

Patented **Review Board**

Conseil d'examen Medicine Prices du prix des médicaments brevetés

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"

REASONS FOR DECISION (Motion to Request Further Documents)

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

1. A few minutes before the start of the resumption of the hearing on January 23. 2017, Alexion Pharmaceuticals Inc. ("Alexion" or the "Respondent") filed a motion under Rule 24 of the PMPRB Rules of Practice and Procedure¹ (the "Rules") for an order requiring production of further documents from Board Staff. The documents requested are itemized in 7 categories in paragraph 1 of Alexion's Notice of Motion.

2. Board Staff provided written representations in response to the motion late in the evening of January 23, 2017. Board Staff submits that the motion should be dismissed for a number of reasons, which are summarized in paragraph 1 of its written representations.

3. The Panel has considered the materials filed by both Parties and the general submissions made during the hearing on January 23 and 24, 2017 concerning this motion.

4. The motion is dismissed for the following reasons.

SOR/2012-247.



5. This is not the first disclosure motion brought by Alexion. A previous disclosure motion was brought by Alexion on August 21, 2015, and decided by the Panel in reasons dated November 24, 2015. The Panel has already decided, relying on binding Federal Court precedent (see *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*)² that the disclosure obligations of Board Staff are met if the respondent is advised of the case it has to meet and is provided with all of the documents that will be relied on at the hearing. It would be improper for the Panel to revisit its decision, there is no evidence before the Panel that Board Staff has failed to fulfill its disclosure obligation, and the documents requested by Alexion are not being relied on by Board Staff at the hearing.

6. In addition, regarding Alexion's request for calculations relevant to the 2016 and following period, and for detailed summaries of excessive revenues (see paragraphs 1(a) and (b) of the Notice of Motion), the Panel has already dealt with these requests in the context of resolving Alexion's December 23, 2016 motion for particulars of the allegations in the Amended Statement of Allegations, including (i) its order of January 4, 2017, and (ii) its ruling on January 16, 2017, where at the commencement of the hearing the Panel advised the Parties that it did not agree with Alexion that Board Staff had not complied with the January 4, 2017 order, and that the Panel was not prepared to order Board Staff to provide further information prior to the commencement of the hearing. Nothing has occurred since January 16, 2017 that convinces the Panel to revisit its decision of January 16, 2017.

7. In addition, it is not possible for Board Staff to provide their calculations for 2016 and any subsequent periods until the relevant data is available to them. Counsel for Board Staff has advised the Panel and Alexion that all of the necessary information for the 2016 calculations will not be available until sometime in March 2017. Alexion does not need the 2016 calculations in order to fairly respond to the case against it as set out in the Amended Statement of Allegations. Alexion has already been provided with particulars of the Amended Statement of Allegations (by virtue of the Panel's order of January 4, 2017) and has the documents that Board Staff intends to rely on at the

² [1994] 3 F.C.R. 425, aff'd [1994] F.C.J. 884 (FCA) (QL).

hearing. The nature of a hearing before the PMPRB is such that updated calculations are necessary because of the passage of time between the issuance of the statement of allegations and the issuance of any order that flows from the Panel's decision on whether the medicine at issue is being sold at an excessive price. This does not cause unfairness to the respondent in the hearing held to decide whether the medicine is being sold at a price that is excessive as alleged in the statement of allegations.

8. Board Staff raises other reasons why Alexion's motion should be dismissed, including that Rule 24 of the Rules cannot be used to obtain a subpoena to obtain documents independent of an examination of a particular witness, and a subpoena cannot be used to obtain information that extends beyond the scope of Board Staff's disclosure obligations. Considering the conclusion the Panel has reached as stated above, it is not necessary for the Panel to address these issues.

Dated at Ottawa, this 24th day of January, 2017.

Original signed by

Signed on behalf of the Panel by Dr. Mitchell Levine

Panel Members:

Dr. Mitchell Levine Ms. Carolyn Kobernick