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"

REPLY TO THE RESPONDENT'S 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 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 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 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 are arguments, not material facts. In any case, Board Staff disagrees with these arguments.

5. Board Staff denies paragraph 8 of the 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 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. Board Staff denies paragraph 10 of the 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.

8. Board Staff denies paragraphs 11 and 12 of the Response. Board Staff submits that the Highest International Price Comparison ("**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.

9. 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.

10. Board Staff denies paragraph 13 of the 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.

11. Further, contrary to Alexion's allegation in the last sentence of paragraph 13 of the 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.

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

13. Board Staff denies Alexion's economic arguments at paragraphs 15 to 26 of the 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.

14. Board Staff denies paragraph 19 of the 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.

15. Board Staff denies paragraphs 26 and 27 of the 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.

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

Legal Services Branch
1400-333 Laurier Avenue West
Ottawa, Ontario K1P 1C1
Tel: (613) 952-7623
Fax: (613) 952-7626

Parul Shah
Email: parul.shah@pmprb-cepmb.gc.ca

Perley-Robertson, Hill & McDougall LLP
1400-340 Albert Street
Ottawa, ON K1R 0A5
Tel: (613) 566-2833
Fax: (613) 238-8775

David Migicovsky
Email: dmigicovksy@perlaw.ca

Christopher Morris
Email: cmorris@perlaw.ca

Lawyers for Board Staff

APPENDIX A

12 February 2015

Malcolm N. Ruby
Direct 416-862-4314
Direct Fax 416-863-3614
malcolm.ruby@gowlings.com
File No. T999663

VIA E-MAIL: CMorris@perlaw.ca

Christopher P. Morris
Perley-Robertson, Hill & McDougall LLP
340 Albert Street
Suite 1400
Ottawa, Ontario
K1R 0A5

Dear Mr. Morris:

Re: 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" Re: Schedule and Particulars of Allegations

We wish to re-confirm our understanding of the agreed-upon schedule and request further particulars and disclosure regarding the Statement of Allegations ("Statement").

Our understanding of the current schedule is:

1. Delivery of Alexion's Response to Statement of Allegations: 9 March 2015;

2. Delivery of Board Staff's Reply to the Response: 10 April 2015; and

3. Case Management Conference: No later than 30 April 2015.

The schedule is subject to any modifications that may be necessary as a result of interventions by provincial Attorneys General.

In our review of the Statement, we saw no details regarding Board Staff's analysis of the introductory price of Soliris, other than a bare mention that the Board recommended Soliris as a "breakthrough or substantial improvement" drug product when Alexion began selling Soliris in Canada at $224.7333/mL. Moreover, no mention is made in the Statement of the impact of foreign exchange rates on the outcome of the "Highest International Price Comparison test" Alexion's product is alleged to have failed.

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To fully appreciate and answer the claims in the Statement before delivering Alexion's Response, we would be grateful if you would provide the following particulars:

1. Any details concerning Board Staff's conclusions concerning the introductory price of Soliris; and

2. Board Staff's calculations concerning the impact of exchange rates on pricing of Soliris in the comparator countries listed in the Schedule to the *Patented Medicines Regulations*.

In addition, we request disclosure of any documents and/or records, such as notes, memoranda, or emails that illuminate or explain Board Staff's determinations concerning the introductory price and/or the impact of exchange rates under the Price Comparison test.

Please confirm the proposed schedule (subject to any modifications to accommodate provincial Attorneys General), and indicate when we can anticipate receiving a response to our other requests. We are hopeful that particulars and relevant documents can be delivered well in advance of the delivery date for Alexion's Response 9 March 2015.

Yours very sincerely,

GOWLING LAFLEUR HENDERSON LLP

Original signature redacted

Malcolm N. Ruby
MNR:gm:kam

TOR_LAW\ 8627475\2

APPENDIX B

PERLEY-ROBERTSON, HILL & McDOUGALL LLP/s.r.l.

Lawyers / Patent & Trade-Mark Agents
Avocats / Agents de brevets et de marques de commerce

Reply to/Communiquez avec:
David Migicovsky
613.566.2833 dmigicovsky@perlaw.ca

February 20, 2015

BY EMAIL

Malcolm N. Ruby
Gowling Lafleur Henderson LLP
100 King Street West, Suite 1600
Toronto, ON M5X 1G5

Dear Mr. Ruby:

Re: IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris"
Our Reference: PMPR010

This is further to your letter to Mr. Morris of February 12, 2015. The schedule set out in your letter is correct. That said, the Panel's order regarding scheduling does not reflect the agreed upon schedule. Consequently, Board Staff may request additional time to complete its reply if necessary.

In response to the request for particulars, Board Staff asserts that:

1. Alexion was previously provided with information related to the introductory price of Soliris. We refer you to Board Staff's letter to Alexion dated June 21, 2011, which is attached for your reference.

2. Board Staff conducted its calculations concerning the impact of exchange rates in accordance with the *Patented Medicines Regulations* and the 2010 Compendium of Guidelines, Policies and Procedures as Alexion is aware and as alleged in paragraph 15 of the Statement of Allegations.

It follows therefore that the particulars are within Alexion's knowledge. In any event, Alexion does not require these particulars to enable it to plead.

Finally, Alexion's request for documents is premature. Board Staff will deliver its documents within a reasonable timeframe after the parties have exchanged pleadings.

Yours very truly,

Original signature redacted

David Migicovsky
20: dem

c.c. Alan West; Parul Shah, Christopher P. Morris

AC, BM, CL(2)

Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

PROTECTED – S. 87 PRIVILEGE

Via Facsimile: (905) 761-5289

094444

Our File #: 4100-A33-7 - Soliris

June 21, 2011

Mr. John Haslam
General Manager
Alexion Pharma Canada
Suite 120, 400 Applewood Crescent
Vaughan, Ontario
L4K 0C3

RE: Soliris 10 mg/mL (DIN 02322285)

Dear Mr. Haslam:

I am writing in regard to Board Staff's investigation into the price of Soliris 10 mg/mL (DIN 02322285) that was commenced June 25, 2010.

Board Staff has now reviewed all the information pertaining to Soliris and has accepted the company's amended Form 2, Block 5 data submitted by PDCI Market Access on behalf of Alexion Pharma on October 21, 2010 and on November 30, 2010. Based on the company's amended Form 2, Block 5 and Board Staff's Verification of International Prices, the price of Soliris 10 mg/mL no longer triggers the investigation criteria. There are, however, cumulative excess revenues remaining as of December 2010 of [redacted] A copy of Board Staff's analysis is attached for your information.

Alexion Pharma is being given the opportunity to take a voluntary price reduction to offset the cumulative excess revenues. To offset excess revenues via a price reduction, the average price will be considered to have been reduced if it is below the previous year's national non-excessive average price (N-NEAP). The current Guidelines state that excess revenue balances below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six-month reporting periods (three years) will be expected to be offset through a Voluntary Compliance Undertaking (VCU). Alexion Pharma is expected to offset the outstanding [redacted] excess revenues by December 31, 2012 or it may be subject to a VCU for that amount.

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If you have any questions or require further information in this regard, please do not hesitate to contact Anna Chodos at (613) 954-7654 or Béatrice Mullington at (613) 952-2924.

Yours truly,

Original signature redacted

Ginette Tognet
Director, Regulatory Affairs and
Outreach Branch

Attachment