

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 BOARD STAFF**

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

1. In their June 5, 2015 Written Representations Board Staff argue Alexion’s motion for particulars should be dismissed because Board Staff have already provided all necessary particulars. Board Staff also urge the Panel to dismiss Alexion’s motion for leave to cross-examine Eric Lun on the grounds that the evidence would be inadmissible on a motion to strike Attorney General’s appearance, would prejudice the hearing on the merits, and is premature.

2. Board Staff are incorrect on both issues. The particulars sought by Alexion are required to ensure that it fully and correctly understands the case it has to meet; and (2) the Board has the regulatory authority to hear evidence on a motion to strike, and so the cross-examination of Eric Lun is not premature.

Board Staff have Not Provided Particulars

3. Board Staff assert in paragraph 28 of their submissions that Alexion does not require further particulars because Alexion has already pled. While Alexion acknowledges having filed a Response, it did so explicitly reserving its rights to amend once further particulars were delivered. Alexion seeks confirmation by means of the delivery of the particulars to which it is entitled that the case disclosed by Board Staff in the Statement of Allegations (“Allegations”) is, in fact, the case Alexion must meet.

4. Board Staff’s argument, summarized in the chart following paragraph 34 of their submissions, is that because the calculations in the Allegations were based upon: (1) information provided to the Board by Alexion; (2) publicly available Regulations and Guidelines; and (3) factors in section 85 of the *Patent Act* that no further particulars are necessary. Board Staff argue that all relevant information is either already within Alexion’s knowledge, or is “evidence and argument”.

5. Board Staff’s position is unprincipled and fundamentally disingenuous. By their logic, Board Staff have no obligation to provide any “material facts” at all. They need only allege that the price is “excessive” and leave a patentee to review its filings with the Board, the *Patent Act*, and the Guidelines, and simply “figure it out for themselves”.

6. Board Staff’s approach does not comport with the process contemplated in the *Patented Medicine Prices Review Board Rules of Practice and Procedure* (the “Rules”) or the principles of fairness. In subsection 15(3), the Rules expressly provide, that a Statement of Allegations must contain “...the material facts, the allegations, and the order sought by Board Staff in the proceedings”. To state a comprehensible case for

Alexion to meet, the “material facts” must include details of how Alexion’s conduct results in an excessive price under the *Patent Act* and/or the Guidelines assuming Board Staff’s case theory is correct. In the circumstances, Board Staff essentially allege that: (1) Soliris is expensive; (2) if Soliris is expensive it must be “excessive” under s. 85 of the *Patent Act* ; and (3) Soliris fails the highest international price comparison test (“HIPC”) under the Guidelines. There are no material facts asserted whatsoever as to how Soliris fails to meet the criteria under s. 85. The allegation that Soliris fails to meet the HIPC test is unsupported by material facts: foreign prices relied upon, foreign exchange rates relied upon, and the calculations used to show how the test was failed. Board Staff refuse to provide these details.

7. Moreover, in the compliance report prepared by Board Staff for the period ended December 2014 and sent to Alexion by Board Staff in early 2015, Board Staff omitted the pricing and compliance information that is ordinarily provided to patentees and replaced it with the words, “Notice of Hearing”. To date the Board Staff have not provided Alexion with their position as to whether they believe the average prices for January to December 2014 are or are not excessive, nor have they provided any supporting analysis or calculations. In effect, in relation to both this and the matters set out in paragraph 6, above, Board Staff or their counsel assert that it is all self-evident and Alexion should go and figure it out for themselves. Board Staff’s approach is antithetical to a fair, open, and transparent process.

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

8. Board Staff asserts in paragraph 43 that “the Minister was not required to file an affidavit” and further, that the “intended basis for the cross-examination is to strike the Amended Notice of Appearance” and that as “a matter of law such a motion should be decided without evidence”.

9. These arguments display a fundamental misunderstanding of procedures established by the Rules. The Rules provide ample 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.

10. Board Staff have asserted in paragraph 50, without citing any authority, that the issue ought to be decided by analogy to the Federal Court Rules. However, the Rules of this tribunal do not expressly provide for comparisons with Federal Court practice. While *some* federal tribunals have rules that 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/2010-277¹, there is no such provision in the *Patent Act* or Regulations; Parliament did not impose such a requirement on the PMPRB.

11. When interpreting its own legislation, the Panel ought not to confer on itself powers that it has not been granted by the legislation. The Rules provide in subsection 5(2):

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 or by reference to the Federal Courts Rules and the rules of other tribunals to which the subject matter of the proceeding most closely relates. [Emphasis added]

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.

Subsection 6(2) of the Rules states:

6(2) The Board may, at any time, direct

(a) that a party provide any information or documents, in paper or electronic format, that the Board considers concerned to any proceeding; and

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

12. These provisions confer on the Panel ample authority to request or, indeed, to require the Minister to submit an affidavit in support of his Amended Notice of Appearance. Indeed, the Minister complied with the request.

13. The Rules also provide that 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

(a) a witness to give testimony orally in relation to any points at issues raised in the motion; and

(b) the cross-examination of any person making an affidavit.

14. There is nothing to limit the generality of this Rule or to preclude its operation in circumstances where an affidavit is filed to support an intervention.

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

16. An absolute prohibition on the use of evidence on a motion to strike is specific to the Federal Court Rules. As previously stated those Rules have not been adopted as a source of authority in hearings before this Board.

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

18. The *fairness* of requiring cross-examination in this case is clear. It is only through cross-examination that Alexion will be provided an opportunity to obtain evidence necessary to establish the irrelevance of of the Minister's allegations.

19. The expeditious conduct of this proceeding will be enhanced by permitting cross-examination and 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 irrelevant issues raised by the Minister. The result will be savings in time and expense for all parties and the Panel.

20. Given that:

- (1) the Panel had authority to require the Minister to provide an affidavit;
- (2) the Minister proffered the Lun Affidavit;
- (3) there is no legal prohibition to the cross-examination of Eric Lun on a motion to strike; and
- (4) the motion will ensure the fair and expeditious conduct of the proceedings, cross-examination of Mr. Lun is not "premature" as alleged by Board Staff.

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