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.
and the medicine "Soliris"

NOTICE OF MOTION OF THE RESPONDENT, Alexion Pharmaceuticals Inc.

RESPONDENT, ALEXION Pharmaceuticals Inc. ("Alexion") will make a motion before the Hearing Panel ("Panel") at the commencement of the Hearing on 16 January 2016 in Ottawa.

THE MOTION IS FOR:

1. An Order precluding Board Staff from entering into evidence IMS Midas pricing data ("IMS Data") for the purpose of proving any alleged future price reduction of, or any alleged past excessive revenue relating to, Soliris.

THE GROUNDS FOR THE MOTION ARE:

Introduction

2. The IMS Data is inadmissible hearsay. The IMS Data has no relevance to the statutory tests the Panel must apply. The source of the IMS Data is unclear, and the IMS Data is potentially highly prejudicial. Furthermore, the IMS Data for 2016 has not even been produced by Board Staff.

3. The use of the IMS Data, as Board Staff have proposed in their Amended Statement of Allegations, would involve significant confiscatory financial liability based on foreign source data that:

(a) is not a publicly available foreign source as required under the *Patented Medicines Regulations* (the "*Regulations*");

(b) is not provided for in the PMPRB *Compendium of Policies, Guidelines and Procedures* as a source of foreign pricing information for a patented medicine; and

(c) has never even been mentioned in the Board's annual published "Formulas for Verification of Foreign Patented Drug Prices."

4. It was improper for Board Staff to assert price reduction or forfeiture allegations based on the IMS Data. This problem is exacerbated by Board Staff's admission that they do not even have a complete set of IMS Data available for the impending hearing.

5. Board Staff have not proposed any witness capable of providing any direct evidence concerning the IMS Data or compilation of the data. Allowing the use of the IMS Data as the basis for asset forfeiture or price reduction would be unfairly prejudicial to Alexion. Alexion will have no opportunity to test the IMS Data through cross-examination, and the IMS Data for 2016 has not even been produced yet.

The IMS Data Is Inadmissible and Irrelevant Hearsay

6. The IMS Data is inadmissible as irrelevant and as rank hearsay. The IMS Data is based upon statements made, and information gathered, by persons who will not testify in the proceeding. The IMS Data will be tendered as proof of its contents or as proof of assertions implicit within the data. The IMS Data do not fall within any exception to the

hearsay rule and are unnecessary to resolution of the proceeding before the Panel.[1] The relevant comparative pricing information is established by the *Regulations*, which provide:

> 4 (1) For the purposes of paragraphs 80(1)(b) and (2)(b) of the Act, information identifying the medicine and concerning the price of the medicine shall indicate:
>
> ...
>
> (f) in respect of the day or period referred to in paragraph (d),
>
> ...
>
> (ii) the **publicly available** ex-factory price for each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory, and
>
> (iii) if the medicine is being sold in one or more of the countries set out in the schedule, the **publicly available** ex-factory price for each dosage form, strength and package size in which the medicine was sold to each class of customer in each of those countries.
>
> ...
>
> (9) For the purposes of this section, publicly available ex-factory price includes any price of a patented medicine that is agreed on by the patentee or former patentee and the appropriate regulatory authority of the country in which the medicine is sold by the patentee. [Emphasis added.]

7. The IMS Data does not provide "publicly available" ex-factory prices. The data is only privately available.

8. Board Staff's case has been based on publicly available ex-factory prices for Soliris in Canada and the seven other countries specified in the *Regulations*. The publicly available information has been reported and relied upon by Alexion and the Board.

---

[1] *The Law of Evidence in Canada* (4th ed), Sopinka, Lederman & Bryant, ss. 6.1-6.3, p. 237

9. The Board's published materials, including its annual published "Formulas for Verification of Foreign Patented Drug Prices", at no time make any mention of the use of IMS Data as a "source" for reporting or verifying the foreign prices of a medicine. To the contrary, all of the Board's published materials describe from year to year which foreign sources the Board will rely on—IMS Data has *never* been mentioned as an appropriate foreign source.

10. There is no justification for introducing a new, and completely irrelevant (and incomplete), set of data into this proceeding, particularly when there is no reliable and effective way to validate the data.

11. Even if the IMS Data were submitted through an IMS expert who could explain and interpret the data, it would nevertheless fail the requirement to be from a publically available source and to be relevant. Acceptance of this evidence will only prejudice and impose an undue burden on Alexion, and complicate and delay the fair and just resolution of this proceeding.

THE FOLLOWING DOCUMENTARY EVIDENCE is being relied upon by Alexion for the purpose of this motion:

1. The pleadings and proceedings herein and such material as counsel may adduce and the Panel admit.

Dated: 13 January 2017

Original signature redacted

Malcolm Ruby
GOWLING WLG (CANADA) LLP
1 First Canadian Place
100 King Street West
Suite 1600
Toronto, ON M5X 1G5

Malcolm N. Ruby
Tel: 416-862-4314
Fax: 416-862-7661
malcolm.ruby@gowlings.com

Alan West
Tel: 416-862-4308
Fax: 416-862-7661
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

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

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, B.C. V8W 9J7
Tel: (250) 356-893
Fax: (250) 356-8992

Ms. Sharna Kraitberg
Sharna.Kraitberg@gov.B.C..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

AND TO: **BORDEN LADNER GERVAIS LLP**
World Exchange Plaza
100 Queen Street
Suite 1300
Ottawa, ON K1P 1J9

Jamie Mills
jmills@blg.com

Beverley Moore
bmoore@blg.com

Lawyers for BIOTECanada