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"

NOTICE OF MOTION

(DISCLOSURE OF DOCUMENTS)

RESPONDENT, ALEXION Pharmaceuticals Inc. ("Respondent" or "Alexion"), will present a motion before the Panel at the Hearing currently scheduled for 16 September 2015 at the Board's offices in Ottawa for:

ORDERS THAT BOARD STAFF DISCLOSE:

- All evidence and documents underlying factual allegations and expert opinions Board
 Staff will be relying on at the hearing;
- 2. All documents Board Staff will use in chief to examine its own witness and to crossexamine Alexion's witnesses at the hearing;
- 3. Any other evidence, documentary or otherwise, that Board Staff will be adducing or relying upon at the hearing; and
- 4. Such further or other evidence as Alexion may request and the Panel deem appropriate for Board Staff to disclose to Alexion before the hearing.

THE GROUNDS FOR THE MOTION ARE:

- 5. On 12 February 2015, Alexion's counsel asked Board Staff's counsel to disclose documentation underlying allegations made in the Statement of Allegations ("Allegations") dated 15 January 2015.
- 6. On 20 February 2015, Board Staff counsel refused to disclose the requested documents, stating that the request for documents was premature and that "Board Staff will deliver its documents within a reasonable time frame after the parties have exchanged pleadings".
- Alexion delivered its Response to the Allegations on 9 March 2015.
- 8. Board Staff delivered its Reply to the Alexion Response on 10 April 2015.
- 9. Despite the exchange of pleadings, Board Staff did not deliver its documents.
- On 16 April 2015, following delivery of Board Staff's Reply, Alexion informed the Board
 Secretary that it would seek production of documents relating to the Allegations.
- 11. On 21 April 2015, the Board Secretary requested that the parties deliver, by 27 April 2015, details concerning: the volume, nature, and method of delivery and format of documents; information on fact witnesses; and, information concerning the use of expert witnesses.
- 12. On 27 April 2015, Alexion's counsel indicated that an expert witness had been retained to deal issues raised in relation to the Highest International Price Comparison (HIPC) test. The Board Secretary was informed by Alexion that, without particulars and disclosure, the company could not provide assistance on delivery of documents or information on fact witnesses. Indeed, Alexion stated in the 27 April 2015 letter that without knowing the case it had to meet it was "not possible...to make written submissions on documentary productions, witnesses, experts, or the expected duration of proceedings."

- 13. Board Staff responded to the Board Secretary's inquiries on 27 April 2015 stating that: "the parties should exchange electronic and hard copies of the documents which they will rely on at the hearing"; that they intended to call "at least two witnesses at the hearing" and provide "will-say statements"; and, that they would call "at least one expert prepare a report and testify at the hearing." Board Staff have provided no further detail identifying their witnesses and expert. Nor have they disclosed any documents or other evidence they intend to rely on at the hearing.
- On 15 May 2015, Alexion brought a motion requesting particulars of the Allegations.
 Board Staff opposed the motion.
- 15. On 23 June 2015, the Panel ruled on Alexion's motion for particulars, ordering Board Staff to provide particulars concerning several assertions in the Allegations. In the oral reasons for the Order, Panel member Kobernick observed, in relation to documents sought by Alexion, that Alexion would:

...receive these documents as part of the document discovery process in advance of the hearing. Indeed, <u>Board Staff Counsel stated that these documents will be provided</u>. [Underlining added.]

- 16. Following the June 2015 hearing of Alexion's motion, Alexion's counsel wrote Board Staff counsel asking that Board Staff make their documentary disclosure on the same date, 3 July 2015, as Board Staff were required under the Panel's Order to deliver the particulars ordered by the Board.
- 17. On 3 July 2015, Board Staff provided documents along with the particulars ordered by the Panel.

- 18. On 6 July 2015, Alexion counsel wrote to Board Staff counsel requesting confirmation that the documents received on 3 July 2015 comprised the documents Board Staff intended to rely on at the Hearing.
- 19. On 7 July 2015, Board Staff counsel sent an email to Alexion counsel indicating that the documents provided on 3 July 2015 "were not intended to constitute the disclosure of Board Staff." For a second time, Board Staff counsel stated that it "would be premature to have documentary disclosure at the present time."
- 20. Since 7 July 2015, Board Staff have not provided documentary disclosure.
- 21. The duty of procedural fairness, including the opportunity to be heard, requires Board Staff to disclose all facts, documents, testimony, and other evidence they will rely on for purposes of the hearing. Board Staff have consistently refused to disclose the documents and evidence they rely on in support of the Allegations. Their filings in this proceeding demonstrate Board Staff misapprehend their role as prosecutors acting in the public interest.
- 22. Board Staff have failed to act in conformance with their obligations as prosecutors acting in the public interest. Board Staff, and their counsel, have been overly adversarial in the prosecution of this case. They have a clear duty to disclose the documents and evidence they will be relying upon at the hearing but, for strategic reasons, are withholding disclosure to surprise and prejudice Alexion. Their tactical approach is particularly egregious and detrimental to Alexion in this case because the process lacks even civil discovery rights, including documentary and oral discovery, designed to protect Alexion from surprise.
- 23. Indeed, it would appear Board Staff did not have relevant evidence when the case was commenced and are currently in the midst of attempting to obtain evidence and information to make the case Board staff commenced several months ago. On 14 July 2015, Alexion received

- 5 -

an email indicating Board Staff was using Isabel Raasch, a former Gowlings partner who had

only recently left the firm, to make inquiries of Health Canada in July 2015 to obtain evidence in

support of the Allegations. Quite apart from ethical concerns about Ms. Raasch's conduct, her

efforts in July 2015 demonstrate that Board Staff did not have the evidence necessary to prove

their case at the time the Allegations were delivered in January 2015.

24. Board Staff's tactical litigation strategy is unfair and prejudicial. Disclosure of the case

Alexion has to meet, which is vital to Alexion's ability to respond, should take place early in the

process and continue before the hearing. Withholding disclosure harms the process, is

prejudicial to Alexion, and undermines confidence in the Board's integrity.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of this motion:

25. The Affidavit of Anna Di Domenico, sworn 21 August 2015; and

Such further and other evidence as Alexion may adduce and the Panel admit. 26.

Dated: 21 August 2015

Original signature redacted

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

Alan West

Tel:

416-862-4308

Fax: 416-863-3480

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

Parul Shah (Legal Counsel PMPRB) parul.shah@pmprb-cepmb.gc.ca

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

Christopher Morris

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

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

CAnderson@clhia.ca

Lawyer for Canadian Life and Health Insurance Association

TOR_LAW\ 8762544\2