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"

ALEXION'S SURREPLY TO BOARD STAFF'S AMENDED REPLY

1. In paragraph 7 of the Amended Reply, Board Staff cite, for the first time, subsection 85(2) of the *Patent Act*. The allegations in paragraph 7 do not arise out of any issue or material fact raised in Alexion's Response or in Board Staff's Statement of Allegations and are irrelevant.

2. Alexion does not have an obligation to "justify" its price. The current price for Soliris was first established in 2009 under Schedule 5 of the Compendium of Policies, Guidelines, and Procedures ("Guidelines") when Soliris was first sold in Canada. The price for Soliris has never increased in Canada in the 6 years it has been sold here. Documents eventually disclosed by Board Staff in these proceedings demonstrate that the price of Soliris was not deemed excessive by the Board in either 2010 or 2011. Given that no Consumer Price Index (CPI) increases were requested by Alexion, the price of Soliris in Canada in real terms has actually decreased in Canada over the last six years. In the circumstances, Board Staff are precluded by, among other legal reasons, the principles of fairness and estoppel from asserting that Alexion is required to justify a price that has been established for 6 years, has decreased, and is only the

subject of review because of fluctuations in the value of the Canadian dollar against certain foreign currencies selected by Board Staff.

3. Nothing in the *Patent Act*, the Guidelines, or the Board's jurisprudence suggests that s. 85(2)(a) is an independent basis for reviewing a patentee's price during the period of patent exclusivity particularly, as in this case, when the price of Soliris was established based on a published formula six years ago, has decreased in real terms, and is only under review because of changes in the value of the Canadian dollar in relation to certain foreign currencies.

4. In paragraph 9 of the Amended Reply, Board Staff assert that "Board must take into account all factors in the Act that relate to whether a price is excessive under subsection 85(1)" and that "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."

5. Apart from allegations in the Statement of Allegations relating to the Highest International Price Comparison (HIPC) test under Schedule 6 of the Guidelines, Board Staff have provided no details of how (i.e., in what way or ways) the price of Soliris violates "factors...under subsection 85(1)" or any factor under subsection 85(2)(b) of the *Act*.

6. The absence of any specificity concerning existing factors under subsection 85(1) and Board Staff's failure to identify any factor at all under 85(2)(b) mean Alexion does not, and cannot, know the case it has to meet other than the application of the HIPC test mentioned in the Statement of Allegations.

7. Alexion asserts that on any fair and impartial application of the factors under subsection 85(1) of the *Act* the Panel will be able to determine that the price of Soliris is not excessive. As indicated above in paragraph 2, the price of Soliris has remained the same since it was first sold in Canada in June 2009 and the introductory price was not deemed excessive by the Board in either 2010 or 2011. Moreover, the price of Soliris in comparator countries has not decreased in the last six years (and, indeed, Soliris has been the subject of slight price increases in some other countries). The only thing that has changed since 2009 is the value of the Canadian dollar in relation to other currencies: a phenomenon entirely beyond Alexion's control and of no consequence whatsoever to patients in Canada who (given the absence of CPI increases) have seen the price of Soliris prescriptions in Canada decrease in real terms since Soliris was first introduced in 2009.

8. Board Staff's suggestion that subsection 85(2) works as a notional 'tie breaker' is premature. The Panel will be able to determine that the price of Soliris is not excessive under subsection 85(1) for the reasons submitted in the Amended Response and this Surreply. Alexion denies that subsection 85(2) has any application to this proceeding. Without conceding that subsection 85(2) in any way applies or is relevant, Alexion asserts that Board Staff's failure to state any factor under subsection 85(2)(b) of the *Act* means Alexion has no way of knowing the rule (or factor) that could break a notional tie. Board Staff's approach to subsection 85(2)(b), like their vague allegations under subsection 85(1), expose a serious breach of the rules of natural justice and fairness. Alexion cannot meet a case it does not know, is based on rules or factors that are

unstated or left deliberately vague, or that involve fresh attacks on a price established more than six years ago and that has actually declined in real terms.

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