph 31:

> To sum up, the Board was not bound by the rules of evidence and did not err by failing to apply those rules to the evidence which was put before it. There was an evidentiary foundation for the conclusions which it drew so that it cannot be said that it erred in law in drawing its conclusions upon no evidence at all. In the result, CRIA's arguments on this issue fail.

55. The admission of expert evidence is governed by the rules of procedural fairness. Alexion was put on notice at the beginning of this litigation that Board Staff would be relying upon expert evidence. The expert evidence has been filed in a timely fashion, thereby permitting Alexion to file responding expert evidence. Moreover, Alexion will have full opportunity to cross-examine Dr. Addanki and Professor Schwindt at the hearing.

56. Alexion has demonstrated no prejudice from the expert evidence and has not provided any rationale for deviating from the Board's Scheduling Order.

VI. IN ANY EVENT THE EXPERT EVIDENCE MEETS ALL THE *MOHAN* FACTORS

57. Even if it was necessary for the Hearing Panel to apply the *Mohan* factors (which Board Staff submits it is not), the expert reports meet the criteria outlined in *Mohan*.

(1) Relevance

58. In order to meet the *Mohan* criteria, expert evidence must have logical relevance to a fact in issue.

> ***R. v. Mohan*, [1994] 2 SCR 9 [Mohan], at p. 10 (cited to CanLII),Board Staff's Authorities Brief, Tab 18**

59. The Addanki Report and the Schwindt Report are both related to economic issues raised in the pleadings and therefore meet the relevance threshold.[3]

(2) Necessity

60. In order for expert evidence to be considered necessary, it should provide evidence outside of the experience and knowledge of the decision-maker.

> ***Mohan, supra*, at p. 23, Board Staff's Authorities Brief, Tab 18**

61. In *Mohan*, Sopinka J., for the Court, noted at page 12 (cited to CanLII):

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[3] See Section IV, paras. 29-43 above

> This pre-condition is often expressed in terms as to whether the evidence would be helpful to the trier of fact. The word "helpful" is not quite appropriate and sets too low a standard. However, I would not judge necessity by too strict a standard. What is required is that the opinion be necessary in the sense that it provide information "which is likely to be outside the experience and knowledge of a judge or jury":

62. The opinions of Prof. Schwindt and Dr. Addanki are economic. The field of economics is highly specialized and is outside the experience of the Hearing Panel.

63. Economic evidence is clearly relevant and necessary to the Board in an excessive pricing hearing.

> ***PMPRB-07-D5-QUADRACEL and PENTACEL – Merits,* December 21, 2009,[4] Board Staff's Authorities Brief, Tab 12**
> ***PMPRB-06-D2-COPAXONE,* February 25, 2008,[5] Board Staff's Authorities Brief, Tab 13**
> ***PMPRB-08-D3-ratio-Salbutamol HFA – Merits,* May 27, 2011, Board Staff's Authorities Brief, Tab 14**

64. In *PMPRB-07-D5-QUADRACEL and PENTACEL – Merits*, one of the issue before the Board was whether the Board should reject the CPI methodology in the Guidelines and use a different methodology. The Board received expert economic evidence from Board Staff and the patentee as outlined in paragraphs 33 and 35:

> 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

[4] Rev'd on other grounds 2011 FC 859 (NB – The Federal Court referenced the expert evidence without censure)

[5] Rev'd on other grounds 2009 FC 1155, Redetermination Decision PMPR-2010-D3-Copaxone, February 23, 2012, on consent based on record (and on new evidence which was disputed), rev'd on other grounds 2013 FC 448, settled by VCU PMPR-13-D1-COPAXONE Redetermination 2013. Nothing in history undermines expert economic evidence.

> 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. ...
>
> 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.

65. In *PMPRB-06-D2-COPAXONE*, February 25, 2008, the Board admitted expert economic evidence in the context of determining excessive pricing on the issue of the patentee's intention relating to its pricing scheme, and noted at paragraph 19:

> Board Staff rejected the suggestion that it had represented to Teva, expressly or by implication, that its introductory benchmark price would be deferred until a time much closer to the date the patent was issued – i.e., until some time after the price increase on July 1, 2004. Counsel contended that as a result of discussions and correspondence as early as 1997, Teva knew, or ought to have known, the significance of the Guidelines, both with respect to the setting of the benchmark price and the CPI methodology limitations on subsequent price increases. Counsel cited the evidence of Dr. Weir, an economist, whose supposition was that Teva's pricing strategy was deliberately planned in the hope that it could maximize revenues and profits before the Board's restrictive Guidelines on post-benchmark pricing became operative. Since the scheme, according to counsel, was a deliberate policy to evade the Board's restrictions on excessive pricing, he urged the Panel to exercise its discretion under subsection 83(4) of the Act and order Teva to pay twice the amount of excess revenues it received as a result of its excessive pricing practices.

66. In *PMPRB-08-D3-ratio-Salbutamol HFA – Merits*, May 27, 2011 the Board accepted expert economic evidence relating to the appropriateness of using the introductory price of a medicine as a benchmark, in the context of CPI adjustments pursuant to the Guidelines. The Board noted at paragraphs 81 and 82:

> Dr. Richard Schwindt, an expert economist, testified on behalf of Board Staff regarding the appropriateness of using ratio HFA's introductory price as the benchmark to calculate subsequent price increases. He was of the view that the evidence indicates that the price constraint on ratiopharm for ratio HFA at introduction was likely the presence of CFC-free Airomir in the market at a list price of $4.65 per MDI, at parity with the competing CFC MDIs, and of CFC-free Apo-Salvent at $4.64 per MDI and that, effectively, ratio HFA was introduced in a price competitive market in 2002 that informed its pricing strategy at the time. The introductory price of ratio HFA thus was not arbitrarily or artificially low, but rather calculated on the basis of the market conditions prevailing at the time of introduction.
>
> Dr. Schwindt's expert opinion was that the Board's CPI-adjustment methodology in the Board's Guidelines, which permits a limit of a three-year "bank" of price increases, reflects the desirability of avoiding excessive changes in the price of a medicine in a given period, changes which would be at the expense of price stability and predictability for consumers and contrary to the Act's objective. Dr. Ronald J. Corvari, Director of the Policy and Economic Branch of the Board until 2008, testified that sudden and significant price increases was one of the major concerns of the Board during the extensive stakeholder consultations that led to the 1994 changes in the CPI-adjustment methodology in the Board's Guidelines.

67. It is notable that even in the *Sandoz* case referred to by Alexion, the Board received extensive expert evidence, described at paragraphs 23 and 25 as follows:

> ... b. Daniel Sher, a patent agent, provided evidence on the manner in which each of the patents in question "pertains" to a medicine being sold by Sandoz in Canada; and
> c. Dr. Richard Schwindt, an economist, replied to evidence tendered by Sandoz regarding how generic companies hold patents and participate in the market.
>
> ... b. Leonard Arsenault responded primarily to the evidence of Mr. Sher regarding the connections between the patents and the medicines in question; and
> c. Dr. Jonathan Putnam, an economist, who discussed the purpose of the patented medicine price regulation provisions of the Act and whether Sandoz should be considered a patentee within the meaning of subsection 79(1) of the Act.

68. Despite not ultimately relying upon the "opinion" parts of the expert reports the Board did rely on the facts provided by these experts as outlined in paragraph 30:

> Accordingly, having considered the evidence and argument in relation to the opinions in the affidavits and cross-examinations of Messrs. Sher, Schwindt, Arsenault and Putnam, these reasons will focus on the facts in the evidence of those witnesses and in the evidence of Ms. Tognet and Mr. Danis.

69. It is clear that the Board must have regard to many different factors, when making a determination as to whether a patented medicine has been excessively priced. The Board has noted that many factors such as medical, scientific, economic and sociological perspectives are important when coming to the determination of whether a medicine is excessively priced.

> ***PMPRB-06-D3-ADDERALL XR – Merits, supra*, Board Staff's Authorities Brief, Tab 11**
>
> Board Staff and Shire each presented evidence, and they and Janssen-Ortho presented written and oral argument, to a panel of the Board (the "Panel") at a public hearing that lasted 11 days and heard evidence from 14 witnesses. The evidence was often extremely technical and complex from medical, scientific, economic and sociological perspectives. The proceeding raised important considerations of policy concerning the manner in which the Board should determine when a medicine is excessively priced.

(3) Absence of any exclusionary rule

70. There is no exclusionary rule relating to the type of economic evidence that Prof. Schwindt and Dr. Addanki have addressed in their reports.

(4) Properly Qualified Expert

71. Dr. Addanki and Professor Schwindt each have a Ph.D in economics and have testified as economic experts on many previous occasions.

(5) The Addanki Report is not based on novel science

72. Dr. Addanki applies well recognized economic measures, tests and considerations to assist in determining whether the price of Soliris is excessive. The Addanki Report does not involve novel economic theories or techniques.

73. The fact that Dr. Addanki looked at the price of Orphan Drugs in the U.S. and elsewhere does not mean that he strayed from the usual methods of conducting an economic analysis. Dr. Addanki's opinions on the appropriate comparators medicines were based on economic considerations. He noted that the determination as to whether a price was excessive may be informed by comparing the price to benchmarks or yardsticks. Dr. Addanki noted that from an economic standpoint the search for comparators should be narrow, although not so narrow that it becomes impossible to conduct an economic analysis. The decision as to whether the comparators used in the Addanki Report are appropriate in the context of an inquiry into the excessive price of Soliris will be a matter for the Hearing Panel to determine after hearing the evidence and argument.

74. 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.

75. The Addanki Report does not offer an opinion on the scientific meaning of the words "therapeutic class". Dr. Addanki's expertise is in economics and he applies economic tests in his report. The Addanki Report analyzes what is a therapeutic class in economic terms. The opinions expressed in the Addanki Report are expressly noted to be given without regard to the Guidelines.

(6) The Addanki Report does not address the ultimate issue before the Hearing Panel

76. In paragraph 7 of its Written Representations, Alexion erroneously asserts that Dr. Addanki's opinion seeks to answer the ultimate legal issue under review.

77. Dr. Addanki's report does not seek to answer the ultimate issue that will be before the Hearing Panel at the hearing. The ultimate issue for the Hearing Panel to determine is whether the price of Soliris is or has been excessively priced based on the Panel's consideration of the factors set out in s. 85(1) of the *Act* and the weight to be given to the factors in s. 85(1).

78. The Addanki Report presents an opinion on the appropriate economic measures, tests and considerations which may assist the Panel in determining whether Soliris is or has been excessively priced. Dr. Addanki also analyzes the disparity between the Canadian price of Soliris and the U.S. price of Soliris, and also analyzes the price of Soliris relative to other medicines that also have Orphan Drug designations. Board Staff asserts that these economic considerations will

assist the Panel in making its determination as to whether Soliris is or has been excessively priced.

(7) An expert's consideration of the ultimate issue does not preclude admission of the expert's evidence

79. As noted above, the Addanki Report does not answer the ultimate issue that will be before the Panel at the hearing. Even if it did, there is no general prohibition against the Hearing Panel receiving expert evidence that addresses the ultimate issue.

> ***R. v. Graat,*** **[1982] 2 S.C.R. 819 [Graat], Board Staff's Authorities Brief, Tab 15**
> ***Khan v. College of Physicians & Surgeons (Ontario),*** **1992 CanLII 2784 (ON CA) [Khan], Board Staff's Authorities Brief, Tab 9**
> ***R. v. Lindsay,*** **2004 CanLII 34074 [Lindsay], Board Staff's Authorities Brief, Tab 17**
> ***Almrei*****, 2009 FC 3 (CanLII) [Almrei #1], Board Staff's Authorities Brief, Tab 3**
> ***Almrei*****, 2009 FC 1263 (CanLII) [Almrei #2], Board Staff's Authorities Brief, Tab 4**

80. In *Graat,* the Supreme Court of Canada considered an argument that the trial judge had erred in permitting both civilian witnesses and police officers to testify with respect to their opinions about whether or not the accused, who was charged with impaired driving, was impaired. The Court rejected the argument that the evidence should not have been heard because it went to the "ultimate issue" before the Court, observing at page 14 (cited to CanLII):

> ...They were in a position to give the court real help. They were not settling the dispute. They were not deciding the matter the court had to decide, the ultimate issue. The judge could accept all or part or none of their evidence. In the end he accepted the evidence of two of the police officers and paid little heed to the evidence of the third officer or of Mr. Wilson.

> I agree with Professor Cross (at p. 443) that "the exclusion of opinion evidence on the ultimate issue can become something of a fetish". I can see no reason in principle or in common sense why a lay witness should not be permitted to testify in the form of an opinion if, by doing so, he is able more accurately to express the facts he perceived.

81. In *Khan,* a physician who was being disciplined for misconduct claimed that the discipline committee improperly accepted evidence relating to whether or not a child had been sexually abused, contrary to the prohibition against receiving evidence relating to the ultimate issue. The Court of Appeal held that there was no prohibition on receiving such evidence, noting at pages 21 and 22 (cited to CanLII):

> This ground of appeal renews the well-known "ultimate issue" debate. Authority certainly exists which denies the admissibility of expert evidence going to the very factual issue to be decided by the trier of fact. However, the weight of more recent authority is to the contrary and does not preclude such opinion evidence. ...
>
> The expert is permitted to testify where he or she has the necessary expertise and the evidence would assist the trier of fact. To automatically exclude the expert's evidence that a certain factual inference should be drawn because that fact is at the core of the dispute before the court excludes the potentially most probative part of the expert's evidence. (emphasis added)

82. In *Lindsay,* the Ontario Superior Court reviewed the development of the ultimate issue doctrine and concluded that it could receive evidence which touched on the ultimate issue before the Court. The Court observed that this issue was one that was less important where there was no jury which would likely be overly impressed by a scientific expert. At paragraph 26:

> Finally, while I am alive to the concerns that underpin the "ultimate issue rule", this is a trial by judge alone. I am well aware that I may accept or reject the opinion of any expert witness in whole or in part, and that I should give any expert opinion only the weight that it deserves. It is for me, and not for Staff Sergeant Lemieux, or any other expert witness who may be called, to make the final decisions on all issues in the case. In the

> circumstances of this trial, the "ultimate issue rule" does not preclude admission of the evidence of Staff Sergeant Lemieux.

83. In *Almrei #1*, the Federal Court observed at paragraph 195:

> ... While his evidence touched upon the ultimate issue, that is the risk of injury to national security that release on conditions would pose, I am satisfied that it did not go so far as to usurp the Court's function in determining that question: see *Mohan*, above at pp. 24-25

84. Similarly, in *Almrei #2*, the Court held at paragraph 294:

> Opinions such as this go to the ultimate issue and it falls to the Court and not to the expert to make these determinations: *Mohan*, above at paragraph 24. Nonetheless, I thought it was useful to hear Mr. Quiggin's views on these matters as no one within the government has attempted to interview Mr. Almrei in recent years to determine whether he supports the Bin Laden ideology.

85. In summary, there is no prohibition on a court receiving evidence on the ultimate issue. Such evidence is admissible and the court may then decide the weight to be accredited to the evidence.

(8) IMS Data

86. Alexion argues that IMS data is inadmissible as irrelevant and as hearsay. As noted earlier, the Panel should not make any determination as to relevancy or admissibility until it has heard all of the fact and opinion evidence which will be put forward by Board Staff's witnesses at the hearing.

87. In any event an expert is entitled to rely upon hearsay evidence in forming their opinion. This point was made clear by the Supreme Court of Canada in *R. v. Lavallee*. At page 29 (cited to CanLII) Justice Wilson noted:

> For present purposes I think the ratio of *Abbey* can be distilled into the following propositions:
>
> 1. An expert opinion is admissible if relevant, even if it is based on second-hand evidence.
>
> 2. This second-hand evidence (hearsay) is admissible to show the information on which the expert opinion is based, not as evidence going to the existence of the facts on which the opinion is based.
>
> ...
>
> ***R. v. Lavallee*, 1990 CanLII 95 (SCC) at p. 29, Board Staff's Authorities Brief, Tab 16**

88. Alexion also argues that IMS data is not relevant because it is not "publicly available" as described in the *Patented Medicines Regulations* (the "*Regulations*").

89. Alexion's argument that IMS data is irrelevant is based on a misleading and erroneous reliance on s. 80 of the *Act* and s. 4(1) of the *Regulations* which require patentees to provide "publicly available ex- factory price" information to the Board on a regular basis. S. 80 of the *Act* and s. 4(1) of the *Regulations* do **not** however preclude a Hearing Panel from examining pricing information from other sources at a public hearing. The weight to be given such evidence will be a matter for the Hearing Panel to determine.

90. S. 85 of the *Act* does not require a Hearing Panel to only examine "publicly available prices". A Hearing Panel may consider prices from other sources

91. Moreover, IMS data is routinely relied upon by Board Staff and has been considered by hearing panels in other cases. In *Salbutamol HFA Merits* the Board noted as follows at paragraph 76:

> Ms. Tognet referred to the public price used for Ventolin HFA as an average public price as collected by IMS in the ordinary course on the basis of total sales and total number of units sold, rather than the 'constructed' price claimed by ratiopharm. She emphasized that this approach for determining average price is consistently applied by the Board, most recently in its investigation of the comparable medicine, Airomir.
>
> ***PMPRB-08-D3-ratio-Salbutamol HFA – Merits, supra*, Board Staff's Authorities Brief, Tab 14**

92. In any event, Professor Schwindt is not a member of Board Staff. Professor Schwindt may review and rely on any information that he considers germane to the issues on which he opines. The reliability of any foundational facts will be for the Hearing Panel to consider at the hearing.

93. Furthermore, Professor Schwindt specifically noted that the IMS data "did not materially change" his findings.[6]

VII. CONCLUSION

94. Even if the *Mohan* factors were relevant (which is specifically denied), both the Schwindt and Addanki Reports are admissible. Dr. Addanki and Professor Schwindt are highly qualified economists. Their reports are relevant to matters to be determined by the Board which are raised in the pleading. Dr. Addanki and Professor Schwindt have specialized knowledge outside the expertise of the

[6] Appendix 2 of the Schwindt Report

Hearing Panel. Their expert reports contain economic analysis. There is no rule against their admissibility.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 14th day of March, 2016

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