



Patented Medicine
Prices Review Board
Canada

Conseil d'examen du prix
des médicaments brevetés
Canada

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IN THE MATTER OF the Patent Act, R.S.C. 1985, c. P-4, as amended

**AND IN THE MATTER of HORIZON PHARMA (the “Respondent”) and the medicine
Cysteamine Bitartrate sold by the Respondent under the trade name Procysbi**

**DECISION ON CONFIDENTIALITY REQUESTS MADE IN RESPECT OF MATERIALS
FILED FOR BOARD STAFF’S BIFURCATION/PRODUCTION MOTION**

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.

1. The Panel has carefully reviewed and considered the requests for confidentiality filed by the Respondent on December 6, 2019, December 20, 2019 and January 17, 2020 (the “**Confidentiality Requests**”). The Confidentiality Requests were made pursuant to the confidentiality protocol issued by this Panel on October 29, 2019 (the “**Confidentiality Protocol**”).

2. The Confidentiality Requests concern the following materials filed in respect of Board Staff’s motion to bifurcate the hearing, strike evidence and for the production and inspection of documents, that was heard by the Panel on January 15, 2020:

- (a) Motion Record of Board Staff;
- (b) Responding Motion Record of the Respondent;
- (c) Supplementary Motion Record of Board Staff; and

- (d) Supplementary Responding Motion Record of the Respondent (collectively, the “**Motion Materials**”).

3. More specifically, the Respondent’s Confidentiality Requests concern the following eight documents contained (and often repeated) in the Motion Materials:

- (a) The Expert Report of Dr. Joel Hay dated September 9, 2019 (the “**Hay Report**”);
- (b) Exhibit “B” to the Affidavit of Howard Rosen sworn November 28, 2019;
- (c) Board Staff’s Written Submissions dated November 28, 2019;
- (d) The Affidavit of Andrew Harington sworn December 13, 2019 (without exhibits);
- (e) Exhibit “E” to the Affidavit of Andrew Harington sworn December 13, 2019;
- (f) Horizon’s Written Submissions dated December 13, 2019;
- (g) The Affidavit of Howard Rosen sworn January 6, 2020; and
- (h) The Sur-Reply Affidavit of Andrew Harington sworn January 10, 2020 (collectively, the “**Relevant Documents**”).

4. The Respondent’s Confidentiality Requests propose certain redactions to the version of the Relevant Documents that will be filed on the public record. The Respondent used yellow highlighting to identify the portions of each Relevant Document that it proposes to redact. In support of its requests, the Respondent filed written submissions which argued that the Relevant Documents contain commercially sensitive information which, if disclosed publicly, would cause significant and irreparable harm to its commercial interests.

5. Board Staff took no position on the Respondent's Confidentiality Requests.¹

6. After carefully considering the materials filed by the Respondent, the Panel grants the Respondent's Confidentiality Requests in part. The Panel has provided copies of the Relevant Documents to the Parties with this Decision and has underlined in red the portions of each Relevant Document that it accepts are confidential and should be redacted from the public record.

7. For greater clarity, the Panel only permits the redaction of the portions of each Relevant Document that are underlined in red. Where there is yellow highlighting, but no red underlining, the Panel has denied the request and that portion of the Relevant Document shall not be redacted from the version filed on the public record.

A. THE LAW

8. In *Sierra Club of Canada v. Canada (Minister of Finance)*² the Supreme Court of Canada set out the general test for granting a confidentiality order under Rule 151 of the *Federal Court Rules*³, which provides that, on motion, the Court may order that material to be filed shall be treated as confidential. At paragraph 53, Iacobucci J., states:

"A confidentiality order under R. 151 should only be granted when:

- (a) such an order is necessary in order to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonably alternative measures will not prevent the risk; and
- (b) the salutary effects of the confidentiality order, including the effects on the right of civil litigants to a fair trial, outweigh its deleterious effects, including the effects on the right to free expression, which in this context includes the public interest in open and accessible court proceedings."

¹ Bifurcation Motion Hearing Transcript (January 15, 2020), at p. 3, lines 14-25.

² 2002 SCC 41.

³ SOR/98-106.

9. Section 86(1) of the *Patent Act*⁴ requires this Panel to hold a public hearing unless it is satisfied that it would cause specific, direct and substantial harm:

86 (1) 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. [Emphasis added]

10. In addition, Rule 16(1)(c) of the PMPRB Rules⁵ provides that, "[a] notice of hearing issued by the Board must state that the hearing will be held in public unless, on representations made by a respondent, the Board is satisfied that specific, direct and substantial harm would be caused to the respondent by the disclosure of information or documents relating to the hearing".

11. The application of these principles is confirmed in the Confidentiality Protocol:

2. The Parties acknowledge that subsection 86(1) of the Patent Act provides that a hearing shall be held in public unless the Patented Medicine Prices Review Board ("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... [Emphasis added]

12. Moreover, the Confidentiality Protocol requires that the party making the confidentiality request provide a detailed explanation in support of their request:

7. Where a Party asserts in a Request for Confidentiality that specific, direct and substantial harm would be caused to the Party claiming confidentiality, the Party's Request for Confidentiality shall contain sufficient details so as to explain fully the nature and extent of such harm. [Emphasis added]

⁴ R.S.C., 1985, c. P-4.

⁵ *Patented Medicine Prices Review Board Rules of Practice and Procedure*, SOR/2012-247.

13. Finally, the Confidentiality Protocol confirms that a document shall cease to be confidential if: (a) the confidential information becomes publicly available; (b) the parties agree in writing that the document should no longer be confidential; or (c) the Panel determines that the document shall not be confidential.⁶

B. ANALYSIS

14. As a preliminary matter, the Panel notes that the submissions filed by the Respondent were generic, not specifically related to the particular redactions proposed to the Relevant Documents and were conclusory in nature. The submissions were unhelpful to the Panel as they failed to provide specific reasons for the various redactions and failed to provide sufficient details concerning the nature and extent of the harm alleged to be caused. This issue was exacerbated by the fact that, in numerous instances, the Respondent requested overly-broad redactions or redactions of information that is clearly not confidential.

15. The Panel only grants the Respondent's Confidentiality Requests in part. Where the Panel denied a requested redaction, it was for one or more of the following reasons:

- (a) The information is already in the public domain and therefore is not confidential pursuant to paragraph 12 of the Confidentiality Protocol. For example, the Respondent's own public disclosure documents refer to: (i) the API Supply Agreement with Cambrex Profarmaco Milano; (ii) the Manufacturing Services Agreement with Patheon Pharmaceuticals Inc.; (iii) the 2034 patent expiry date for Procysbi; and (iv) the fact that Innomar Strategies Inc. is the exclusive distributor for Procysbi in Canada. Accordingly, redactions of this publicly available information are denied.
- (b) The Respondent has not satisfied the Panel that specific, direct and substantial harm will be caused by the public disclosure of the information proposed to be redacted. For example, there is a distinction between the

⁶ Confidentiality Protocol (October 29, 2019), at para. 12.

methodology used by Professor Hay (as described in the Hay Report) and the specific commercial and financial information that Professor Hay includes in the Hay Report and applies that methodology to. The Panel is of the view that in this case, the latter is confidential, while the former is not. The Panel does not permit the Respondent to redact references to the methodology used in the Hay Report (e.g., the fact that the conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers) because it has not been established that public disclosure of Dr. Hay's methodology will cause specific, direct and substantial harm to the Respondent.

- (c) Further, the Panel is of the view that, for the most part, the Respondent has not established that publicly disclosing the names of the documents requested in Exhibit "B" to the Affidavit of Howard Rosen will cause specific, direct and substantial harm to the Respondent. Most of the documents that are requested are generic records that any company would maintain, such as profit and loss statements and audited financial statements. As such, the Panel denies Horizon's request to redact this document request list in its entirety. For greater clarity, this decision applies only to the title of the documents contained in this list and not the contents of those documents. Whether the contents of the documents requested are confidential is a separate issue that can be addressed if and when such documents are tendered as evidence in this matter.

16. Going forward, the Panel requires that any requests for confidentiality must be supported by a chart that lists, on the left side of the page, each requested redaction cross-referenced to where the relevant document is in the record and, on the right side, provides a specific and detailed reason for why that redaction should be permitted in accordance with the Confidentiality Protocol. The Panel hopes that this will ensure that a party making a confidentiality request proposes thoughtful, justified and precise redactions, consistent with the Panel's mandate to conduct open hearings except where

a party has satisfied the Panel that specific, direct and substantial harm shall be caused from public disclosure of certain information. Unjustified or over-broad requests for confidentiality will not be tolerated by this Panel.

17. Moreover, the Panel was surprised and disappointed by Board Staff's decision to not take a position on Horizon's confidentiality requests. The Panel expects that Board Staff would be interested in ensuring that the Board's hearing process is as open and public as possible. Going forward, the Panel expects Board Staff to clearly indicate whether it agrees or disagrees with the Respondent's requests for confidentiality. This will assist the Panel in ensuring that its process is as open and public as possible.

C. DISPOSITION

18. For the reasons above, it is ordered that:

- (a) Horizon shall provide to the Secretary of the Board public versions of the Motion Materials by March 6, 2020, redacting only the portions of each of the Relevant Documents that the Panel has underlined in red; and
- (b) Any future requests for confidentiality must be supported by a chart that:
 - (i) lists, on the left side of the page, each requested redaction cross-referenced to where the relevant document is in the record; and
 - (ii) provides, on the right side of the page, a specific and detailed reason(s) for why that redaction should be permitted in accordance with the Confidentiality Protocol.

Dated at Ottawa, this 24th day of February, 2020.

Signed on behalf of the Panel by
Carolyn Kobernick

Panel Members

Carolyn Kobernick
Mitchell Levine

Counsel for Board Staff

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Christopher Morris
Courtney March

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