# PATENTED MEDICINE PRICES REVIEW BOARD IN THE MATTER OF the Patent Act, R.S.C., 1985, c. P-4, as amended

# AND THE MATTER OF Alexion Pharmaceuticals Inc. ("Respondent") And the medicine "Soliris"

# NOTICE OF MOTION

**TAKE NOTICE THAT** Board Staff will bring a motion before the Panel on June 1, 2016 at the Board's offices in Ottawa.

## THIS MOTION IS FOR:

- 1. An Order permitting Board Staff to file the <u>Amended</u> Statement of Allegations attached at Schedule "A"; and,
- 2. An Order striking out certain portions of paragraphs 7, 8, 9, 10 and 11 of the Witness Statement of Barry Katsof as filed by Alexion Pharmaceuticals Inc. ("Alexion") on May 13, 2016.<sup>1</sup> In the alternative, an order requiring Alexion to file an amended witness statement containing particulars of the vague allegations contained in paragraphs 10 and 11 of Mr. Katsof's witness statement.

<sup>&</sup>lt;sup>1</sup> Board Staff does not object to the first sentences in paragraphs 7, 8, and the first and third sentences in paragraph 9 of Mr. Katsof's witness statement.

#### **GROUNDS FOR THE MOTION ARE:**

#### Amendment of Board Staff's Statement of Allegations

- 3. Board Staff seeks an order permitting it to file an updated <u>Amended</u> Statement of Allegations to reflect the alternative remedies it will be seeking at the hearing. In particular, Board Staff's proposed <u>Amended</u> Statement of Allegations makes it clear that Board Staff is seeking a remedy consistent with the evidence and remedy advanced by the Provinces for an order that Alexion be required to reduce the price of Soliris to a price that does not exceed the lowest price among the comparator counties. In the alternative, Board Staff intends to seek a remedy consistent with its original Statement of Allegations for an order that Alexion be required to required to reduce the price of Soliris to a price that does not exceed the lowest price among the required to reduce the price of Soliris to a price that does not exceed the international median price among the comparator countries. Board Staff's proposed <u>Amended</u> Statement of Allegations also makes it clear that Board Staff is relying on sources available to Board Staff for the purposes of calculating the amount of excess revenues sought.
- 4. Rule 6(1)(d) of the *Patented Medicine Prices Review Board Rules of Practice and Procedure* provides that the Board may permit the amendment of any document filed with the Secretary.
- 5. Board Staff submits that it should be permitted to amend its Statement of Allegations for, *inter alia*, for the following reasons:
  - the proposed amendments are consistent with the evidence and remedy being advanced by the Provinces;
  - (b) the alternative remedies sought by Board Staff are consistent with the relief sought by Board Staff in its original Statement of Allegations; and,
  - (c) the proposed amendments do not result in any prejudice to Alexion.

#### Striking Portions of the Witness Statement of Barry Katsof

- The Panel's amended Order Regarding Scheduling required Alexion to file its expert reports by April 18, 2016 and its witness statements for its non-expert witnesses by May 13, 2016.
- 7. On April 18, 2016, Alexion filed three expert reports.
- 8. On May 13, 2016, Alexion filed its non-expert witness statements, including the witness statement of Barry Katsof.
- 9. Board Staff asserts that paragraphs 7, 8, 9, 10 and 11 of the non-expert witness statement of Mr. Katsof contains inadmissible opinion evidence related to issues for which Mr. Katsof has not been qualified as an expert.<sup>1</sup> In addition, paragraphs 10 and 11 of Mr. Katsof's witness statement contain no meaningful details regarding the evidence he intends to give at the hearing.
- 10. Board Staff submits that Alexion's attempt to rely on Mr. Katsof's inadmissible opinion evidence violates the Order Regarding Scheduling, the *Patented Medicine Prices Review Board Rules of Practice and Procedure* regarding the admissibility of expert evidence and the common law which precludes non-expert witnesses from giving opinion evidence on matters which require expertise.
- 11. Board Staff submits that Mr. Katsof's opinion evidence is inadmissible and should be struck. In the alternative, Board Staff submits that Alexion should be ordered to provide an amended witness statement containing particulars of the vague allegations contained in paragraphs 10 and 11 of Mr. Katsof's witness statement.
- 12. Rules 5, 6 and 8 of the Patented Medicine Prices Review Board Rules of Practice and Procedure.

# THE FOLLOWING DOCUMENTARY EVIDENCE WILL BE USED AT THE HEARING OF THE MOTION:

- 1. The pleadings.
- 2. The Non-Expert Witness Statement of Barry Katsof as filed on May 13, 2016.
- 3. Board Staff's proposed <u>Amended</u> Statement of Allegations of Board Staff attached at Schedule "A".
- 4. Such further and other evidence as counsel may advise and the Panel may permit.

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