



Patented
Medicine Prices
Review Board

Conseil d'examen
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"

ORDER REGARDING CONFIDENTIALITY

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. The Panel has reviewed the requests for confidentiality in respect of certain documents filed for the purposes of the hearing by Alexion Pharmaceuticals Inc. ("**Alexion**" or the "**Respondent**") on January 17, 2017, and by the British Columbia Minister of Health (the "**Minister**") on January 16, 2017. Those requests propose certain redactions to the documents that will be filed on the public record in order to address concerns about confidentiality.
2. The basis for the Minister's request is that the disclosure of the redacted information could result in financial disadvantage to the Ministers of Health as well as financial harm to the Respondent and, in some cases, financial harm to the manufacturers of other expensive drugs for rare diseases funded by British Columbia.
3. The basis for the request for confidentiality by Alexion is that the redacted portions of the documents:

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- i. contain, or otherwise deal with, commercially sensitive financial information provided by Alexion to the Board in confidence;
 - ii. contain Alexion work product, including materials Alexion has prepared or collected from sources both privately and publicly available; and/or
 - iii. consist of communications in furtherance of settlement negotiations.
4. Alexion submits that all of these materials are privileged in accordance with section 87 of the *Patent Act*. Among other things, Alexion submits that:
- i. the disclosure of its pricing and sales information will cause specific, direct and substantial harm to Alexion. This information is not available in the public domain and its disclosure "could be of significant value to Alexion's competitors" as the competitors will be able to "determine pricing and other strategies to provide them with a competitive advantage over Alexion." The exact magnitude of that advantage cannot be easily projected in advance of the harm actually materializing but it will undoubtedly be "substantial";¹ and
 - ii. with respect to documents for which Alexion has requested confidentiality on the basis that it is Alexion's work product, "the revelation of these materials to potential competitors will cause specific, direct and substantial harm to Alexion, in that it will reveal significant aspects of Alexion's marketing, reimbursement and sales strategies, and potential strategies, as chosen by Alexion itself, which may then be utilized by Alexion's competitors to gain a commercial advantage over Alexion."²
5. Board Staff provided its response to Alexion's request for confidentiality on January 22, 2017.

¹ Alexion's Request for Confidentiality, paras. 8 - 9.

² Alexion's Request for Confidentiality, para. 12.

6. Board Staff does not object to the request for confidentiality of the Minister if the Panel is satisfied that the province will suffer specific, direct and substantial harm if the information is disclosed.

7. Board Staff submits that the Panel should not grant Alexion's request for confidentiality if (i) the information claimed as confidential is publicly available, or (ii) the Panel is not satisfied that Alexion will suffer specific, direct and substantial harm if Alexion's request for confidentiality is not granted. Board Staff submits that no further redactions should be made, as Alexion has not led any evidence demonstrating that it would suffer specific, direct and substantial harm if the information in Alexion's request for confidentiality is made public.

8. Alexion filed a reply on January 24, 2017, stating that none of the reasons provided by Board Staff for opposing Alexion's request for confidentiality are supported on the facts.

9. Section 86(1) of the *Patent Act* provides: "A hearing under section 83 shall be held in public unless the Board is satisfied on representations made by the person to whom the hearing relates that specific, direct and substantial harm would be caused to the person by the disclosure of information or documents at a public hearing, in which case the hearing or any part thereof may, at the discretion of the Board, be held in private."

10. In its decision dated November 24, 2015 and the Confidentiality Protocol attached thereto, the Panel stated that "public disclosure, in whole or in part, of certain documents in this proceeding could cause specific and direct harm as such documents contain competitively sensitive and/or proprietary information."

11. The Panel has reviewed the submissions of the Parties as well as the information claimed to be confidential. For greater clarity, with respect to Alexion's claim for confidentiality, this is the information that was highlighted in yellow in the documents provided by Alexion along with its request for confidentiality.

12. The Panel grants the requests for confidentiality of Alexion and the Minister in respect of the documents and information specifically identified in Appendix A to this Order, subject to the Party claiming confidentiality waiving it in the course of the hearing. The Panel is satisfied that the public disclosure of this information would cause specific, direct and substantial harm to Alexion or the Minister, as applicable: see the Board's decision in *Habitrol*.³

13. The Panel has denied the request for confidentiality in respect of any other documents or information which are the subject of Alexion's request for confidentiality because either:

- i. the Panel is not satisfied on the submissions and evidence that the disclosure of the information claimed as confidential would cause specific, direct and substantial harm to Alexion; or
- ii. the information claimed as confidential is already available in the public domain.

14. Alexion made a request for confidentiality in respect of information related to research and development (R&D) expenditures in certain documents. The Panel asked the Parties to make submissions on this issue considering that some R&D expenditures are reported in the PMPRB's annual reports. The R&D expenditures in the annual reports are reported on a company by company basis, but in the aggregate and potentially for multiple drugs.

15. The Parties made submissions on January 25, 2017 in respect of this issue.

16. The Panel grants Alexion's request for confidentiality in respect of R&D expenditures in one document, as identified in Appendix A to this Order. The Panel rejects Alexion's other requests for confidentiality in respect of R&D expenditures. The Panel is of the view that disaggregated R&D expenditures are and shall remain confidential. But if, as was the case here, there are no R&D expenditures by a patentee

³ Decisions/Reasons - PMPRB-94-1/HABITROL/PHC (1 February 1994).

in any given period as reflected on their filed Form 3s, and this information is also reflected in the PMPRB's annual reports, it is not confidential.

17. The BC Minister of Health has already provided redacted versions of the documents over which they claimed confidentiality as found in Appendix A for filing on the public record. Alexion shall file redacted versions of the documents over which it claimed confidentiality as found in Appendix A for filing on the public record on or before February 3, 2017.

Dated at Ottawa, this 1st day of February, 2017.

Original signed by

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members:

Dr. Mitchell Levine
Ms. Carolyn Kobernick