

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®

SUPPLEMENTARY RESPONDING MOTION RECORD OF THE RESPONDENT

(Motion to Bifurcate, Strike Evidence and for the Inspection and Production of Documents)

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TAB1

PATENTED MEDICINE PRICES REVIEW BOARD

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**AND IN THE MATTER OF
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and the medicine Cysteamine Bitartrate sold by the Respondent under the trade
name PROCYSBI**

SUR-REPLY AFFIDAVIT OF ANDREW HARINGTON

I, **ANDREW HARINGTON**, of the City of Toronto, in the Province of Ontario, MAKE OATH AND SAY:

1. I previously affirmed an affidavit on December 13, 2019 (my first affidavit). In my first affidavit, I provided my opinion as to (i) whether the items requested by Mr. Rosen in his affidavit dated November 28, 2019 (the “Rosen Affidavit”) are relevant and/or necessary for Mr. Rosen to fulfill his mandate, and (ii) whether an on-site inspection of Horizon Pharma (and any manufacturing and distribution facilities), which includes analyzing and validating any documents provided by Horizon, is necessary for Mr. Rosen to fulfill his mandate.
2. On January 7, 2020, counsel for Horizon provided me with a copy of the Reply Affidavit of Mr. Howard Rosen sworn January 6, 2020 (the “Rosen Reply Affidavit”), which is attached as **Exhibit “A”**. I have been asked by counsel for Horizon to review and respond to any new issues raised in the Rosen Reply Affidavit.
3. In providing this opinion, I continue to comply with the Code of Conduct for Expert Witnesses, which is attached as **Exhibit “B”**.
4. I have provided a summary of my opinion in response to the memorandum contained in the Rosen Reply Affidavit, below. I have also provided specific responses

to Mr. Rosen's comments on each item requested in Exhibit "E" to my first affidavit. A copy of my responses is attached as **Exhibit "C"**.

Summary of Opinion

5. *Information Relating to Transfer Pricing.* I have extensive experience with transfer pricing. As set out at paragraph 45 of my curriculum vitae, attached to my affidavit dated December 13, 2019, I have, among other things, (i) authored transfer pricing studies for income tax purposes in connection with cross border pricing of transactions between non-arm's length parties within multi-national enterprises for purposes of section 247 of the *Income Tax Act* and compliance with the OECD, and (ii) I have been invited to speak at both the Canadian and International Tax Executive Institutes' conferences on topics related to transfer pricing.

6. Transfer pricing is applicable to enterprises, such as Horizon, that operate in various income tax jurisdictions (referred to as multi-national enterprises or MNEs) and where transactions occur between entities across those jurisdictions. Because each jurisdiction has a different income tax rate, absent oversight, management would maximize profitability by setting the prices between those entities such that the profits will be earned in those jurisdictions with the lowest income tax rates.

7. To mitigate against this, the OECD requires MNE entities to trade with one another at prices which reflect those that would exist if the parties were acting at "arm's length." This is referred to as the "arm's length principle," and the resulting prices are referred to as "arm's length prices."

8. While the approach will differ depending on the structure of each organization, the effect of transfer pricing regulations is to share the total profits generated by the global corporation between each tax jurisdiction to reflect the value of each entity's contributions.

9. In other words, the global profits generated by Horizon from sales of PROCYSBI® in Canada must reflect the value of each entity's contribution. If, for example, the sale of one dose of PROCYSBI® in Canada generates \$1,000 of profit for

Horizon globally, Horizon's profits would reasonably be shared among each Horizon entity, including:

- a. The entity that manufactures the product;
- b. The entity that sells the product;
- c. The entity that facilitates the distribution of the product to Canada; and
- d. The entity(ies) that own(s) each aspect of the intellectual property relating to the sales made in Canada.

10. Because the total profits generated by the global corporation must be shared to reflect the value of each entity's contribution, [REDACTED]

11. However, if the price of PROCYSBI® in Canada is reduced, as reflected in the Hay Report, [REDACTED]

12. This is because, under the arm's length principle, the parties are considered to have set a price as if they were acting at arm's length. In that case (*i.e.*, if the parties were acting at arm's length), [REDACTED]

13. [REDACTED]

14. Mr. Rosen provides no details as to why he believes that the [REDACTED] are relevant. [REDACTED]

[REDACTED]

15. Moreover, and in any event, the transfer pricing documents will not provide any basis on which to verify the profits quantified by Dr. Hay because Dr. Hay does not

[REDACTED]


[REDACTED]

[REDACTED]

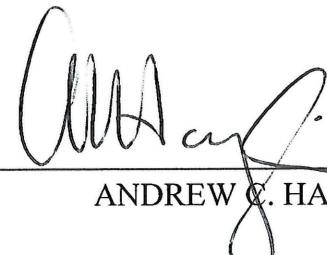
16. *Information relating to financial statements.* Mr. Rosen misstates my response to his requests for monthly and/or quarterly financial statements. I understand the distinction between audited annual financial statements and monthly and quarterly management accounts. My response to Mr. Rosen's request contained in row A(3) of Exhibit "E" to my first affidavit clearly indicated that the provision of monthly management accounts (as requested at row A(5)) will address, and negate, the need for quarterly management accounts.

17. I understand that Mr. Rosen is requesting monthly and quarterly financial statements for each legal entity. In my opinion, however, this is not a reasonable request. These statements do not provide meaningful information for the purpose of assessing the profitability of any one product, and they are rarely, if ever, prepared for each legal entity.

AFFIRMED BEFORE ME at the
City of Toronto, in the Province of
Ontario, this 10th day of January,
2020.



Commissioner for Taking Affidavits
STACEY KEISMAN

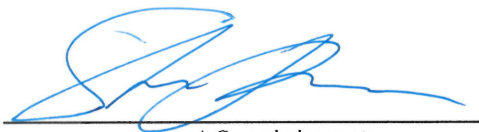
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ANDREW C. HARINGTON



TABA

This is Exhibit "A" referred to in the
affidavit of ANDREW C. HARINGTON
affirmed before me, this 10th
day of January, 2020.



A Commissioner, etc.

STACEY REISMAN

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**

AFFIDAVIT OF HOWARD ROSEN

I, Howard Rosen, of the City of Toronto, in the Province of Ontario,

MAKE OATH AND SAY:

1. I have reviewed the Affidavit of Andrew Harington, affirmed December 13, 2019. Attached as **Exhibit A** to this my affidavit is a copy of Secretariat International's memorandum dated January 6, 2020 detailing our response to Mr. Harington's affidavit.
2. I make this affidavit in support of a motion by Board Staff for the production and inspection of documents and for no other or improper purpose.

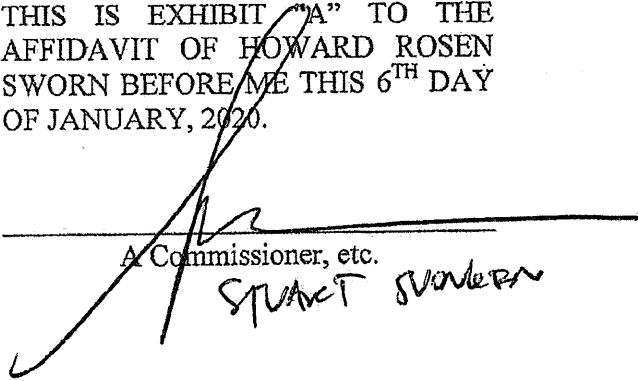
SWORN BEFORE ME in the City of Toronto,
in the Province of Ontario, on Friday,
the 6th day of January, 2020.

(A Commissioner of Oaths)

STUART PROCTOR

Howard Rosen

THIS IS EXHIBIT "A" TO THE
AFFIDAVIT OF HOWARD ROSEN
SWORN BEFORE ME THIS 6TH DAY
OF JANUARY, 2020.


A Commissioner, etc.

STUART SWINER



MEMORANDUM

FROM: Secretariat International – Howard Rosen, Julius Koo

DATE: January 6, 2020

SUBJECT: PMPRB v Horizon Pharma – PROCYSBI
Response to the Affidavit of Andrew Harington dated Dec. 13, 2019

Introduction

We have been requested by Perley-Robertson, Hill & McDougall LLP ("Counsel"), on behalf of Board Staff of the Patented Medicine Prices Review Board ("PMPRB"), to review and respond to the Affidavit of Andrew Harington of the Brattle Group dated December 13, 2019 (the "Harington Affidavit").

In summary, Mr. Harington opined that certain categories of documents previously requested in my Affidavit dated November 28, 2019 are not relevant or necessary, including:

- A. Information relating to transfer pricing between the Horizon entities and the resulting share of profit earned in each individual country – Mr. Harington states that the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers.
- B. Horizon's monthly and/or quarterly financial statements – Mr. Harington states that my requests for monthly and/or quarterly financial statements are included within his broader requests for annual financial statements, thus they are not necessary to fulfill my mandate.
- C. Furthermore, Mr. Harington opined that an on-site inspection of Horizon Pharma (and any manufacturing and distribution facilities) is not necessary to fulfill my mandate.

In the sections below, I provide my responding comments to Mr. Harington's opinions above. I have also attached a chart that provides my specific responses to Mr. Harington's comments on each item requested in Exhibit E of the Harington Affidavit.

- A. Information relating to transfer pricing

The Organization for Economic Co-operation and Development ("OECD") – of which Canada, the United States, and Ireland, amongst other countries, are members – issues guidelines for multinational companies to follow in determining transaction prices between non-arm's length

entities for tax purposes.¹ Transfer prices are “the prices at which an enterprise transfers physical goods and intangible property or provides services to associated enterprises.”² OECD member countries have adopted the arm’s length principle,³ which is defined as:

“Where conditions are made or imposed between the two associated enterprises in their commercial or financial relations which differ from those which would be made between independent enterprises, then any profits which would, but for those conditions, have accrued to one of the enterprises, but, by reason of those conditions, have not so accrued, may be included in the profits of that enterprise and taxed accordingly.”⁴

In other words, when transfer pricing between associated enterprises does not reflect market forces, the tax liabilities of the associated enterprises (and the resulting tax revenues of the respective countries’ tax authorities) may be distorted. Therefore, OECD member countries have agreed that, for tax purposes, the profits of associated enterprises may be adjusted accordingly, to correct any such distortions.⁵

The setup of Horizon’s corporate legal entities in different countries and tax jurisdictions, as well as the various agreements which dictate the allocations of profits through transfer pricing, all represent a choice made for various reasons which are not uncommon for multinational enterprises, especially for pharmaceutical companies, such as Horizon – reasons such as:

- Location of the original business setup,
- Allocation of risk between different aspects of the overall “value chain”,
- Tax considerations, and
- Cash flow requirements of associated enterprises.

For example, a company may move its headquarters or transfer all its intellectual property from a relatively higher tax jurisdiction, such as the United States, to a lower tax jurisdiction, such as Ireland. Then, through inter-corporate agreements, the company can set up transfer prices at which each entity transacts with another in order to allocate profits to each country/tax jurisdiction. For example, if the company’s intellectual property is held in Ireland, that entity may charge the US or Canadian entity an inter-corporate charge for the use of the intellectual property. This will affect the cost and profits in each of the operating entities in the US and Canada.

¹ OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, July 2017.

² OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, July 2017, page 17.

³ OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, July 2017, page 16.

⁴ OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, July 2017, page 35.

⁵ OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations, July 2017, page 34.

 Secretariat

In the assessment of Horizon's profits related to the sales of PROCYSBI in Canada in this matter, it is important to analyze from an economic perspective the form and the substance of the corporate setup of the multinational enterprise.

On one hand, the economic substance of the corporate setup is important because this dictates where and under which entities the actual economic activities take place and how the entities transact with each other.

On the other hand, the form of the corporate setup is also important because Horizon has chosen a specific corporate structure for income tax purposes in different countries and tax jurisdictions. Horizon has also chosen specific transfer pricing policies that dictate how profits are allocated between Horizon corporate legal entities.

Once corporate entities are set up for transfer pricing purposes, each entity is deemed to deal at arm's length and considered economically no different than unrelated parties such as third-party suppliers. Therefore, in the assessment of Horizon's profits related to PROCYSBI sales in Canada, documents relating to transfer pricing are just as relevant as documents for third party suppliers (e.g. invoices supporting API cost).

Dr. Hay and Mr. Harington state that profits have been assessed at an aggregate global level, but we need the requested documents to understand Horizon's transfer pricing and corporate set up related to PROCYSBI sold in Canada in order to:

1. Understand and verify the basis of the profits quantified by Dr. Hay, and
2. Perform an assessment of the profits for both the Canadian entity and in the aggregate – which we believe are both relevant – which may differ from the profits quantified by Dr. Hay since there are different levels of corporate profits associated with PROCYSBI sales in Canada that may be calculated and assessed, and different assumptions which may be used to calculate such profits.

Since intercompany profits are eliminated on consolidation for financial reporting purposes, the aggregate consolidated financial statements do not provide sufficient information for us to assess the costs and profits associated with PROCYSBI sales in Canada. For example, Horizon Pharma's Response dated February 18, 2019 stated that the total investment required to bring PROCYSBI to market was in excess of US\$180 million,⁶ but the consolidated financial statements do not provide information on where or how this investment has been made. Specifically, they do not provide the cost to obtain marketing authorization (i.e. a notice of compliance) for PROCYSBI in Canada.⁷

⁶ Horizon Pharma's Response dated February 18, 2019, page 12, para. 34.

⁷ Horizon Pharma's Response dated February 18, 2019, page 12, para. 34.

 Secretariat

We require the requested transfer pricing documents to examine the details of transactions between the Horizon entities, and to understand all the economic activities and associated relevant costs surrounding the sale of PROCYSBI in Canada – we believe that this request is relevant and reasonable.

Also, if Horizon or any specific Horizon corporate legal entity is audited by a tax authority for its transfer pricing, it will be based on the form of the corporate structure chosen by Horizon for income tax purposes, and this cannot be unwound or ignored for the assessment of profits in this matter. Therefore, we believe that our request for any correspondence with income tax authorities and other income tax information is relevant and reasonable.

B. Monthly and/or quarterly financial statements

My request for the monthly and quarterly financial statements is separate from my request for the annual financial statements. The annual financial statements are typically audited and consolidated as at a fiscal year date, prepared for financial reporting purposes.

Quarterly financial statements are typically unaudited and provides financial results by fiscal quarter, prior to a fiscal year end, prepared for financial reporting purposes and may be prepared on an unconsolidated basis for each legal entity.

Monthly profit & loss/income statements typically provide more detail than annual and quarterly financial statements, for example more detailed expense line items, and are prepared for internal management reporting or decision-making purposes. For example, a company may prepare monthly profit & loss/income statements for specific products, product groups, regions or countries.


Since each of these types of financial statements provide different information, they are all relevant in the assessment of Horizon's profits from PROCYSBI in Canada.

C. On-site inspection

In my Affidavit, we had requested for the opportunity to conduct an on-site inspection at the offices of Horizon Pharma (and manufacturing and distribution facilities) as necessary. This was to get access to Horizon Pharma's in-house knowledgeable staff to discuss and respond to our questions regarding Horizon's accounting processes and documentation.

Dr. Hay had the benefit of discussions with Horizon personnel and business representatives regarding a number of different aspects of the profits calculation, as specifically noted and relied upon in the Hay Report.⁸ We believe that it is a reasonable request to have the opportunity for an

⁸ For example, the Hay Report, page 6, para. 18; page F-3, para. 7; page F-4, para. 9.

 **Secretariat**
MINISTRE DE LA JUSTICE

on-site inspection, as necessary, as an efficient way to get access to the relevant documents and to discuss these documents with Horizon's staff.

Mr. Harington states that an on-site inspection is only appropriate where there is a reason to doubt the accuracy of the documents, and that because these documents were prepared in the ordinary course of business, there is no reason to contest their accuracy. While we are not doubting the accuracy of the documents requested at this time, we have not yet had the opportunity to review documents supporting the profits calculation, or to assess their accuracy. We cannot determine at this point whether the requested documents were prepared in the ordinary course of business. As this was part of the scope of Dr. Hay's work which he has relied upon, and for the reasons set out above, we believe that our request for an on-site inspection, as necessary, is reasonable.

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Secretariat Request	Hattington Response to Secretariat Request	Secretariat Response
A. Documents related to Horizon Pharma's Canadian subsidiary – HZNP Therapeutics Canada Limited (also known as Horizon Therapeutics Canada):		
1. HNZP.xlsx (Horizon Financial Information) – listed in the Hay Report, Appendix D – Scope of Review, item C.iii. – in Excel format	Reasonable Request	
2. Audited or unaudited annual financial statements – from the fiscal year ended 2015 (2 years prior to the launch of PROCYSBI in Canada in September 7, 2017) to the current fiscal year	Reasonable Request	
3. Unaudited quarterly financial statements – from the first fiscal quarter of 2015 to the current fiscal quarter	The quarterly statements duplicate the request for the monthly statements in Item A(5), below.	This is not a duplicate request – this request is for unaudited quarterly financial statements prepared for financial reporting purposes, compiled or reviewed by the auditors. This request is similar to Item D(4), second bullet point, below. The request for Item A(5), below, is for detailed internal monthly profit & loss/income statements.
4. Financial statements (balance sheet, income statement, statement of cash flows) prepared for internal reporting purposes/consolidation purposes – from the fiscal year ended 2015 (2 years prior to the launch of PROCYSBI in Canada in September 7, 2017) to the current fiscal year	Reasonable Request	
5. Detailed monthly profit & loss/income statements – from the first fiscal month of 2015 to the current month	Reasonable Request	
6. Detailed monthly profit & loss/income statements specifically for PROCYSBI, or any other documents that report profit & loss related to PROCYSBI sales in Canada – from September 2017 to the current month	Reasonable Request	
7. Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on sales, expenses, and profit & loss of PROCYSBI in Canada – from prior to the launch of PROCYSBI in Canada in September 7, 2017 to the current date	Reasonable Request	
8. Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on	This information is covered by the request in Item A(7).	This request is specifically for information on conversion of patients from Cystagon to PROCYSBI in Canada, which is in

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conversion of patients from Cystagon to PROCYSBI in Canada – from prior to the launch of PROCYSBI in Canada in September 7, 2017 to the current date		addition to information on sales, expenses, and profit & loss of PROCYSBI in Canada requested in Item A(7). We reserve the right to review the information produced for Item A(7) and to request the information in Item A(8) if it is not covered.
9. Data from IQVIA (formerly IMS Health) used by Horizon Pharma to analyze market share of PROCYSBI relative to Cystagon in each country – from January 2015 to the current month	Not a Reasonable Request Information relating to sales of PROCYSBI relative to Cystagon in countries other than Canada is not relevant to the analysis.	The Hay Report relies on Horizon's forecasts [REDACTED] My request is reasonable to verify if the forecasts [REDACTED] are supported [REDACTED], and to obtain data used by Horizon from IQVIA (formerly IMS Health) to analyze market share of PROCYSBI relative to Cystagon.
10. Federal and provincial corporate income tax returns and schedules, specifically including the reconciliation of taxable income with accounting income – from the taxation year 2015 to current	Not a Reasonable Request The income tax payable in Canada is not relevant to the conclusions in the Hay Report.	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.
B. Documents related to PROCYSBI sales:		
1. Detailed listing of all PROCYSBI sales transactions in Canada (from the sales subledger) from launch to the current date – detailing actual sales in units for all stock keeping units ("SKU") (i.e. 25 mg 60 capsule bottles and 75 mg 250 capsule bottles) and unit price for each sale	It is not clear as to which sales this request relates (i.e., sales to wholesalers and pharmacies (which would be relevant for comparisons to information from IQVIA (formerly IMS Health) or sales by Horizon Pharma to Innomar Strategies. In any event, this appears to be a reasonable request.	This request is for all PROCYSBI sales transactions in Canada, including sales to wholesalers, pharmacies, and to Innomar Strategies.
2. The above listing should include sales units provide free-of-charge ("free goods"), sales returns, and any other sales credit or debit transactions	It is not clear as to which sales this request relates (i.e., sales to wholesalers and pharmacies (which would be relevant for comparisons to information from IQVIA (formerly IMS Health)	This request is for all PROCYSBI sales transactions in Canada, including sales to wholesalers, pharmacies, and to Innomar Strategies.

¹ The Hay Report, page F-1, para. 3.

² The Hay Report, page F-2, para. 5.

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	or sales by Horizon Pharma to Innomar Strategies. In any event, this appears to be a reasonable request.	
3. A sample of purchase orders, sales invoices, credit notes, and debit notes for each type of sales transaction, for each SKU	Reasonable Request	
4. Documents that support the assumption that [REDACTED] of Horizon's patients will be covered by provincial and territorial drug benefit plans and [REDACTED] will be covered by private insurance plans	Reasonable Request	
5. Documents that support Horizon's copay discount of [REDACTED] of covered costs to patients covered under private-insurance plans	Reasonable Request	
C. Documents related to PROCYSBI expenses:		
1. All agreements and amendments related to royalties to the Regents of the University of California, including but not limited to:	Reasonable Request	
<ul style="list-style-type: none"> Amended and Restated License Agreement, dated May 31, 2017, by and between Horizon Orphan LLC and The Regents of the University of California 	Reasonable Request	
<ul style="list-style-type: none"> Amendment No. 1 to Amended and Restated License Agreement, dated September 11, 2018, by and between Horizon Orphan LLC and The Regents of the University of California 	Reasonable Request	
2. Documents that support the calculation of royalties payable from sales of PROCYSBI in Canada and the payment of the royalties	Reasonable Request	
3. Documents supporting reported cost of goods sold and per unit standard cost for PROCYSBI Canada for both SKUs (figures contained in the Hay Report, Exhibit B)	Reasonable Request	
4. Purchase orders and invoices for all PROCYSBI units purchased for sale in Canada	<p>It is not clear to which entity this request relates.</p> <p>If the requested documents are for purchases by Horizon Canada from other Horizon entities, then this is not a reasonable request. The conclusions in the Hay Report relate to profit for Horizon as a whole.</p>	This request is for purchases by Horizon Canada from other Horizon entities, or to the extent that Horizon Canada purchases PROCYSBI for sale in Canada from third parties, then the request is for those entities.

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	If the requested documents are for purchases by Horizon from third parties, then this request is addressed by the request in D(3) below.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.
5. Documents supporting cost of goods sold for PROCYSBI Global (figures contained in the Hay Report, Exhibit C)	Reasonable Request	
6. Documents that support each expense item under other cost of sales and supply chain (figures contained in the Hay Report, Exhibit C), including but not limited to:	Reasonable Request	
• Expense subledgers	Reasonable Request	
• Internal reports used to analyze these expenses	Reasonable Request	
• Allocations of these costs to specific products, geographic regions, or countries	Reasonable Request	
7. Documents that explain what "manufacturing operations" expenses relate to and whether any of these costs are imbedded in the standard cost/cost of goods sold for PROCYSBI sold in Canada	Reasonable Request	
8. Documents that explain what "inventory adjustments" relate to and whether any inventory adjustments were specific to PROCYSBI sold in Canada	Reasonable Request	
9. Documents that explain what "supplychain" and "freight & warehouse" expenses relate to and whether any of these expenses were specific to PROCYSBI sold in Canada	Reasonable Request	
10. Documents that explain what each "sales and marketing expense" item (and "medical affairs") relates to and support how each item should be allocated to PROCYSBI sold in Canada	Reasonable Request	
11. Documents that explain what each "general and administrative" expense item relates to and support how each item should be allocated to PROCYSBI sold in Canada	Reasonable Request	
12. Documents relating to executive and managerial salaries and bonuses, and other employee costs that support how these expenses should be allocated to PROCYSBI sold in Canada	Reasonable Request	
13. Documents that detail selling, general and administrative expenses that should be specifically excluded from an	Reasonable Request	

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allocation to PROCYSBI sold in Canada, [REDACTED] [REDACTED]		
14. Documents that explain what "ongoing research and development" expenses relate to and support how these expenses should be allocated to PROCYSBI sold in Canada	Reasonable Request	
15. Documents that support why a growth rate of [REDACTED] is reasonable for continuing R&D expenditures for PROCYSBI sold in Canada	Reasonable Request	
16. Documents that support Horizon Pharma's acquisition of the worldwide marketing rights to PROCYSBI through its acquisition of Raptor Pharmaceutical Corp. in October 2017 ("Raptor Acquisition Cost" or "Raptor Development Costs") and the allocation of the development and commercial expenditures for PROCYSBI to PROCYSBI sold in Canada, including but not limited to:	Reasonable Request	
<ul style="list-style-type: none"> Documents that supported the due diligence of all research and development, regulatory, and quality costs 	Reasonable Request	
<ul style="list-style-type: none"> Valuation reports done by external third party consultants or internally by Horizon Pharma relating to this acquisition transaction, and other related documents used in the allocation of the purchase price into tangible and intangible assets and liabilities 	Reasonable Request	
<ul style="list-style-type: none"> Detailed costing documents that provide a build-up of historical research and development expenditures, and regulatory and quality costs spent prior to the Raptor transaction 	Reasonable Request	
<ul style="list-style-type: none"> Any internal analysis comparing these past costs to those spent by Horizon Pharma after the acquisition 	Reasonable Request	
17. Documents that detail which Horizon Pharma legal entity holds and records the intellectual property/intangible	This information is covered by the request in Item D(1).	Agreed, but we reserve the right to review the information produced for Item D(1) and to request further relevant information if necessary to understand and verify the

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assets (the developed technology) associated with PROCYSBI	It is not clear whether this request relates to Horizon Pharma Canada or Horizon Pharma globally.	accounting for the intellectual property/intangible assets (the developed technology) associated with PROCYSBI. This request relates to Horizon Pharma Canada.
18. Documents which support Horizon Pharma's impairment tests relating to PROCYSBI	This is a reasonable request only as it relates to Horizon Pharma Canada, as the documents are relevant only to the extent of impairment relating to Canadian related assets of PROCYSBI. To the extent this request relates to Horizon Pharma globally, it is not a reasonable request.	We note that stating this request is not reasonable if it relates to Horizon Pharma globally is contradictory to all the other statements in Mr. Harington's response that the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally or profit for Horizon as a whole.
D. Documents related to PROCYSBI transfer pricing:		
HARRINGTON RESPONSE: As stated in paragraph 18(i) of my affidavit, the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers. Thus, information relating to the transfer pricing system and resulting share of profit in each legal entity or country is not relevant.		
However, this section also contains requests for information that I consider appropriate as providing relevant background information, but which do not relate to transfer pricing. For those documents, I have indicated the item as being a Reasonable Request.		
Reasonable Request		
1. Corporate organizational charts that present all Horizon Pharma legal entities and third parties globally that are involved with all economic activities associated with PROCYSBI, including but not limited to entities that:		
• Manufacture the active pharmaceutical ingredient ("API") cysteamine bitartrate		
• Purchase and receive the API		
• Supply the excipients		
• Manufacture the finished product (capsulation of the PROCYSBI capsules), including the application of PROCYSBI's enteric coating, delayed release formulation		
• Package and label the finished SKUs for the Canadian market		
• Warehouse and distribute the finished SKUs in the Canadian market		

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<ul style="list-style-type: none"> • Provide other services such as arranging for the above activities, accounting services such as invoicing, managing intercompany relationships • Hold the rights to the intellectual property (intangible assets) related to PROCYSBI • Hold the distribution rights for the Canadian market 			
<p>2. All agreements and amendments between Horizon Pharma legal entities involved with PROCYSBI, and other related documents to understand transfer pricing arrangements, price adjustment mechanisms, profit adjustment mechanisms, any mark-ups and fees charged, and intercompany arrangements</p>	<p>Not a Reasonable Request</p> <p>The analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers. Thus, information relating to the transfer pricing system and resulting share of profit in each legal entity or country is not relevant.</p>		<p>Please refer to my responding comments above in Section A.</p> <p>Information relating to transfer pricing.</p>
<p>3. All agreements and amendments with third parties involved with PROCYSBI, including but not limited to:</p> <ul style="list-style-type: none"> • API Supply Agreement, dated November 3, 2010, by and among Cambrex Profarmaco Milano, Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to Raptor Pharmaceuticals Europe B.V.), as amended April 9, 2013 • Any other raw materials supply agreements • Manufacturing Services Agreement, dated November 15, 2010, by and among Patheon Pharmaceuticals Inc., Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to Raptor Pharmaceuticals Europe B.V.), as amended April 5, 2012 and June 21, 2013 • Any other contract manufacturing services agreements • Any distribution agreements and amendments with Innomar Strategies Inc. • Any other warehousing, logistics, or co-distribution agreements 	<p>Reasonable Request</p>		

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4. For all Horizon Pharma legal entities that are involved with the economic activities associated with PROCYSBI, financial documents including but not limited to:	See individual responses, below.	
<ul style="list-style-type: none"> Audited or unaudited annual financial statements – from the fiscal year ended 2015 (2 years prior to the launch of PROCYSBI in Canada in September 7, 2017) to the current fiscal year 	<p>These documents have already been provided. For 2016, 2017 and 2018 see Horizon Pharma Annual Report 2016, Horizon Pharma Annual Report 2017 and Horizon Pharma Annual Report 2018 listed in the Hay Report, Appendix D, items lxxxiv, lxxxv and xc.</p> <p>For 2015, see https://ir.horizontherapeutics.com/static-files/96f5aad2-7e30-4c3c-950c-f77097623f59.</p>	<p>The documents referred to in Mr. Harington's Response are Horizon's consolidated financial statements in the annual reports. My request was for the financial statements for each Horizon Pharma legal entity involved with the economic activities associated with PROCYSBI.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>
<ul style="list-style-type: none"> Unaudited quarterly financial statements – from the first fiscal quarter of 2015 to the current fiscal quarter 	<p>These documents are publicly available.</p> <p>See Quarterly financial statements available at https://ir.horizontherapeutics.com/financial-information/sec-filings?field_nir=see_form_group_target_id%5B%5D=496&field_nir_sec_date_filed_value=&items_per_page=10#views-exposed-form-widget-see-filings-table.</p>	<p>The documents referred to in Mr. Harington's Response are Horizon's consolidated financial statements in the quarterly reports. My request was for the financial statements for each Horizon Pharma legal entity involved with the economic activities associated with PROCYSBI.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>
<ul style="list-style-type: none"> Financial statements (balance sheet, income statement, statement of cash flows) prepared for internal reporting purposes/consolidation purposes – from the fiscal year ended 2015 (2 years prior to the launch of PROCYSBI in Canada in September 7, 2017) to the current fiscal year 	<p>Not a Reasonable Request</p> <p>These documents are not relevant as the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally based on sales to Canadian customers.</p>	<p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>
<ul style="list-style-type: none"> Detailed monthly profit & loss/income statements – from the first fiscal month of 2015 to the current month 	<p>Not a Reasonable Request</p> <p>These documents are not relevant as the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally based on sales to Canadian customers.</p>	<p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>
<ul style="list-style-type: none"> Detailed monthly profit & loss/income statements specifically for PROCYSBI, or any other documents that report profit & loss related to PROCYSBI sales globally – from the first fiscal month of 2015 to the current month 	<p>Reasonable Request</p>	

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<ul style="list-style-type: none"> Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on sales, expenses, and profit & loss of PROCYSBI globally – from prior to the launch of PROCYSBI in each country/market to the current date 	This is a reasonable request only to the extent that it relates to sales of PROCYSBI in Canada.	<p>We note that this is contradictory to all the other statements in Mr. Harington's response that the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally or profit for Horizon as a whole.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>
<ul style="list-style-type: none"> Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on conversion of patients from Cystagon to PROCYSBI globally – from prior to the launch of PROCYSBI in each country/market to the current date 	This is a reasonable request only to the extent that it relates to sales of PROCYSBI in Canada.	<p>We note that this is contradictory to all the other statements in Mr. Harington's response that the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally or profit for Horizon as a whole.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>
<ul style="list-style-type: none"> Data from IQVIA (formerly IMS Health) used by Horizon Pharma to analyze market share of PROCYSBI relative to Cystagon in each country – from prior to the launch of PROCYSBI in each country/market to the current date 	<p>Not a Reasonable Request</p> <p>Information as to sales of PROCYSBI relative to Cystagon in countries other than Canada is not relevant to the analysis. Further, this information request is covered by the request in Item A(9), above.</p>	<p>The Hay Report relies on Horizon's forecasts [REDACTED]</p> <p>[REDACTED]</p> <p>My request is reasonable to verify if the forecasts [REDACTED] are supported [REDACTED] and to obtain data used by Horizon from IQVIA (formerly IMS Health) to analyze market share of PROCYSBI relative to Cystagon.</p>
<ul style="list-style-type: none"> Income tax returns and schedules, specifically including the reconciliation of taxable income with accounting income for each jurisdiction – from the taxation year 2015 to current 	<p>Not a Reasonable Request</p> <p>The income tax returns for any country are not relevant to the conclusions in the Hay Report.</p>	Please refer to my responding comments above in Section A. Information relating to transfer pricing.
5. Documents relating to the actual cost of API supplied by Cambrex Profarmaco Milano that was used in PROCYSBI	Reasonable Request	

³ The Hay Report, page F-1, para. 3.

⁴ The Hay Report, page F-2, para. 5.

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<p>6. Documents relating to the actual cost of excipients used in PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, and debit/credit memos</p> <p>7. Documents relating to the actual cost of manufacturing (capsulation) by Patheon Pharmaceuticals Inc. for PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, and debit/credit memos</p> <p>8. Documents relating to the actual cost of packaging and labelling of finished SKUs for PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, and debit/credit memos</p> <p>9. To the extent that Horizon Pharma performs any manufacturing (capsulation, application of PROCYSBI's enteric coating, delayed release formulation), packaging and/or labelling, and supply chain (freight, distribution, warehouse, logistics) functions for PROCYSBI sold in Canada, documents relating to the actual cost of performing these functions, including but not limited to:</p> <ul style="list-style-type: none"> • Master formula card/recipe sheets • Internal cost sheets • Calculations of standard cost (by month) • Tracking of actual costs and cost variances • Physical process diagram of all machinery used in each process (including the location and cost of each asset owned or leased) • Information regarding the annual theoretical capacity and actual usage for each machine (by dosage/capsule/SKU) • Physical process diagram of all supply chain functions used globally (including the location and cost of each warehouse, distribution centre, logistics fleet owned or leased) <p>10. The documents above should cover all cost categories, including but not limited to:</p>	<p>This information does not relate to transfer pricing.</p> <p>Reasonable Request</p> <p>This information does not relate to transfer pricing.</p> <p>Reasonable Request</p> <p>This information does not relate to transfer pricing.</p> <p>Reasonable Request</p> <p>This information does not relate to transfer pricing.</p> <p>Reasonable Request</p> <p>This information does not relate to transfer pricing.</p>	
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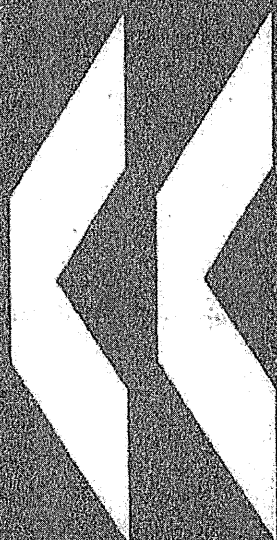
<ul style="list-style-type: none"> • Raw material costs (including API, excipients, other) • Packaging material costs • Direct labour costs (including set up, clean up, other) • Direct overhead costs • Direct quality assurance and quality control costs • Direct regulatory affairs costs • All indirect overhead costs (including indirect labour, allocated general and administrative expenses) • Other cost of sales (including manufacturing operations costs, inventory adjustments) • Supply chain costs (including freight distribution, warehouse, logistics) • Sales and marketing expenses (including medical affairs) • All research and development costs, past and ongoing 	This information does not relate to transfer pricing.	
11. Documents relating to the actual cost of distribution by Innomar Strategies Inc. for PROCYSBI sold in Canada, including but not limited to invoices and debit/credit memos	Reasonable Request This information does not relate to transfer pricing.	
12. Documents related to the calculation of transfer prices between all Horizon Pharma legal entities involved with PROCYSBI sold in Canada, and any adjustments to transfer prices, from the date of launch in Canada to the current date	Not a Reasonable Request These documents are not relevant as the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally based on sales to Canadian customers.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.
13. Documents related to any intercompany transfers of funds and/or product between all Horizon Pharma legal entities with respect to PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, debit/credit memos, intercompany payables/receivables, payment of dividends, payment of fees, and profit adjustments	Not a Reasonable Request These documents are not relevant as the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally based on sales to Canadian customers.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.
14. Any correspondence with income tax authorities in any jurisdiction regarding the transfer price of PROCYSBI	Not a Reasonable Request	Please refer to my responding comments above in Section A. Information relating to transfer pricing.

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	The income tax returns for any country are not relevant to the conclusions in the Hay Report. Not a Reasonable Request		Please refer to my responding comments above in Section A. Information relating to transfer pricing.
15. Any correspondence with income tax authorities in any jurisdiction regarding income taxes (income tax assessments) related to the sales of PROCYSBI	These documents are not relevant as the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally based on sales to Canadian customers. Not a Reasonable Request		Please refer to my responding comments above in Section A. Information relating to transfer pricing.
16. Any transfer pricing studies or reports done by external third party consultants or internally by Horizon Pharma relating to PROCYSBI	These documents are not relevant as the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally based on sales to Canadian customers. Reasonable Request		
17. Any breakeven analysis or analysis of internal rate of return ("IRR") done by Horizon Pharma regarding the sales of PROCYSBI globally, by region, by country	This information does not relate to transfer pricing. Reasonable Request		
<p>E. In order to analyze and validate the documents which we anticipate receiving and reviewing, we request for the opportunity to conduct an on-site inspection at the offices of Horizon Pharma (and manufacturing and distribution facilities) as necessary. For the purposes of performing this inspection, we would require access to the documents requested herein and access to Horizon Pharma's in-house knowledgeable staff to discuss and respond to our questions regarding Horizon's accounting processes and documentation, including but not limited to:</p> <p>HARRINGTON RESPONSE:</p> <p>As indicated in paragraph 21 of my affidavit, it is my opinion that an on-site inspection of Horizon Pharma (and any manufacturing and distribution facilities) is not necessary for Mr. Rosen to fulfill his mandate. Thus, the following responses refer only to Secretariat's request for document production.</p> <p>ROSEN RESPONSE:</p> <p>Please refer to my responding comments above in Section C. On-site inspection.</p>			
1. Documents that outline the economic relationships and activities of all Horizon Pharma legal entities and third parties globally that are involved with all economic activities associated with PROCYSBI	This request for documents is covered by the request in Item D(1), above.		Agreed, but we reserve the right to review the information produced for Item D(1) and to request further relevant information if necessary to understand the economic relationships and activities of all Horizon Pharma legal

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		entities and third parties globally that are involved with all economic activities associated with PROCYSBI.
2. Documents that detail the actual and forecasted revenues and costs of PROCYSBI earned/incurred by Horizon Pharma	Reasonable Request	
3. Documents that detail the nature of the actual cost of goods sold, standard cost of goods sold, and transfer pricing of PROCYSBI, and how the profits from the sales of PROCYSBI in Canada flow through all related Horizon Pharma legal entities for financial reporting purposes and for income tax purposes	Not a Reasonable Request These documents are not relevant as the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally based on sales to Canadian customers.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.
4. Documents that detail the nature of the Raptor Acquisition Cost	Reasonable Request	
5. Documents that detail the nature of Ongoing R&D Expenses	Reasonable Request	
6. Documents that detail the nature of each expense item under Other Cost of Sales and Supply Chain that are recorded on a global basis	Reasonable Request	
7. Documents that detail the nature of Sales and Marketing (and Medical Affairs) expenses that are recorded on a Canada wide basis	Reasonable Request	
8. Documents that detail the nature of General and Administrative expenses that are recorded on a global basis	Reasonable Request	



OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations

OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations

JULY 2017

This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

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Preface

1. The role of multinational enterprises (MNEs) in world trade has continued to increase dramatically since the adoption of these Guidelines in 1995. This in part reflects the increased pace of integration of national economies and technological progress, particularly in the area of communications. The growth of MNEs presents increasingly complex taxation issues for both tax administrations and the MNEs themselves since separate country rules for the taxation of MNEs cannot be viewed in isolation but must be addressed in a broad international context.
2. These issues arise primarily from the practical difficulty, for both MNEs and tax administrations, of determining the income and expenses of a company or a permanent establishment that is part of an MNE group that should be taken into account within a jurisdiction, particularly where the MNE group's operations are highly integrated.
3. In the case of MNEs, the need to comply with laws and administrative requirements that may differ from country to country creates additional problems. The differing requirements may lead to a greater burden on an MNE, and result in higher costs of compliance, than for a similar enterprise operating solely within a single tax jurisdiction.
4. In the case of tax administrations, specific problems arise at both policy and practical levels. At the policy level, countries need to reconcile their legitimate right to tax the profits of a taxpayer based upon income and expenses that can reasonably be considered to arise within their territory with the need to avoid the taxation of the same item of income by more than one tax jurisdiction. Such double or multiple taxation can create an impediment to cross-border transactions in goods and services and the movement of capital. At a practical level, a country's determination of such income and expense allocation may be impeded by difficulties in obtaining pertinent data located outside its own jurisdiction.
5. At a primary level, the taxing rights that each country asserts depend on whether the country uses a system of taxation that is residence-based, source-based, or both. In a residence-based tax system, a country will include in its tax base all or part of the income, including income from

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sources outside that country, of any person (including juridical persons such as corporations) who is considered resident in that jurisdiction. In a source-based tax system, a country will include in its tax base income arising within its tax jurisdiction, irrespective of the residence of the taxpayer. As applied to MNEs, these two bases, often used in conjunction, generally treat each enterprise within the MNE group as a separate entity. OECD member countries have chosen this separate entity approach as the most reasonable means for achieving equitable results and minimising the risk of unrelieved double taxation. Thus, each individual group member is subject to tax on the income arising to it (on a residence or source basis).

6. In order to apply the separate entity approach to intra-group transactions, individual group members must be taxed on the basis that they act at arm's length in their transactions with each other. However, the relationship among members of an MNE group may permit the group members to establish special conditions in their intra-group relations that differ from those that would have been established had the group members been acting as independent enterprises operating in open markets. To ensure the correct application of the separate entity approach, OECD member countries have adopted the arm's length principle, under which the effect of special conditions on the levels of profits should be eliminated.

7. These international taxation principles have been chosen by OECD member countries as serving the dual objectives of securing the appropriate tax base in each jurisdiction and avoiding double taxation, thereby minimising conflict between tax administrations and promoting international trade and investment. In a global economy, coordination among countries is better placed to achieve these goals than tax competition. The OECD, with its mission to contribute to the expansion of world trade on a multilateral, non-discriminatory basis and to achieve the highest sustainable economic growth in member countries, has continuously worked to build a consensus on international taxation principles, thereby avoiding unilateral responses to multilateral problems.

8. The foregoing principles concerning the taxation of MNEs are incorporated in the *OECD Model Tax Convention on Income and on Capital* (OECD Model Tax Convention), which forms the basis of the extensive network of bilateral income tax treaties between OECD member countries and between OECD member and non-member countries. These principles also are incorporated in the Model United Nations Double Taxation Convention between Developed and Developing Nations.

9. The main mechanisms for resolving issues that arise in the application of international tax principles to MNEs are contained in these bilateral treaties. The Articles that chiefly affect the taxation of MNEs are:

Article 4, which defines residence; Articles 5 and 7, which determine the taxation of permanent establishments; Article 9, which relates to the taxation of the profits of associated enterprises and applies the arm's length principle; Articles 10, 11, and 12, which determine the taxation of dividends, interest, and royalties, respectively; and Articles 24, 25, and 26, which contain special provisions relating to non-discrimination, the resolution of disputes, and exchange of information.

10. The Committee on Fiscal Affairs, which is the main tax policy body of the OECD, has issued a number of reports relating to the application of these Articles to MNEs and to others. The Committee has encouraged the acceptance of common interpretations of these Articles, thereby reducing the risk of inappropriate taxation and providing satisfactory means of resolving problems arising from the interaction of the laws and practices of different countries.

11. In applying the foregoing principles to the taxation of MNEs, one of the most difficult issues that has arisen is the establishment for tax purposes of appropriate transfer prices. Transfer prices are the prices at which an enterprise transfers physical goods and intangible property or provides services to associated enterprises. For purposes of these Guidelines, an "associated enterprise" is an enterprise that satisfies the conditions set forth in Article 9, sub-paragraphs 1a) and 1b) of the OECD Model Tax Convention. Under these conditions, two enterprises are associated if one of the enterprises participates directly or indirectly in the management, control, or capital of the other or if "the same persons participate directly or indirectly in the management, control, or capital" of both enterprises (i.e. if both enterprises are under common control). The issues discussed in these Guidelines also arise in the treatment of permanent establishments as discussed in the *Report on the Attribution of Profits to Permanent Establishments* that was adopted by the OECD Council in July 2010, which supersedes the OECD Report *Model Tax Convention: Attribution of Income to Permanent Establishments* (1994). Some relevant discussion may also be found in the OECD Report *International Tax Avoidance and Evasion* (1987).

12. Transfer prices are significant for both taxpayers and tax administrations because they determine in large part the income and expenses, and therefore taxable profits, of associated enterprises in different tax jurisdictions. Transfer pricing issues originally arose in transactions between associated enterprises operating within the same tax jurisdiction. The domestic issues are not considered in these Guidelines, which focus on the international aspects of transfer pricing. These international aspects are more difficult to deal with because they involve more than one tax jurisdiction and therefore any adjustment to the transfer price in one

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jurisdiction implies that a corresponding change in another jurisdiction is appropriate. However, if the other jurisdiction does not agree to make a corresponding adjustment the MNE group will be taxed twice on this part of its profits. In order to minimise the risk of such double taxation, an international consensus is required on how to establish for tax purposes transfer prices on cross-border transactions.

13. These Guidelines are intended to be a revision and compilation of previous reports by the OECD Committee on Fiscal Affairs addressing transfer pricing and other related tax issues with respect to multinational enterprises. The principal report is *Transfer Pricing and Multinational Enterprises* (1979) (the “1979 Report”) which was repealed by the OECD Council in 1995. Other reports address transfer pricing issues in the context of specific topics. These reports are *Transfer Pricing and Multinational Enterprises – Three Taxation Issues* (1984) (the “1984 Report”), and *Thin Capitalisation* (the “1987 Report”). A list of amendments made to these Guidelines is included in the Foreword.

14. These Guidelines also draw upon the discussion undertaken by the OECD on the proposed transfer pricing regulations in the United States [see the OECD Report *Tax Aspects of Transfer Pricing within Multinational Enterprises: The United States Proposed Regulations* (1993)]. However, the context in which that Report was written was very different from that in which these Guidelines have been undertaken, its scope was far more limited, and it specifically addressed the United States proposed regulations.

15. OECD member countries continue to endorse the arm’s length principle as embodied in the OECD Model Tax Convention (and in the bilateral conventions that legally bind treaty partners in this respect) and in the 1979 Report. These Guidelines focus on the application of the arm’s length principle to evaluate the transfer pricing of associated enterprises. The Guidelines are intended to help tax administrations (of both OECD member countries and non-member countries) and MNEs by indicating ways to find mutually satisfactory solutions to transfer pricing cases, thereby minimising conflict among tax administrations and between tax administrations and MNEs and avoiding costly litigation. The Guidelines analyse the methods for evaluating whether the conditions of commercial and financial relations within an MNE satisfy the arm’s length principle and discuss the practical application of those methods. They also include a discussion of global formulary apportionment.

16. OECD member countries are encouraged to follow these Guidelines in their domestic transfer pricing practices, and taxpayers are encouraged to follow these Guidelines in evaluating for tax purposes whether their transfer pricing complies with the arm’s length principle. Tax

Chapter I

The Arm's Length Principle

A. Introduction

1.1 This Chapter provides a background discussion of the arm's length principle, which is the international transfer pricing standard that OECD member countries have agreed should be used for tax purposes by MNE groups and tax administrations. The Chapter discusses the arm's length principle, reaffirms its status as the international standard, and sets forth guidelines for its application.

1.2 When independent enterprises transact with each other, the conditions of their commercial and financial relations (e.g. the price of goods transferred or services provided and the conditions of the transfer or provision) ordinarily are determined by market forces. When associated enterprises transact with each other, their commercial and financial relations may not be directly affected by external market forces in the same way, although associated enterprises often seek to replicate the dynamics of market forces in their transactions with each other, as discussed in paragraph 1.5 below. Tax administrations should not automatically assume that associated enterprises have sought to manipulate their profits. There may be a genuine difficulty in accurately determining a market price in the absence of market forces or when adopting a particular commercial strategy. It is important to bear in mind that the need to make adjustments to approximate arm's length conditions arises irrespective of any contractual obligation undertaken by the parties to pay a particular price or of any intention of the parties to minimize tax. Thus, a tax adjustment under the arm's length principle would not affect the underlying contractual obligations for non-tax purposes between the associated enterprises, and may be appropriate even where there is no intent to minimize or avoid tax. The consideration of transfer pricing should not be confused with the consideration of problems of tax fraud or tax avoidance, even though transfer pricing policies may be used for such purposes.

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1.3 When transfer pricing does not reflect market forces and the arm's length principle, the tax liabilities of the associated enterprises and the tax revenues of the host countries could be distorted. Therefore, OECD member countries have agreed that for tax purposes the profits of associated enterprises may be adjusted as necessary to correct any such distortions and thereby ensure that the arm's length principle is satisfied. OECD member countries consider that an appropriate adjustment is achieved by establishing the conditions of the commercial and financial relations that they would expect to find between independent enterprises in comparable transactions under comparable circumstances.

1.4 Factors other than tax considerations may distort the conditions of commercial and financial relations established between associated enterprises. For example, such enterprises may be subject to conflicting governmental pressures (in the domestic as well as foreign country) relating to customs valuations, anti-dumping duties, and exchange or price controls. In addition, transfer price distortions may be caused by the cash flow requirements of enterprises within an MNE group. An MNE group that is publicly held may feel pressure from shareholders to show high profitability at the parent company level, particularly if shareholder reporting is not undertaken on a consolidated basis. All of these factors may affect transfer prices and the amount of profits accruing to associated enterprises within an MNE group.

1.5 It should not be assumed that the conditions established in the commercial and financial relations between associated enterprises will invariably deviate from what the open market would demand. Associated enterprises in MNEs sometimes have a considerable amount of autonomy and can often bargain with each other as though they were independent enterprises. Enterprises respond to economic situations arising from market conditions, in their relations with both third parties and associated enterprises. For example, local managers may be interested in establishing good profit records and therefore would not want to establish prices that would reduce the profits of their own companies. Tax administrations should keep these considerations in mind to facilitate efficient allocation of their resources in selecting and conducting transfer pricing examinations. Sometimes, it may occur that the relationship between the associated enterprises may influence the outcome of the bargaining. Therefore, evidence of hard bargaining alone is not sufficient to establish that the transactions are at arm's length.

B. Statement of the arm's length principle

B.1 Article 9 of the OECD Model Tax Convention

1.6 The authoritative statement of the arm's length principle is found in paragraph 1 of Article 9 of the OECD Model Tax Convention, which forms the basis of bilateral tax treaties involving OECD member countries and an increasing number of non-member countries. Article 9 provides:

[Where] conditions are made or imposed between the two [associated] enterprises in their commercial or financial relations which differ from those which would be made between independent enterprises, then any profits which would, but for those conditions, have accrued to one of the enterprises, but, by reason of those conditions, have not so accrued, may be included in the profits of that enterprise and taxed accordingly.

By seeking to adjust profits by reference to the conditions which would have obtained between independent enterprises in comparable transactions and comparable circumstances (i.e. in “comparable uncontrolled transactions”), the arm's length principle follows the approach of treating the members of an MNE group as operating as separate entities rather than as inseparable parts of a single unified business. Because the separate entity approach treats the members of an MNE group as if they were independent entities, attention is focused on the nature of the transactions between those members and on whether the conditions thereof differ from the conditions that would be obtained in comparable uncontrolled transactions. Such an analysis of the controlled and uncontrolled transactions, which is referred to as a “comparability analysis”, is at the heart of the application of the arm's length principle. Guidance on the comparability analysis is found in Section D below and in Chapter III.

1.7 It is important to put the issue of comparability into perspective in order to emphasise the need for an approach that is balanced in terms of, on the one hand, its reliability and, on the other, the burden it creates for taxpayers and tax administrations. Paragraph 1 of Article 9 of the OECD Model Tax Convention is the foundation for comparability analyses because it introduces the need for:

- A comparison between conditions (including prices, but not only prices) made or imposed between associated enterprises and those which would be made between independent enterprises, in order to determine whether a re-writing of the accounts for the purposes of

calculating tax liabilities of associated enterprises is authorised under Article 9 of the OECD Model Tax Convention (see paragraph 2 of the Commentary on Article 9); and

- A determination of the profits which would have accrued at arm's length, in order to determine the quantum of any re-writing of accounts.

1.8 There are several reasons why OECD member countries and other countries have adopted the arm's length principle. A major reason is that the arm's length principle provides broad parity of tax treatment for members of MNE groups and independent enterprises. Because the arm's length principle puts associated and independent enterprises on a more equal footing for tax purposes, it avoids the creation of tax advantages or disadvantages that would otherwise distort the relative competitive positions of either type of entity. In so removing these tax considerations from economic decisions, the arm's length principle promotes the growth of international trade and investment.

1.9 The arm's length principle has also been found to work effectively in the vast majority of cases. For example, there are many cases involving the purchase and sale of commodities and the lending of money where an arm's length price may readily be found in a comparable transaction undertaken by comparable independent enterprises under comparable circumstances. There are also many cases where a relevant comparison of transactions can be made at the level of financial indicators such as mark-up on costs, gross margin, or net profit indicators. Nevertheless, there are some significant cases in which the arm's length principle is difficult and complicated to apply, for example, in MNE groups dealing in the integrated production of highly specialised goods, in unique intangibles, and/or in the provision of specialised services. Solutions exist to deal with such difficult cases, including the use of the transactional profit split method described in Chapter II, Part III of these Guidelines in those situations where it is the most appropriate method in the circumstances of the case.

1.10 The arm's length principle is viewed by some as inherently flawed because the separate entity approach may not always account for the economies of scale and interrelation of diverse activities created by integrated businesses. There are, however, no widely accepted objective criteria for allocating between associated enterprises the economies of scale or benefits of integration resulting from group membership. The issue of possible alternatives to the arm's length principle is discussed in Section C below.

OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations

The *OECD Transfer Pricing Guidelines for Multinational Enterprise and Tax Administrations* provide guidance on the application of the "arm's length principle", which is the international consensus on transfer pricing, i.e. on the valuation for tax purposes of cross-border transactions between associated enterprises. In a global economy where multinational enterprises (MNEs) play a prominent role, transfer pricing continues to be high on the agenda of tax administrations and taxpayers alike. Governments need to ensure that the taxable profits of MNEs are not artificially shifted out of their jurisdiction and that the tax base reported by MNEs in their country reflects the economic activity undertaken therein. For taxpayers, it is essential to limit the risks of economic double taxation that may result from a dispute between two countries on the determination of the arm's length remuneration for their cross-border transactions with associated enterprises.

This 2017 edition of the *OECD Transfer Pricing Guidelines* incorporates the substantial revisions made in 2016 to reflect the clarifications and revisions agreed in the 2015 BEPS Reports on Actions 8-10 *Aligning Transfer pricing Outcomes with Value Creation* and on Action 13 *Transfer Pricing Documentation and Country-by-Country Reporting*. It also includes the revised guidance on safe harbours approved in 2013 which recognises that properly designed safe harbours can help to relieve some compliance burdens and provide taxpayers with greater certainty. Finally, this edition also contains consistency changes that were made to the rest of the *OECD Transfer Pricing Guidelines*. The *OECD Transfer Pricing Guidelines* were approved by the OECD Council in their original version in 1995.

Consult this publication on line at <http://dx.doi.org/10.1787/tpg-2017-en>

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23 2016 33 1 P





TABB

This is Exhibit "B" referred to in the
affidavit of ANDREW C. HARINGTON
affirmed before me, this 10th
day of January, 2020.



A Commissioner, etc.

STACEY REISMAN

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

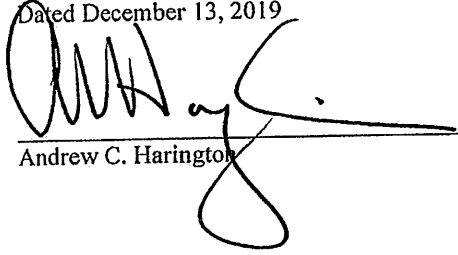
**AND IN THE MATTER OF
Horizon Pharma (the "Respondent")
and the medicine Cysteamine Bitartrate sold by the Respondent under the trade
name PROCYSBI®**

EXPERT WITNESS DECLARATION

I, Andrew Harington, of the City of Toronto, in the province of Ontario, DECLARE
THAT:

1. I have been retained by Torys LLP to provide evidence in the matter Horizon Pharma and the medicine Cysteamine Bitartrate sold by the Respondent under the trade name PROCYSBI®
2. It is my duty to provide evidence in relation to this proceeding as follows:
 - (a) to provide opinion evidence that is impartial;
 - (b) to provide opinion evidence that is related only to matters that are within my area of expertise; and
 - (c) to provide any additional assistance that the Board may reasonably require to determine a matter at issue.
3. I acknowledge that the duties referred to above take precedence over any obligation which I may owe to any party by whom or on whose behalf I am engaged.

Dated December 13, 2019

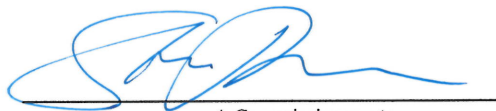


Andrew C. Harington



TABC

This is Exhibit "C" referred to in the
affidavit of ANDREW C. HARINGTON
affirmed before me, this 10th
day of January, 2020.



A Commissioner, etc.

STACEY REISMAN

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
A. Documents related to Horizon Pharma's Canadian subsidiary – HZNP Therapeutics Canada Limited (also known as Horizon Therapeutics Canada):			
1. HNZIP.xlsx (Horizon Financial Information) – listed in the Hay Report, Appendix D – Scope of Review, Item C.iii. – in Excel format	Reasonable Request		
2. Audited or unaudited annual financial statements – from the fiscal year ended 2015 (2 years prior to the launch of PROCTSB in Canada in September 7, 2017) to the current fiscal year	Reasonable Request		
3. Unaudited quarterly financial statements – from the first fiscal quarter of 2015 to the current fiscal quarter	The quarterly statements duplicate the request for the monthly statements in Item A(5), below.	This is not a duplicate request -this request is for unaudited quarterly financial statements prepared for financial reporting purposes, compiled or reviewed by the auditors. This request is similar to Item D(4), second bullet point, below. The request for Item A(5), below, is for detailed internal monthly profit & loss/income statements.	
4. Financial statements (balance sheet, income statement, statement of cash flows) prepared for internal reporting purposes/consolidation purposes – from the fiscal year ended 2015 (2 years prior to the launch of PROCYSBI in Canada in September 7, 2017) to the current fiscal year	Reasonable Request		
5. Detailed monthly profit & loss/income statements – from the first fiscal month of 2015 to the current month	Reasonable Request		
6. Detailed monthly profit & loss/income statements specifically for PROCYSBI, or any other documents that report profit & loss related to PROCYSBI sales in Canada – from September 2017 to the current month	Reasonable Request		

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
7. Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on sales, expenses, and profit & loss of PROCYSBI in Canada – from prior to the launch of PROCYSBI in Canada in September 7,2017 to the current date	Reasonable Request		
8. Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on conversion of patients from Cystagon to PROCYSBI in Canada-from prior to the launch of PROCYSBI in Canada in September 7,2017 to the current date	This information is covered by the request in Item A(7).	<p>This request is specifically for information on conversion of patients from Cystagon to PROCYSBI in Canada, which is in addition to information on sales, expenses, and profit & loss of PROCYSBI in Canada requested in Item A(7).</p> <p>We reserve the right to review the information produced for Item A(7) and to request the information in Item A(8) if It is not covered.</p>	<p>This information is covered by the request in Item A(7).</p> <p>Note that the assumptions regarding [REDACTED]</p> <p>[REDACTED]</p>
9. Data from IQVIA (formerly IMS Health) used by Horizon Pharma to analyze market share of PROCYSBI relative to Cystagon in each country – from January 2015 to the current month	<p>Not a Reasonable Request</p> <p>Information relating to sales of PROCYSBI relative to Cystagon in countries other than Canada is not relevant to the analysis.</p>	<p>The Hay Report relies on Horizon's forecasts [REDACTED]</p> <p>My request is reasonable to verify if the [REDACTED] are supported [REDACTED]</p> <p>[REDACTED] and to obtain data used by Horizon from IQVIA (formerly IMS Health) to analyze market share of PROCYSBI relative to Cystagon.</p>	[REDACTED]
10. Federal and provincial corporate income tax returns and schedules, specifically	Not a Reasonable Request	Horizon's Canadian corporate income tax returns are relevant to verify the income/profits	Neither the Canadian profit nor the income tax payable in Canada is relevant to the

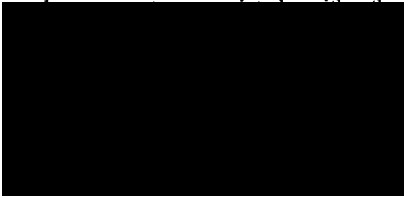

¹ The Hay Report, page F-1, para. 3.

² The Hay Report, page F-2, para. 5.

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
including the reconciliation of taxable income with accounting income-from the taxation year 2015 to current	The income tax payable in Canada is not relevant to the conclusions in the Hay Report.	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.	conclusions in the Hay Report. Please refer to my Summary of Opinion on transfer pricing.
B. Documents related to PROCYSBI sales:			
1. Detailed listing of all PROCYSBI sales transactions in Canada (from the sales subledger) from launch to the current date – detailing actual sales in units for all stock keeping units (“SKU”) (i.e. 25 mg 60 capsule bottles and 75 mg 250 capsule bottles) and unit price for each sale	It is not clear as to which sales this request relates (i.e., sales to wholesalers and pharmacies (which would be relevant for comparisons to information from IQVIA (formerly IMS Health) or sales by Horizon Pharma to Innomar Strategies. In any event, this appears to be a reasonable request.	This request is for all PROCYSBI sales transactions in Canada, including sales to wholesalers, pharmacies, and to Innomar Strategies.	
2. The above listing should include sales units provide free- of-charge (“free goods”), sales returns, and any other sales credit or debit transactions	It is not clear as to which sales this request relates (i.e., sales to wholesalers and pharmacies (which would be relevant for comparisons to information from IQVIA (formerly IMS Health) or sales by Horizon Pharma to Innomar Strategies. In any event, this appears to be a reasonable request.	This request is for all PROCYSBI sales transactions in Canada, including sales to wholesalers, pharmacies, and to Innomar Strategies.	
3. A sample of purchase orders, sales invoices, credit notes, and debit notes for each type of sales transaction, for each SKU	Reasonable Request		
4. Documents that support the assumption that [REDACTED] of Horizon’s patients will be covered by provincial and territorial drug benefit plans and [REDACTED] will be covered by private insurance plans	Reasonable Request		
5. Documents that support Horizon’s copy discount of [REDACTED] of covered costs to patients covered under private- insurance plans	Reasonable Request		
C. Documents related to PROCYSBI expenses:			
1. All agreements and amendments related to royalties to the Regents of the	Reasonable Request		

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
University of California, including but not limited to:			
<ul style="list-style-type: none"> Amended and Restated License Agreement, dated May 31, 2017, by and between Horizon Orphan LLC and The Regents of the University of California 	Reasonable Request		
<ul style="list-style-type: none"> Amendment No. 1 to Amended and Restated License Agreement, dated September 11, 2018, by and between Horizon Orphan LLC and The Regents of the University of California 	Reasonable Request		
2. Documents that support the calculation of royalties payable from sales of PROCYSBI in Canada and the payment of the royalties	Reasonable Request		
3. Documents supporting reported cost of goods sold and per unit standard cost for PROCYSBI Canada for both SKUs (figures contained in the Hay Report, Exhibit B)	Reasonable Request		
4. Purchase orders and invoices for all PROCYSBI units purchased for sale in Canada	<p>It is not clear to which entity this request relates.</p> <p>If the requested documents are for purchases by Horizon Canada from other Horizon entities, then this is not a reasonable request. The conclusions in the Hay Report relate to profit for Horizon as a whole.</p> <p>If the requested documents are for purchases by Horizon from third parties, then this request is addressed by the request in D(3) below.</p>	<p>This request is for purchases by Horizon Canada from other Horizon entities, or to the extent that Horizon Canada purchases PROCYSBI for sale in Canada from third parties, then the request is for those entities.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>	<p>Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.</p>
5. Documents supporting cost of goods sold for PROCYSBI Global (figures contained in the Hay Report, Exhibit C)	Reasonable Request		

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
6. Documents that support each expense item under other cost of sales and supply chain (figures contained in the Hay Report, Exhibit C), including but not limited to:	Reasonable Request		
• Expense subledgers	Reasonable Request		
• Internal reports used to analyze these expenses	Reasonable Request		
• Allocations of these costs to specific products, geographic regions, or countries	Reasonable Request		
7. Documents that explain what “manufacturing operations” expenses relate to and whether any of these costs are imbedded in the standard cost/cost of goods sold for PROCYSBI sold in Canada	Reasonable Request		
8. Documents that explain what “inventory adjustments” relate to and whether any inventory adjustments were specific to PROCYSBI sold in Canada	Reasonable Request		
9. Documents that explain what “supplychain” and “freight & warehouse” expenses relate to and whether any of these expenses were specific to PROCYSBI sold in Canada	Reasonable Request		
10. Documents that explain what each “sales and marketing expense” item (and “medical affairs”) relates to and support how each item should be allocated to PROCYSBI sold in Canada	Reasonable Request		
11. Documents that explain what each “general and administrative” expense item relates to and support how each item	Reasonable Request		

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
should be allocated to PROCYSBI sold in Canada			
12. Documents relating to executive and managerial salaries and bonuses, and other employee costs that support how these expenses should be allocated to PROCYSBI sold in Canada	Reasonable Request		
13. Documents that detail selling, general and administrative expenses that should be specifically excluded from an allocation to PROCYSBI sold in Canada, 	Reasonable Request		
14. Documents that explain what “ongoing research and development” expenses relate to and support how these expenses should be allocated to PROCYSBI sold in Canada	Reasonable Request		
15. Documents that support why a growth rate of  is reasonable for continuing R&D expenditures for PROCYSBI sold in Canada	Reasonable Request		
16. Documents that support Horizon Pharma’s acquisition of the worldwide marketing rights to PROCYSBI through its acquisition of Raptor Pharmaceutical Corp. in October 2017 (“Raptor Acquisition Cost” or “Raptor Development Costs”) and the allocation of the development and commercial expenditures for PROCYSBI to PROCYSBI sold in Canada, including but not limited to:	Reasonable Request		

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
<ul style="list-style-type: none"> Documents that supported the due diligence of all research and development, regulatory, and quality costs 	Reasonable Request		
<ul style="list-style-type: none"> Valuation reports done by external third party consultants or internally by Horizon Pharma relating to this acquisition transaction, and other related documents used in the allocation of the purchase price into tangible and intangible assets and liabilities 	Reasonable Request		
<ul style="list-style-type: none"> Detailed costing documents that provide a build-up of historical research and development expenditures, and regulatory and quality costs spent prior to the Raptor transaction 	Reasonable Request		
<ul style="list-style-type: none"> Any internal analysis comparing these past costs to those spent by Horizon Pharma after the acquisition 	Reasonable Request		
17. Documents that detail which Horizon Pharma legal entity holds and records the intellectual property/intangible assets (the developed technology) associated with PROCYSBI	This information is covered by the request in Item D(1).	Agreed, but we reserve the right to review the information produced for Item D(1) and to request further relevant information if necessary, to understand and verify the accounting for the intellectual property/intangible assets (the developed technology) associated with PROCYSBI.	
18. Documents which support Horizon Pharma's impairment tests relating to PROCYSBI	<p>It is not clear whether this request relates to Horizon Pharma Canada or Horizon Pharma globally.</p> <p>This is a reasonable request only as it relates to Horizon Pharma Canada, as the documents are relevant only to the extent of impairment relating to Canadian related assets of PROCYSBI. To the extent this request relates</p>	<p>This request relates to Horizon Pharma Canada. We note that stating this request is not reasonable if it relates to Horizon Pharma globally is contradictory to all the other statements in Mr. Harington's response that the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by</p>	<p>An impairment test that looks at Horizon Pharma globally is not relevant because the profits generated by Horizon on sales in other markets is a function of:</p> <ul style="list-style-type: none"> The selling price in those markets, which is not relevant to Mr. Rosen's mandate;

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
	to Horizon Pharma globally, it is not a reasonable request.	Horizon globally or profit for Horizon as a whole.	<ul style="list-style-type: none"> - The market specific selling expenses incurred in those markets, which is not relevant to Mr. Rosen's mandate; and - The costs of manufacturing the product sold in those markets which, while relevant to Mr. Rosen's mandate, is fully addressed by the information requested by Mr. Rosen at D(10).
<p>D. Documents related to PROCYSBI transfer pricing:</p> <p>HARINGTON RESPONSE: As stated in paragraph 18(1) of my affidavit, the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers. Thus, information relating to the transfer pricing system and resulting share of profit in each legal entity or country is not relevant. However, this section also contains requests for information that I consider appropriate as providing relevant background information, but which do not relate to transfer pricing. For those documents, I have indicated the item as being a Reasonable Request.</p>			
1. Corporate organizational charts that present all Horizon Pharma legal entities and third parties globally that are involved with all economic activities associated with PROCYSBI, including but not limited to entities that:	Reasonable Request		
<ul style="list-style-type: none"> • Manufacture the active pharmaceutical ingredient ("API") cysteamine bitartrate 			
<ul style="list-style-type: none"> • Purchase and receive the API 			
<ul style="list-style-type: none"> • Supply the excipients 			
<ul style="list-style-type: none"> • Manufacture the finished product (capsulation of the PROCYSBI capsules), including the application of PROCYSBI's enteric coating, delayed release formulation 			
<ul style="list-style-type: none"> • Package and label the finished SKUs for the Canadian market 			

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
<ul style="list-style-type: none"> Warehouse and distribute the finished SKUs in the Canadian market 			
<ul style="list-style-type: none"> Provide other services such as arranging for the above activities, accounting services such as invoicing, managing intercompany relationships 			
<ul style="list-style-type: none"> Hold the rights to the intellectual property (intangible assets) related to PROCYSBI 			
<ul style="list-style-type: none"> Hold the distribution rights for the Canadian market 			
<p>2. All agreements and amendments between Horizon Pharma legal entities involved with PROCYSBI, and other related documents to understand transfer pricing arrangements, price adjustment mechanisms, profit adjustment mechanisms, any mark-ups and fees charged, and intercompany arrangements</p>	<p>Not a Reasonable Request</p> <p>The analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally based on sales to Canadian customers. Thus, information relating to the transfer pricing system and resulting share of profit in each legal entity or country is not relevant.</p>	<p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>	<p>Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.</p>
<p>3. All agreements and amendments with third parties involved with PROCYSBI, including but not limited to:</p>	<p>Reasonable Request</p>		
<ul style="list-style-type: none"> API Supply Agreement, dated November 3, 2010, by and among Cambrex Profarmaco Milano, Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to RaptorPharmaceuticals Europe B.V.), as amended April 9, 2013 			
<ul style="list-style-type: none"> Any other raw materials supply agreements 			

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
<ul style="list-style-type: none"> Manufacturing Services Agreement, dated November 15, 2010, by and among Patheon Pharmaceuticals Inc., Horizon Orphan LLC (as successor in interest to Raptor Therapeutics Inc.) and Horizon Pharma Europe B.V. (as successor in interest to Raptor Pharmaceuticals Europe B.V.), as amended April 5, 2012 and June 21, 2013 			
<ul style="list-style-type: none"> Any other contract manufacturing services agreements 			
<ul style="list-style-type: none"> Any distribution agreements and amendments with Innomar Strategies Inc. 			
<ul style="list-style-type: none"> Any other warehousing, logistics, or co-distribution agreements 			
4. For all Horizon Pharma legal entities that are involved with the economic activities associated with PROCYSBI, financial documents including but not limited to:	See individual responses, below.		
<ul style="list-style-type: none"> Audited or unaudited annual financial statements – from the fiscal year ended 2015 (2 years prior to the launch of PROCYSBI in Canada in September 7, 2017) to the current fiscal year 	<p>These documents have already been provided. For 2016, 2017 and 2018 see Horizon Pharma Annual Report 2016, Horizon Pharma Annual Report 2017 and Horizon Pharma Annual Report 2018 listed in the Hay Report, Appendix D, items ixxxiv, ixxxv and xc.</p> <p>For 2015, see https://ir.horizontherapeutics.com/static-files/96f5aad2-7e30-4c3c-950c-f77097623f59.</p>	<p>The documents referred to in Mr. Harington's Response are Horizon's consolidated financial statements in the annual reports. My request was for the financial statements for each Horizon Pharma legal entity involved with the economic activities associated with PROCYSBI.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>	<p>Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.</p>
<ul style="list-style-type: none"> Unaudited quarterly financial statements – from the first fiscal quarter of 2015 to the current fiscal quarter 	<p>These documents are publicly available. See Quarterly financial statements available at https://ir.horizontherapeutics.com/financial-information/sec-filings?field_nir=see_form_group_target_id%5B%5D=496&field_nir=sec</p>	<p>The documents referred to in Mr. Harington's Response are Horizon's consolidated financial statements in the quarterly reports. My request was for the financial statements for each Horizon Pharma legal entity involved with the</p>	<p>Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.</p>

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
	<p><u>date filed value=&items per page=10#views-exposed-form-widget-see-filings-table.</u></p>	<p>economic activities associated with PROCYSBI.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>	
<ul style="list-style-type: none"> Financial statements (balance sheet, income statement, statement of cash flows) prepared for internal reporting purposes/consolidation purposes – from the fiscal year ended 2015 (2 years prior to the launch of PROCYSBI in Canada in September 7, 2017) to the current fiscal year 	<p>Not a Reasonable Request</p> <p>These documents are not relevant as the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers.</p>	<p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>	<p>Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.</p>
<ul style="list-style-type: none"> Detailed monthly profit & loss/income statements – from the first fiscal month of 2015 to the current month 	<p>Not a Reasonable Request</p> <p>These documents are not relevant as the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers.</p>	<p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>	<p>Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.</p>
<ul style="list-style-type: none"> Detailed monthly profit & loss/income statements specifically for PROCYSBI, or any other documents that report profit & loss related to PROCYSBI sales globally – from the first fiscal month of 2015 to the current month 	<p>Reasonable Request</p>		
<ul style="list-style-type: none"> Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on sales, expenses, and profit & loss of PROCYSBI globally-from prior to the launch of PROCYSBI in each country/market to the current date 	<p>This is a reasonable request only to the extent that it relates to sales of PROCYSBI in Canada.</p>	<p>We note that this is contradictory to all the other statements in Mr. Harington's response that the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally or profit for Horizon as a whole.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>	<p>The profits generated by Horizon on sales in other markets is a function of:</p> <ul style="list-style-type: none"> The selling price in those markets, which is not relevant to Mr. Rosen's mandate; The market specific selling expenses incurred in those markets, which is not relevant to Mr. Rosen's mandate; and The costs of manufacturing the product sold in those markets which, while relevant to Mr. Rosen's

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
			mandate, is fully addressed by the information requested by Mr. Rosen at D(10)
<ul style="list-style-type: none"> Business plans, marketing plans, forecasts, budgets, and management presentations that contain information on conversion of patients from Cystagon to PROCYSBI globally – from prior to the launch of PROCYSBI in each country/market to the current date 	This is a reasonable request only to the extent that it relates to sales of PROCYSBI in Canada.	<p>We note that this is contradictory to all the other statements in Mr. Harington's response that the analysis and conclusions in the Hay Report are based on the <u>aggregate</u> profit generated by Horizon globally or profit for Horizon as a whole.</p> <p>Please refer to my responding comments above in Section A. Information relating to transfer pricing.</p>	<p>The profits generated by Horizon on sales in other markets is a function of:</p> <ul style="list-style-type: none"> The selling price in those markets, which is not relevant to Mr. Rosen's mandate; The market specific selling expenses incurred in those markets, which is not relevant to Mr. Rosen's mandate; and The costs of manufacturing the product sold in those markets which, while relevant to Mr. Rosen's mandate, is fully addressed by the information requested by Mr. Rosen at D(10)
<ul style="list-style-type: none"> Data from IQVIA (formerly IMS Health) used by Horizon Pharma to analyze market share of PROCYSBI relative to Cystagon in each country – from prior to the launch of PROCYSBI in each country/market to the current date 	<p>Not a Reasonable Request</p> <p>Information as to sales of PROCYSBI relative to Cystagon in countries other than Canada is not relevant to the analysis. Further, this information request is covered by the request in Item A(9), above.</p>	<p>The Hay Report relies on Horizon's forecasts</p> <p>[REDACTED]</p> <p>My request is reasonable to verify if the forecasts [REDACTED] and to obtain data used by Horizon from IQVIA (formerly IMS Health) to analyze market share of PROCYSBI relative to Cystagon.</p>	[REDACTED]
<ul style="list-style-type: none"> Income tax returns and schedules, specifically including the reconciliation of taxable income with accounting income for each jurisdiction – from the taxation year 2015 to current 	<p>Not a Reasonable Request</p> <p>The income tax returns for any country are not relevant to the conclusions in the Hay Report.</p>	Please refer to my responding comments above in Section A. Information relating to transfer pricing.	Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.

³ The Hay Report, page F-1, para. 3.

⁴ The Hay Report, page F-2, para. 5.

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Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
5. Documents relating to the actual cost of API supplied by Cambrex Profarmaco Milano that was used in PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, and debit/credit memos	Reasonable Request This information does not relate to transfer pricing.		
6. Documents relating to the actual cost of excipients used in PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, and debit/credit memos	Reasonable Request This information does not relate to transfer pricing.		
7. Documents relating to the actual cost of manufacturing (capsulation) by Patheon Pharmaceuticals Inc. for PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, and debit/credit memos	Reasonable Request This information does not relate to transfer pricing.		
8. Documents relating to the actual cost of packaging and labelling of finished SKUs for PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, and debit/credit memos	Reasonable Request This information does not relate to transfer pricing.		
9. To the extent that Horizon Pharma performs any manufacturing of (capsulation, application of PROCYSBI's enteric coating, delayed release formulation), packaging and/or labelling, and supply chain (freight, distribution, warehouse, logistics) functions for PROCYSBI sold in Canada, documents relating to the actual cost of performing these functions, including but not limited to:	Reasonable Request This information does not relate to transfer pricing.		
• Master formula card/recipe sheets			
• Internal cost sheets			

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Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
<ul style="list-style-type: none"> • Calculations of standard cost (by month) 			
<ul style="list-style-type: none"> • Tracking of actual costs and cost variances 			
<ul style="list-style-type: none"> • Physical process diagram of all machinery used in each process (including the location and cost of each asset owned or leased) 			
<ul style="list-style-type: none"> • Information regarding the annual theoretical capacity and actual usage for each machine (by dosage/capsule/SKU) 			
<ul style="list-style-type: none"> • Physical process diagram of all supply chain functions used globally (including the location and cost of each warehouse, distribution centre, logistics fleet owned or leased) 			
10. The documents above should cover all cost categories, including but not limited to:	Reasonable Request This information does not relate to transfer pricing.		
<ul style="list-style-type: none"> • Raw material costs (including API, excipients, other) 			
<ul style="list-style-type: none"> • Packaging material costs 			
<ul style="list-style-type: none"> • Direct labour costs (including set up, clean up, other) 			
<ul style="list-style-type: none"> • Direct overhead costs 			
<ul style="list-style-type: none"> • Direct quality assurance and quality control costs 			
<ul style="list-style-type: none"> • Direct regulatory affairs costs 			

Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
<ul style="list-style-type: none"> All indirect overhead costs (including indirect labour, and allocated general and administrative expenses) 			
<ul style="list-style-type: none"> Other cost of sales (including manufacturing operations costs, inventory adjustments) 			
<ul style="list-style-type: none"> Supply chain costs (including freight distribution, warehouse, logistics) 			
<ul style="list-style-type: none"> Sales and marketing expenses (including medical affairs) 			
<ul style="list-style-type: none"> All research and development costs, past and ongoing 			
11. Documents relating to the actual cost of distribution by Innomar Strategies Inc. for PROCYSBI sold in Canada, including but not limited to invoices and debit/credit memos	Reasonable Request This information does not relate to transfer pricing.		
12. Documents related to the calculation of transfer prices between all Horizon Pharma legal entities involved with PROCYSBI sold in Canada, and any adjustments to transfer prices, from the date of launch in Canada to the current date	Not a Reasonable Request These documents are not relevant as the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.	Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.
13. Documents related to any intercompany transfers of funds and/or product between all Horizon Pharma legal entities with respect to PROCYSBI sold in Canada, including but not limited to purchase orders, invoices, debit/credit memos, intercompany payables / receivables, payment of dividends, payment of fees, and profit adjustments	Not a Reasonable Request These documents are not relevant as the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.	Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.

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Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
14. Any correspondence with income tax authorities in any jurisdiction regarding the transfer price of PROCYSBI	Not a Reasonable Request The income tax returns for any country are not relevant to the conclusions in the 1 lay Report.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.	Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.
15. Any correspondence with income tax authorities in any jurisdiction regarding income taxes (income tax assessments) related to the sales of PROCYSBI	Not a Reasonable Request These documents are not relevant as the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.	Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.
16. Any transfer pricing studies or reports done by external third party consultants or internally by Horizon Pharma relating to PROCYSBI	Not a Reasonable Request These documents are not relevant as the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.	Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.
17. Any breakeven analysis or analysis of internal rate of return ("IRR") done by Horizon Pharma regarding the sales of PROCYSBI globally, by region, by country	Reasonable Request This information does not relate to transfer pricing.		
<p>E. In order to analyze and validate the documents which we anticipate receiving and reviewing, we request for the opportunity to conduct an on-site inspection at the offices of Horizon Pharma (and manufacturing and distribution facilities) as necessary. For the purposes of performing this inspection, we would require access to the documents requested herein and access to Horizon Pharma's in-house knowledgeable staff to discuss and respond to our questions regarding Horizon's accounting processes and documentation, including but not limited to:</p> <p>HARINGTON RESPONSE:</p> <p>As indicated in paragraph 21 of my affidavit, it is my opinion that an on-site inspection of Horizon Pharma (and any manufacturing and distribution facilities) is not necessary for Mr. Rosen to fulfill his mandate. Thus, the following responses refer only to Secretariat's request for document production.</p> <p>ROSEN RESPONSE:</p> <p>Please refer to my responding comments above in Section C. On-site inspection.</p>			
1. Documents that outline the economic relationships and activities of all Horizon Pharma legal entities and third parties globally that are involved with all	This request for documents is covered by the request in Item D(1), above.	Agreed, but we reserve the right to review the information produced for Item D(1) and to request further relevant information if necessary to understand the economic relationships and activities of all Horizon Pharma legal entities and third parties globally.	

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Secretariat Request	Harington Response to Secretariat Request	Secretariat Response	Harington Reply
economic activities associated with PROCYSBI		that are involved with all economic activities associated with PROCYSBI.	
2. Documents that detail the actual and forecasted revenues and costs of PROCYSBI earned/incurred by Horizon Pharma	Reasonable Request		
3. Documents that detail the nature of the actual cost of goods sold, standard cost of goods sold, and transfer pricing of PROCYSBI, and how the profits from the sales of PROCYSBI in Canada flow through all related Horizon Pharma legal entities for financial reporting purposes and for income tax purposes	Not a Reasonable Request These documents are not relevant as the analysis and conclusions in the Hay Report are based on the aggregate profit generated by Horizon globally based on sales to Canadian customers.	Please refer to my responding comments above in Section A. Information relating to transfer pricing.	Please refer to my Summary of Opinion regarding transfer pricing and the profits of Horizon Canada.
4. Documents that detail the nature of the Raptor Acquisition Cost	Reasonable Request		
5. Documents that detail the nature of Ongoing R&D Expenses	Reasonable Request		
6. Documents that detail the nature of each expense item under Other Cost of Sales and Supply Chain that are recorded on a global basis	Reasonable Request		
7. Documents that detail the nature of Sales and Marketing (and Medical Affairs) expenses that are recorded on a Canada wide basis	Reasonable Request		
8. Documents that detail the nature of General and Administrative expenses that are recorded on a global basis	Reasonable Request		