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"**

ALEXION'S REPLY ARGUMENT

Overview

1. Board Staff assert in their Written Submissions that they rely on all factors in s. 85 of the *Patent Act* ("*Act*") but the pleadings they filed tell a different story. The Statement of Allegations refers only to: (a) the Highest International Price Comparison (or "HIPC") test under the Guidelines; and (b) the difference between the price of Soliris in Canada and the United States. Both of these allegations engage only s. 85(1)(c).

2. The core issues addressed in the Addanki and Schwindt Opinions were not raised in the pleadings. The Opinions are therefore irrelevant and inadmissible under Rule 8(1). Board Staff may not introduce new issues in the proceedings through expert opinions when those issues have not been properly pled.

3. In addition to being irrelevant, the Addanki and Schwindt Opinions assert legal arguments that go to the ultimate issue before the Panel. Legal argument disguised as expert evidence cannot be admitted.

4. Board Staff counsel mislead the Panel. In response to Alexion's motion for particulars argued in June 2015, they represented that the factors they relied on under s. 85(1) of the *Act* were "argument" that did not require disclosure or the provision of particulars. Board Staff now attempt to broaden the scope of their pleadings to introduce new issues under ss. 85 (1)(a), (b), and (c) through expert evidence. Board Staff cannot have it both ways. The expert opinions are either legal argument in support of their current pleadings or expert evidence supporting allegations outside the pleadings.

Either way, the opinion evidence is irrelevant and inadmissible. Admitting the evidence will give rise to incurable prejudice.

Issues Raised in the Pleadings

5. In their Written Submissions at paragraphs 29 – 43, Board Staff assert that the Addanki and Schwindt opinions are relevant to issues raised in the pleadings. Yet a brief review of the pleadings belies these assertions.

1) Statement of Allegations

6. There are only two excessive price "issues" raised by Board Staff in the Statement of Allegations ("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."

7. In paragraph 15 of the Allegations, Board Staff elaborate on the HIPC test, stating that the National Average Transaction Price was compared with "publicly available list prices of Soliris...in the comparator countries."

8. Board Staff allege in paragraphs 16, 17, 19, and 21 that their investigation resulted in a determination that "Alexion was selling Soliris in Canada at the highest international price among the comparator countries, contrary to the 2010 Guidelines." In paragraph 25, Board Staff submit that "it is appropriate in this case for the Board to apply the approach and methodology set out in [the] 2010 Guidelines when applying the factors...in subsection 85 (1) of the *Act*."

9. The HIPC test and the price differential between the price of Soliris in Canada and the United States[1] are the only two issues raised in the Allegations. Based on the Allegations and the "Investigation" letter appended to the Allegations[2], the only aspect of s. 85(1) raised in the Allegations is 85(1)(c), which specifically addresses "the prices

[1] Allegations concerning the price differential between Canada and the United States are repeated in paragraph 17, 19, 21, and 26.
[2] Allegations, Attachment 4.

at which the medicine [have]...been sold in countries other than Canada." There is no reference whatsoever in the 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).

10. Indeed, in paragraph 7 of the Allegations, Board Staff explicitly acknowledge that the Human Drug Advisory Panel ("HDAP") determined that Soliris was a "breakthrough" drug and that HDAP "did not identify any comparators for Soliris." For Board Staff and Dr. Addanki to now argue that comparisons can be drawn among admittedly different products defies logic, the scientific procedures in the Guidelines, and Board Staff's own allegations.

2) Amended Response

11. Alexion's Amended Response answers the two excessive pricing issues raised in the Allegations. In relation to the HIPC test, Alexion asserts that this test should not apply on the facts of this case because:

(a) the nominal price of Soliris in Canada has not increased since it was first introduced in 2009[3];

(b) there have been no material decreases in the price of Soliris in the seven comparator countries since 2009[4];

(c) the "real" price of Soliris in Canada has actually declined since 2009 by more than 8% due to normal inflationary increases measured by the CPI;[5]

(d) the price of Soliris in Canada was deemed compliant by Board Staff in 2010 and 2011[6];

(e) nominal (or market) international exchange rates do not reflect differences in purchasing power of consumers in Canada and the seven comparator countries[7];

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[3] Amended Response, at paragraph 5.
[4] Amended Response, at paragraph 6.
[5] Amended Response, at paragraph 18.
[6] Amended Response, at paragraph 4.
[7] Amended Response, at paragraph 17.

(f) variations in international exchange rates made no difference to consumers in Canada, who were not harmed or otherwise worse off because of the change in value of the Canadian dollar;[8]

(g) Soliris is a non-traded good and cannot be imported into Canada by Canadian consumers;[9] and

(h) Alexion has no control over foreign currency fluctuations.[10]

12. Alexion does not reject HIPC test in its Amended Response. Nor does Alexion assert in the Amended Response that the system of external reference pricing used by the Board is unreasonable. Alexion complied with the *Patent Act*, Regulations, and Guidelines by filing information relating to publicly available prices in the seven comparator countries. Alexion asserts in its Amended Response that the HIPC test should have no application on the facts of this case because there was no patent abuse and no adverse impact on Canadian consumers.

13. Alexion also asserts that, even if there were a price differential between Canada and the United States for Soliris, the allegation is "irrelevant" under applicable law. Section 85(1)(c) of the *Act* refers to "countries other than Canada". The pertinent Regulation requires reporting of publicly available in prices in seven other countries. The HIPC test under the Guidelines, which Board Staff explicitly rely upon, depends upon comparisons with the seven reference countries. Nothing in the *Patent Act*, the Regulations, the Guidelines, or any Board decision suggests that a comparison of the Canadian price with only one other country, be it the United States or any other nation, is an appropriate basis for a finding of excessive pricing under s. 85(1). Indeed, the price of Soliris in Canada in 2010 and 2011 was deemed compliant in circumstances where the Canadian price, in Canadian dollars, actually exceeded the U.S. price.

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[8] Amended Response, at paragraph 13, 24.
[9] Amended Response, at paragraph 21 – 23.
[10] Amended Response, at paragraph 13, 20, 24.

3) Amended Reply and Surreply

14. In the Amended Reply, Board Staff allege that the HIPC is "a generous application of paragraph 85(1)(c) of the Act"[11] and that they "applied the HIPC test consistent with the Guidelines and the Regulations."[12] Board Staff also acknowledge, as they did in the Allegations, that there are "no domestic comparators" for Soliris.[13] There is no allegation in the Amended Reply that any factor of s. 85(1) other than s. 85(1)(c) is at issue. Nor is there a suggestion that there are any comparator medicines to Soliris.

15. The Amended Reply included the additional allegations that Alexion had "failed to justify its excessive price under s. 85(2) of the *Act*"[14] and that if the Board "is unable to determine whether the medicine is being or has been sold at an excessive price under s. 85(1), it may take the factors under s. 85(2) into account."[15] The Panel concluded in its reasons released on 24 November 2015 that these allegations were not proper reply and provided Alexion with the right of surreply.

16. In its Surreply, Alexion asserted that:

> (a) Board Staff were precluded by principles of fairness and estoppel from raising allegations under s. 85(2)(a)[16];
>
> (b) nothing in the *Patent Act*, Guidelines, or relevant jurisprudence provided a basis for independently reviewing a patentee's "costs of making and marketing" during the period of exclusivity;
>
> (c) apart from 85(1)(c) and the HIPC test, Board Staff had provided "no details of <u>how</u> (i.e., in what way or ways)" the price of Soliris had violated s. 85(1); and
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> (d) s. 85(2) could not be engaged based on the issues pleaded by Board Staff.

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[11] Amended Reply, paragraph 9.
[12] Amended Reply, paragraph 19.
[13] Amended Reply, paragraph 11.
[14] Amended Reply, paragraph 7.
[15] Amended Reply, paragraph 9.
[16] Surreply, paragraph 2.

Issues in Addanki Opinion Not Raised in Pleadings

A - Economic Classification

17. 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).

18. The Allegations acknowledge that HDAP found "no comparators" for Soliris. HDAP's role is to make recommendations to Board Staff on the proper categorization of new drug products based on the level of therapeutic improvement a new medicine offers—moderate, breakthrough, or "line extension" (i.e., no improvement over existing medicines)—and the selection of proper comparable medicines and the relevant dosage regimens (i.e., "comparators"). HDAP's recommendations are to be evidence-based and reflect scientific and medical knowledge and current clinical practice. The composition of HDAP reflects its scientific, medical, and clinical purpose. HDAP is composed of up to six members who hold qualifications as a physician, a pharmacist, or other professional designation with recognized expertise in drug therapy, clinical research methodology, statistical analysis and the evaluation of new drugs. Classification of medicines based on 'economic' factors like those chosen by Dr. Addanki are a significant departure from HDAP's "Terms of Reference" posted on the Board's website.

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 expert opinion based on a purported "economic" class of products is therefore irrelevant under Rule 8(1).

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."

21. In responding motion material and in their Written Representations in response to this motion (at paragraphs 31 and 37), Board Staff have cited correspondence and pleadings as far back as April 2015 indicating a strategy of relying on different factors in s. 85 (1) of the *Act*. Yet in response to the Motion for Particulars presented in June 2015 requesting details of their position, Board Staff explicitly represented to the Panel that the factors they would rely on under s. 85(1) were a matter of "argument." Notwithstanding their previous representations, Board Staff have now introduced evidence from experts in support of previously undisclosed legal positions they now appear to be taking under ss. 85(1)(a), (b), and (c). The opinions expressed in the Addanki Opinion are not based on any pleaded issue in s. 85(1). The Panel should not permit Board Staff to engage in these sorts of surprise tactics.

B - Affordability, Opportunity Cost, Etc.

22. Neither the Allegations nor Amended Reply make any reference to "affordability", "opportunity cost", or other social costs of Soliris. The *Patent Act* contains no such terminology and the Guidelines are entirely silent on the applicability of these considerations.

23. The Board's jurisprudence demonstrates that the "Regulatory Framework" for assessing whether a price is excessive under s. 85(1) is a comparative process. As the panel in PMPRB-07-D2-Penlac (Sanofi-Aventis Canada Inc. and the medicine "Penlac Nail Lacquer") observed:

Regulatory Framework

14. In the assessment of the factors in subsection 85 (1) of the Act, the starting point is the price at which the medicine is being sold [paragraph 85 (1) (a)]. There are provisions in the Act and the Regulations that require a patentee to report the price at which its medicine is sold, so this information is on file with the Board. The price is then considered in light of:

i. the prices of medicines in the same therapeutic class sold in Canada [paragraph 85(1)(b)];

ii. the international pricing of the medicine [paragraph 85(1)(b)];

iii. the price of medicines in the same therapeutic class outside of Canada [also paragraph 85(1)(c)]; and

iv. changes in the CPI [paragraph 85(1)(d)].

15. The relationship between section 85 and the Board's Guidelines has been discussed in prior decisions of the Board, most particularly the decisions involving the medicines Dovobet and Adderall XR.

See Also: PMPRB-06-D3 – Adderall XR (Shire BioChem Inc.); PMPRB-2010-D3-Copaxone (Teva Neuroscience G.P-S.E.N.C.)

24. By asking the Panel to consider notions of "affordability" and "opportunity cost" under s. 85(1), the Addanki Opinion represents a sharp departure from the interpretive and evaluative process in the Guidelines as applied in the Board's jurisprudence. These are entirely novel concepts not found within the pleadings and lie outside the existing "Regulatory Framework." Moreover, to permit Board Staff to pursue this un-pleaded issue is to compel Alexion to respond with rebuttal evidence demonstrating the value of the product, the reasonableness of the price in general, and other non-probative evidence. Such an exercise would quickly cause the hearing to devolve into a protracted back and forth on irrelevant issues—all of which will significantly delay resolution of this matter and increase the costs of the hearing for all parties.

C - Price in the United States is Excessive

25. The final paragraphs of the Addanki Opinion express his view that the price of Soliris is "excessive" in the United States. This opinion is irrelevant to any pleaded issue. It is also irrelevant to the Panel's role under s. 85 (1) of the *Act*, which requires a determination "whether a medicine is being or has been sold at an excessive price in any market *in Canada*." Furthermore, the prices reported by Alexion to the Board under the *Act* and Regulations, all of which are before the Panel and not in dispute, definitively establish the price differences in Canada and the United States. Dr. Addanki's opinions on the price difference are therefore not probative of any factual issue in dispute and are neither relevant nor necessary to the Panel's determination. Rather, Dr. Addanki's opinion in this respect is a bald attempt to bootstrap a legal position unsupported by the *Act* , the Regulations, the Guidelines, or the jurisprudence.

D - Addanki Opinion Disregards the Guidelines

26. The Guidelines are an essential component of Board Staff's claim in the Allegations. Without an alleged violation of the HIPC test, Board Staff's investigative criteria would and could not have been triggered.

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.

Schwindt Opinion Irrelevant to Pleaded Issues

28. The introductory paragraph to the Schwindt Opinion demonstrates why significant parts of the opinion are inadmissible. The concept of "external reference

pricing" (or "ERP") is not "raised in the pleadings" at all. ERP is not mentioned by Board Staff in the Allegations or the Amended Reply.

29. In the Amended Response, Alexion asserts that the HIPC test should not be applied in this case to an analysis under s. 85 (1) because prices "in Canada" and in "countries other than Canada" never changed to the detriment of Canadian consumers and fluctuations in exchange rates were beyond Alexion's control. Alexion does not object to the HIPC test specifically, or to the ERP concept generally. To the extent the Schwindt Opinion addresses ERP, it raises a "straw man" issue because Alexion has never pled, or argued, that the ERP system was unreasonable. To the extent it deals with ERP issues, the Schwindt Opinion is irrelevant to the case as pleaded and should be struck.

Admissibility Determination May be Made Immediately

30. Board Staff argue in paragraphs 6 through 15, of their Written Submissions that admissibility of expert evidence ought to be determined at the hearing on the merits, not in a preliminary motion. They submit that admissibility should be considered at the hearing in the context of all potential issues and evidence.

31. In this case, however, the "issues" have all been established by the pleadings. Perversely, Board Staff are now attempting to introduce new issues that have not been pled by either party via the impugned opinions. No additional context is needed to determine admissibility at this stage.

32. Preliminary motions on the admissibility of expert reports—particularly where, as here, such opinions address legal issues—are granted in the administrative law context. For example, in labour arbitration, *York University and York University Faculty Assn. (Re)*, [2005] O.L.L.A. No. 776 and municipal law, *BCE Place Ltd. v. Municipal Property Assessment Corp., Region No. 9*, [2007] O.A.R.B.D. No. 237, motions to dismiss expert reports were decided on the basis of preliminary motions.

33. The policy considerations raised in the cases cited by Board Staff are irrelevant in a hearing before a panel of this Board. For example, *Harrop* [Board Staff's Brief Tab 7] and *Ivetic* [Board Staff's Brief Tab 8] were based on concerns about splitting the case between a motion judge and a trial judge. The context makes *White* [Board Staff's Brief Tab 20] entirely distinguishable because it is based on a narrow examination of Nova Scotia's summary judgment rules. Other Canadian courts have struck expert evidence on a preliminary motion when it was not relevant to a proceeding: See, *New Brunswick v. Rothmans Inc.*, 2009 NBQJ 60.

34. In contrast with civil cases, where concerns are raised about interlocutory motions and trial proceedings before different adjudicators, proceedings before this Board are heard by the same panel from start to finish. This Panel, which possesses scientific, medical, and legal expertise, now has extensive familiarity with the pleadings and issues arising in the proceeding. The Panel can, and should, apply Rule 8(1) to police admissibility of opinion evidence that is not relevant to pleaded issues.

Experts Should Not Interpret Statutes

35. As the Board in *BCE Place Ltd. v. Municipal Property Assessment Corp., Region No. 9*, [2007] O.A.R.B.D. No 237 (Ont. Ass. Rev. Bd.) stated at para. 30, expert witnesses are *never* qualified to provide legal opinions: "Stated another way, counsel make legal arguments, witnesses provide evidence". In a case similar to the matter before this Panel, the Board in *BCE Place* went on to note (at para. 31) that so-called "expert opinions" purporting to interpret statutory provisions for an administrative board are inadmissible:

> Further, the Board accepts the law as submitted by Counsel for the taxpayers, that evidence, other than that from Hansard, on legislative intent, or the background and purpose of legislation, is inadmissible. Counsel will argue, in due course, how the Act should be interpreted, including the words "fee simple, if unencumbered". The Board will weigh arguments and, using appropriate principles of statutory interpretation, will determine what the Act says and what follows from that, for the assessment of the subject properties. Any evidence of Mr. Hummel on legislative intent or on the background and purpose of the 1997

> amendments to the Act, howsoever obtained, is inadmissible. [Underlining added.]

36. In Decision 127-09 [2010] O.W.S.I.A.T.D. No. 705, the Workplace Safety and Insurance Appeals Tribunal observed that the "interpretation of Board policy is a matter within the Tribunal's specialized expertise and it was therefore not necessary to hear evidence from a law professor on corporate law principles."

37. Experts cannot usurp the role of an adjudicator. The rational for inadmissibility of such evidence is just as compelling before an administrative tribunal as before a court. An expert's legal analysis lies outside his or her expertise. This was expressly stated in *York University and York University Faculty Assn (Re)*, *supra* (Ont. Arb.) at para. 36:

> 36 A review of all of the cases to which reference was made by the parties indicate an underlying concern that the admission of expert opinion evidence not "distort the fact-finding process" and "that experts not be permitted to usurp the functions of the trier of fact." (See *Mohan, supra*, at p. 430.) Both these concerns have also caused judges, arbitrators and other adjudicators to look carefully at expert opinion evidence to ensure that it does not assume those functions which are reserved to the adjudicator, namely the determination of the issues of law and the findings of fact. The cases also clearly indicate that expert opinion should not assume the function of counsel, and expert opinion should be more than the argument of the party seeking to introduce it "dressed up" in the guise of expert opinion... [Underlining added.]

38. In *4145356 Canada Limited and Her Majesty the Queen*, 2010 TCC 613 the Tax Court of Canada wrote:

> 9...As noted by Justice C. J. Horkins of the Ontario Superior Court of Justice in *Corviga v. Corviga* [2009] O.J. 3359:
>
> > 20. Pleadings define the issues and serve as a framework for determining what evidence is relevant to trial.
>
> 10. As well statements related to positions or opinions in relation to matters of domestic law are not admissible. In *Eco-Zone Engineering Ltd. v. Grand Falls-Windsor (Town)*, 2000 NFCA 21 (Nfld. C.A.) Justice Cameron, writing on behalf of the Newfoundland Supreme Court - Court of Appeal stated that:

> 15 What the parties did not directly address before this Court, is the long accepted view that courts do not accept opinion evidence on questions of domestic law (as opposed to foreign law). This is part of the principle that courts do not accept expert evidence on the ultimate issue which is for the court to decide, which was referred to by the appellant. Though one could perhaps say that there has been a relaxation of the rule regarding opinion on the ultimate issue, there is little support for the admissibility of expert opinion regarding domestic law...

39. In Sopinka, Lederman & Bryant *The Law of Evidence in Canada*, 4th ed., 2014, at paragraph 12.164 (p. 836), the authors state:

> Questions of domestic law as opposed to foreign law are not matters upon which a court will receive opinion evidence.

40. The Addanki and Schwindt Opinions purport to answer the legal questions raised in the pleadings. Dr. Addanki's opinion is particularly egregious. At the explicit direction of Board Staff counsel, Dr. Addanki purports to engage in statutory interpretation of s. 85 of the *Act*. He redefines the statutory language "therapeutic class" to mean "economic class" in contravention of all previous and reasonable applications and constructions of that term. He then proceeds to offer an opinion on the ultimate issue before the Panel, whether the price of Soliris is excessive in Canada. Such legal argument disguised as expert opinion should not be countenanced.

41. Dr. Schwindt's opinion similarly advances legal argument at Board Staff counsel's request. The first paragraph of the Schwindt Opinion explains in clear terms that he was asked to provide an "evaluation of Alexion's allegations" in the Amended Response. Evaluating the parties' legal positions and allegations is the role of the Panel, not of an expert. An expert may not provide what is, in essence, a further legal argument.

Administrative Tribunals and the *Mohan* criteria

42. Board Staff submit (at paragraph 45) that "the strict rules of evidence that are enforced in court hearings are not appropriate in the context of hearings before

administrative tribunals". This misstates the law. While strict rules of evidence developed in the common law are not binding on administrative tribunals, they are nonetheless to be "considered" and not "lightly ignored." The first *Mohan* criterion, relevance, is the bedrock of all evidentiary principles. Evidence that is not probative of a matter in issue is irrelevant, and irrelevant evidence should never be admitted. By definition, issues of appropriate comparators and "ERP" that are not pleaded are irrelevant. It necessarily follows that expert opinion relating to such issues is similarly irrelevant and inadmissible.

43. Several administrative tribunals have concluded that they should apply common law rules, including the *Mohan* criteria, even though not required: see *York University and York University Faculty Assn (Re)*, 2005 O.L.A.A. No. 776 (Ont. Arb.); *BCE Place Ltd. v. Municipal Property Assessment Corp., Region No. 9*, [2007] O.A.R.B.D. No 237 (Ont. Ass. Rev. Bd.); Order F15-43; *British Columbia (Lottery Corp.) (Re)*, [2015] B.B.I.P.C.D. No. 46 (B.C. Info. & Privacy Comm.); Decision No. 1748/131, [2014] O.W.S.I.A.T.D. No. 2593 (Ont. Work. Safety & Insurance App. Trib.); Decision No. 2106/03, [2006] O.W.S.I.A.T.D 2743 (Ont. Work. Safety & Insurance App. Trib.)

44. In *York University, supra*, the arbitrator stated that although she may not be "bound by the same strict rules regarding the admissibility of evidence, criteria laid out by the courts, such as those which address the admissibility of expert opinion evidence, should not be lightly ignored, especially where, as here, they are designed to provide for a fair and expeditious process." (at paragraph 37)

45. In Decision No. 1748/131, [2014] O.W.S.I.A.T.D. No. 2593 (Ont. Work. Safety & Insurance App. Trib.) the tribunal similarly stated that although it was "not subject to the same evidentiary rules of a Court, the reliability of evidence is an important consideration for the Tribunal, just as it is for the Courts." Furthermore, the tribunal has the same "gatekeeper" function as a court:

> In the *J.-L.J.* decision, the Court emphasized the importance of an adjudicator's role as a "gatekeeper" when determining whether to admit expert evidence. Potential expert evidence should be carefully scrutinized

> when it is proffered. It should not be assumed that the weaknesses of expert evidence will be cured later by the amount of weight it is given. This is particularly true when the expert evidence relates to the ultimate issue to be decided. The closer the expert opinion answers the ultimate issue, the more scrutiny this evidence should be given. [Underlining added.]

46. Concerns about fairness assume increased importance the closer the impugned expert opinion approaches the "ultimate issues" before the tribunal, particularly where, as here, the experts purport to provide "expert" opinions concerning statutory interpretation, or assume the role of advocate by attempting to counter the opposing party's case. This tribunal should function as a gatekeeper and not simply take the "path of least resistance" by admitting the evidence and only permitting arguments on weight. It is particularly important in this case because admitting the Addanki Opinion or the impugned portions of the Schwindt Opinion compels Alexion to adduce significant evidence from additional witnesses to rebut Board Staff's arguments on irrelevant issues. Failure to do so risks inappropriately according weight to improper opinion evidence.

Prejudice

47. Board Staff argue in paragraph 56 that Alexion has demonstrated no prejudice arising from the admission of the putative expert evidence.

48. The "prejudice" is clear. If the impugned opinion evidence is admitted, Alexion 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.

49. In *GlaxoSmithKline Inc. v. Apotex Inc.* (2003) FC 920 (F.C.), the Federal Court made the following comment about the prejudice inherent in admitting irrelevant affidavit evidence:

> ...I do not agree with the applicants' argument that Apotex will not be prejudiced by the inclusion of these two affidavits. Their position is that these are only two among many affidavits and most likely the shortest two at that. That does not change the fact that both time and money will have to be spent dealing with these clearly irrelevant affidavits and that this will result in delays that would indeed cause prejudice to the applicants. [Underlining added.]

50. This type of prejudice was also aptly described by the arbitrator in *York University and York University Faculty Assn (Re)*, *supra*, at para. 42:

> In addition "prejudicial effect" here includes not only unnecessarily confusing the issues to be determined in this case, but also unnecessarily prolonging the hearing of these grievances by admitting evidence which is of only marginal relevance. The prejudicial effect question also draws into consideration whether the expert opinion evidence attempts to usurp the function of the arbitrator by determining issues of law and findings of fact.

IMS Data

51. In paragraphs 86-93 of their Written Submissions, Board Staff attempt to convince the Panel of the relevance of the IMS data.

52. The HIPC test involves a comparison of "publicly available" prices. Accordingly, the Allegations refer only to "publicly available" prices. The Amended Response raises issues about how "publicly available" prices are selected by Board Staff and the fairness or consistency of the "back-out" formulae applied by Board Staff. Alexion argues that only publicly available prices, which are required by the governing Regulation, are an appropriate basis for comparison. Any other non-public sources of pricing data, like the proposed IMS Data, are clearly irrelevant to the pleaded issues.

53. 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. In the absence of such a witness, Dr. Schwindt's reliance on the IMS Data in his expert opinion is similarly inadmissible hearsay. It would also appear that the IMS Data is superfluous because, as Dr. Schwindt expressed in his report, the IMS Data would not "materially change" his opinions. It naturally begs the question why Board Staff is

relying on non-public data that is disconnected from the applicable legal standard (and therefore irrelevant), constitutes hearsay, and had to be purchased at great expense to support its case.

54. It should also be noted that the IMS Data is incomplete. Board Staff have not identified any IMS Data for Canada.

Compliance with Rule 8(3)

55. In paragraphs 23 – 28 of their written submissions, Board Staff address the requirements of Rule 8(3)(a). 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).

Misstatements in Paragraph 32 of Board Staff's Written Submissions

56. In paragraph 32, Board Staff have misstated Alexion's Written Submissions. Alexion made no assertion concerning the price of Soliris "prior to 2012." Paragraph 15 of Alexion's Written Submissions accurately states that it is "undisputed the price of Soliris was not considered excessive by Board Staff in 2010 and 2011." Board Staff's

own Allegations confirm Alexion's assertion.[17] Board Staff should be collaterally estopped from arguing otherwise.

57. Paragraph 32 contains an additional misstatement. The second sentence of paragraph 32 erroneously asserts that paragraph 14 of Board Staff's Statement of Allegations contained an assertion that the introductory price of Soliris in Canada was excessive. Paragraph 14 of the Allegations says nothing about the introductory price: it reads: "On 25 February 2013, Board Staff commenced an investigation into the 2012 price of Soliris."

58. It is apparent that Board Staff counsel are misstating both Alexion's submissions, and their own pleadings, to create opportunities to level general criticism in relation to the introductory price of Soliris in 2009. As Board Staff well know, the *de minimis* nature of excess revenues arising from the introductory price fell below Board Staff's enforcement criteria.

Dated: 16 March 2016

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[17] Statement of Allegations, paragraph 30.

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