



IN THE MATTER OF the Patent Act, R.S.C. 1985, c. P-4, as amended
AND IN THE MATTER of HORIZON PHARMA (“Horizon”) and the medicine
Cysteamine Bitartrate sold by Horizon under the trade name Procysbi

REASONS FOR DECISION

(Board Staff’s Motion for Production of Documents (the “Motion”))

1. On January 15, 2020, the panel (the “**Panel**”) of the Patented Medicine Prices Review Board (the “**Board**”) seized with this proceeding heard Board Staff’s Motion seeking, *inter alia*, an order directing the production of certain documents set out in Exhibit “B” to the Affidavit of Howard Rosen sworn November 28th, 2019 (the “**Rosen Affidavit**”).
2. On January 17th, 2020, this Panel issued its decision on the Motion with Reasons to follow (the “**Decision**”).¹ At paragraph 5 of the Decision, the Panel granted Board Staff’s Motion for production of documents in part, and ordered (among other things): (i) Horizon to produce certain requested documents; and (ii) the Parties’ experts to meet and confer to endeavor to come to agreement on certain disputed document requests.
3. The Panel is advised that six categories of document requests remain in dispute following the meet and confer:
 - (a) various transfer pricing documents;²
 - (b) federal and provincial corporate income tax returns and schedules;³

¹ The Reasons for the Decision were issued by the Panel on February 28, 2020.

² Joint Memorandum of Howard Rosen and Andrew Harington dated April 3, 2020 (“**Joint Memorandum**”), Exhibit “A”, sections D(2), D(4), D(12), D(13), D(14), D(15), D(16), E(3).

³ Joint Memorandum, Exhibit “A”, section A(10).

- (c) purchase orders and invoices for purchases by HZNP Therapeutics Canada Limited (“**Horizon Canada**”) from other Horizon entities and third parties;⁴
- (d) documents explaining what certain line items relate to and how each item should be allocated to Procysbi sold in Canada;⁵
- (e) documents that detail the nature of certain expenses;⁶ and
- (f) various financial statements of Horizon Canada.⁷

4. The Panel is of the view that it is not necessary to hold a further oral hearing or obtain additional submissions on the remaining disputed document requests. Both Parties have had the opportunity to fully and fairly present their arguments and the Panel has the information that it needs to make a decision in respect of all six categories of disputed document requests.

5. While the Parties’ submissions will be referred to in this decision only to the extent necessary to explain the Panel’s decision, the Panel has carefully considered all of the oral and written submissions made by the Parties in respect of the Motion over the past six months and has taken them fully into account in its deliberations.

6. For the reasons set out below, the Panel grants Board Staff’s request for production of documents identified in paragraphs 3(a) to 3(c) above to the extent they are in Horizon’s possession and have not already been produced to Board Staff, and denies Board Staff’s request for production of documents identified in paragraphs 3(d) to 3(f) above.

⁴ Joint Memorandum, Exhibit “A”, section C(4).

⁵ Joint Memorandum, Exhibit “A”, sections C(10), C(11), C(12), C(13).

⁶ Joint Memorandum, Exhibit “A”, sections E(5), E(6), E(7), E(8).

⁷ Joint Memorandum, Exhibit “A”, sections A(2), A(3), A(4).

A. BACKGROUND

(i) The Proceeding

7. This Motion arises in the context of a proceeding commenced by Board Staff where it is alleged that Horizon is selling the medicine Cysteamine Bitartrate under the trade name Procysbi (“**Procysbi**”) at a price that is excessive under section 83 of the *Patent Act*⁸ (the “**Act**”).

8. Board Staff submits that the maximum non-excessive price of Procysbi should be reduced in accordance with one of three alternative pricing models which Board Staff describes as: (1) the same medicine comparison; (2) the premium price approach; and (3) the market share approach.

9. In response to Board Staff’s allegations, Horizon retained Dr. Joel W. Hay to evaluate the impact of Board Staff’s three alternative pricing models (the “**Hay Report**”).

10. In turn, Board Staff retained Howard Rosen to analyze, test, verify and potentially respond to the assumptions, calculations and conclusions set out in the Hay Report.

(ii) The Motion

11. In late 2019, Board Staff brought this Motion, seeking *inter alia*, an order directing the production of certain documents set out in Exhibit “B” to the Rosen Affidavit. Mr. Rosen indicated that he required access to the requested documents to review and potentially respond to, the Hay Report.

12. In response to Board Staff’s Motion, Horizon retained Andrew Harington to review and provide an opinion on the reasonableness of Mr. Rosen’s document requests. Mr. Harington concluded, among other things, that certain document requests made by Mr. Rosen were reasonable, while other document requests were neither relevant nor necessary to Mr. Rosen’s mandate.⁹

⁸ R.S.C., 1985, c. P-4.

⁹ For those requests deemed reasonable, Mr. Harington expressly noted that his opinion should not be taken as an indication that Horizon had the document in its possession or was able to produce that document.

13. On January 15, 2020, the Panel heard this Motion and counsel for each of the Parties presented oral arguments regarding (among other things) the reasonableness and relevance of Mr. Rosen's document requests (the "**Hearing**").

14. As discussed above, on January 17th, 2020, the Panel issued its Decision on the Motion.¹⁰ At paragraph 5 of the Decision, the Panel granted Board Staff's Motion for production of documents in part and ordered (among other things):

- (a) Horizon to produce all requested documents that its expert, Andrew Harington, identified as "reasonable" in Exhibit "C" to his Affidavit sworn January 10, 2020 (the "**Harington Affidavit**");
- (b) the Parties' experts to meet and confer to endeavour to come to an agreement on several document requests that were not identified as "reasonable" in Exhibit "C" to the Harington Affidavit; and
- (c) the Parties to file a joint memorandum prepared by Messrs. Harington and Rosen that identifies the requests that have been resolved and the requests that remain in dispute, if any.

15. In accordance with the Panel's Decision: (i) Horizon produced all requested documents in its possession that were identified as "reasonable" in Exhibit "C" to the Harington Affidavit (a total of 113 documents);¹¹ (ii) the Parties' experts, in the presence of counsel and representatives for the Parties, held the meet and confer on February 21, 2020 (the "**Meet and Confer**"); and (iii) the Parties filed a joint memorandum prepared by Messrs. Harington and Rosen on April 3, 2020 (the "**Joint Memorandum**").

16. As set out above, the Joint Memorandum identifies six categories of document requests that were not resolved by the Parties during the Meet and Confer. Counsel for

¹⁰ The Reasons for the Decision were issued by the Panel on February 28, 2020.

¹¹ Joint Memorandum, at para. 7; Written Submissions of the Respondent dated April 15, 2020, at paras. 12 and 19.

each of the Parties have filed additional written submissions explaining why each of the six remaining disputed document requests should be resolved in their favour.

(iii) The Procedure Following the Decision

17. In addition to providing the Parties with the opportunity to provide further written submissions on the remaining disputed document requests, the Panel's Decision provided for the possibility of hearing further oral submissions from the experts and counsel for each of the Parties on any document requests remaining in dispute. In accordance with this Decision, March 24, 2020 was reserved as the potential hearing date.¹²

18. However, due to the COVID-19 pandemic, on March 16, 2020, the Panel cancelled the March 24 hearing and established a procedure to be followed for the balance of the Motion. This procedure was summarized in the Board Secretariat's email to counsel for the Parties dated March 16, 2020:

... The Panel will review the written materials and advise counsel whether it requires additional information before making a decision on the disputed documents. In this regard, the Panel may, if it deems appropriate, forgo an oral hearing and/or pose questions to counsel and/or Messrs. Harington and Rosen in writing or through a conference call.

19. As indicated above and explained further below, the Panel has concluded that a further oral hearing on the remaining disputed document requests is not necessary.

B. HORIZON'S REQUEST FOR AN ORAL HEARING

20. In its written submissions filed on April 15, 2020, Horizon submitted that this Panel should hold a further oral hearing on the remaining disputed document requests. Horizon submits that an oral hearing is necessary to allow the Panel to probe Mr. Rosen's "late-breaking" request for "financial documents used by Horizon management to review or assess the actual financial performance (revenues, costs and profits) of Horizon's Canadian operations on an annual basis from 2015 to the current fiscal year". Further, and more generally, Horizon submits that the disputed document requests

¹² Email from Board Secretariat, Riaz Awadia, to counsel for the Parties dated February 4, 2020.

relate to complex concepts that are best explained by the experts and probed by the Parties and the Panel at an oral hearing.

21. Board Staff submits that an oral hearing is not necessary, efficient or required.¹³ Board Staff submits that the Parties already made oral submissions to the Panel at the Hearing, and notes that the Panel already made a determination as to the procedure to be followed for the balance of the Motion, as summarized in the Board Secretariat's email to counsel dated March 16, 2020.¹⁴

22. The Panel has concluded that it is not necessary to hold a further oral hearing on the remaining disputed document requests. Subsection 97(1) of the Act requires all proceedings before the Board to be "dealt with as informally and expeditiously as the circumstances and considerations of fairness permit". The Parties have had the opportunity to fully and fairly advocate their position on the disputed document requests. Having had the benefit of counsel's thorough oral submissions at the Hearing, as well as the Parties' detailed written submissions and the Joint Memorandum, the Panel does not have any further questions for the experts or counsel and is fully able to decide the balance of the Motion at this time.

23. With respect to Horizon's submission regarding Mr. Rosen's "late breaking" request for further financial documents, the Panel also notes that no further submissions are required on this issue because, as set out in paragraphs 50 to 53 below, the Panel accepts Horizon's submission that it has satisfied this request.

¹³ Email from counsel for Board Staff to Board Secretariat, Riaz Awadia, and counsel for Horizon dated April 16, 2020.

¹⁴ The relevant portion of this email is reproduced at paragraph 18 above.

C. BOARD STAFF'S REQUEST FOR THE PRODUCTION OF DOCUMENTS

(i) Applicable Law

24. The Board has broad powers under subsection 96(1) of the Act and Rules 24(1) and 6(2) of the *Patented Medicine Prices Review Board Rules of Practice and Procedure*¹⁵ (the “**PMPRB Rules**”) to order the production of documents:

- (a) subsection 96(1) of the Act grants the Board “all such powers, rights and privileges as are vested in a superior court” with respect to “the production and inspection of documents”;
- (b) Rule 24(1) of the PMPRB Rules provides that the Board may, in any proceeding, order “the production or inspection of documents”; and
- (c) Rule 6(2)(a) of the PMPRB Rules confirms that the Board may direct “that a party provide any information or documents” that it considers relevant to the proceeding.

25. As a general principle, the Board will order the production of documents where such documents are relevant to the issues in the proceeding, and their production furthers the fair and expeditious resolution of the proceeding.¹⁶

26. More specifically, where an expert has requested documents to aid in their analysis and can satisfy the Panel that the documents are relevant to their analysis, it is appropriate for the Board to order the production of the requested documents.¹⁷

¹⁵ SOR/2012-247.

¹⁶ See for example, Board Decision - *Alexion Pharmaceuticals Inc. and the Medicine “Soliris”* (January 24, 2017) at para. 7, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Panel_order_production_Board_Staff.pdf>.

¹⁷ *Air Canada v. West Jet Airlines Ltd.*, 2006 CarswellOnt 3920 at para. 17 (S.C.J.); *Sa Majesté la Reine c. Rothmans Inc. et al*, 2019 NBQB 44 at paras. 126-127; *Walsh v. TRA Company Limited*, 2019 NLSC 168 at para. 8.

(ii) **Board Staff's Requests for Transfer Pricing Documents and Tax Returns**

(a) *Submissions of the Parties*

27. Board Staff submits that Horizon should produce various transfer pricing documents identified in sections D(2), D(4), D(12), D(13), D(14), D(15), D(16) and E(3) of Exhibit "A" to the Joint Memorandum (the "**Transfer Pricing Documents**"). Board Staff's expert, Mr. Rosen, maintains that the Transfer Pricing Documents are relevant to his mandate for several reasons, including: (i) to understand and verify the basis of the profits quantified by Dr. Hay; (ii) to perform an assessment of the profits both for Horizon Canada and in the aggregate; (iii) to examine the details of transactions between the Horizon entities, and to understand the allocation of costs for sales of Procysbi in Canada; and (iv) more generally, to enable Mr. Rosen to perform his own analysis, which is not necessarily a replication of the methodology used in the Hay Report.

28. Relatedly, Board Staff submits that Horizon should produce various income tax returns and schedules identified in section A(10) of Exhibit "A" to the Joint Memorandum (the "**Tax Returns**"). In this regard, Mr. Rosen submits that the Tax Returns are relevant for the purposes of his own analysis, including to verify the income/profits reported for income tax purposes in Canada compared to: (i) the profits reported in Canada for accounting and financial reporting purposes; and (ii) the profits calculated globally in the Hay Report.

29. In response, Horizon explained that the Transfer Pricing Documents prior to July 31, 2019 relate only to the reimbursement of marketing expenses by Horizon Pharma Ireland Limited to Horizon Canada and, as at April 3, 2020, the Transfer Pricing Documents for the period post July 31, 2019 have not been prepared.¹⁸ In any event, Horizon submits that the Transfer Pricing Documents and Tax Returns are not relevant to this proceeding and therefore need not be produced.

¹⁸ Joint Memorandum, at para. 19.

30. While Horizon went into considerable detail about the concept of transfer pricing in its oral and written submissions, the main argument advanced by Horizon for why it should not be required to produce the Transfer Pricing Documents and Tax Returns can be summarized as follows – the Transfer Pricing Documents and Tax Returns are not relevant because Dr. Hay did not consider Horizon’s transfer pricing and, even if Dr. Hay had considered Horizon’s transfer pricing, the effect of doing so would only increase Horizon’s losses (to the detriment of Board Staff’s position).

(b) *Analysis*

31. The Panel grants Board Staff’s request for the production of the Transfer Pricing Documents and Tax Returns in Horizon’s possession.

32. Board Staff has satisfied the Panel that Mr. Rosen requires these documents to complete his own financial analysis of Horizon and of the costs of making and marketing Procysbi.¹⁹ The Panel agrees that these documents likely contain information that may allow Mr. Rosen to: (i) assess Dr. Hay’s methodology and analysis, including any analysis that Dr. Hay may not have done; and (ii) to provide an alternative methodology.²⁰

33. Horizon may ultimately be correct that the Transfer Pricing Documents and Tax Returns are not relevant to an assessment of Dr. Hay’s analysis but that is not a determination that the Panel can or should make at this early stage of the proceeding.

34. In any event, that is not the end of the inquiry. Even if the Panel was convinced that the Transfer Pricing Documents and Tax Returns were not relevant to an assessment of Dr. Hay’s analysis, Board Staff is entitled, through Mr. Rosen, to provide an alternative methodology. It will be up to the Panel at the hearing on the merits to determine which expert’s methodology is preferable. Both Parties should be given the opportunity to advance the methodology that it wishes the Panel to adopt. To deny

¹⁹ *Air Canada v. West Jet Airlines Ltd.*, 2006 CarswellOnt 3920 at para. 17 (S.C.J.); *Sa Majesté la Reine c. Rothmans Inc. et al*, 2019 NBQB 44 at paras. 126-127; *Walsh v. TRA Company Limited*, 2019 NLSC 168 at para. 8.

²⁰ *Sa Majesté la Reine c. Rothmans Inc. et al*, 2019 NBQB 44 at para. 127.

Board Staff the information in Horizon's possession that Mr. Rosen maintains is required to do his own analysis would in effect prejudice this issue by limiting or restricting Mr. Rosen's ability to put forward an alternative methodology for the Panel to consider.

35. Further, it is not for Horizon's expert to decide what the parameters of Board Staff's expert analysis should be or to determine what documents are relevant to that analysis. Horizon will have the opportunity to challenge Mr. Rosen's evidence at the hearing on the merits, including on the basis that he relied on faulty assumptions or misplaced theories. At this stage, as long as the documents requested appear relevant to the issues raised, they should be produced.²¹

36. Lastly, production of the Transfer Pricing Documents and Tax Returns to enable Mr. Rosen to complete his mandate is consistent with the important goal of ensuring that the Panel has the benefit of comprehensive expert evidence and submissions as to the relevance of the expert evidence from both Parties.

(iii) Board Staff's Request for Purchase Orders and Invoices

(a) Submissions of the Parties

37. Board Staff submits that Horizon should produce purchase orders and invoices for purchases by Horizon Canada from third parties and other Horizon entities.²²

38. Since Horizon states that, prior to July 31, 2019, it did not purchase Procysbi from any Horizon entities or third parties, the relevant time period for this request appears to be August 1, 2019 forward.

39. Horizon submits that it need not produce purchase orders and invoices between Horizon Canada and other Horizon entities because they reflect an allocation of total Procysbi profit between Horizon entities for transfer pricing purposes, and do not affect

²¹ *Air Canada v. West Jet Airlines Ltd.*, 2006 CarswellOnt 3920 at para. 17 (S.C.J.).

²² Joint Memorandum, Exhibit "A", section C(4).

or represent the aggregate profit of Horizon – which served as the basis for the conclusions in the Hay Report.

40. Board Staff submits that Horizon should produce the purchase orders and invoices for purchases by Horizon Canada from other Horizon entities for the same reason that it submits the Transfer Pricing Documents are relevant; namely, because these documents relate to the expenses associated with Procysbi and are necessary to enable Mr. Rosen to undertake and offer to the Panel an alternative methodology and analysis (as opposed to simply replicating the methodology used in the Hay Report).

(b) Analysis

41. The Panel grants Board Staff's request for the production of purchase orders and invoices for purchases by Horizon Canada from third parties and other Horizon entities (as set out in section C(4) of Exhibit "A" to the Joint Memorandum), to the extent such documents exist and have not already been produced, for the same reasons it has ordered production of the Transfer Pricing Documents and Tax Returns as set out in paragraphs 31 to 36 above.

(iv) Board Staff's Request for Documents Explaining Certain Line Items and Expenses

(a) Submissions of the Parties

42. Board Staff submits that Horizon should produce documents that:

- (a) explain what certain line items set out in sections C(10), C(11), C(12) and C(13) of Exhibit "A" to the Joint Memorandum relate to;
- (b) explain how certain line items set out in sections C(10), C(11), C(12) and C(13) of Exhibit "A" to the Joint Memorandum should be allocated to Procysbi sold in Canada; and
- (c) explain the nature of certain expenses set out in sections E(5), E(6), E(7) and E(8) of Exhibit "A" to the Joint Memorandum.

43. Horizon submits that it has produced the documents in its possession relevant to the requests set out in paragraphs 42(a) and 42(c) above.²³ Such documents include Horizon's general ledger, which reflects the most particularized level of detail that exists for each expense item. Horizon submits that it has conducted a thorough investigation and has confirmed that no additional documents exist, including any documents relating to the request in paragraph 42(b) above.²⁴

44. Mr. Rosen does not accept Horizon's confirmation that additional documents do not exist. Mr. Rosen submits that the documents produced to date do not provide sufficient detailed support for the allocation of various costs associated with Procysbi sales in Canada and that such detailed support is required for the purposes of his own analysis.

(b) Analysis

45. The Panel accepts Horizon's representation that it has produced the documents in its possession that are responsive to this request. While more detailed support regarding the allocation of costs may be helpful for the purposes of Mr. Rosen's analysis, the Panel cannot order production of documents that do not exist. Accordingly, Board Staff's request for further production of documents in response to the requests set out in sections C(10), C(11), C(12), C(13), E(5), E(6), E(7) and E(8) of Exhibit "A" to the Joint Memorandum is denied on the basis that such documents do not exist.

(v) Board Staff's Request for Financial Statements

(a) Submissions of the Parties

46. Board Staff submits that Horizon should produce various types of financial statements for Horizon Canada identified in sections A(2), A(3) and A(4) of Exhibit "A" to the Joint Memorandum (the "**Financial Statements**").

47. Horizon submits that it has conducted a thorough investigation and has confirmed that it is not in possession of the requested Financial Statements because

²³ Joint Memorandum, at pp. 11-13.

²⁴ Joint Memorandum, at p. 11.

neither audited nor unaudited financial statements for Horizon Canada are prepared in the ordinary course of business.²⁵

48. Board Staff's expert, Mr. Rosen, does not accept Horizon's representation. In his opinion, local corporate reporting entities typically prepare annual financial statements for purposes such as: (i) internal management reporting; (ii) consolidation of a subsidiary into a parent entity; and (iii) local statutory tax reporting.

49. Horizon's expert, Mr. Harington, disagrees and notes that in his experience the preparation of audited or unaudited annual financial statements is not required for these purposes.

50. Alternatively, Mr. Rosen submits that if the Financial Statements truly do not exist, he requires Horizon to produce any financial documents used by Horizon management to review or assess the actual financial performance (revenues, costs and profits) of Horizon's Canadian operations on an annual basis from 2015 to the current fiscal year.

51. Horizon submits that it has provided extensive productions which are responsive to this alternative request, including: (i) monthly profit and loss/income statements; (ii) business plans, marketing plans, forecasts, budgets, and management presentations that contain information on sales, expenses, and profits & loss of Procysbi in Canada; and (iii) forecasts reflecting actual results to mid 2019 and management projections beyond that point.

(b) Analysis

52. The Panel accepts Horizon's representation that neither audited nor unaudited financial statements for Horizon Canada are prepared in the ordinary course of business and that the Financial Statements therefore do not exist. While the Financial Statements may be helpful for the purposes of Mr. Rosen's analysis, the Panel cannot order production of documents that do not exist.

²⁵ Joint Memorandum, at p. 6.

53. The Panel also accepts Horizon's submission that it has satisfied Mr. Rosen's request for additional financial documents used by Horizon management to assess the actual financial performance of Horizon Canada, by producing the documents summarized in paragraph 51 above.

D. DISPOSITION

54. For the foregoing reasons, the Panel hereby orders Horizon to produce the following documents that are in its possession, to the extent such documents have not already been produced to Board Staff, on or before July 31, 2020:

- (a) the Transfer Pricing Documents requested in sections D(2), D(4), D(12), D(13), D(14), D(15), D(16) and E(3) of Exhibit "A" to the Joint Memorandum;
- (b) the Tax Returns requested in section A(10) of Exhibit "A" to the Joint Memorandum; and
- (c) the purchase orders and invoices for purchases by Horizon Canada from other Horizon entities and third parties requested in section C(4) of Exhibit "A" to the Joint Memorandum.

55. The remainder of Board Staff's document requests are denied.

56. If Horizon discovers that its representations set out in paragraphs 45 and 52 above are wrong and that there are additional documents in its possession that are responsive to the requests in sections A(2), A(3), A(4), C(10), C(11), C(12), C(13), E(5), E(6), E(7) and E(8) of Exhibit "A" to the Joint Memorandum, it shall produce them immediately to Board Staff.

57. The Panel's Order is without prejudice to any position either Party may wish to take regarding the admissibility or weight to be ascribed to any of the documents ordered to be produced herein.

Dated at Ottawa, this 26th day of June, 2020.

Signed on behalf of the Panel by
Carolyn Kobernick

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