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"

ALEXION PHARMACEUTICALS INC.

REPLY TO

Written Submissions of Her Majesty the Queen
in Right of British Columbia, as Represented by
the Minister of Health ("The Ministry")

AND

Written Submission on Remedy of the
Canadian Life and Health Insurance Association Inc. ("CLHIA")

1. Alexion responds in this submission to the written submissions of both interveners adverse in interest to Alexion: Her Majesty the Queen in Right of British Columbia as Represented by the Minister of Health (the "Ministry"); and the Canadian Life and Health Insurance Association Inc. ("CLHIA").

2. Should this Panel dismiss the case against Alexion on the basis that the price of Soliris is not "excessive" under the tests in the *Patent Act*, the Panel need not consider the submissions of the Ministry or CLHIA.

3. In any event, for the reasons described in detail below, the written submissions of both interveners are unhelpful and should be disregarded. The submissions expose the overall purpose of both interveners to improperly obtain commercial advantages in the proceeding and penalize Alexion in contravention of the Board's statutory mandate.

Reply to the Written Submissions of the Ministry

4. The Ministry's submissions raise issues outside the ambit of matters this Panel can properly consider. The submissions are also contrary to representations the Ministry previously made to the Panel.

5. When the Ministry first intervened, Alexion acknowledged the Ministry had a statutory right of intervention under the *Patent Act*, but objected to the scope of the intervention on three grounds:

> (1) the intervention raised issues outside "the matter being heard", by advancing claims materially different from those of Board Staff based on the "lowest international price", a concept not in the *Guidelines*;
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> (2) the intervention involved commercial arrangements between Alexion and the Ministry that were beyond the Board's jurisdiction and were an attempt by the Ministry to improperly use the proceeding to obtain commercial advantages; and
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> (3) the intervention raised matters of evidence that were irrelevant to the proceeding.

6. The Ministry's current submissions demonstrate how Alexion's original objections were well founded.

7. Despite statements made by the Ministry in response to Alexion's original challenge, it is now apparent from the Ministry's written submission that the sole purpose of the Ministry's intervention is to obtain commercial advantages. The Ministry's intervention does not assert facts or arguments that assist the Panel in making its determination under the factors in section 85(1) of the *Patent Act*. The purpose of the Ministry's intervention is to reduce the price of Soliris and improve the Ministry's position to re-negotiate the PLAs with Alexion.

8. In its Reasons on the scope of the intervention, the Panel stated:[1]

> 43. The Respondent relies on the decision of *Pfizer v. Canada (AG)* ("*Pfizer*"), and submits that the Panel lacks jurisdiction to consider any submissions that may be made by the Ministers of Health relating to downstream arrangements for the sale of medicines.
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> 44. The applicants in *Pfizer* asserted that the Board's jurisdiction is limited to reviewing prices associated with the sales of patented medicines at the "factory gate" and the Board's jurisdiction does not extend to transactions involving third parties that may take place further downstream in the supply chain. The Federal Court agreed and found that the Board was acting outside of its jurisdiction by

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[1] PMPRB, REASONS FOR DECISION (Various Motions Related to Procedural Matters Heard on October 28, 2015), at paras. 43-45.

> requiring the reporting of rebates or payments made to third parties by the manufacturers of patented medicines.
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> 45. To the extent that a price reduction would result in a lower factory-gate price for Soliris, the Ministers of Health admit that, as a primary source of funding for the purchase of patented medicines, provincial governments could recognize financial savings. However, the Ministers of Health submit that they do not intend to use a statutory entitlement to make representations to the Panel in order to assert private economic interests, or in order to seek a commercial advantage.[2] [Emphasis added.]

9. The *Pfizer* decision expressly holds that the Board's jurisdiction is subject to a "constitutional limitation" that does not permit compelling disclosure of information "beyond the factory-gate price of patented medicines" or consideration of "contractual arrangements involving patentees and entities further down the distribution chain."[3]

10. The Ministry's submission relates to the PLA's, a type of "contractual arrangement...down the distribution chain". Furthermore, the Minister's written argument, on its face, contains representations asserting "economic interests" and seeks "commercial advantages" contrary to what was previously represented by the Ministry to the Panel.

Ministry Submissions on s. 85(1)(a)

11. The first substantive section of the Ministry's Written Submissions purports to deal with s. 85(1)(a) of the *Patent Act*.[4] The Ministry repeats Board Staff's argument that s. 85(1)(a) contemplates an inquiry into the cost impact of a drug, including "opportunity costs" that may prevent the Ministry from reapportioning expenditures to other drugs or medical services.

12. The Ministry argues that as more "expensive drugs for rare diseases" (EDRDs) are approved each year, even small amounts of extra spending by the Ministry on Soliris can have a significant budgetary impact. These submissions relate to "economic interests" that are irrelevant to an inquiry under s. 85(1)(a). As noted in Alexion's written argument responding to Board Staff, the inquiry under paragraph 85(1)(a) is intended to determine the ex-factory price of the medicine in the relevant market in Canada based on information reported to the Board under s 80(1) of the *Act*. The amount the Ministry has, by contract, agreed to pay for the

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[2] Original Response of Minister of Health of British Columbia dated October 19, 2015, para. 37.
[3] *Pfizer Canada Inc. v. Canada (Attorney General)*, [2009] FC 719 at para. 83 (FC).
[4] Submissions of the Ministry, paras. 8-23.

medicine is not a relevant inquiry; nor is the impact of any payment by the Ministry for Soliris on the overall finances of the province. Applying the Federal Court's holding in *Pfizer,* any alleged improvidence in a commercial arrangement between the Ministry and Alexion necessarily lies outside the Board's jurisdiction. The Panel's decision notes that the Ministry previously represented that it would not pursue these types of issues in the hearing.

13. Citing another commercial consideration, the Ministry complains that [redacted], such that by [redacted] British Columbia will be paying the full list price.[5] In other words, the Ministry asserts that unless the Panel makes a ruling that considerably lowers the price of Soliris, given inflationary increases, the Ministry at a future date will pay the current full list price for Soliris. The Ministry also notes that because it has no agreement for the aHUS indication, one BC hospital pays full list price for one aHUS patient. Both grounds of argument necessarily involve the Panel being asked to consider economic and commercial considerations and even to interfere with contractual arrangements by setting a lower price that the Ministry can use to negotiate future agreements.

14. It was apparent from the evidence that the Ministry has already obtained significant commercial advantages under the PLA and in other ways. The Ministry witness, Mr. Eric Lun, admitted that under [redacted] Furthermore, by refusing (unlike other provinces) to pay normal wholesaler markups for Soliris the Ministry also receives greater commercial advantages than other provinces.

85(1)(c) of the *Patent Act*

15. The Ministry's arguments concerning s. 85(1)(c) of the *Act* are irrelevant.[7] The arguments detail commercial negotiations between the pCPA, the Ministry (through Ontario as the lead negotiator), and Alexion over the reimbursement price.

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[55] Submissions of the Ministry, paras. 20-21.
[6] Transcripts, Volume 12, at pgs. C382-C383.
[7] Submissions of the Ministry, paras. 24-29.

16. The Ministry asserts that the negotiation strategy for the [redacted] They further assert [redacted] in Canada".[8] By their own admission, the Ministry obtained the price it sought. This reflects the considerable commercial buying power of the Ministry and the other provinces, which is not disputed by Alexion.

17. The *Act* and *Regulations* require the reporting of information on prices of 7 comparator countries. The comparison under s. 85(1)(c) involves all 7 countries. The *Guidelines* do not focus on any one country, or the country with the lowest price. While it may be appropriate for the Ministry to use the country with the lowest price as a bargaining tool, their negotiation strategy in dealings with Alexion has no bearing on the Panel's obligation to interpret and apply the *Act*.

18. The Ministry complains in its submissions that its bargaining power is affected, because of " ... external pressures to provide coverage ..." by patient groups and others.[9] These are also extraneous considerations for the Panel when applying the s. 85(1) criteria. How PLAs are negotiated, including commercial considerations involving competing sources and interests, are outside the Board's mandate.

Minister's Evidence Irrelevant

19. In the motion to strike the Further Amended Notice of Appearance of the Ministry, Alexion argued that the evidentiary matters the Ministry intended to raise were irrelevant. This Panel stated that any such consideration was premature at that time:

> 49. Indeed, Counsel for the Ministers of Health indicated at the hearing of this motion that the Ministers of Health have not yet determined the nature of any evidence that will be introduced at the hearing, or even if the Ministers of Health intend to submit any evidence at the hearing.
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> ...

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[8] Submissions of the Ministry, paragraph 29.
[9] Submissions of the Ministry, paragraph 30(c). Incredibly, the Ministry complains Alexion "... exerted additional pressure on the Ministry by pursuing multiple requests for information under the British Columbia *Freedom of Information and Protection of Privacy Act* ...". The implication is that the Ministry providing access to information as it is statutorily required to do is somehow "unfair" to the Ministry.

> 50. In the event that the Ministers of Health submit evidence on issues that are not relevant to the matters before the Panel this will be addressed at the time and in the context of the full proceeding, and with the benefit of the evidentiary record from Board Staff and the Respondent.

20. The Panel now has the "benefit of" a full "evidentiary" record from Board Staff and Alexion. The Ministry has submitted evidence and written submissions. The evidence, and arguments based on the evidence, are irrelevant to issues properly before the Panel concerning the s. 85(1) factors. The evidence proffered by the Ministry through its witness, Mr. Lun, should be given no weight, and arguments raised in the Ministry's submissions should be disregarded.

Reply to the Written Submissions of CLHIA on Remedy

21. CLHIA was granted leave to intervene solely for the purpose of addressing remedies.

22. In paragraphs 2 and 3 of its submission, CLHIA makes factual assertions that are not in evidence before the Panel and which must therefore be disregarded by the Panel on that basis alone.

23. The only distinct legal submission made by CLHIA is that if the Panel concludes that excess revenues were earned by Alexion, the Panel could order the excess revenues to be quantified in the form of a price reduction going forward, which CLHIA refers to as a "Further Reduced Price".

24. The alleged purpose of the proposed price reduction is to "... assist Canadian insurers, benefit plan sponsors or individual Canadians." Given that "individual Canadians" do not pay for Soliris, the only beneficiary of CLHIA's proposed remedy would be "insurers" and "benefit plan sponsors" who are CLHIA members.

25. CLHIA would benefit commercially in any case where the price of a medicine has been found "excessive", if the price were reduced going forward rather than excess "excess revenues" being paid to Her Majesty in Right of Canada. This process is not provided for in the *Act* or *Guidelines* and has never been undertaken in any case before this Board to date. No reasons are provided as to why CLHIA should be granted this unique treatment. In contrast, the *Act* does provide, in s. 103, that the Federal Minister "may enter into agreements" with the provinces relating to "amounts received or collected by the Receiver General under section 83

or 84." No such agreements have been entered into previously that are a matter of public record.

26. The remedy sought by CLHIA does not fall within the statutory jurisdiction of the Board. As stated in the *Pfizer* decision, this Board is confined to determining the ex-factory price of the medicine and may not consider, "...contractual arrangements involving patentees and entities further down the distribution chain".

27. Accordingly, Alexion submits that the Panel should not adopt the remedy requested by CLHIA.

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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

David Woodfield
Tel: 416-862-4313
Fax: 416-862-7661
david.woodfield@gowlings.com

Lawyers for Alexion Pharmaceuticals Inc.

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

TOR_LAW\ 9152814\3