PATENTED MEDICINE PRICES REVIEW BOARD

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

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

RESPONSE TO BOARD STAFF'S MOTION and WRITTEN REPRESENTATIONS OF THE RESPONDENT ALEXION PHARMACEUTICALS INC.

RESPONDENT, ALEXION Pharmaceuticals Inc. ("Alexion") submits this response to Board Staff's motion to the Hearing Panel ("Panel") for determination before recommencement of the Hearing on 23 January 2017 in Ottawa.

RELIEF REQUESTED :

1. An Order dismissing the motion brought by Board Staff after the close of business on Friday 20 January 2017.

THE GROUNDS FOR THE MOTION ARE:

2. Rather than taking the time to comply with the Panel's directions concerning delivery of meaningful particulars of liability and all relevant documents, Board Staff have effected yet another surprise during the hearing: a motion to request production

from Alexion and British Columbia of "Product Listing Agreements" ("PLAs"), negotiated between Alexion and provincial Ministers.

3. The information in the PLAs is irrelevant to this proceeding. The jurisdiction of this Board does not extend to regulation of third-party reimbursement of medicines. Board Staff expressly rejected any consideration of the payment of rebates or other consideration given to provincial governments on the basis that they were third parties, and Alexion has taken no issue with that decision in the pleadings. It is disingenuous and unfair for Board Staff to now claim, at this late date and in the midst of the hearing, that provincial rebates are suddenly relevant to the Panel's determination on the merits.

4. In pursuing its motion, Board Staff has argued for an extended definition of "relevance", and has claimed, in paragraph 18 of its Motion, that "…relevant evidence typically concerns the key facts on which the decision will turn". Even applying this definition, the PLAs are "not relevant" because the decision of this Panel could not conceivably "turn" on the amount of provincial rebates or the details of the PLAs between Alexion and the provinces.

5. The motion brought by Board Staff is an obvious and colourable attempt to circumvent the decision of the Federal Court in *Pfizer Canada Inc. v. Canada (Attorney General)*,¹ ("*Pfizer"*). In *Pfizer*, the Federal Court held that the jurisdiction of the Board is constitutionally limited to the "factory-gate" price of patented drugs—in its consideration of which, the Board was not permitted to look to "contractual

¹ Pfizer Canada Inc. v. Canada (Attorney General), [2009] F.C.J. No. 882 (T.D.)

arrangements involving patentees and entities further down the distribution chain." The court wrote:

[83] I would also observe that my interpretation of the Patent Act and the Patented Medicines Regulations is consistent with the constitutional limitation on the Board's ability to look beyond the factory-gate price of patented medicines, to consider contractual arrangements involving patentees and entities further down the distribution chain.

6. Given that this Board's jurisdiction does not extend to consideration of contractual arrangements like the PLAs, that Board Staff previously rejected any consideration of the PLAs, and that the PLAs are not relevant to any decision the Panel will make, Board Staff's request for an order to produce the PLAs should be denied.

7. Another compelling reason to deny Board Staff's request is that at this late stage of the proceeding, after examination in chief of their own fact witness, the request is dilatory, abusive, and is being made merely as a litigation tactic to distract Alexion, to cause unnecessary delay of the proceedings, and to needlessly increase litigation costs.

8. Board Staff have known since the outset of this proceeding about the existence of the provincial PLAs. Indeed, the British Columbia Minister of Health, through its proffered witness, Eric Lun, indicated in a sworn affidavit as early as April 1, 2015 (less than 3 months after the hearing commenced) that the PLAs existed. The Witness Statements of John Haslam and Eric Lun were circulated more than 8 months ago. No reason has been provided for making the request during Alexion's cross-examination of Board Staff's principal fact witness. THE FOLLOWING DOCUMENTARY EVIDENCE is being relied upon by Alexion for the

purpose of this motion:

9. The pleadings and proceedings herein and such material as counsel may adduce and the Panel admit.

Dated: 23 January 2017

Original signature redacted

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