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

BOARD STAFF'S SUPPLEMENTARY REPLY TO THE SUPPLEMENTARY RESPONSE TO BOARD STAFF'S AMENDED STATEMENT OF ALLEGATIONS

1. Board Staff repeats and relies on its Amended Statement of Allegations and the defined terms contained therein.

2. Board Staff denies paragraphs 1-8, 10-12, 15-25 of the Supplementary Response to Board Staff's Amended Statement of Allegations.

3. Board Staff asserts that the majority of Alexion's allegations in its Supplementary Response to Board Staff's Amended Statement of Allegations are legal arguments, not material facts and they ought to be struck. In any event Board Staff disagrees with these arguments.

4. The Amended Statement of Allegations does not advance a new liability theory by Board Staff. Board Staff has merely set out alternative remedies for the Hearing Panel to consider should it find that the price of Soliris is excessive.

5. Alexion has misunderstood the role of the *Guidelines* and of the Highest International Price Comparison Test ("HIPC test") and the Median International Price Comparison Test ("MIPC test") in the determination of whether a medicine is excessively priced. The determination of whether a medicine is excessively priced is determined based on the factors set out in s. 85(1) and (2) of the *Patent Act* ("*Act*") and not solely on the application of the HIPC test or the MIPC test which are set out in the Guidelines.

6. Soliris was introduced by Alexion into the Canadian market in June 2009. In 2010 Board Staff concluded that the introductory price of Soliris exceeded the median international price as established by the MIPC. Alexion subsequently amended its Form 2 Block 5 Filings with the Board. As a result of the amendments, the investigation criteria under the *Guidelines* was no longer triggered. The fact that the investigation criteria was not triggered however was not an indication by Board Staff that the price of Soliris was not excessive. Only a Board panel can make a conclusive determination of whether the price of a patented medicine is excessive. Board Staff cannot make such conclusive determinations and its analysis based on the *Guidelines* can only serve as guidance.

7. Pursuant to the *Guidelines* the price of a medicine cannot exceed the HIPC in the years subsequent to introduction. The HIPC test is a test applied by Board Staff which identifies only those extreme cases in which a medicine is excessively priced. However, the fact that the price of a medicine does not exceed the HIPC

test does not on its own establish whether the price of that medicine is excessive. Furthermore, the HIPC test does not determine the extent of the excessivity.

8. In 2012 the application of the HIPC test resulted in Board Staff commencing an investigation into the price of Soliris. The results of that investigation have led Board Staff to conclude that the price of Soliris was (and still is) excessive and that the Hearing Panel should issue an Order in accordance with Scenario A, Scenario B or Scenario C in paragraph 31 of the Amended Statement of Allegations.

9. On introduction of Soliris and in all subsequent years, Alexion has known that the price of Soliris is subject to regulation and that the determination as to whether the price is excessive can only be made subsequent to an investigation and a decision by a Hearing Panel based upon all of the factors set out in s. 85(1) and (2) of the *Act*. Moreover, by pricing Alexion in the manner in which it did, Alexion chose to accept the risk that the price of Soliris would trigger a Board Staff investigation which would result in the possibility that a Hearing Panel could issue an Order for the repayment of excess revenues.

10. Contrary to the allegations contained throughout Alexion's Supplementary Response to Board Staff's Amended Statement of Allegations, Board Staff are not seeking to "confiscate" Alexion's assets. Board Staff merely seeks to recover a debt to Her Majesty which arises from Alexion's decision to sell Soliris at an

excessive price. Consequently, Board Staff merely seeks restitution from Alexion of the excess amounts it charged.

11. In specific response to paragraph 12 of the Supplementary Response to Board Staff's Amended Statement of Allegations, Alexion has mischaracterized the "Discussion Paper" released by the Board, which in any event has no application to this case. The determination as to whether a price is excessive must be based solely on the factors set out in s. 85(1) and (2) of the *Act*.

12. Contrary to the allegations contained in paragraphs 17 and 18 of the Supplementary Response to Board Staff's Amended Statement of Allegations, data obtained from IMS "is publicly available" and is a reliable price source to conduct international price comparisons.

13. To the extent that Alexion relied upon "publications, practices and representations" of the Board, it did so at its own peril. The administrative steps taken by Board Staff in its review and investigation of the price of Soliris do not fetter the Hearing Panel in determining whether the price of Soliris is excessive. Such a determination can only be reached by application of the factors set out in s. 85(1) and (2) of the *Act*.

Dated at Ottawa this 11th day of August, 2016

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