



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"

PANEL ORDER REGARDING MOTION FOR PARTICULARS AND SCHEDULING

Decided by the Panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**Board**") seized with this proceeding on the basis of the written record.

I. Motion for Particulars

1. Board Staff filed a letter on December 15, 2016 containing "updated tables which Board Staff will be relying upon at the hearing" and which contained "Board Staff's updated alternative calculations of excess revenues".
2. Alexion Pharmaceuticals Inc. ("**Alexion**") filed a motion on December 23, 2016 (the "**Motion**") requesting an Order from the Panel that Board Staff deliver to Alexion and the Panel the following particulars of the allegations in the Amended Statement of Allegations:
 - i. the specific reduction (or reductions) in price for Soliris that Board Staff requests the Panel to order in relation to future sales of Soliris in Canada;
 - ii. the specific amount (or amounts) of alleged excess revenues for which Alexion is liable, including the particular years for which relief is sought;
 - iii. the specific test (or tests) relied on by Board Staff for any request for a reduction in the price of Soliris in relation to future sales of Soliris in Canada or any liability for alleged excess revenues based upon past sales of Soliris in Canada in particular years;

- iv. the sources, and specific identification, of the international prices used by Board Staff for purposes of comparing the Canadian price of Soliris with the price of Soliris sold in other countries under any test referred to in subparagraph "iii" above;
- v. the actual international exchange rates used by Board Staff to convert any international price used by Board Staff for purposes of comparing the Canadian price of Soliris with the price of Soliris sold in other countries under any test referred to in subparagraph "iii" above; and
- vi. the calculations used by Board Staff under any test referred to in subparagraph "iii" above.

3. On December 28, 2016, Board Staff filed a letter stating that it "withdraws the concessions described in [its] letters of December 15 and 20, 2016" and since "Board Staff has withdrawn the concessions, there is no basis for Alexion's motion." However, in an e-mail sent to the Secretariat of the Board (Mr. Guillaume Couillard) on December 29, 2016, counsel for Board Staff wrote:

Board Staff reserves its right to lead evidence regarding all issues related to international price sources including the impact of those sources on some of Board Staff's alternative calculations of excess revenues. This evidence may include testimony from Board Staff's witnesses regarding the calculations in the updated tables attached to [Board Staff's] letter of December 15, 2016. Board Staff's withdrawal of the concessions described in [its] letters of December 15 and 20, 2016 do not preclude it from leading evidence which compares Alexion's position on international pricing sources with the position of Board Staff on those issues

4. In response, Alexion filed a letter on December 29, 2016 stating that it does not agree with Board Staff's position that withdrawing the concessions renders Alexion's motion moot, and requested that Board Staff adduce the particulars requested in the Motion.

5. In an e-mail sent to Mr. Couillard on December 30, 2016, counsel for Board Staff wrote:

Board Staff's case theory has not changed and Alexion has already been provided with particulars of the original and Amended Statement of Allegations. Alexion knows the case it has to meet and has details of all of Board Staff's alternative calculations of excess revenues.

[...]

These are not new issues and Alexion is fully aware of their relevance to the issues raised in the pleadings.

6. In a responding e-mail sent to Mr. Couillard on December 30, 2016, counsel for Alexion maintained its request for particulars.

7. The Panel is of the view that Alexion is entitled to the information requested in the Motion (and as set out in paragraph 2 above) in order to adequately respond to the allegations made and the relief requested in this proceeding. The Panel acknowledges Board Staff's position, as set out in paragraph 5 above, that it has already provided Alexion with particulars, including the details of all of Board Staff's alternative calculations.

8. Rule 6(2)(a) of the *Patented Medicine Prices Review Board Rules of Practice and Procedure*¹ provides that the "Board may, at any time, direct that a party provide any information or documents, in paper or electronic format, that the Board considers concerned to any proceeding".

9. In order to assist the Panel and Alexion, and to ensure the fair and expeditious conduct of this proceeding, the Panel orders Board Staff to provide clear references, including page, paragraph and/or line numbers, where applicable, to documents or any other sources in which each of the items of information requested by Alexion in its Motion (and summarized in paragraph 2 above) was previously provided by Board Staff, no later than January 9, 2017.

¹ SOR/2012-247.

II. SCHEDULING

10. The Panel directed Alexion and Board Staff in the case conference held on December 21, 2016 to file a proposed schedule for the hearing to be held on January 16 to 19, and 23 to 27; February 20 to 24, 27 and 28; and March 1 to 3, 2017, inclusive.

11. Board Staff filed a proposed schedule on December 29, 2016. In its letter, Board Staff notes that "Board Staff is preparing its examinations-in-chief and cross-examinations based on the time estimates set out in its proposed schedule unless the Panel orders otherwise prior to the hearing." These estimates exceed 90 minutes for examinations-in-chief for each of its three witnesses.

12. In an e-mail sent to Mr. Couillard dated December 30, 2016, Alexion indicates that it "is generally in agreement with the schedule proposed by... Board Staff". Furthermore, it does "not plan to object if the direct examination of any Board Staff witness exceeds 90 minutes, as proposed... on the understanding that Board Staff will afford Alexion similar latitude if any of Alexion's witnesses require more than 90 minutes."

13. The Parties are aware of the dates set aside for the hearing and the approximate hours that the Panel will be sitting. Considering that the parties' proposed schedule completes the evidence for this proceeding within the parameters previously directed by the Panel, the Panel is prepared at this time to proceed on the basis of the schedule proposed by the parties, including the estimated times for examinations-in-chief, subject to the Panel's discretion at the hearing.

14. The Panel orders the parties to file a joint proposed schedule, which should include the updated order and days on which Alexion's witnesses will appear at the hearing as advised by Alexion's counsel in an e-mail to Mr. Couillard on December 30, 2016, no later than January 9, 2017.

15. The Panel also understands that Alexion wishes to have Mr. Barry Katsof testify by video link, that Board Staff objects, and that Alexion intends to file a formal motion.

The Panel directs that Alexion file its motion for an order permitting Mr. Katsof to testify by video link forthwith.

DATED in Ottawa, this 4th day of January, 2017.

Original signed by

Signed on behalf of the Panel by
Mitchell Levine

Panel Members:
Mitchell Levine
Carolyn Kobernick
Normand Tremblay