

**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 Horizon Pharma (the “Respondent”)  
and the medicine Cysteamine Bitartrate sold by the Respondent  
under the trade name Procysbi**

**JOINT MEMORANDUM OF  
HOWARD ROSEN AND ANDREW HARINGTON**

## TABLE OF CONTENTS

<b>PART I - INTRODUCTION.....</b>	<b>1</b>
<b>PART II - SUMMARY OF TOPICS DISCUSSED DURING THE MEET AND CONFER.....</b>	<b>2</b>
A. Status of Document Production .....	2
B. Horizon’s Canadian Operations as of July 2019 .....	3
C. Requests for Additional Information .....	4
<b>PART III - REQUESTS THAT REMAIN IN DISPUTE .....</b>	<b>5</b>

## **PART I - INTRODUCTION**

1. On January 17, 2020, the Panel of the Patented Medicine Prices Review Board issued a decision (the “Decision”) in which it made the following orders:
  - (a) The Respondent shall produce all requested documents that Andrew Harington has identified as “reasonable” in Exhibit “C” to his Affidavit (the “Harington Affidavit”) sworn January 10, 2020 as soon as possible.
  - (b) Howard Rosen and Andrew Harington shall meet and confer as soon as possible to endeavour to come to an agreement on the remaining document requests that were not identified as “reasonable” in Exhibit “C” to the Harington Affidavit. The meet and confer shall take place in the presence of counsel for the Parties, unless the Parties agree otherwise. The Panel trusts that the Parties will make best efforts to ensure that the meet and confer is as productive as possible. Following the meet and confer, Mr. Rosen and Mr. Harington shall prepare, and the Parties shall file with the Panel, a joint memorandum that identifies the requests that have been resolved and the requests that remain in dispute, if any.
2. In accordance with the Panel’s Decision, Mr. Rosen and Mr. Harington (the “Experts”) held a meeting on February 21, 2020 (the “meet and confer”) in the presence of counsel and representatives for the Parties.
3. This Joint Memorandum (i) summarizes the issues discussed during the meet and confer, and (ii) identifies the document requests that remain in dispute.
4. Exhibit A to this Joint Memorandum sets out the status of each request. There are four categories:
  - (a) **Request Complete:** The documents have been produced. No issues remain in dispute.
  - (b) **Request in Dispute:** These requests remain in dispute.

- (c) **Document Does Not Exist:** The Respondent has advised that it conducted a thorough investigation and has advised that the requested documents do not exist.
- (d) **Additional Documents Requested:** The Respondent has advised that it produced all relevant documents in its possession. However, Board Staff's expert, Mr. Rosen, does not accept that additional documents do not exist. In his opinion, the documents produced do not provide sufficient detailed support for the allocation of certain expenses to PROCYSBI® sales in Canada.

## **PART II - SUMMARY OF TOPICS DISCUSSED DURING THE MEET AND CONFER**

### ***A. Status of Document Production***

- 5. The parties discussed the status of the documents that Mr. Harington identified as "reasonable". To date, the Respondent has produced five tranches of documents:
  - (a) Production 1: February 4, 2020
  - (b) Production 2: February 19, 2020
  - (c) Production 3: February 28, 2020
  - (d) Production 4: March 5, 2020 (further to a request from Mr. Rosen, the Respondent produced native versions of excel files previously produced in PDF format)
  - (e) Production 5: March 19, 2020
- 6. During the meet and confer, the Respondent identified the outstanding requests for which it was (i) in the process of vetting documents for production, or (ii) still investigating to determine whether the requested documents exist.
- 7. The Respondent has since produced all documents in its possession.

**B. *Horizon's Canadian Operations as of July 2019***

8. During the meet and confer, Mr. Harington advised Mr. Rosen of certain changes to Horizon's Canadian operations that occurred on July 31, 2019. The Respondent provided Mr. Rosen with additional information on Horizon's Canadian operations following the meet and confer.

9. The following is a summary of the Experts' understanding of Horizon's Canadian operations, before and after July 31, 2019, based on the information provided to them by the Respondent.

10. On May 18, 2019, Horizon Pharma's Canadian subsidiary, HZNP Therapeutics Canada Limited ("Horizon Canada"), obtained its Drug Establishment License ("DEL"). A DEL permits Canadian establishments to fabricate, package, label, distribute, import, wholesale, or test a drug.<sup>1</sup>

11. Before Horizon Canada received its DEL, Horizon Pharma Ireland Limited ("Horizon Ireland") sold PROCYSBI® directly to Innomar Strategies Inc. ("Innomar"), which performed all warehousing, importation, and distribution functions. Horizon Canada conducted all other activities including sales, marketing, and medical functions in Canada

12. Innomar distributed PROCYSBI® to patients either directly through its warehouses located across various Canadian provinces, or through another intermediary, including partner pharmacies.

13. Prior to receiving its DEL, Horizon Canada's function was primarily to perform sales and marketing activities in Canada. Horizon Ireland had an arrangement with Horizon Canada whereby Horizon Ireland would reimburse Horizon Canada for expenses incurred for the sale of PROCYSBI® in Canada.

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<sup>1</sup> <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/drug-establishment-licences.html>

14. Horizon Canada acquired title to the inventory of PROCYSBI<sup>®</sup> held by Innomar in Canada in August 2019. As of this date, the scope of Innomar's services was restricted to the warehousing and distribution of PROCYSBI<sup>®</sup> in Canada.

15. The process by which Horizon Canada accounted for revenue is explained in paragraph 18, below. Note, however, that although Horizon Canada received its DEL in May 2019, it did not change its accounting process until August 1, 2019. In other words, the accounting of revenues from May 18 to July 31, 2019 reflects the Canadian operations as they existed prior to Horizon Canada receiving its DEL.

16. Currently, Horizon Canada acquires the title to PROCYSBI<sup>®</sup> from Horizon Ireland after its manufacturing and packaging is completed in the United States. However, the physical product flow has effectively remained unchanged; Innomar continues to receive, store, and distribute PROCYSBI<sup>®</sup> to patients either directly through its warehouses or through other healthcare professionals.

***C. Requests for Additional Information***

17. During the meet and confer, Mr. Rosen requested further information about:

- (a) the process by which the information contained in the monthly profit & loss/income statements (provided in response to Exhibit A – Request A(5)) was obtained and which entity prepared those statements;
- (b) the existence of transfer pricing documents prepared before and after July 31, 2019; and
- (c) data from IQVIA data used by Horizon Pharma.

18. In response to (a), the Respondent has confirmed that, prior to August 1, 2019, the sales information used to prepare these statements was provided by Innomar to Horizon. The sales information was based on the prescriptions filled by Innomar (*i.e.*, based on quantities shipped). Since August 1, 2019, the sales information used to prepare these statements is based on purchase orders from Innomar. The statements were prepared by Horizon Pharma (both before and after July 2019).

19. In response to (b), the Respondent has confirmed that the transfer pricing documents prepared prior to July 31, 2019 relate only to the reimbursement of marketing expenses by Horizon Ireland to Horizon Canada. The transfer pricing documents for the period after July 31, 2019 have not yet been prepared.
20. In response to (c), the Respondent has confirmed that data from IQVIA does not exist for any Canadian product, including PROCYSBI<sup>®</sup>, and was therefore not relied on by Dr. Hay.
21. Mr. Rosen subsequently requested further information about which entity holds the rights to the intellectual property related to PROCYSBI<sup>®</sup>.
22. In response to this request for information, the Respondent has confirmed that there are two patents relevant to this proceeding: Canadian Patent No. 2,640,531 (entitled “Enterically Coated Cysteamine, Cysteamine and Derivatives Thereof” issued January 3, 2017) (the “531 Patent”) and Canadian Patent No. 2,914,770 (entitled “Delayed Release Cysteamine Bead Formulation, and Methods of Making and Using Same” issued September 27, 2016) (the “770 Patent”). The 770 Patent is owned by Horizon Orphan LLC. The 531 Patent is licensed to Horizon Orphan LLC by the Regents of the University of California.
23. Neither Mr. Rosen, nor Board Staff are in a position to confirm and verify all the representations made in paragraphs 8 to 22 above regarding the general descriptions of Horizon Pharma’s operations.

### **PART III - REQUESTS THAT REMAIN IN DISPUTE**

24. The following chart summarizes the requests that remain in dispute along with the experts’ position on each issue:

	<b>Document Request</b>	<b>Horizon’s Position</b>	<b>Mr. Rosen’s Position</b>	<b>Mr. Harington’s Position</b>
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1.	<p><b>Annual Financial Statements of HZNP Therapeutics Canada Limited (“Horizon Canada”)</b></p> <p>Reference: Exhibit A – A(2), A(3), A(4)</p>	<p>Horizon has conducted a thorough investigation and has confirmed that neither audited nor unaudited financial statements exist, as Horizon does not prepare financial statements for Horizon Canada.</p>	<p>Mr. Rosen does not accept Horizon’s confirmation that such documents do not exist.</p> <p>In his opinion, local corporate reporting entities typically prepare financial statements on an annual basis for purposes such as (i) internal management reporting, (ii) consolidation of a subsidiary into a parent entity, and (iii) local statutory tax reporting.</p> <p>If the documents do not exist, which Mr. Rosen does not accept, then Mr. Rosen requests Horizon to provide 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.</p>	<p>In response to Mr. Rosen, Mr. Harington notes that, in his experience, the preparation of audited or unaudited financial statements is not required for the purposes of internal management reporting, consolidation of a subsidiary into a parent entity, or local statutory tax reporting.</p> <p>Specifically:</p> <p>(a) Internal management reporting can be easily undertaken without the preparation of financial statements, especially for entities with limited operations, such as those that existed for Horizon Canada prior to July 2019.</p> <p>(b) Mr. Harington has never seen financial statements prepared for the purpose of consolidation of a subsidiary into a parent entity.</p> <p>(c) While financial statements are typically prepared for local statutory tax reporting for larger entities, this is not always the case for small companies.</p> <p>In any event, even if financial statements did exist (which he understands they do not), those statements would only have been prepared for years up to December 2018 and so would provide information only as to the costs incurred in Canada for sales and marketing, which information has already been provided to Secretariat. These statements would not provide any information relating to sales made in Canada prior to July 31, 2019.</p> <p>In response to Mr. Rosen’s subsequent request that Horizon provide “any financial documents used by Horizon management to review or assess the actual financial performance (revenue, costs and profits) of Horizon’s Canadian operations on an annual</p>
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			<p>basis from 2015 to the current fiscal year,” Horizon has already produced these documents, including:</p> <ul style="list-style-type: none"> <li>- monthly profit and loss/income statements (Exhibit A – A(5), A(6))</li> <li>- Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on sales, expenses, and profits &amp; loss of PROCYSBI in Canada (Exhibit A – A(7))</li> <li>- Forecasts from 2020 to [REDACTED] reflecting actual results to mid 2019 and management projections beyond that point (Exhibit A – A(1))</li> <li>- Documents supporting reported cost of goods sold and per unit standard cost for PROCYSBI Canada for both SKUs (Exhibit A – C(3))</li> <li>- Expense subledgers itemizing the expense items under other cost of sales and supply chain (Exhibit A – C(6))</li> <li>- Expense subledgers itemizing the manufacturing operations expense items, inventory adjustments, and freight &amp; warehouse expenses (Exhibit A – C(7), (8), (9))</li> <li>- Expense subledgers itemizing the sales and market expense items, including medical affairs (Exhibit A – C(10), C(13))</li> <li>- Expense subledgers itemizing the general and administrative expense items as well as executive and managerial salaries and bonuses, and other employee costs (Exhibit A – C(11), C(12))</li> </ul>
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				<ul style="list-style-type: none"> <li>- Expense subledgers itemizing the ongoing R&amp;D expenses (Exhibit A – C(14))</li> <li>- Documents relating to the actual cost of API supplied by Cambrex Profarmaco Milano that was used in PROCYSBI sold in Canada (Exhibit A – D(5))</li> <li>-Documents relating to the actual cost of manufacturing (capsulation) by Patheon Pharmaceuticals Inc. for PROCYSBI sold in Canada (Exhibit A – D(7))</li> <li>- Documents relating to the actual cost of distribution by Innomar Strategies Inc. for PROCYSBI sold in Canada (Exhibit A – D(11))</li> </ul>
2.	<p><b>Income Tax Returns and Schedules</b></p> <p>Reference: Exhibit A – A(10)</p>	These documents have not been produced to date.	<p>Horizon’s Canadian corporate income tax returns are relevant to verify the income/profits reported for income tax purposes in Canada compared to income/profits reported for accounting and financial reporting purposes, and to the conclusions in the Hay Report.</p> <p>In addition, and in any event, it is Mr. Rosen’s opinion that he requires these documents for the purposes of his own analysis, which is not necessarily a replication of what Dr. Hay has done in his report.</p>	<p>Neither the Canadian profits nor the income tax payable in Canada is relevant to the conclusions in the Hay Report.</p> <p>As described above, in the years up to December 2018, being the only years for which income tax returns have likely been prepared, Horizon Canada’s corporate profits will comprise only a markup on the sales and marketing costs as provided by Horizon Ireland. The income tax returns will not be reflective, in any way, of the profits earned in Canada on the sale of PROCYSBI® or any other drug.</p> <p>For the year ended December 2019, which includes the period after August 1, 2019, the income tax returns for Horizon Canada are not relevant as they are dependant on intercompany purchase prices which reflect an allocation of the total PROCYSBI® profit between Horizon entities. These do not represent the profit to Horizon as a</p>

				whole. The conclusions in the Hay report relate to the profit for Horizon as a whole. In addition, the revenues and profits will include every other drug sold by Horizon Canada.
3.	<p><b>Purchase orders and invoices for purchases by Horizon Canada from other Horizon entities or third parties</b></p> <p>Reference: Exhibit A – C(4)</p>	<p>Horizon has produced the relevant invoices and purchase orders (i.e., as between Horizon and third parties).</p> <p>To the extent they exist, purchase orders and invoices by Horizon Canada from other Horizon entities have not been produced.</p>	<p>The purchase orders and invoices for purchases by Horizon Canada from other Horizon entities are relevant for the same reason the transfer pricing documents are relevant.</p> <p>In addition, and in any event, it is Mr. Rosen’s opinion that he requires these documents for the purposes of his own analysis, which is not necessarily a replication of what Dr. Hay has done in his report.</p>	<p>Prior to July 31, 2019, Horizon Canada did not purchase PROCYSBI® from any other Horizon entities or third parties. After July 31, 2019, the purchase orders and invoices for purchases by Horizon Canada from other Horizon entities are not relevant as the purchase price reflects an allocation of total PROCYSBI® profit between Horizon entities for transfer pricing purposes and does not affect, or represent, the profit to Horizon as a whole. The conclusions in the Hay report relate to the profit for Horizon as a whole.</p>
4.	<p><b>Transfer Pricing Documents</b></p> <p>Reference: Exhibit A – D(2), D(4), D(12), D(13), D(14), D(15), D(16), E(3)</p>	<p>These documents have not been produced.</p>	<p>The transfer pricing documents are relevant for the reasons given in Mr. Rosen’s Affidavit sworn January 6, 2020, namely to:</p> <p>(a) Understand and verify the basis of the profits quantified by Dr. Hay; and</p> <p>(b) Perform an assessment of the profits both for the Canadian entity and in the aggregate.</p> <p>Additionally, the transfer pricing documents before and after July 2019 may contain relevant information regarding the allocation of costs for sales of PROCYSBI® in Canada.</p> <p>In addition, and in any event, it is Mr. Rosen’s opinion that he requires these documents for the purposes of his own</p>	<p>The transfer pricing documents are not relevant.</p> <p>As stated in Mr. Harington’s Affidavit sworn January 9, 2020, the analysis and conclusions in Dr. Hay’s report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers. Dr. Hay did not consider Horizon Canada’s profits.</p> <p>The transfer pricing studies provide no information relating to the aggregate profits of Horizon from sales of PROCYSBI® in Canada. All information relating to Horizon’s aggregate profits from sales of PROCYSBI® in Canada has been produced (See Exhibit A – Sections B, C, and D). In any event, as described in Mr. Harington’s Affidavit sworn January 9, 2020, any assessment of Horizon Canada’s profits after July 31, 2019 [REDACTED]</p>

			<p>analysis, which is not necessarily a replication of what Dr. Hay has done in his report.</p>	<p>██████████, as the purpose of transfer pricing is to distribute the total profit between the entities that contribute to that profit for income tax purposes. Therefore, the portion allocated to Horizon Canada is ██████████ ██████████ ██████████</p> <p>Moreover, neither Horizon Canada’s financial results nor the existing transfer pricing studies reflect the sales of PROCYSBI® in Canada prior to August 1, 2019. Horizon Canada’s financial results for this period reflect only the marketing costs incurred in Canada and the reimbursement for those costs by Horizon Ireland.</p> <p>Thus, in response to Mr. Rosen’s statement that the transfer pricing documents before and after July 2019 may contain relevant information regarding the allocation of costs for sales of PROCYSBI® in Canada, Mr. Harington’s position is that:</p> <p>(a) The transfer pricing stud(ies) related to the period prior to July 31, 2019 (which are the only transfer pricing studies that he understands have been prepared) reflect only the reimbursement from Horizon Ireland to Horizon Canada of Horizon Canada’s marketing costs, will relate only to costs that are, by definition, 100% attributable to sales made in Canada and will therefore not provide any “relevant information regarding the allocation of costs for sales of PROCYSBI® in Canada.” Further, all details of these costs have already been provided to Secretariat; and</p>
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				<p>(b) Even if a transfer pricing study did exist for the period after July 31, 2019 (which he understands it does not), such a study would consider an allocation of costs for income tax purposes. This may or may not reflect the appropriate allocation of costs for current regulatory pricing purposes, for which all information has been provided.</p>
<p>5.</p>	<p><b>Documents explaining what the following line items relate to and how each item should be allocated to PROCYSBI® sold in Canada:</b></p> <p>(a) Sales and Marketing;</p> <p>(b) Medical Affairs;</p> <p>(c) General and Administrative;</p> <p>(d) Executive and managerial salaries and bonuses and other employee costs; and</p> <p>(e) Documents that detail selling, general, and administrative expenses that should be specifically excluded from an allocation to PROCYSBI® sold in Canada</p> <p>Reference: Exhibit A – C(10), C(11), C(12), C(13)</p>	<p>There are two parts to this request: (1) documents explaining what the line items relate to, and (2) documents explaining how each item should be allocated</p> <p>Horizon has produced all documents relevant to the first part of this request (i.e., documents indicating what each line item relates to). The documents produced include Horizon’s general ledger, which reflects the most particularized level of detail that exists for each expense item.</p> <p>Horizon has conducted a thorough investigation and has confirmed that no additional documents exist, including documents that explain how each line item is allocated to PROCYSBI® sold in Canada.</p> <p>This is because, as explained in the Hay Report, [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	<p>Mr. Rosen does not accept Horizon’s confirmation that additional documents do not exist.</p> <p>In his opinion, the documents produced do not provide sufficient detailed support for the allocation of Medical Affairs, Sales &amp; Marketing, and General and Administrative costs to PROCYSBI® sales in Canada as presented in the Hay Report.</p> <p>In addition, and in any event, it is Mr. Rosen’s opinion that he requires these documents for the purposes of his own analysis, which is not necessarily a replication of what Dr. Hay has done in his report.</p>	

		<p>(a) Horizon tracks Other Cost of Sales [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] (Hay Report, Exhibit F, para. 16).</p> <p>(b) Horizon tracks sales and marketing expenses in Canada at [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] (Hay Report, Exhibit F, para. 19).</p> <p>(c) Horizon tracks general and administrative expenses at [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] (Hay Report, Exhibit F, para. 21).</p> <p>To the extent Mr. Rosen disagrees with Dr. Hay's methodology, such disagreement is not relevant to the request for document production.</p>		
<p>6.</p>	<p><b>Documents that detail the nature of the following expenses:</b></p> <p>(a) Ongoing R&amp;D Expenses</p>	<p>This requests relates only to documents that detail the nature of the expenses. Horizon has produced all documents relevant to this request (<i>i.e.</i>, documents indicating what each line item</p>	<p>Mr. Rosen does not accept Horizon's confirmation that additional documents do not exist.</p> <p>In his opinion, the documents produced do</p>	

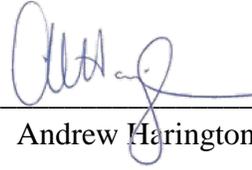
<p>(b) Items under Other Cost of Sales and Supply Chain (recorded on a global basis)</p> <p>(c) Sales and Marketing (and Medical Affairs) expenses (recorded on a Canada wide basis)</p> <p>(d) General and Administrative expenses (recorded on a global basis)</p> <p>Reference: Exhibit A – E(5), E(6), E(7), E(8)</p>	<p>relates to). The documents produced include Horizon’s general ledger, which reflects the most particularized level of detail that exists for each expense item.</p> <p>Note that Mr. Rosen’s request does not ask for documents that indicate how each item should be allocated. In the event this is what Mr. Rosen is seeking, Horizon has conducted a thorough investigation and has confirmed that no additional documents exist, including documents that explain how each line item is allocated to PROCYSBI® sold in Canada.</p> <p>See Item #5, above, for an explanation of how each item was allocated in the Hay Report.</p> <p>To the extent Mr. Rosen disagrees with Dr. Hay’s methodology, such disagreement is not relevant to the request for document production.</p>	<p>not provide sufficient detailed support for the allocation of these expense line items to PROCYSBI® sales in Canada as presented in the Hay Report.</p> <p>In addition, and in any event, it is Mr. Rosen’s opinion that he requires these documents for the purposes of his own analysis, which is not necessarily a replication of what Dr. Hay has done in his report.</p>	
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Signed:



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Howard Rosen



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Andrew Harrington

Dated:

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April 3, 2020

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