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"

NOTICE OF MOTION

Alexion's Motion to Strike Evidence as Inadmissible

RESPONDENT, ALEXION Pharmaceuticals Inc. ("Respondent" or "Alexion"), will present a motion before the Panel on a date to be scheduled at the Board's offices in Ottawa, by video-teleconference, or by teleconference, as the Panel may direct.

Alexion seeks:

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

2. An order striking out 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");

3. An order striking out documents, and references to documents, relating to 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");

4. In the alternative, an order postponing the hearing of this matter until the Autumn of 2016 to permit Alexion an opportunity to respond to the new and extraordinary issues raised by the Addanki Opinion, the Schwindt Opinion, and the IMS Data (collectively the "impugned evidence"); and

5. Such further or other relief as Alexion may request and the Panel deem appropriate to grant in relation to the impugned evidence.

GROUNDS FOR THE MOTION ARE:

6. The impugned evidence is inadmissible under prevailing standards of relevancy and necessity recognized by the Board in the *Sandoz Canada Inc* decision released in August 2012 (PMPRB-10-D2-Sandoz) ("*Sandoz*").

Addanki Opinion

7. The Addanki Opinion is inadmissible based upon the criteria articulated by the Supreme Court of Canada in *R. v. Mohan* [1994] 2 S.C.R. 9 ("Mohan") and *R. v. J. (J.L.)* [2000] 2 S.C.R. 600 because the opinion:

(a) does not meet the threshold requirements of relevance and necessity for admissible expert evidence;

(b) goes to the ultimate issues to be determined in the proceeding;

(c) does not fall within the expert's areas of expertise;

(d) relies on a novel application of scientific or technical knowledge; and

(e) has a prejudicial effect that clearly outweighs any possible probative value as evidence in the proceeding.

8. The Addanki Opinion is formulated to address the very issues to be determined by the Panel: (i) the interpretation of s. 85 of the *Patent Act*; and (ii) whether, in accordance with that interpretation, the price of Soliris is "excessive".

9. Remarkably, in preparing his "putative expert" opinion (see *Sandoz*, at paragraph 27) Dr. Addanki was asked by Board Staff to ignore the PMPRB *Compendium of Policies, Guidelines and Procedures* (the "Guidelines"), which include clear references to, and the requirement to apply, recognized scientific principles for therapeutic classification and categorization of medicines. The Addanki Opinion also completely overlooks and ignores the accumulated practice and jurisprudence of the Board, and of courts, interpreting the *Patent Act* based on scientific principles used to determine therapeutic classification of medicines.

10. Dr. Addanki opines on statutory interpretation and scientific issues. The author is not, and does not purport to be, an expert in Canadian law. Nor is he a scientist with expertise in principles relating to therapeutic classification of medicines. The Addanki Opinion therefore does not, and cannot, fall within the area of Dr. Addanki's expertise. In particular, the meaning of a "therapeutic class" in the *Patent Act*, as interpreted in the Guidelines and by the Board and courts, follows an accepted scientific definition. The Addanki Opinion runs contrary to the accepted scientific definition, and is contrary to the Board's long-established practices.

11. The Addanki Opinion is expressly predicated on the author's original research and defies the plain wording of the *Patent Act* and generally accepted scientific principles or approaches to evaluating therapeutic classes of medicines. Indeed, Dr.

Addanki dismisses, as economically unreasonable, the scientific therapeutic classification taxonomy actually referred to in the *Patent Act*, as applied by the Human Drug Advisory Panel ("HDAP") and accepted in both the Compendium and case law. The novel and unscientific approach used by Dr. Addanki is objectionable *per se* and his opinion is neither relevant nor necessary to determination of the issues before the Panel.

12. The proffered evidence similarly has no probative value because Dr. Addanki's proposed interpretation defies the plain wording of the *Patent Act,* established definitions of "therapeutic class", scientific principles, and the practices of the Board. The Panel's decision will not be aided by a novel application of economic expertise that reads out of the *Patent Act* the plain language of the statute requiring the Board to consider products in "the same therapeutic class." Expert evidence that is directly addressed to issues of legal interpretation or application is inadmissible.

13. Moreover, the Addanki Opinion introduces a new legal theory of the Board's case not found in the Board Staff's own pleadings. At no time since Alexion first submitted information about Soliris to Board Staff in 2009 has the Board, HDAP, or even Board Staff in its Statement of Allegations suggested there are comparator drugs to Soliris, whether in the same therapeutic class sold in Canada or in any of the seven foreign jurisdictions listed in the Regulations. Indeed, the Addanki Opinion is adduced in violation of the Board's Rules of Practice and Procedure: subsection 8(1) provides that, "[e]xpert 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." [Italics added.]

14. The prejudice to Alexion is clear. Requiring Alexion to evaluate and respond to such a novel and legally unsupportable application of economic analysis at this late stage of proceedings will demand more time to prepare rebuttal expert reports, result in a delayed and considerably longer hearing, and give rise to substantial additional expense that is not commensurate with the value of the Addanki Opinion as evidence before the Panel. The cost, and injustice, to Alexion in having to obtain its own responding expert evidence and participating in an extended hearing dealing with this evidence outweighs any possible probative value of the Addanki Opinion.

The Schwindt Opinion

15. The Schwindt Opinion will not aid the Panel in making a determination of whether the price of Soliris was "excessive" under s. 85 of the *Patent Act*. In the *Sandoz* decision, the panel made it clear that it would not rely upon a similar opinion of Professor Schwindt proffered by Board Staff.

16. Even assuming Board Staff can establish that the Schwindt Opinion meets the criteria articulated in *Mohan* and subsequent jurisprudence, section 6, of the Schwindt Opinion, entitled "Alexion's Criticisms", should be ruled inadmissible. In section 6 Professor Schwindt presents a legal opinion directed at Alexion's Response on the merits the case before the Board. The validity of legal claims or defences raised by a party constitutes legal argument and is not properly advanced as expert opinion. It is for the Panel, and not an economic expert, to determine the validity of claims or answers

raised in this case. Expert testimony that amounts to direct legal argument is patently irrelevant and inadmissible.

IMS Data

17. The IMS Data is inadmissible because it is irrelevant (and therefore of no probative value) and is hearsay that falls within no known exception to the hearsay rule. The applicable foreign pricing comparators are expressly prescribed in the regulations to come from *"publicly available"* sources. Board Staff are precluded from using evidence from private sources like IMS under a plain reading of the regulations.

Alternative

18. In the alternative, should the Panel not exclude the impugned evidence as requested, Alexion will require additional time to respond, and therefore requests that the Panel extend the time for Alexion to respond to the impugned evidence by 90 days to 16 June 2016. The requested extension will also require the Panel to adjourn the hearing to the Autumn of 2016.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of this motion:

(a) The Addanki Opinion;

(b) The Schwindt Opinion;

(c) The IMS Data; and

(d) Such further and other material as Alexion may adduce and the Panel admit.

Dated: 26 February 2016

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