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"

WRITTEN SUBMISSIONS, RESPONDING TO ALEXION'S CONFLICT OF INTEREST MOTION BY COUNSEL FOR MARY CATHERINE LINDBERG

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Part I - Introduction

1. Alexion states that Ms. Lindberg is in "an irreconcilable conflict of interest" as Chair of this Board, and as a director of Green Shield Canada. Her conduct is said to present "a serious and important issue that must be dealt with to protect the integrity of the administration of justice in this

proceeding, and in any other present or future proceedings before the Board".

2. Alexion has misconceived the facts, and additionally seeks to extend established principles of administrative fairness well past their amply considered length and breadth.

3. With the misconceived facts, ample legal support for Ms. Lindberg's role and conduct, and absence of any legal precedent that supports Alexion's position, the Alexion motion should be dismissed.

Part II – The Facts

4. Ms. Lindberg, since March of 2011, has been both Chairperson and Chief Executive Officer of the Patented Medicine Prices Review Board. She holds those two positions pursuant to the enabling legislation, the *Patent Act*,, which provides that the Chairperson is also the CEO.

5. In accordance with the enabling legislation, in particular subsection 83(6) of the *Patent* Act, in her capacity as CEO she was informed of the Board Staff's investigation, and issued the Notice of Hearing and appointed the Hearing Panel members.

6. Ms. Lindberg is not, and never has been, any part of the Hearing Panel in this matter.

7. Ms. Lindberg is also a publicly listed director of Green Shield Canada Foundation, hereafter referred to as "Green Shield".

8. The Notice of Hearing issued on January 20, 2015.

9. In her role as Chairperson, Ms. Lindberg selected the Hearing Panel members. There is no suggestion that the Hearing Panel members are or were in any way tainted with any bias or conflict of interest through this process, and their adjudicative independence is unassailed.

10. Alexion argues, in paragraph 7 of its written submissions, that Green Shield had "a direct pecuniary interest in the outcome of thee proceeding" at the time the Notice of Hearing issued. To support this alleged "direct pecuniary interest" Alexion argues, in paragraph 13 of its written submissions, that the fiduciary duties of directors "typically" include maximizing the value of the corporation.

11. Alexion's allegations concerning Ms. Lindberg are based upon the Affidavit of Mr. Ruby's law clerk, Anna Di Domenico. Exhibit "I" to that Affidavit reflects the results of a corporate search concerning "Green Shield Canada Foundation". That is the document where Ms. Lindberg is publicly listed as a director of Green Shield. Notably, Exhibit "I" also records that the "Governing Legislation" for "Green Shield Canada Foundation" is the "*Canada Not for profit Corporations Act – 2014-06-10*".

12. On May 12, 2015, the Canadian Life and Health Insurance Association Inc., "CLHIA", applied to intervene in this matter. That was months after the Notice of Hearing had issued.

13. Green Shield is one of the many members of CLHIA.

14. Alexion states in paragraph 4 of their written submissions that "CLHIA has argued that <u>all its members</u> have an interest in this litigation because they bear the cost burden of the price of Soliris". CLHIA's submissions appear

to include statements that CLHIA represents persons who bear the cost burden of the price of Soliris – however it is not evident that all its members are in that category[1].

15. As a "not for profit" corporation, Green Shield cannot operate with the aim to increase value, maximize shareholder returns or generate personal gain. As a "not for profit" it does not have shareholders. As noted in Reiter's *Directors' Duties in Canada* (CCH Canada Limited, 2006):

> Not-for-profit corporations differ from for-profit corporations in that they are composed of members who do not receive a financial benefit from the corporation because of their membership, whereas shareholders of business corporations may receive dividend payments.
>
> *Directors' Duties in Canada*, page 481

Part III – Legal Submissions

16. As stated by the Federal Court of Appeal in *Arthur v. Canada (Attorney General)*, 2001 FCA 223 (CanLII), [2001] F.C.J. No. 1091 (QL) per Mr. Justice Létourneau at paragraph 8:

> ...An allegation of bias, especially actual and not simply apprehended bias, against a tribunal is a serious allegation. It challenges the integrity of the tribunal and of its members who

[1] The full submissions of CLHIA respecting intervention are not presently available to Ms. Lindberg's counsel, however from what is available it appears to be an overstatement that it claimed that "all of its members" have an interest in the litigation because they bear the cost burden of the price of Soliris. Furthermore, it is unclear whether those submissions differentiate between administrative service providers, who would receive a revenue based fee and therefore may economically prefer higher prices, and providers of rated insurance who may economically prefer lower prices.

> participated in the impugned decision. It cannot be done lightly. It cannot rest on mere suspicion, pure conjecture, insinuations or mere impressions of an applicant or his counsel. It must be supported by material evidence demonstrating conduct that derogates from the standard …

17. Allegations of bias and conflict of interest attract two different tests. Which test should be applied depends upon the role of the decision maker concerning whom the allegation is made – whether the decision making subjected to challenge is administrative or adjudicative in nature.

    i. At the stage of the administrative decision-making, to overcome the decision the party challenging must demonstrate that the official had a closed mind;

    ii. At the adjudicative stage, the well-known appearance of justice test applies.

18. The structure of the Board is discussed in *PMPRB-99-D2-Nicoderm*. At pages two and three, the Hearing Panel carefully reviewed the procedures in place to ensure that the Board could function and perform its statutory mandate, while maintaining adjudicative fairness. In particular, it noted the difference between the decision to initiate a public hearing, and the hearing itself:

> …There is no prejudice to a patentee in the Chairperson's decision to initiate a public hearing, only the requirement that the matters in issue be presented and determined in public instead of internally by the Board alone. To the extent that any

> confidential information is involved in the public hearing, the *Act* and the Board's *Rules* provide for protection of the patentee.
>
> *PMPRB-99-D2-Nicoderm*, page 8, top paragraph.

19. The administrative nature of the Chairperson's decision to issue a Notice of Hearing was considered and the analysis of the Panel in Nicoderm upheld by the Federal Court in *Hoeschst Marion Roussel Canada Inc. v. Canada (Attorney General)*, [2006] 3 FCR 536, per Heneghan J. Amongst other things, Hoeschst, the maker of Nicoderm, challenged the fact that the Chairperson who issued the Notice of Hearing sat on the Hearing Panel in that matter. The administrative nature of the issuance of the Notice of Hearing was considered:

> [88]In this regard, I refer to the Board's reasons in its decision on jurisdiction, Part I. The Board noted that in deciding whether to issue a notice of hearing, the Chairperson considers whether the results of the investigation, if proven true, would show a prima facie case of excessive pricing.
>
> [89]The issue of actual excessive pricing is a matter to be resolved at the public hearing, when all interested parties are given the opportunity to lead evidence, cross-examine and make submissions. That being so, I agree with the arguments of the respondent Attorney General of Canada and the intervener that the issuance of the notice of hearing does not represent the Board's conclusion on the issue, but rather constitutes an allegation that is sufficiently substantiated to justify a hearing

on the merits. I conclude that no objectionable bias has been proven in this regard

Participation by the Chairperson in the Board panel

[91]The applicant has argued that, on the basis of *MacBain v. Lederman*, [1985] 1 F.C. 856 (C.A.) and 2747-3174 *Québec Inc. v. Quebec (Régie des permis d'alcool)*, 1996 CanLII 153 (SCC), [1996] 3 S.C.R. 919, the fact that the Chairperson, after reviewing the Staff report and considering the VCU submitted by the applicant, then decided to hold a hearing and to participate in the adjudication process, gives rise to a reasonable apprehension of bias.

[92]In my opinion, this issue is closely related to the question of predetermination of key issues, discussed above. As noted above, the Chairperson, when reviewing the Staff report and VCU, was acting in his administrative capacity as chief executive officer, for the limited purpose of deciding whether or not to issue a notice of hearing. I agree with the submissions of the respondent and the intervener that no independent analysis was conducted by the Chairperson as to whether the results of the investigation are, or may be, established.

[93]Finally, the *Act* does not ban the Chairperson from sitting as a member of a Board panel, notwithstanding his role in the issuance of a notice of hearing. Having regard to the fact that the Board is an expert tribunal, that the Chairperson is presumably highly knowledgeable in this field, and that the

> Chairperson, to date, has had no role in determining the well-foundedness of the allegation contained in the Staff report, I see no basis upon which an informed person, viewing the matter realistically and practically, and having thought the matter through, would conclude that there is a reasonable apprehension of bias arising from the Chairperson's participation in the panel. This view is reinforced by my opinion as to the degree of flexibility to be afforded to the Board in satisfying the duty of fairness.
>
> [94]For these reasons, the application for judicial review in respect of the Board's decision on jurisdiction, Part I, is dismissed.

20. *Newfoundland Telephone Co. v. Newfoundland (Board of Commissioners of Public Utilities)*, 1992 CanLII 84 (SCC), [1992] 1 S.C.R. 623, at pages 636-639, Cory J. for the Court ruled as follows:

> The Composition and Function of Administrative Boards
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> Administrative boards play an increasingly important role in our society. They regulate many aspects of our life, from beginning to end. Hospital and medical boards regulate the methods and practice of the doctors that bring us into this world. Boards regulate the licensing and the operation of morticians who are concerned with our mortal remains. Marketing boards regulate the farm products we eat; transport boards regulate the means and flow of our travel; energy boards control the price and distribution of the forms of energy we use;

planning boards and city councils regulate the location and types of buildings in which we live and work. In Canada, boards are a way of life. Boards and the functions they fulfil are legion.

Some boards will have a function that is investigative, prosecutorial and adjudicative. It is only boards with these three powers that can be expected to regulate adequately complex or monopolistic industries that supply essential services.

The composition of boards can, and often should, reflect all aspects of society. Members may include the experts who give advice on the technical nature of the operations to be considered by the Board, as well as representatives of government and of the community. There is no reason why advocates for the consumer or ultimate user of the regulated product should not, in appropriate circumstances, be members of boards. No doubt many boards will operate more effectively with representation from all segments of society who are interested in the operations of the Board.

Nor should there be undue concern that a board which draws its membership from a wide spectrum will act unfairly. It might be expected that a board member who holds directorships in leading corporations will espouse their viewpoint. Yet I am certain that although the corporate perspective will be put forward, such a member will strive to act fairly. Similarly, a consumer advocate who has spoken out on numerous occasions

> about practices which he, or she, considers unfair to the consumer will be expected to put forward the consumer point of view. Yet that same person will also strive for fairness and a just result. Boards need not be limited solely to experts or to bureaucrats.

21. Additionally, in *Newfoundland Telephone*, the Supreme Court of Canada through Cory J., commented on the sliding scale, depending on function, to be applied in assessing bias, and set out what has been referred to above as the test as to whether the official had a closed mind:

> It can be seen that there is a great diversity of administrative boards. Those that are primarily adjudicative in their functions will be expected to comply with the standard applicable to courts. That is to say that the conduct of the members of the Board should be such that there could be no reasonable apprehension of bias with regard to their decision. At the other end of the scale are boards with popularly elected members such as those dealing with planning and development whose members are municipal councillors. With those boards, the standard will be much more lenient. In order to disqualify the members a challenging party must establish that there has been a pre-judgment of the matter to such an extent that any representations to the contrary would be futile. Administrative boards that deal with matters of policy will be closely comparable to the boards composed of municipal councillors. For those boards, a strict application of a reasonable

apprehension of bias as a test might undermine the very role which has been entrusted to them by the legislature.

Janisch published a very apt and useful Case Comment on *Nfld. Light & Power Co. v. P.U.C. (Bd.)* (1987), 25 Admin. L.R. 196. He observed that Public Utilities Commissioners, unlike judges, do not have to apply abstract legal principles to resolve disputes. As a result, no useful purpose would be served by holding them to a standard of judicial neutrality. In fact to do so might undermine the legislature's goal of regulating utilities since it would encourage the appointment of those who had never been actively involved in the field. This would, Janisch wrote at p. 198, result in the appointment of "the main line party faithful and bland civil servants". Certainly there appears to be great merit in appointing to boards representatives of interested sectors of society including those who are dedicated to forwarding the interest of consumers.

22. The difference in standard, between the high standard of the appearance of justice test for adjudicators, to the closed mindedness such that “pre-judgment of the matter to such an extent that any representations to the contrary would be futile” for boards dealing with policy (at the other end of the scale from adjudication of rights), provides a useful framework. At its highest, the Chairperson engaged in the administrative act of determining that a Notice of Hearing should issue, might be subject to the closed mindedness test – if there was any adjudicative function at that stage at all. But there was not – there is not – the adjudication takes place with the Hearing Panel.

23. Alexion has the burden of proving that Ms. Lindberg's conduct may attract the legal remedies they seek, grounded in allegations of bias and conflict of interest.

24. In order to succeed, Alexion must prove the following:

    i. That Ms. Lindberg's role as CEO issuing a Notice of Hearing is even susceptible to the legal principles surrounding an allegation of bias – whereas those principles, by their very nature, apply to adjudicators whereas her role as CEO was administrative in nature;

    ii. that the alleged apprehension of bias is "reasonable".

25. At its highest Alexion has shown that:

    i. Ms. Lindberg's function as CEO in issuing a Notice of Hearing was administrative and not adjudicative;

    ii. Ms. Lindberg was a director of a not for profit company at the time the Notice of Hearing was issued;

    iii. the not for profit company might have an interest, the materiality of which is unknown, in the price of Soliris – although whether its economic interest is in higher or lower prices is unknown;

    iv. the not for profit company is one of many members of an organization;

v. Ms. Lindberg issued the Notice of Hearing in this matter as CEO and appointed Hearing Panel members as Chairperson, then had no other involvement in the matter;

vi. the organization later sought to intervene; and

vii. the organization was granted intervenor status, by the independent Hearing Panel.

Part IV - Conclusion

26. As noted at the start of the Legal Submissions portion of this written argument, the allegations "cannot rest on mere suspicion, pure conjecture, insinuations or mere impressions of an applicant or his counsel". They must be "supported by material evidence demonstrating conduct that derogates from the standard".

27. At their highest, the allegations of any conflict of interest or bias are misplaced speculation, founded on a misconception.

28. As to "the standard", even if it was the legal test, there is no evidence of closed mindedness on the part of Ms. Lindberg. In fact, Alexion relies and has reiterated its reliance upon the adjudicative test of appearance of justice.

29. Alexion's motion should be dismissed.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

Original signature redacted

Dated: September 14, 2015

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