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 THE RESPONDENT
(Alexion's Motion to Strike Evidence as Inadmissible)

PART 1 - OVERVIEW

1. Since the commencement of this proceeding, Alexion has sought particulars and disclosure of the Board Staff's case. The doctrines of fairness and natural justice demand no less. Alexion has requested disclosure not only to plead its defences, but to prepare evidence for the hearing, including expert reports.

2. Board Staff counsel have refused to respond to Alexion's basic disclosure requests in a responsive and timely way and, throughout the proceeding, have resisted providing requisite disclosure and particulars.

3. The resulting unfairness and injustice to Alexion is now self-evident. Board Staff have produced expert reports and other evidence (the "impugned evidence") that is irrelevant to the case they have pled in either the Statement of Allegations or their Reply. Admitting the evidence would violate the Board's own Scheduling Order released on 7 December 2015, disregard the Board's Rules of Practice and Procedure, undermine basic rules of procedural fairness, and ignore the well-established rule against admission of irrelevant and unnecessary opinion evidence.

4. On 7 December 2015, the Panel delivered a Scheduling Order (the "Scheduling Order") providing that the "parties shall file expert witness reports *supported by*

affidavits in accordance with Rule 8." The Panel's order specifically stated that "Board Staff shall file expert reports" by 16 February 2016. Yet, on 16 February 2016 Board Staff filed expert reports without the required affidavits.

5. Board Staff have disregarded the requirements under Rule 8(3)(a) that expert reports be "supported by an affidavit that must include":

(a) "a statement of the issues addressed in the report";

(b) "a description of the qualifications of the expert 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 document specifically relied on in support of the opinions expressed"; and

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

The failure to file affidavits addressing these mandatory points is a continuation of Board Staff's pattern of not disclosing fundamental and vitally important information to Alexion and the Panel.

6. In addition to the direct violations of the Scheduling Order and Rule 8, the *Expert Report of Sumanth Addanki* (the "Addanki Opinion") is inadmissible in its entirety under Rule 8(1), which binds the Panel in the admissibility of expert evidence. Under Rule 8(1), the Addanki Opinion is "not admissible in [the] proceeding before" the Panel because "the issue[s]" addressed by Dr. Addanki have not "been raised in the pleadings." Through the Addanki Opinion, Board Staff are attempting to amend their pleadings and raise entirely new allegations and issues through an expert, which is expressly prohibited under Rule 8(1).

7. The Addanki Opinion is also inadmissible, on its face, because common law principles prohibit the admission of expert evidence that is irrelevant and seeks to answer the ultimate legal question under review. While administrative tribunals may be less strict in their application of evidentiary rules than courts, the Addanki Opinion breaches well-established rules governing admissibility of expert evidence because the Opinion adduces irrelevant expertise and purports to answer the ultimate legal issues before the Panel. In particular, the Addanki Opinion's argument regarding the statutory interpretation of the words "therapeutic class", and whether the price of Soliris is "excessive" based on that interpretation, demonstrate why the opinion has no probative value.

8. 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 Opinion") is similarly inadmissible. Section 6 of the Schwindt Opinion asserts legal argument against Alexion's legal position asserted in the Response. It is axiomatic that expert evidence that is directly argumentative on legal issues is neither relevant nor admissible.[1]

9. The IMS Midas data found in Tabs 75, 76, 77 and 82 of the Board Staff Disclosure List of documents and referred to in the Schwindt Opinion (the "IMS Data") is also irrelevant. The pleaded case refers exclusively—as it must to comply with the *Patented Medicines Regulations*—to *publicly* available data used to make price comparisons. The IMS Data is *private* information purchased by Board Staff. The IMS Data does not relate to any pleaded issue and is irrelevant to the Panel's determination.

10. Permitting irrelevant and inadmissible evidence to be adduced before the Panel creates undue prejudice to Alexion and calls into question the objectivity and fundamental fairness of the proceeding. If the Panel admits the impugned evidence, Alexion has no choice but to retain its own experts, at great cost and inconvenience, to

[1] Board Staff and Dr. Schwindt are well aware of the fundamental evidentiary principle that experts should not opine on legal issues before the Board. Another panel of the Board disregarded previous expert reports proffered by Dr. Schwindt and others for similar reasons: "... the Panel did not find that it needed or ought to rely on the opinion portions of the evidence of the second and third of each parties' witnesses"... The Panel was able to come to the conclusions outlined in these reasons without relying on any expert (or putative expert) opinions, at paragraphs 26-27."

rebut this irrelevant and inadmissible evidence. The impugned evidence will also complicate and expand the proceeding, resulting in the waste of time and costs for the Panel and both parties, to litigate issues that have no bearing on the Panel's determination whether the price of Soliris is "excessive" based on relevant evidence and consistent with pleaded issues.

PART 2 – ALLEGATIONS IN THE PLEADINGS

11. In the Statement of Allegations, Board Staff acknowledge that the Human Drug Advisory Panel "did not identify any comparators for Soliris."

12. The Statement of Allegations contains no assertion that "medicines in the same therapeutic class" are at issue. Neither section 85(1)(b) nor the words "other medicines in the same therapeutic class" within s. 85(1)(c) are cited as forming any basis for liability for "excessive" pricing.

13. In the Amended Reply, Board Staff expressly state that there are "no domestic comparators" for Soliris.

14. The case framed by the current pleadings under s. 85(1) is based on application of the Highest International Price Comparison ("HIPC") test found in the Guidelines. It is undisputed based on the pleadings and documentary disclosures that: (a) the nominal price of Soliris has not increased since it was introduced on the Canadian market in 2009; (b) the real price of Soliris has decreased since 2009 due to normal inflation, as reflected by the Consumer Price Index (CPI); and, (c) relative prices of Soliris in other countries (as expressed in local currency), have not materially changed since 2009.

15. Based on the pleadings and document filings, it is also undisputed that the price of Soliris was not considered "excessive" by Board Staff in 2010 and 2011. Board Staff's investigation was commenced in 2013 because fluctuations in foreign currency values, in particular increases in value of the Canadian dollar against other foreign currencies, triggered their interest in re-evaluating the price of Soliris under the HIPC test. The Guidelines acknowledge that "exchange rate variations" are "beyond the control of the patentee."

16. The Scheduling Order required the parties to file expert reports "supported by affidavits in accordance with Rule 8." Board Staff's expert reports were to be filed by 16 February 2016. Board Staff filed the Addanki and Schwindt reports on 16 February but without the supporting affidavits required by Rule 8. No leave was sought from, nor was permission granted by, the Panel for Board Staff to dispense with filing the affidavits.

PART 3 – SUBMISSIONS

17. An administrative tribunal's ability to admit evidence is "[s]ubject to the principles of natural justice and to the specific rules set out in their enabling legislation...": *Québec (Commission des droits de la personne et des droits de la jeunesse) c. Bombardier Inc.*, 2015 SCC 39, at paragraph 68.

18. Rule 8 specifically addresses expert evidence proffered before the Board, including admissibility of expert evidence:

> **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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> ...
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> **Report, declaration and availability**
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> **(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,
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> **(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 ...

19. The Scheduling Order and Rule 8 both required Board Staff to file affidavits that would provide fundamental information for determining the relevance, necessity, and overall admissibility of the expert evidence. To reiterate, the affidavit "must include":

(a) a statement of the issues;

(b) a description of the expert's qualifications with respect to the issuers;

(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 ore documents specifically relied upon in support of the opinions expressed; and

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

20. The failure to provide the affidavits not only contravenes the Scheduling Order and Rule 8 but unduly prejudices Alexion in its ability to prepare rebuttal expert reports and undermines the fairness of the proceeding. The information required in the affidavits is also critical for Alexion to comply with the requirement in Rule 8(3)(a)(vi), which requires responding experts to indicate "the points of agreement and disagreement with the other expert's opinions."

21. Rule 8(1) 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." Here, the expert evidence is inadmissible on its face because it purports to address issues—for example, in relation to the meaning of "therapeutic class" and "excessive pricing"—that are not raised in the pleadings.

22. Evidence admitted before an administrative tribunal must be relevant or logically probative to the question at issue. "Nothing is to be received which is not logically probative of some matter requiring to be proved": *R. Seaboyer* [1991] 2 SCR 577, at paragraph 37. In *Deemar v College of Veterinarians (Ontario)*, 2008 ONCA 600, the Court of Appeal for Ontario approved a tribunal's decision to reject an expert report because the affiant "had strayed from the function of an expert" and had "taken on the role of advocate and possibly the role of the trier of fact" (at paragraphs 20-22).

23. While administrative tribunals may be less stringent in their application of evidentiary rules than courts, they are guided by common law rules and should exercise the same measured approach as courts in admitting and evaluating expert evidence: see *British Columbia Lottery Corp. v. Skelton,* [2013] B.C.J. No. 12 (BCSC) at paragraphs 57-59, citing decision F06-07, *Fraser Health Authority (Re)*, [2006] B.C.I.P.C.D. No. 26 at para. 13.

24. The criteria for admissibility of expert evidence were well-established in *R. v. Mohan*, [1994] 2 S.C.R. 9 (S.C.C.), as follows:

(a) relevance;
(b) necessity;
(c) no exclusionary rule; and
(d) properly qualified expert. (at paragraph 17)

25. This Board has expressly disregarded expert evidence on the basis that it was neither relevant nor necessary under *Mohan*-related criteria: see *Sandoz Canada Inc.* decision (PMPRB-10-D2-SANDOZ) at paragraphs 23-27.

26. Significantly, the *Mohan* test is applied more stringently in two circumstances: (1) where the expert is using untested theories, or using accepted theories in a manner that is unusual; and (2) where the evidence is directed at one of the ultimate issues in the

case: see *Mohan*, *supra* (at pargraphs 24-25), and *R. v. J. (JL)*, [2000] 2 S.C.R 600 (SCC) (at paragraphs 33-35).

27. An expert may only speak to matters involving the expert's own expertise. The principle that experts may not opine on legal issues has been repeated in several Canadian decisions: *Ugbazghi v Canada (Minister of Citizenship & Immigration)*, 2008 FC 694 at para 27 ("as a general principle, affidavits are to deal in matters of fact – not law...domestic law is not a subject about which a Canadian court will receive opinion evidence."); and *Deemar v College of Veterinarians, supra*.

The Addanki Opinion

28. The Addanki Opinion is predicated on an entirely novel and un-pleaded theory of the case and disregards existing PMPRB Guidelines (see paragraph 7 of the Addanki Opinion). The Guidelines, in tandem with s. 85(1)(c) ("prices at which the medicine ... [has] been sold in countries other than Canada") are the only pleaded basis for liability of Alexion under s. 85(1) of the *Patent Act*. Yet, the Addanki Opinion introduces a novel, untested, and un-scientific approach to classifying medicines so as to provide his expert opinion on the statutory interpretation of the words "therapeutic class" within s. 85(1) of the *Patent Act*.

29. The selection of comparators used by Dr. Addanki defies the pleadings, in which all parties, and HDAP, have agreed that Soliris has no comparators.

30. The statutory interpretation suggested by Dr. Addanki runs contrary to established Canadian jurisprudence, the Board's own decisions, and the clear language of the Guidelines, which Dr. Addanki was apparently instructed to ignore.

31. The meaning of the "therapeutic class", as used in ss. 85(1)(b) and (c) of the *Patent Act*, is specifically defined in clauses C.8.1 - C 8.3 of the *Guidelines* by reference to the World Health Organization's (WHO) Collaborating Centre for Drug Statistics Methodology's Anatomical Therapeutic Chemical (ATC) Classification System. The term has also been interpreted in previous decisions of the Board and the Federal Court: See, for example, PMPRB-04-D2-DOVOBET (p.13) ("its normal meaning...is the class of medicines that typically work for a particular condition, or are considered similar

by the disease they treat and/or the effect they have on the body"); *Leo Pharma Inc. v. Canada (Attorney General)*, [2007] F.C.J. No. 425 (para. 26) ("the "Scientific Review Procedures" states that comparable medicines are "clinically equivalent in addressing the approved indication that is anticipated to be the primary use of the new drug product under review", and will typically be those identified under the World Health Organization (WTO) Drug Utilization Research Group's Anatomical Therapeutic Chemical Classification System (ATC), at the sub-class level above the single chemical substance". The Board has also noted that if a drug is a "breakthrough" product it will by definition not have comparators in the same therapeutic class: see PMPRB-06-D3-ADDERALL XR (p. 8) ("A therapeutic class comparison is undertaken by reference to therapeutic equivalence. By definition, if a medicine is a breakthrough, or even if it represents a substantial improvement over existing medicines, it could be unreasonable to attempt to establish a therapeutic class based on therapeutic equivalence"). In Decision: PMPRB-2010-D3-Copaxone (p. 8-10), the panel, in accepting Dr. Levine's evidence, noted that "HDAP is not concerned with the pricing of drugs. Rather, it assesses which drugs have similar therapeutic purposes and characteristics such that they can be considered to be in the same therapeutic class."

32. An expert opinion is inadmissible under Rule 8(1) if it is introduced to address an issue not raised in the pleadings. Moreover, an expert opinion is not admissible where it is irrelevant and unnecessary, and where it opines directly on a point of legal interpretation. The Addanki Opinion is thus inadmissible based on the plain wording of the "specific rules set out in" the Board's "enabling legislation."

33. Board Staff's manifest failure to comply with Rule 8(3) also supports a determination that the Addanki Opinion is inadmissible. Had this required information been filed, it would have thrown into sharp relief that Dr. Addanki's "opinions" are neither relevant to "any issue raised in the pleadings" nor supported by any conventional scientific literature or methodology relating to the definition of "therapeutic classification" of medicines.

The Schwindt Opinion

34. The Schwindt Opinion should likewise be ruled inadmissible based upon noncompliance with Rule 8(3). In the absence of a properly sworn affidavit, it is not clear which pleaded issue or issues his opinion purports to address, if any.

35. Section 6 of the Schwindt Opinion is inadmissible on its face. The section asserts legal argument in opposition to the legal defences Alexion has raised in its Response. An expert's opinion on an ultimate legal issue to be addressed by the tribunal is irrelevant and falls outside the expert's role.

The IMS Data

36. The IMS data is inadmissible as irrelevant and as rank hearsay. The IMS Data are based upon statements made by persons who will not testify in the proceeding, tendered as proof of their contents or as proof of assertions implicit within the data. The IMS Data do not fall within any exception to the hearsay rule and are unnecessary to resolution of the proceeding before the Panel.[2] The relevant comparative pricing information is established by the *Patented Medicines Regulations*, which provide:

> 4 (1) For the purposes of paragraphs 80(1)(b) and (2)(b) of the Act, information identifying the medicine and concerning the price of the medicine shall indicate:
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> ...
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> (f) in respect of the day or period referred to in paragraph (d),
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> ...
>
> (ii) the **publicly available** ex-factory price for each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory, and
>
> (iii) if the medicine is being sold in one or more of the countries set out in the schedule, the **publicly available** ex-factory price for each dosage form, strength and package size in which the medicine was sold to each class of customer in each of those countries.
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> ...
>
> (9) For the purposes of this section, publicly available ex-factory price includes any price of a patented medicine that is agreed on by the patentee or former patentee and the appropriate regulatory authority of the country in which the medicine is sold by the patentee. [Emphasis added.]

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[2] *The Law of Evidence in Canada* (4th ed), Sopinka, Lederman & Bryant, ss. 6.1-6.3, p. 237

37. The IMS Data is not based on "publicly available" ex-factory prices. The data is only privately available.

38. To date, and as pled, the Board Staff's entire case has been based on publicly available ex-factory prices for Soliris in Canada and the seven other countries specified in the *Regulations*. The publicly available information has been reported and relied upon by Alexion and the Board. There is no justification for introducing a new, and completely irrelevant, set of data into this proceeding, particularly when there is no reliable and effective way to validate the data.

39. If the IMS data were submitted through an IMS expert who could explain and interpret the data, it would fail the same relevance criteria required by Rule 8(1) and the affidavit requirements of Rule 8(3). An examination of the IMS Data through the lens of Rule 8 shows that it is irrelevant and inadmissible. Acceptance of this evidence will only prejudice and impose an undue burden on Alexion, and complicate and delay the resolution of the proceedings.

Dated: 7 March 2016

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