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September 1, 2015

**BY EMAIL**

Mr. Guillaume Couillard
Secretary of the Board
Patented Medicine Prices Review Board
Legal Services Branch
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Dear Mr. Couillard:

**Re: Alexion Pharmaceuticals Inc. and the medicine "Soliris"**
**Our Reference: PMPR010**

Please find enclosed the Amended Reply to the Respondent's Amended Response to Board Staff's Statement of Allegations which is being filed pursuant to the *Rules of Practice and Regulations*.

Yours very truly,

Original signature redacted

David Migicovsky
20:llc
Encl.
cc Christopher Morris (by email)
Nathalie Beaulieu (by email)
Isabel Jaen Raasch (by email)
Parul Shah (by email)
Craig Anderson (by email)
Malcolm Ruby (by email)
Alan West (by email)
Sharna Kraitberg (by email)
Anil Kapoor (by email)

**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"**

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

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

2. Board Staff admits paragraphs 3 and 5 of the Amended Response. Board Staff alleges that Alexion's National Average Transaction Price ("**N-ATP**") in Canada, which is the same as its publicly available list price, is excessive over a three-year period beginning in 2012; and that Alexion has not increased (or reduced) the publicly available list price of Soliris since it was introduced.

3. Board Staff has no knowledge of the actual ex-factory prices of Soliris in any of the comparator countries referenced in paragraphs 6 and 7 of the Amended Response. Board Staff's investigation into the price of Soliris compared the N-ATP with the publicly available list prices in each of the comparator countries, as alleged in paragraph 15 of the Statement of Allegations.

4. Board Staff denies the balance of the allegations contained in the Amended Response generally and more specifically as set out below. Board Staff further asserts that the majority of Alexion's allegations in paragraphs 8 to 27 and 31 to 38 are arguments, not material facts. In any case, Board Staff disagrees with these arguments.

5. Board Staff denies paragraph 8 and footnote 1 of the Amended Response. Board Staff did not conclude that the introductory price of Soliris was "non-excessive". Alexion deliberately chose to price Soliris at introduction above the ceiling price set by the Maximum Non-Excessive Price ("**MNE**") (now the Maximum Average Potential Price "**MAPP**") under the Board's then Guidelines. The MNE was set by the median international price among the comparator countries, which is a premium ceiling price only afforded to medicines that are breakthrough or of substantial therapeutic improvement. As Alexion is aware, Board Staff determined that Alexion's introductory price of Soliris exceeded the median international price among the comparator countries; however, the excess revenues Alexion generated did not meet the criteria for continuing the investigation. These criteria were established to allow Board Staff to allocate its resources to investigations as efficiently as possible. In deciding not to pursue the investigation, Board Staff did not therefore deem the introductory price of Soliris to be "non-excessive".

6. Contrary to paragraphs 8 and 9 of the Amended Response, Board Staff has not alleged that the price of Soliris is excessive due to changes in exchange rates.

Board Staff submits that based on the factors under subsection 85(1) of the Act, the Regulations and the Board's Guidelines, Alexion has been selling Soliris to Canadians at an excessive price since 2012. Board Staff further submits that its application of the factors, the Regulations and the Board's Guidelines in this case is appropriate and reasonable.

7. Additionally, Alexion has failed to justify its excessive price under subsection 85(2) of the Act. In any event, there appears to be no justification for Alexion's excessive price based on costs or other factors. For example:

   (i) for as long as Alexion has been selling Soliris in Canada, it has spent a total of zero dollars on research and development costs in Canada; and

   (ii) it appears that from 2009 to 2014, Alexion's total cost of global sales for Soliris has been approximately 10 to 12 percent of its net product sales; and therefore, Alexion's gross profit margin for Soliris has been approximately 90%.

8. Board Staff denies paragraphs 10 and 14 (e) of the Amended Response. Alexion requested particulars that were both within its knowledge and not required to enable it to plead. Alexion does not therefore require particulars. ~~A copy of Alexion's request and Board Staff's response is attached at Appendix A and B respectively.~~ In any event, particulars were provided on 3 July 2015 pursuant to the Panel's Order of 23 June 2015. Board Staff also denies and

disagrees with Alexion's characterization and description of the particulars provided on 3 July 2015. Particulars were provided of the factual basis for the sources Board Staff used and the calculations made under the Highest International Price ("**HIPC**") test, not to advance legal argument (which would be improper). Board Staff's position is and always has been that the price of Soliris is excessive under the Act. Alexion's "belief" as to Board's Staff's "apparent conclusions" is irrelevant as the only relevant issue in this proceeding is whether the price of Soliris has been excessive under the Act. In this regard, Alexion misunderstands the purpose of an investigation into excessive pricing and how that differs from a proceeding before the Board in the context of a hearing. Board Staff's interpretation of the Guidelines and the Regulations are not binding on the Board during a hearing. The hearing is a fresh opportunity for the Board to determine whether a medicine's price is excessive under the Act.

9. Board Staff denies paragraphs 11 and 12 of the Response. Board Staff submits that the HIPC test, which is long-established and the result of extensive consultation with stakeholders, is a generous application of paragraph 85(1)(c) of the Act. It targets those extreme cases where the Canadian price of a patented medicine not only exceeds the international median but the prices in all other comparator countries listed in the Regulations. Board Staff admits, however, that the Board must take into account all factors in the Act that relate to whether a price is excessive under subsection 85(1) and that the Guidelines are not binding on the Board. Further, where the Board determines that it is unable to determine whether the medicine is being or has been sold at an excessive price under

subsection 85(1), it may take the factors under subsection 85(2) into account.

10. The exchange rate methodology used to compare prices in Canada with those in the comparator countries is also long-established and the result of extensive consultation with stakeholders. The methodology uses the simple average of the thirty-six monthly average noon spot exchange rates, as published by the Bank of Canada, to convert international prices to prices in Canadian dollars. The thirty-six month period, among other things, provides predictability to patentees, reduces short term volatility without insulating the international price comparison from long term trends in international currency relationships, and is not inherently biased in favour of the patentee or consumers. It is also the same methodology that is used to calculate the MAPP or the ceiling price at introduction under the Board's Guidelines. The methodology allows for meaningful international price comparisons so that the extreme cases where the Canadian price exceeds the price in all other comparator countries may be identified.

11. Board Staff denies paragraph 13 of the Amended Response. Board Staff asserts that at all material times Alexion knew or ought to have known that its decision to set the Canadian price for Soliris — for which there are no domestic comparators — above the international median and among the highest international prices of the comparator countries may result in the price of Soliris contravening the Act. Moreover, Alexion has deliberately chosen not to reduce the price of Soliris in Canada since it became the highest international price among the comparator countries at least three years ago.

12. Further, contrary to Alexion's allegation in the last sentence of paragraph 13 of the Amended Response, Board Staff is not required under the Act to demonstrate that any consumer is "worse off" as a result of Alexion's pricing decisions. In any case, Canadians are harmed by the excessive price of Soliris.

13. Board Staff denies paragraph 14 of the Amended Response. Board Staff did not make any errors in concluding that the price of Soliris has been excessive since 2012.

14. Board Staff denies Alexion's economic arguments at paragraphs 15 to 26 of the Amended Response. The Act requires that the Board must consider "the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada." If accepted, Alexion's economic arguments would mean that no comparisons between Canadian and foreign prices could be made under subsection 85(1)(c) of the Act, thus rendering the statutory factor meaningless.

15. Board Staff denies paragraph 19 of the Amended Response. Patentees are not entitled to price increases under the Act. A patentee's choice not to increase the price of its medicine does not make the price of the drug "non-excessive". In this case, had Alexion increased the price of Soliris in Canada, it would have generated even greater excess revenues.

16. Board Staff denies paragraphs 26 and 27 of the Amended Response. The purpose of the relevant provisions of the Act is to protect Canadians by ensuring

that the prices of patented medicines in Canada are not excessive.

17. Board Staff denies paragraphs 28, 29 and 30 of the Amended Response. Board Staff has not made any factual errors in its Statement of Allegations.

18. Board Staff denies paragraphs 32 to 35 of the Amended Response. No legally binding factual finding has been made that the price of Soliris from 2009 to 2011 was not excessive. Alexion misunderstands the purpose of an investigation into excessive pricing and how that differs from a proceeding before the Board in the context of a hearing. Board Staff's interpretation of the Guidelines and the Regulations are not binding on the Board during a hearing. The hearing is a fresh opportunity for the Board to determine whether a medicine's price is excessive under the Act.

19. Board Staff denies paragraph 36 of the Amended Response. Board Staff applied the HIPC test consistent with the Guidelines and the Regulations. Alexion is aware of how Board Staff applied the HIPC test. The test was applied based on information Alexion itself provided to Board Staff.

20. Board Staff denies paragraph 38 of the Amended Response. As stated above, Alexion misunderstands the purpose of an investigation into excessive pricing and how that differs from a proceeding before the Board in the context of a hearing. The hearing is a fresh opportunity for the Board to determine whether a medicine's price is excessive under the Act. Board's staff position is and has always been that the price of Soliris is excessive under the Act.

21. Board Staff also denies and disagrees with Alexion's characterization of Board Staff's disclosure obligations in paragraph 38 of the Amended Response. Board Staff has repeatedly stated that the disclosure of materials that Board Staff intend to rely on during the hearing can and shall be disclosed once the pleadings are closed. Contrary to Alexion's allegations, therefore, Board Staff has not refused to disclose evidence after the close of pleadings. To the extent Board Staff will rely on expert evidence to support its allegation that the price of Soliris is and has been excessive under the Act, the procedure set out in the PMPRB Rules of Practice and Procedure ensures that Alexion will have sufficient notice and opportunity to respond. To the extent Board Staff will rely on other evidence (such as documents) to support its allegation that the price of Soliris is and has been excessive under the Act, Board Staff has, as stated above, agreed to make that material available after the close of pleadings. Alexion will therefore have sufficient notice and opportunity to respond. Alexion has not pleaded any specific reason why this procedure will cause it "extreme prejudice", and Board Staff does not know of any. Finally, the question of whether Board Staff is or was obligated to provide disclosure prior to the close of the pleadings is *res judicata* given the Board's 23 June 2015 Order, which was made further to the motions heard during the pre-hearing conference held on 22-23 June 2015.

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