ABRIDGED

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"

STATEMENT OF ALLEGATIONS OF BOARD STAFF

I. OVERVIEW

1. Soliris (*eculizumab*) 10mg/mL ("**Soliris**") is a breakthrough life-saving medicine. It is also one of the most expensive medicines in Canada and the world. The annual cost of treatment for Soliris in Canada is over half a million dollars per patient. Patients who are treated with Soliris remain on the medicine for life.

2. Since 2012 — and thus for the past three years — Alexion Pharmaceuticals Inc. ("**Alexion**") has been selling Soliris to Canadians at the highest international price among the comparator countries. Further, Alexion has been selling Soliris to Canadians at a price that is appreciably higher than in the United States — which generally has the highest drug prices in the world. Alexion has therefore been selling Soliris to Canadians at an excessive price.

3. Board Staff seeks an Order under section 83 of the *Patent Act* (the "**Act**") requiring Alexion, among other things, to stop selling Soliris at an excessive price ($224.7333/mL) and to offset the excess revenues that Alexion has generated from the sale of Soliris at an excessive price.

II. FACTUAL BACKGROUND

A. The Respondent

4. Alexion is a publicly-traded biopharmaceutical company that is incorporated pursuant to the laws of Delaware. It is headquartered in Cheshire, Connecticut. Alexion develops and commercializes therapeutic products for patients with rare disorders.

B. Medicine

5. Soliris is the first and only treatment for patients with Paroxysmal Nocturnal Hemoglobinuria ("**PNH**"). PNH is a rare and life-threatening blood disorder that is characterized by complement-mediated hemolysis (the destruction of red blood cells). Soliris is indicated to reduce complement-mediated hemolysis (**Attachment 1**). The annual cost of treatment for Soliris for a single patient in Canada suffering from PNH is over $500,000.

6. On 28 January 2009, Health Canada issued to Alexion a Notice of Compliance for Soliris for the treatment of PNH (**Attachment 2**).

7. In May 2009, based on the scientific review procedures under the pre-2010 Compendium of Guidelines, Policies and Procedures ("**Former Guidelines**"), the Patented Medicine Prices Review Board's ("**PMPRB**") Human Drug Advisory Panel ("**HDAP**") recommended Soliris as a Category 2 (breakthrough or substantial improvement) drug product. The HDAP also did not identify any comparators for Soliris.

8. On 12 June 2009, Alexion began selling Soliris in Canada at $224.7333/mL.

9. Since Alexion began selling Soliris in Canada, Soliris has been approved for indications other than PNH. In 2013, Health Canada issued to Alexion a Notice of

Compliance for Soliris for Atypical Hemolytic Uremic Syndrome ("**aHUS**"). aHUS is a rare and life-threatening genetic disorder that is characterized by complement-mediated thrombotic microangiopathy or TMA (blood clots in small vessels). Soliris is the first and only treatment for aHUS and is indicated to inhibit complement-mediated TMA. The annual cost of treatment for Soliris for a single patient in Canada suffering from aHUS is over $700,000.

10. Soliris has also received orphan drug designations ("**ODD**") (in addition to those received for PNH and aHUS in the United States and the European Union) for the following rare diseases or conditions: in 2014 for the prevention of delayed graft function in renal transplant patients in the United States and for the treatment of refractory myasthenia gravis in the United States and the European Union. (An ODD provides a drug sponsor with special status for seeking market authorization for a drug product intended to treat a rare disease or condition. It results in a period of market exclusivity if market authorization is ultimately granted).

C. The Patent

11. Canadian Patent No. 2189015 ("**015 Patent**") pertains to Soliris (**Attachment 3**).

12. The 015 Patent was granted to Alexion on 13 April 2010 and will expire on 1 May 2015.

13. Alexion is a patentee within the meaning of subsection 79(1) of the Act, as it is entitled to exercise rights in relation to the aforementioned patent.

D. Investigation into Alexion's 2012 Price of Soliris

14. On 25 February 2013, Board Staff commenced an investigation into the 2012 price of Soliris ($224.7333/mL) (**Attachment 4**).

15. In accordance with the 2010 Compendium of Guidelines, Policies and Procedures ("**2010 Guidelines**"), and the Highest International Price Comparison ("**HIPC**") test, Board Staff compared the National Average Transaction Price ("**N-ATP**") to the publicly available list prices of Soliris sold in the comparator countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States) listed in the Schedule of the *Patented Medicines Regulations* (the "**Regulations**").

16. Board Staff determined that in 2012 Alexion was selling Soliris in Canada at the highest international price among the comparator countries, contrary to the 2010 Guidelines.

17. Alexion was also selling Soliris in Canada at a price that was appreciably higher than in the United States, where Soliris was sold below the international median price among the comparator countries.

18. In accordance with the 2010 Guidelines, Alexion was given the opportunity to adjust the price of Soliris by the end of 2013 to below the previous year's national non-excessive average price ("**N-NEAP**"). Alexion declined to do so.

19. In 2013 and for the first half of 2014, Alexion continued to sell Soliris in Canada at the highest international price among the comparator countries ($224.7333/mL). It also continued to sell Soliris to Canadians at a price that was appreciably higher than in the United States.

20. Board Staff requested that Alexion submit a Voluntary Compliance Undertaking ("**VCU**") to repay the excess revenues that it accumulated from the sale of Soliris at an excessive price. Alexion refused. Attached hereto at **Appendix A** is a confidential chart setting out the excess revenues for Soliris as of 30 June 2014.

21. Alexion continues to sell Soliris to Canadians at the highest international price among the comparator countries. Alexion's price of Soliris in Canada has also remained appreciably higher than the price of Soliris in the United States.

III. SUBSECTION 85(1) OF THE ACT

22. Subsection 85(1) of the Act sets out the factors the Board shall take into consideration in determining whether a medicine is being or has been sold at an excessive price in any market in Canada. It states:

> In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> *(a)* the prices at which the medicine has been sold in the relevant market;
>
> *(b)* the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
>
> *(c)* the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
>
> *(d)* changes in the Consumer Price Index; and

> *(e)* such other factors as may be specified in any regulations made for the purposes of this subsection.

23. To date, no additional factors have been specified by regulation for the purposes of subsection 85(1) of the Act.

24. In accordance with the factors set out in subsection 85(1) of the Act, the Board, following considerable deliberation and consultation with all stakeholders pursuant to subsection 96(5) of the Act, published the 2010 Guidelines.

25. Although the 2010 Guidelines are not binding on the Board, Board Staff submits that it is appropriate in this case for the Board to apply the approach and methodology set out in these 2010 Guidelines when applying the factors set out in subsection 85(1) of the Act to determine whether Soliris is being or has been sold at an excessive price in any market in Canada.

IV. ALEXION SELLS SOLIRIS AT AN EXCESSIVE PRICE

26. Since 2012 — and thus for the past three years — Alexion has been selling Soliris in Canada at the highest international price among the comparator countries. Further, Alexion has been selling Soliris to Canadians at a price that is appreciably higher than in the United States, where Soliris has been sold at one of the lowest international prices among the comparator countries.

27. Board Staff submits that when applying the factors under subsection 85(1) of the Act, there are grounds for the Board to conclude, pursuant to section 83 of the Act, that Alexion is selling or has sold the medicine known as Soliris in any market in Canada at a price that is or was excessive.

28. Board Staff reserves the right to make such other allegations and submissions and to introduce such other documents as Board Staff may advise and the Board may permit.

29. Pursuant to section 86 of the Act, a hearing shall be held in public unless the Board orders otherwise. Board Staff submits that any hearing conducted by the Board into the price of Soliris should be held in public and, subject to the Order of the Board, all information and documents filed should form part of the public record.

V. ORDER REQUESTED

30. Board Staff seeks the issuance of an Order as against Alexion, the terms of which are as follows:

a) The Introductory Maximum Non-Excessive Price (MNE price) and National-Non-Excessive Average Prices (N-NEAP) of Soliris are as follows:

Year	Introductory MNE price
2009	[redacted]
	N-NEAP
2010	[redacted]
2011	[redacted]
2012	[redacted]
2013	[redacted]
2014	[redacted]

b) The 2014 N-NEAP is subject to change if the HIPC for 2014 changes.

c) Alexion shall reduce the price of Soliris within 30 days from the date of the

Board's Order to a price that does not exceed the international median among the comparator countries.

d) Alexion shall offset the cumulative excess revenues it has received during the period of 1 January 2012 to 30 June 2014 by making a payment to Her Majesty in Right of Canada, within 30 days of the date of the Board's Order, in the amount of [redacted].

e) Alexion shall offset the cumulative excess revenues it has received during the period of 1 July 2014 to the date on which the price reduction referred to in paragraph c) above comes into effect by making a payment to Her Majesty in Right of Canada of an amount that is equal to the excess revenues the Board estimates that Alexion has generated from the sale of Soliris at an excessive price. Alexion shall make the payment within 30 days of receipt of a notification from the Board of its estimate of excess revenues based on the information filed in response to paragraph g) below.

f) Alexion shall ensure that the price of Soliris remains within the PMPRB's Guidelines in all future periods in which Soliris remains under the PMPRB's jurisdiction.

g) Alexion shall within 30 days of the date of the Board's Order:

   (i) notify federal/provincial/territorial ministers of health, or their representatives, and all customers of the price decrease as required by the Board's Order (a copy of which shall be included in such notifications) and the effective date of such price decrease;

(ii) submit copies of the above-noted notifications and any other notice to the Board; and

(iii) provide to the Board information concerning the quantity of Soliris sold and either the average price or the net revenue from sales of Soliris in Canada, in the same form as required by subsection 4(1) of the Regulations for the period of 1 July 2014 to the date on which the price reduction referred to in paragraph c) comes into effect.

h) Any other remedies Board Staff may seek and the Board may permit.

Dated at Ottawa this 15th day of January 2015.

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LIST OF ATTACHMENTS

Attachment 1 – Product Monograph SOLIRIS dated 28 January 2009

Attachment 2 – Notice of Compliance dated 28 January 2009

Attachment 3 – Canadian Patent No. 2189015

Attachment 4 – Letter from A. Chodos, PMPRB, to J. Haslam, Alexion dated 25 February 2013