



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 ADDITIONAL CONFIDENTIALITY CLAIMS AND ADMISSIBILITY OF CERTAIN EXPERT REPORTS

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.

Background To The Issues Determined By This Order

1. On July 27, 2017, the Secretary of the Board advised the Parties that, in order to complete the public record in this proceeding, the Secretariat required public versions of any expert report admitted into evidence at the hearing on which there are confidentiality claims. The Secretary asked the Parties to make best efforts to agree on redacted versions of those reports where confidentiality was claimed, and to report on the status of their discussions by August 25, 2017. Failing agreement, the Parties were instructed to follow the Confidentiality Protocol and the issues would be presented to the Panel for determination.

2. On August 21, 2017, Counsel for Alexion Pharmaceuticals Inc. ("**Alexion**" or the "**Respondent**") advised the Secretary that the Parties disagreed on three issues:

- i. Alexion wished to redact the paragraphs and related appendices/attachments of Dr. Addanki's expert report that were struck from the record pursuant to a ruling by the Panel on February 21, 2017. Board Staff opposed these redactions.

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- ii. Similarly, Alexion wished to redact those portions of Dr. Anis' expert report (which responded to Dr. Addanki's report) falling exclusively within the sections of Dr. Addanki's report that were struck by the Panel. Board Staff opposed these redactions.
- iii. Alexion sought redactions to sales-related data contained in Mr. Soriano's expert report. Board Staff opposed these redactions.

3. On September 8, 2017, the Panel directed the Parties to file brief written submissions on the three issues in dispute by September 12. Counsel for Board Staff requested that the deadline be extended to September 15, and the Panel granted an extension to September 14. Board Staff and Alexion filed written submissions on September 14.

4. In its written submissions, Board Staff argued that Alexion did not comply with the Confidentiality Protocol and should be precluded from advancing a confidentiality claim at this time. Board Staff also submitted that Alexion had not demonstrated the nature and extent of the specific, direct and substantial harm that Alexion alleges it would suffer if the proposed redactions were made public. Board Staff argued that the portions of Dr. Addanki's report which were not admitted into evidence should remain on the public record, to allow the public to understand the Panel's reasons regarding Dr. Addanki's report or, alternatively, should remain on the confidential record for the purposes of any potential application for judicial review.

5. In its written submissions, Alexion argued that its proposed redactions of Mr. Soriano's report related to sensitive commercial information (number of units sold and revenues earned) that was not publicly available and was information that the Panel had previously accepted as confidential in this proceeding. Regarding the sections of Dr. Addanki's report that were struck, and the corresponding sections of Dr. Anis' report, Alexion submitted that permitting these sections to remain part of the public or confidential record would be inconsistent with the Panel's ruling that the sections of the reports that were struck never formed part of the record in this proceeding.

6. In its written submissions, Alexion also raised a number of additional confidentiality claims which are unrelated to the Secretary's July 27 request for public versions of the expert reports. Alexion requested that certain passages from the transcripts of evidence, as well as certain exhibits, be either redacted or removed entirely from the public record. These additional requests concerned Mr. Lemay's evidence at Volume 2 (public) of the transcript (page 198, line 7 through to page 202), Mr Soriano's evidence at Volume 18 (public) of the transcript (pages 2536 to 2537), and Exhibits 5, 6, 23-31, 46, 47, 50, 77, and 79 (together, the "Additional Confidentiality Claims").

7. On September 15, Board Staff objected to the Additional Confidentiality Claims. Board Staff argued that the Additional Confidentiality Claims were not responsive to the Secretary's request for submissions and claimed confidentiality over information that was already public. Board Staff also asserted that Alexion did not follow the Confidentiality Protocol, waited too long to make these additional claims and had not demonstrated that it will suffer any specific, direct and substantial harm if such information was publicly disclosed.

8. Also on September 15, Counsel for the Ministers of Health requested until September 22 to respond to Alexion's Additional Confidentiality Claims. The Ministers of Health wished to make submissions because Alexion's Additional Confidentiality Claims included Exhibits relevant to the negotiations between the Provinces and Alexion.

9. On September 20, the Panel advised the Parties and Ministers of Health that they had until September 22 to provide the Panel with any additional submissions they would like the Panel to consider before deciding the outstanding issues.

10. On September 22, Alexion filed further written submissions, attaching proposed redacted versions of certain Exhibits which are the subject of the Additional Confidentiality Claims. Alexion asked the Panel to consider the Additional Confidentiality Claims and decide them consistent with the Panel's previous rulings on confidentiality. Alexion also withdrew its claim for confidentiality over Exhibits 29-31.

11. Also on September 22, Counsel for the Ministers of Health responded to the further written submissions of Alexion submitted earlier that day, to clarify the position of the Ministers of Health concerning what redactions needed to be made to Exhibits 23 and 50 in order to protect the Ministers of Health's confidential information.

12. The Panel has carefully reviewed and considered all of the above noted submissions in reaching its decision on the Additional Confidentiality Claims and the issue concerning what version of the Addanki and Anis expert reports form part of the record in this proceeding. The Panel has also given due consideration to the Confidentiality Protocol, and to its previous rulings on confidentiality issues, including the Panel's decision dated February 1, 2017.

The Addanki and Anis Expert Reports

13. The issue to be decided by the Panel is not one of confidentiality. Neither Party claims confidentiality over portions of either report, so any suggestion that the full reports should be filed on the confidential record is rejected.

14. The sole issue is what version of these two reports form part of the record in this proceeding; the complete version, or a redacted version that removes the paragraphs that were struck by the Panel.

15. The Panel recognizes that, while many administrative tribunals (like the Board under section 8(3) of the Board's *Rules of Practice and Procedure*) require the Parties to file documents such as expert reports in advance of a hearing, normally those documents are only made available to the public if they are admitted into evidence at the hearing, subject to any confidentiality claim. This is consistent with the principle that, unless otherwise ordered by the adjudicator, providing an expert report in advance of a hearing is for purposes of notice and that report does not become evidence unless and until the expert is qualified and testifies, and the report is entered as an exhibit.

16. When Dr. Addanki was first tendered as an expert witness during the hearing on February 21, 2017, Alexion brought a motion to strike certain portions of Dr. Addanki's expert report and to preclude him from giving evidence on those portions. In its

decision on this motion, the Panel struck paragraphs 18-23, 28-31, 34-44 and 46-50 (and related exhibits) of Dr. Addanki's report and concluded that the rest of the report was admissible. The paragraphs that were struck contained Dr. Addanki's opinion on how "therapeutic class" should be defined for purposes of section 85(1)(b) of the *Patent Act*. The Panel then proceeded to mark Dr. Addanki's report as Exhibit 17, noting that the specified paragraphs and related exhibits "should be considered struck from the record."

17. The Panel provided detailed reasons for its decision to strike portions of Dr. Addanki's expert report at paragraphs 34-45 of its decision on the merits, dated September 20, 2017 (the "Decision"). The Decision describes the nature of the opinion in the paragraphs that were struck, the reasons why the Panel did not accept that opinion and why that opinion was not relevant or necessary to the Panel's determination of the issues in this proceeding.

18. When Dr. Anis was called to testify, counsel for Board Staff submitted that it was important to note for the record the paragraphs of his report that should not be referred to and struck as a result of the previous ruling concerning Dr. Addanki's expert report. Counsel agreed that the paragraphs of Dr. Anis' report to be struck were paragraphs 29, 33-38, 40-42, 50 and 51 (and related exhibits). The Panel, Counsel and Dr. Anis proceeded to manually strike out these paragraphs from their respective copies of the expert report and the Panel then confirmed that Dr. Anis had a version of his report that he could refer to when giving evidence.

19. The Panel concludes that the paragraphs struck from the Addanki and Anis expert reports must be redacted from the version of these two reports that form part of the record in this proceeding. The Panel did not admit these paragraphs into evidence at the hearing, but rather struck them from the record. These paragraphs did not form any part of the record considered by the Panel when it made the Decision. Since no confidentiality claims are made, the redacted reports are to be filed on the public record.

20. The Panel directs Board Staff to file a version of Dr. Addanki expert report for the public record that redacts the sections not admitted into evidence as set out above in paragraph 16.

21. The Panel directs Alexion to file a version of Dr. Anis' expert report for the public record that redacts the sections not admitted into evidence as set out above in paragraph 18. The Panel notes that the proposed redacted version of the Anis expert report filed by Alexion on September 22 does not correctly implement the Panel's decision because paragraphs 33-35, 38 and 40 were not included in the proposed redacted paragraphs. All paragraphs referred to in paragraph 18 of this order, including paragraphs 33-35, 38 and 40, are to be redacted from the public version of the Anis report.

The Additional Confidentiality Claims

22. 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."

23. Section 5 of the Board's *Rules of Practice and Procedure* provides that the Panel is to ensure the fair and expeditious conduct of this proceeding, and that a proceeding or part of a proceeding may not be defeated by reason only of a defect in form or procedure.

24. 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." The Confidentiality Protocol, which sets out a procedure for making and determining confidentiality claims, is subject to further direction of the Panel and may be varied by the Panel.

25. In its decision dated February 1, 2017, rendered in the course of the hearing on the merits, the Panel reviewed various requests for confidentiality by Alexion and the Ministers of Health regarding certain documents filed by them. The Panel granted some of the requests because it was satisfied that public disclosure of certain information would cause specific, direct and substantial harm to Alexion or the Ministers of Health, as applicable. The Panel rejected those requests where this test was not met, or the information at issue was already on the public record.

26. Further, throughout the course of the hearing, the Panel was required to adjudicate claims of confidentiality (many of which were contested) over specific documents or testimony as the evidence unfolded. The Panel decided those issues consistent with the principles set out in its decisions of November 24, 2015 and February 1, 2017.

27. In its past rulings on confidentiality claims, the Panel concluded that there are categories of information which, if publicly disclosed, would cause specific, direct and substantial harm to Alexion and/or the Ministers of Health, as applicable. It is important that the public versions of the Exhibits and transcripts which are currently the subject of the Additional Confidentiality Claims are consistent with the Panel's past rulings by redacting out the information found to be confidential, subject of course to any waiver of confidentiality by Alexion or the Ministers of Health. Accordingly, the Panel will rule on the Additional Confidentiality Claims.

28. The Panel's decision on the Additional Confidentiality Claims is set out in Schedule A to this Order. The Panel is satisfied that the public disclosure of the information it has determined is confidential (as specified in Schedule A) would cause specific, direct and substantial harm to Alexion and/or the Ministers of Health, as applicable: see the Board's decision in *Habitrol*.¹

29. The Panel has denied the request for confidentiality in respect of some of the Additional Confidentiality Claims because it was not satisfied on the submissions and evidence that the disclosure of the information at issue would cause specific, direct and

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

substantial harm to Alexion and/or the Ministers of Health, as applicable, or the information claimed as confidential is already public.

30. As is evident from Schedule A, some of Alexion's Additional Confidentiality Claims are inconsistent. In some instances, a claim for confidentiality was made over information in one document or portion of document, but not made where that same information appeared elsewhere in the document or another document. The Panel resolved these inconsistencies by first determining whether the information is public or confidential and then ordering that it receive consistent treatment.

31. Further, Alexion's Additional Confidentiality Claims are, in general, narrower than the confidentiality claims it filed on January 17, 2017, which were decided by the Panel in its February 1, 2017 decision. In particular, information which Alexion had claimed as confidential in its January submissions was not claimed as confidential in its September submissions filed in support of the Additional Confidentiality Claims but rather remained part of the proposed public version of the Exhibits. The Panel concludes that Alexion has therefore waived any claim of confidentiality over information that it had claimed as confidential in its January submissions but included in its proposed public version of the Exhibits which are the subject of the Additional Confidentiality Claims. Further, to the extent there is any inconsistency in terms of what information the Panel has concluded is public and what information is confidential, between this order and the Panel's order on February 1, 2017, this order governs.

32. The Panel orders Alexion to file, on or before November 30, 2017, public versions of the Exhibits set out in Schedule A to this order, redacted to protect the information found by the Panel to be confidential as specified in Schedule A, except for Exhibit 25 which is excluded from the public record in its entirety. Prior to doing so, Counsel for Alexion shall consult and coordinate with Counsel for the Ministers of Health in respect of the Exhibits which were the subject of the Ministers of Health's submissions, to ensure there is agreement that the redactions correctly implement this decision.

33. The Panel also directs Alexion to ensure that the public versions of Volumes 2, 17 and 18 of the transcripts from the hearing are corrected so that the information found by the Panel to be confidential, as set out in Schedule A, is moved from the public transcript to the confidential transcript.

Dated at Ottawa, this 27th day of November, 2017.

Original signed by

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members:

Dr. Mitchell Levine
Ms. Carolyn Kobernick

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