

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”

ALEXION’S FURTHER WRITTEN REPRESENTATIONS (Board Staff’s Motion to Strike Paragraphs 37 and 38 of Amended Response

1. Alexion respectfully submits that the Panel ought to dismiss Board Staff’s motion to strike paragraphs 37 and 38 of the Amended Response for the reasons argued in submissions delivered on 9 September 2015.
2. While the paragraphs concerning Isabel Raasch may no longer be in issue given the decision released by the Panel on 5 October 2015, the Board’s decision relating to Ms. Raasch does not constitute a basis for striking the allegations. While the Panel may have disagreed with Alexion’s arguments, the lengthy decision shows it was not “plain and obvious” that Ms. Raasch did not have a conflict, particularly given the evolving scope of the duty of loyalty recognized by the Panel.
3. Characterization of Board Staff’s role in this proceeding remains at issue. In particular, the types of excessive pricing allegations Board Staff can raise, whether Board Staff require an evidentiary foundation for excessive pricing allegations before the allegations are raised in the Statement of Allegations, and Board Staff’s disclosure obligations in relation to excessive pricing allegations remain very much at issue.

4. The disclosure received from Board Staff on 20 October 2015 in response to the Panel's Direction given in the case conference on 13 October 2015 supports Alexion's position in this regard. The documents disclosed, all of which could easily have been provided several months ago, deal only with international pricing of Soliris and, in particular, the introductory price of Soliris in 2009 and application of the Highest International Price Comparison ("HIPC") after the product was introduced. None of the documents produced deals with any other excessive pricing allegation or factor articulated in section 85 of the *Patent Act*.

5. It is apparent that there either are no documents supporting any other excessive pricing allegations or that Board Staff are still searching for documents, which establishes that the allegations were made in the Statement of Allegations without any evidentiary foundation in the first place.

6. Most importantly, Board Staff's Reply Argument does not even address the most basic argument raised in response to their motion—the "plain and obvious" test. Board Staff simply cannot meet the "heavy onus" created by this test and, indeed, have not even tried.

7. Proper characterization of Board Staff's role, how that role affects disclosure obligations, whether excessive pricing allegations can be made in the absence of foundational evidence, and whether Board Staff can support excessive pricing allegations advanced by interveners that have no basis in the *Patent Act* or the Guidelines, are still live issues before the Panel and must be determined. The answers

to these questions are not "plain and obvious" or "beyond doubt" and should await the Panel's determination of these issues at the hearing.

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