March 20, 2015

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**BY EMAIL:** guillaume.couillard@pmprb-cepmb.gc.ca
**and OVERNIGHT COURIER (to Mr. Mr. Guillaume Couillard only)**

**Patented Medicine Prices Review Board**
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1

**Attention: Mr. Guillaume Couillard, Secretary of the Board**

**BY EMAIL ONLY:**

**PATENTED MEDICINE PRICES REVIEW BOARD**
**Legal Services Branch**
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1

**Attention : Ms. Parul Shah , Legal Counsel PMPRB**

**PERLEY-ROBERTSON HILL & MCDOUGAL LLP**
340 Albert Street
Suite 1400
Ottawa, ON K1R 7Y6

**Attention: Messrs. David Migicovsky and Christopher Morris**
**Lawyers for Board Staff**

gowlings

**Ministry of Justice**
**Legal Services Branch**
PO Box 9280 STN PROV GOVT
1001 Douglas Street
Victoria, BC V8W 9J7

**Attention: Ms. Sharna Kraitberg**
**Lawyer for Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health**
**Representative for the Interveners, the Provinces of Manitoba, Ontario, and Newfoundland and Labrador**

Dear Mr. Couillard and Counsel:

**Re: Hearing into the matter of Alexion Pharmaceuticals Inc. and the medicine "Soliris"**

Attached is Alexion's Objection to the Ministers' (of British Columbia, Manitoba, Newfoundland and Labrador, and Ontario) request to file an Amended Notice of Appearance.

Yours very truly,

**GOWLING LAFLEUR HENDERSON LLP**

Original signaure redacted

Alan West

ANW:gm
Enclosure

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## 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 OBJECTION TO AMENDMENT OF MINISTERS' APPEARANCE

1. On 20 January 2015, the Board issued its Notice of Hearing ("Notice") and Statement of Allegations ("Allegations") relating to Alexion Pharmaceuticals Inc. ("Alexion" or "Respondent") and the medicine Soliris. The Board's Notice stated that the "material facts relied upon by Board Staff" were described within the Allegations.

2. The Board's initial correspondence indicated that the public hearing date would be fixed by the Hearing Panel at a case conference to be convened no later than 6 March 2015.

3. On 22 January 2015, the Board issued a press release repeating the allegation of "excessive pricing" against Alexion.

4. The principal assertion in the Allegations is that Alexion has sold Soliris to Canadians "at the highest international price among the comparator countries" listed in the Board's 2010 Compendium of Guidelines, Policies, and Procedures ("Guidelines"). The remedy requested is that Alexion be ordered to "stop selling Soliris at an excessive price" and to disgorge revenues Alexion "has generated from the sale of Soliris at an excessive price."

5. Paragraphs 14 – 21 of the Allegations describe an investigation conducted by Board Staff based upon the Highest International Price Comparison ("HIPC") test found in the Guidelines. The sole theory upon which the allegation of excessive pricing is based relates to alleged application of the HIPC. There is no allegation that any test other than the HIPC, which presumably applies the statutory factor found in subsection 85(1)(c)

("the prices at which the medicine...[has] been sold in countries other than Canada"), is implicated or violated.

6. Alexion was initially given until 9 February 2015 to file a Response to the Allegations. Board Staff were initially given 20 days from delivery of the Response to file a Reply.

7. Copies of the Board's documents, including the Notice and Allegations, were also provided to the Ministers of Health of the various Provinces and Territories ("Ministers"). The Ministers were also directed to deliver a Notice of Appearance by 9 February 2015.

8. On 12 February 2015, counsel for Alexion (Gowlings) wrote to Board Staff's counsel, (Perley-Robertson) confirming an agreement, subject to approval of the Hearing Panel, to modify the schedule for delivery of Alexion's Response, Board Staff's Reply, and to re-scheduling the first case conference.

9. The 12 February 2015 letter from Gowlings to Perley-Robertson also contained a request for particulars and disclosure of documents relating to 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*" and the "impact of exchange rates under the Price Comparison test."

10. On 13 February 2015, the Hearing Panel issued an order adjusting the schedule ("First Scheduling Order"). Alexion was given until 9 March 2015 to file a Response, the Ministers were given until 9 March 2015 to file Notices of Appearance, and Board Staff were given 20 days from receipt of Alexion's Response to file a Reply.

11. On 20 February 2015, counsel for Board Staff delivered a response to the request for particulars and disclosure of documents. Board Staff's counsel unhelpfully refused to provide particulars about exchange rate calculations. Board Staff did indicate that documents would be delivered "within a reasonable time frame after the parties' exchange pleadings" although, to date (almost 2 weeks after the Response was delivered), no documents have been produced by Board Staff.

12. Alexion filed its Response on 9 March 2015 consistent with the Hearing Panel's First Scheduling Order. The Response notes that the Introductory Maximum Non-Excessive ("MNE") for Soliris approved by Board Staff, $223.21, has not increased since Soliris was introduced to the Canadian market in 2009. The Response further notes that

Alexion has foregone any increases in price based on the Consumer Price Index ("CPI"), meaning that the price of Soliris has actually decreased in relative terms since the medicine was first introduced to the Canadian market in 2009. Indeed, as the Response notes, the allegation of "excessive" pricing under the HIPC is not based on actual price increases for Soliris in Canada or price decreases for Soliris in the comparator countries listed in the Guidelines: rather, the allegation is based solely upon fluctuations in the value of international currencies compared to the Canadian dollar. In sum, Alexion asserts in the Response that Board Staff are effectively comparing the relative value of currencies of various jurisdictions rather than the actual prices of Soliris in Canada and the comparator countries.

13. As defined in the Allegations and Response, the sole issue for the Hearing Panel is whether Alexion can be made accountable for fluctuations in the value of international currencies over which Alexion has no control.

14. On 9 March 2015, the Minister of Health for British Columbia ("BC Minister") filed a Notice of Appearance on behalf of the BC Minister and the Minister of Health for Manitoba ("Ministers' Appearance"). The Ministers' Appearance stated that the Ministers intended "to rely upon the material facts set out in", and the documents appended to, the Allegations . The Ministers' Appearance also made reference to an "Affidavit of Eric Lun which will be filed at a later date" and "any documents submitted by a participant to the hearing." There was no suggestion in the Ministers' Appearance that the Ministers would be referring to evidence or issues differing from the international pricing issue contained in the Allegations.

15. On 17 March 2015, eight days after the Ministers' Appearance was filed according to the Board's 9 March deadline, the BC Minister purported to file a separate Notice of Appearance and request the right to amend the Ministers' Appearance. In the accompanying cover letter, counsel for the BC Minister asked the Hearing Panel to extend the time for filing an Amended Notice of Appearance and to permit the BC Minister to make representations in the hearing on behalf of the Ministers of Health of Ontario, Manitoba, and Newfoundland and Labrador.

16. If granted an extension to file an Amended Appearance, counsel for the BC Minister has indicated that the BC Minister will provide "details of further material facts that the Minister intends to rely upon primarily" that relate to:

    (a) recommendations made by the Common Drug Review in relation to reimbursement of Soliris by public drug plans;

    (b) the process which public drug plans review medicines such as Soliris for potential reimbursement;

    (c) the cost of Soliris in comparison to other publicly-funded medicines; and

    (d) the importance of the public list price of a medicine in relation to negotiations and other reimbursement policies."

17. These "concerns" relating to "the pricing of Soliris" raised by the BC Minister bear no relation to the investigation conducted by Board Staff or the sole issue to be determined by the Hearing Panel, which relate entirely to whether Alexion's Canadian pricing violates the HIPC test.

18. The proposed material facts articulated in the BC Minister's letter have nothing whatsoever to do with comparisons of the price of Soliris in Canada with prices in countries where the medication is sold outside Canada. Indeed, for purposes of this proceeding, the Common Drug Review, review procedures of public drug plans, cost of Soliris compared with other publicly-funded medicines in Canada, and public list prices and reimbursement policies, have no relevance to any of the applicable factors under section 85 (1) referred to in the Allegations.

19. It will cause Alexion considerable inconvenience, expense, and prejudice to meet what are essentially issues irrelevant to those contained in the Allegations. Granting the amendment will also create significant delay in the conduct of the hearing.

20. The hearing, it is respectfully submitted, deals with the narrow issue of how the Board should treat fluctuations in international exchange rates when considering the HIPC test. The BC Minister's request is a thinly veiled attempt to convert the hearing into a broad inquiry into the procurement of patented medicines by public entities across Canada.

21. Alexion therefore respectfully submits that the request by the BC Minister should be dismissed. The Board should order that the BC Minister, and any other provincial or territorial minister, should be restricted to addressing the issues and material facts in the pleadings relating to application of the HIPC test in this case.

Original signature redacted

**Malcolm Ruby**

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Date: March 20, 2015

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