

## 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 FURTHER WRITTEN REPRESENTATIONS (Board Staff’s Motion to Strike Paragraphs 37 and 38 of Amended Response

1. Alexion respectfully submits that the Panel ought to dismiss Board Staff’s motion to strike paragraphs 37 and 38 of the Amended Response for the reasons argued in submissions delivered on 9 September 2015.
2. While the paragraphs concerning Isabel Raasch may no longer be in issue given the decision released by the Panel on 5 October 2015, the Board’s decision relating to Ms. Raasch does not constitute a basis for striking the allegations. While the Panel may have disagreed with Alexion’s arguments, the lengthy decision shows it was not “plain and obvious” that Ms. Raasch did not have a conflict, particularly given the evolving scope of the duty of loyalty recognized by the Panel.
3. Characterization of Board Staff’s role in this proceeding remains at issue. In particular, the types of excessive pricing allegations Board Staff can raise, whether Board Staff require an evidentiary foundation for excessive pricing allegations before the allegations are raised in the Statement of Allegations, and Board Staff’s disclosure obligations in relation to excessive pricing allegations remain very much at issue.

4. The disclosure received from Board Staff on 20 October 2015 in response to the Panel's Direction given in the case conference on 13 October 2015 supports Alexion's position in this regard. The documents disclosed, all of which could easily have been provided several months ago, deal only with international pricing of Soliris and, in particular, the introductory price of Soliris in 2009 and application of the Highest International Price Comparison ("HIPC") after the product was introduced. None of the documents produced deals with any other excessive pricing allegation or factor articulated in section 85 of the *Patent Act*.

5. It is apparent that there either are no documents supporting any other excessive pricing allegations or that Board Staff are still searching for documents, which establishes that the allegations were made in the Statement of Allegations without any evidentiary foundation in the first place.

6. Most importantly, Board Staff's Reply Argument does not even address the most basic argument raised in response to their motion—the "plain and obvious" test. Board Staff simply cannot meet the "heavy onus" created by this test and, indeed, have not even tried.

7. Proper characterization of Board Staff's role, how that role affects disclosure obligations, whether excessive pricing allegations can be made in the absence of foundational evidence, and whether Board Staff can support excessive pricing allegations advanced by interveners that have no basis in the *Patent Act* or the Guidelines, are still live issues before the Panel and must be determined. The answers

to these questions are not "plain and obvious" or "beyond doubt" and should await the Panel's determination of these issues at the hearing.

Dated: 23 October 2015

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**Malcolm Ruby**  
**GOWLING LAFLEUR HENDERSON LLP**  
1 First Canadian Place  
100 King Street West, Suite 1600  
Toronto ON M5X 1G5

**Malcolm N. Ruby**  
Tel: 416-862-4314  
Fax: 416-863-3614  
[malcolm.ruby@gowlings.com](mailto:malcolm.ruby@gowlings.com)

**Alan West**  
Tel: 416-862-4308  
Fax: 416-863-3480  
[alan.west@gowlings.com](mailto:alan.west@gowlings.com)

Lawyers for the Respondent

**TO: PATENTED MEDICINE PRICES REVIEW BOARD**  
**Legal Services Branch**  
Standard Life Centre  
333 Laurier Avenue West, Suite 1400  
Ottawa ON K1P 1C1  
Tel: (613) 952-7623  
Fax: (613) 952-7626

**Guillaume Couillard** (*Secretary of the Board*)  
[guillaume.couillard@pmprb-cepmb.gc.ca](mailto:guillaume.couillard@pmprb-cepmb.gc.ca)

**Parul Shah** (*Legal Counsel PMPRB*)  
[parul.shah@pmprb-cepmb.gc.ca](mailto:parul.shah@pmprb-cepmb.gc.ca)

**AND TO: PERLEY-ROBERTSON HILL & MCDOUGAL LLP**  
340 Albert Street, Suite 1400  
Ottawa, ON K1R 7Y6  
Tel: (613) 566-2833  
Fax: (613) 238-8775

**David Migicovsky**  
[dmigicovsky@perlaw.ca](mailto:dmigicovsky@perlaw.ca)

**Christopher Morris**  
[cmorris@perlaw.ca](mailto:cmorris@perlaw.ca)

Lawyers for Board Staff

**AND TO: MINISTRY OF JUSTICE**  
**Legal Services Branch**  
PO Box 9280 STN PROV GOVT  
1001 Douglas Street  
Victoria, BC V8W 9J7  
Tel: (250) 356-893  
Fax: (250) 356-8992

**Ms. Sharna Kraitberg**  
[Sharna.Kraitberg@gov.bc.ca](mailto:Sharna.Kraitberg@gov.bc.ca)  
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

**AND TO: CANADIAN LIFE AND HEALTH INSURANCE ASSOCIATION**  
79 Wellington St. West, Suite 2300  
P.O. Box 99, TD South Tower  
Toronto, ON M5K 1G8  
Tel: (416) 777-2221  
Fax: (416) 777-1895

**Craig Anderson**  
[CAAnderson@clhia.ca](mailto:CAAnderson@clhia.ca)  
Lawyer for Canadian Life and Health Insurance Association