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 OF THE RESPONDENT: REPLY TO RESPONSE OF THE MINISTER OF HEALTH OF BRITISH COLUMBIA

(REQUEST FOR PARTICULARS, CROSS-EXAMINATION OF ERIC LUN, and DIRECTIONS RE: MOTION TO STRIKE PASSAGES OF PROVINCIAL MINISTERS' AMENDED APPEARANCE)

1. The Minister of Health of British Columbia ("Minister") argues that Alexion's request to cross-examine Eric Lun should be dismissed on the grounds that: (1) the Minister can withdraw the affidavit; (2) Eric Lun should not otherwise be cross-examined in relation to Alexion's motion to strike the allegations in the Minister's Amended Notice of Appearance; and (3) the Panel lacks authority to strike out portions of the Amended Notice of Appearance, even if the challenged passages are new allegations irrelevant to issues raised in the Statement of Allegations.

2. The Minister is incorrect on all three points. First, while a court or tribunal has discretion to permit a party to withdraw an affidavit, it should not be permitted when the purpose of withdrawal is strategic and intended to escape cross-examination. Second, the Panel has jurisdiction to hear evidence on a motion to strike. Third, the Panel has ample authority to control its own process to ensure the fair and expeditious conduct of

the proceeding by limiting the Amended Notice of Appearance to relevant issues. While provincial ministers have a statutory right to "make representations", their representations must be limited to bringing their "unique perspective" to bear on issues framed by Board Staff in the Statement of Allegations; provincial ministers cannot raise new issues.

Panel Should Not Permit Withdrawal of Affidavit

3. Although the Panel has discretion to control its own processes, the discretion should not be exercised to permit a party to withdraw an affidavit for purely strategic reasons. In particular, the Panel should not permit an affidavit to be withdrawn for the strategic purpose of shielding an affiant from cross-examination.

4. In *Ominayak v. Lubicon Lake Indian Nation*, [2000] F.C.J. No. 247 (Fed. T.D.)(reversed on other grounds [2000] F.C.J. No. 2056 (Fed. C.A.)) the court wrote:

> 13 In the present case, the withdrawal is clearly sought in order to withdraw from the record relevant evidence that has been filed. The affidavit in question was filed on November 12, 1999, in response to a Court order of October 26, 1999, requiring the respondent to file within 30 days all affidavits on which she intended to rely. The request that the respondent be allowed to withdraw the affidavits must be considered together with the affidavit Ms. Venne has filed, stating she has no knowledge of a band membership list or a list of those eligible to vote at the April 25, 1999, election. Not only will withdrawal prevent cross-examination, the withdrawal appears to be part of a strategy to limit the applicants' access to relevant information. The fact that counsel has now decided that he does not wish to rely upon the affidavit, is not an acceptable reason to grant an order permitting withdrawal. [Emphasis added.]

5. In *Ariss v. Ariss*, [2011] A.J. No. 764 (Alta. Q.B.), the court stated the general rules as follows:

5 Master Brine in the British Columbia case *Gill v. Gill*, 2004, BCSC 518 enumerated a number of factors which may influence a Court's decision on whether to exercise its discretion to allow the withdrawal of an affidavit as follows at paragraph 36: -

> In summary, it appears that there is discretion in the court to order that affidavits filed in the court file may, upon application, be withdrawn. Among the factors to be considered by the court upon such an application are the following:
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> 1. Was the affidavit filed by mistake?
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> 2. Has the affidavit been used, in the sense of having been before the court, during the course of considering an application?
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> 3. Is there a pending application before the court for which a party has indicated it intends to rely upon the affidavit?
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> 4. Is the application to withdraw the affidavit made as a strategic or tactical decision to deny the other party access to relevant information or the ability to cross-examine the deponent?
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> 5. Would the other party be prejudiced in any way by the withdrawal of the affidavit?
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> 6. Are there policy considerations which would militate against a withdrawal of the affidavit?
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> 7. Would the administration of justice be adversely affected by the withdrawal of the affidavit?

6 Some of these factors appear to carry more weight than others. It is fairly clear that an affidavit may not be withdrawn if the purpose of the withdrawal is to prevent the other party from cross-examining a witness: R.O.M. Construction v. Heeley (1982), 46 A.R. 366 (Q.B.). In addition, if the reasons for the withdrawal are tactical or would cause prejudice to the other party, then the withdrawal should not be allowed: Ominayak v. Lubicon Lake Indian Nation Election (Returning Officer) (2000), 185 F.T.R. 33 (Fed. T.D.), rev'd on other grounds (2000) 267 N.R. 96 (Fed. C.A.). [Emphasis added.]

6. In this proceeding, it is apparent that the strategic purpose of the proposed withdrawal is to avoid exposing Mr. Lun to cross-examination and to limit information available to Alexion in its quest to demonstrate that the Amended Notice of Appearance is largely irrelevant to the issues that must be resolved by the Panel.

7. The Minister essentially asserts in paragraph 17 of the Response, that, the affidavit was filed by mistake because it was required by the Board. The Minister denies that the affidavit was filed"...in support of an Amended Notice of Appearance."

8. The flaws in this assertion are obvious on the face of the documents. Paragraph 4 of the Amended Notice of Appearance states, in pertinent part:

> 4. **The Ministers of Health also intend to rely upon the Affidavit of Eric Lun, sworn April 1, 2015 and filed herein, and specifically upon the following facts as stated in the Affidavit of Eric Lun** ... [Emphasis added.]

9. This passage clearly demonstrates that the provincial ministers filed the Lun affidavit in support of their Amended Notice of Appearance. The only reason the Minister now seeks to withdraw the affidavit is to avoid having Mr. Lun cross-examined so that Alexion can obtain information that will support its allegations that the provincial ministers have nothing relevant to add to the substantive claims in the Statement of Allegations. Alexion submits that the Board should not permit what is obviously a 'strategic' withdrawal.

Eric Lun Ought To Be Cross-Examined On the Motion to Strike

10. The Ministers assert in paragraph 15 that "there is no requirement in the Rules that a concerned minister submit an affidavit in support of any notice of appearance ..." and in paragraph 27 that "...evidence is not permissible on a motion to strike".

11. These arguments display a fundamental misunderstanding of procedures established by the Board's Rules. The Rules provide explicit authority for: (1) ordering a

minister to submit an affidavit in support of a notice of appearance; and (2) requiring any person who has submitted an affidavit to be cross-examined.

12. The Minister has not cited any authority for the proposition that evidence is inadmissible on a motion to strike before a panel. Presumably, the Minister intends to support submissions of Board Staff that the issue ought to be decided by analogy to the Federal Court Rules. The Rules do not, however, provide for comparisons or reference to Federal Court practice. While the rules of some federal tribunals refer to the Federal Court's rules by analogy, for example, subsection 5(2) of the *Canadian Radio-television and Telecommunications Commission Rules of Practice and Procedure*, SOR/2010-277[1], there is no such provision in the *Patent Act* or Regulations. Parliament clearly did not impose such a requirement on the PMPRB.

13. When interpreting its own legislation, the Panel should not confer upon itself powers not granted by Parliament in the legislation. The Rules provide in subsection 5(2):

> 5(2) (2) Any procedural matter or question that is not provided for in the Act, in these Rules or in any regulations made pursuant to the Act that arises in the course of any proceeding may be dealt with in any manner that the Board directs in order to ensure the fair and expeditious conduct of any proceeding.
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> Subsection 6(2) of the Rules states:
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> 6(2) The Board may, <u>at any time</u>, direct
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> (a) <u>that a party provide any information or documents</u>, in paper or electronic format, that the Board considers concerned to any proceeding; and

[1] 5 (2) The Commission may provide for any matter of practice and procedure not provided for in these Rules by analogy to these Rules <u>or by reference to the Federal Courts Rules</u> and the rules of other tribunals to which the subject matter of the proceeding most closely relates. [Emphasis added]

(b) that a particular fact be established by affidavit. [Emphasis added]

14. These provisions confer ample authority for the Board, or a panel, to request, or even require, provincial ministers to submit an affidavit in support of the Amended Notice of Appearance. Indeed, the Minister complied with the request by proffering Mr. Lun's affidavit.

15. The Rules also provide the Panel with specific powers to grant leave for the cross-examination of a witness on an affidavit. Subsection 26(2) states:

> 26 (2) The Board, before or during the hearing of a motion on an interlocutory matter, may grant leave for
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> (a) a witness to give testimony orally in relation to any points at issue raised in the motion; and
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> (b) the cross-examination of any person making an affidavit.

16. There is nothing to limit the generality of the Rule. Nor is there any basis for asserting that the Rule has no application to circumstances in which an affidavit is filed to support an intervention.

17. Furthermore, in Ontario at least, Rule 21.01(2)(a) permits use of evidence on a motion to strike "... with leave of a judge".

18. An absolute prohibition on use of evidence on a motion to strike is specific to the Federal Court Rules. As asserted above, the Federal Court Rules have not been adopted in Rules dealing with proceedings before the Board or this Panel.

19. The principal factor applicable to hearings before the Panel is whether a cross-examination will "... ensure the fair and expeditious conduct of [this] proceeding".

20. The *fairness* of permitting cross-examination in this case is clear. It is only through cross-examination that Alexion will be provided an opportunity to obtain information necessary to establish the irrelevance of the Minister's allegations. This is supported by the Minister's own Response, which states in paragraph 29:

> "Because no evidence has been entered by the parties to this matter, the Board has no context in which to assess the relevance of any portions of the Amended Notice of Appearance".

This statement is untrue. The provincial Ministers have themselves introduced Mr. Lun's affidavit. Only by testing Mr. Lun's evidence will Alexion be in a position to establish that the Minister's assertions have no relevance to the Panel's determination. The Panel must "assess the relevance" of any assertions made by a party or intervener to be in proper control of its processes. This requires Mr. Lun to be cross-examined. There is no "unfairness" in permitting the cross-examination, and considerable "unfairness" in permitting the Minister's allegations to stand without allowing cross-examination so that the evidence can be tested.

21. The expeditious conduct of this proceeding will be enhanced by permitting cross-examination and hearing the motion to strike. If the motion succeeds, the issues will be considerably narrowed. Alexion will not be required to produce further expert witnesses to rebut new or irrelevant issues raised by the Minister. The result will be savings in time and expense for all parties and the Panel.

Panel Has Authority to Allow Motion to Strike

22. In paragraphs 29 through 46, the Minister asserts the Panel lacks authority to strike out irrelevant allegations in the Amended Appearance.

23. Alexion concedes that the Minister has a statutory right to appear and "make representations". The right is specifically established by subsection 86(2) of the *Patent Act* which provides:

> 86 (2) The Board shall give notice to the Minister of Industry or such other Minister as may be designated by the regulations and to provincial ministers of the Crown responsible for health of any hearing under section 83, and each of them is entitled to appear and make representations to the Board with respect to the matter being heard. [Emphasis added]

24. A provincial minister cannot appear and make representations on any matter he or she chooses or present a new or different case. The representations must be relevant to the actual case presented by Board Staff "with respect to the matter being heard."

25. Despite the wording of s. 86, the Minister has alleged in paragraph 46 that the *Patent Act* does not restrict issues or facts that may be raised by a concerned minister in a notice of appearance. The key phrase the Minister overlooks is that the right to make representations is limited to "... the matter being heard".

26. The "matter being heard" is the investigation initiated by Board Staff and established, under the Rules, by the Statement of Allegations referred to in subsection 15(3).

27. The Minister's assertion that it has the right to assert an alternative case distinct from the Statement of Allegations— in essence that a minister can raise a completely different case theory distinct from that of Board Staff—makes no sense in the context of the regulatory scheme. The scheme provides interested ministers with a right to make

representations only after issuance of a Notice of Hearing under s. 83 (that is, after an investigation has been initiated by the Board Staff, the Board Staff are unable to resolve issues identified by the investigation, a Voluntary Compliance Undertaking [VCU] has not been accepted by the Board Chair, and the Board Chair has, in the result, issued a notice of hearing based on the statement allegations prepared by Board Staff).

28. There is no statutory right conferred on provincial ministers to initiate a hearing on their own initiative. If the Minister's approach were correct, the statutory scheme would, in effect, provide provincial ministers with the right to initiate alternative investigations and hearings based on theories unrelated to the issues raised by Board Staff. Given that the statutory right extends to all ten provincial ministers of health (and to the federal Minister of Industry), the position advanced by the Minister has the potential to lead to absurd results. In effect, if an investigation is launched by the Board, there is a possibility of 12 different theories being proposed whenever the investigation moves to a hearing. This cannot have been Parliament's intention, which has been explicitly stated as ensuring "the fair and expeditious conduct of any proceeding".

29. The sensible interpretation is that the *content* of the "representations" made by concerned ministers must be typical of all public interest interveners. Provincial ministers are thus confined to addressing the issues raised by Board Staff but they may offer a *different perspective* on those issues. Provincial ministers cannot, however, introduce *new* issues.

30. *Alderville Indian Band v. Canada*, [2014] F.C.J. No. 857 (Fed. TD) is a leading case on this point. While Federal Court Rules are not binding on the Panel in matters of

procedure, the substantive case law in Canada on intervention can, and should, be given weight:

> 23 The jurisprudence emerging after the new Court Rules were introduced in 1998 has indeed looked to previous cases for guidance. Although caution is warranted, the old cases are still helpful. As Prothonotary Hargrave noted in Yale Indian Band v Aitchelitz Indian Band (1998), 151 FTR 36 at paragraph 14 [Yale Indian Band], the substantial case law built around the former Federal Court Rule 1716 could be used as guidance in the exercise of discretion under the new rule. In the course of his discussion Prothonotary Hargrave stated at paragraph 18:
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> > In Canada (A.G.) v Aluminum Co. of Canada [1987] 3 W.W.R. 193, the British Columbia Court of Appeal, referring to various authorities, to the effect that interveners [sic] ought not to be allowed to redefine issues, thus forcing the parties to deal with issues which are not their own, noted:
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> > > "Interveners should not be permitted to take the litigation away from those directly affected by it. Parties to litigation should be allowed to define the issues and seek resolution of matters they determine appropriate to place in issue. <u>They should not be compelled to deal with the issues raised by others</u>." (p. 206) [Underlining added.]

31. The same point is made in Pinnacle *Estates Inc. v. Beam Inc.*, [2013] F.C.J. No. 1319 (Fed. TD):

> 11 First, it should be noted that, even if one admitted for discussion purposes that the allegations that were withdrawn from the initial statement of claim could be of some interest for the ends sought by the Constellation Group, the fact remains that these allegations no longer exist and that the Court must examine the present dispute between the plaintiff and the defendants Beam as it stands according to an analysis of the pleadings between these parties.
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> 12 This aspect is relevant as it is known that any intervener must take the proceeding as it stands between the parties that are already involved. In fact, as noted in Maurice v Canada (Minister of Indian Affairs and Northern Development) (2000), 183 FTR 45, at paragraph 11, interveners cannot, as a result of their status, raise aspects that have not already been raised by the existing parties:
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> > [11] <u>It is common ground that an intervener takes the pleadings and record as it finds them</u>. While an intervener may bring new viewpoints and special knowledge to a proceeding, <u>the intervener may not litigate new issues</u> (Yale Indian Band v. Aitchelitz Indian Band (1998), 151 F.T.R. 36 (Proth.). I am confident that counsel for the applicant is well aware of the

> role that interveners are allowed to play, and that the applicant will not seek to expand the parameters of the claim, which indeed, in any event, it may not do. [Emphasis added.]

32. Confining intervention to issues raised by the direct litigants is particularly important in regulatory enforcement proceedings. It is fundamentally unfair for an intervener like the Minister to introduce entirely new issues. Like other interveners, the Minister must "take the pleadings and record as it finds them".

33. While provincial ministers may differ from other public interest interveners in that they have a statutory right of intervention, that status does not confer a right to, in effect, launch their own prosecution under the *Patent Act*. A provincial minister may bring his or her "unique perspective" to the issues, but the issues are to be established by the Statement of Allegations of Board Staff.

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