
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

Reply Expert Report of Howard Rosen
Secretariat

November 3, 2020

Privileged & Confidential

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LIST OF SCHEDULES

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Schedule 5	Secretariat Analysis of Cost of Goods Sold for PROCYSBI
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GLOSSARY

Term	Description
IRR	Internal rate of return
NC	Nephropathic cystinosis
R&D	Research and development

1. INTRODUCTION

A. Assignment

1.1. I have been requested by Perley-Robertson, Hill & McDougall LLP (“Counsel”), on behalf of Board Staff of the Patented Medicine Prices Review Board (“Board Staff”), to review the responding report prepared by Dr. Joel Hay dated October 6, 2020 (the “Hay Responding Report”) and to calculate the impact, from a financial and economic perspective, of a 47% price reduction of PROCYSBI in Canada on Horizon’s profits based on the methodology set out in my first report dated October 6, 2020 (the “Rosen Report”).

B. Qualifications

1.2. My *curriculum vitae* was attached as Appendix 1 in the Rosen Report.

C. Independence

1.3. In preparing this reply report, I have been assisted by Secretariat staff working under my direction, supervision, and review.¹ The Secretariat professionals engaged on this assignment have acted independently and objectively in carrying out this assignment. None of the Secretariat professionals that were engaged on this assignment has owned, or currently owns, directly or indirectly, any of the shares of the parties involved, nor does Secretariat have any financial interest whatsoever in the outcome of this matter.

1.4. The fees payable to Secretariat related to the delivery of this report are not contingent on the conclusions reached or any action or event relating to this report, including the outcome of this matter. Secretariat’s fees are based on time expended at hourly rates, plus disbursements related to the engagement and any taxes hereon.

1.5. Nothing in this report expresses an opinion on matters of law, which are outside my expertise.

¹ As used herein, other than references to my education and experience, “I” and “We” shall mean either I personally or those personnel working under my supervision. Also, “My”, “Our”, and “Us” shall also refer to actions taken by me personally or by those personnel under my supervision.

D. Reporting Standards

- 1.6. This reply report has been prepared in conformity with the Practice Standards of the Canadian Institute of Chartered Business Valuators (“CICBV”) of which I am a member in good standing. The relevant Practice Standards of the CICBV include those governing the preparation of Limited Critique Reports (CICBV Standards 410, 420, and 430) and Expert Reports (CICBV Standards 310, 320, and 330). I have prepared this reply report to be a Limited Critique Report and an Expert Report under Standards 410 and 310 (Report Disclosure Standards) of the CICBV Practice Standards. CICBV Standards 410 and 310 were appended as Appendix 2 in the Rosen Report.
- 1.7. All currency amounts contained in this report are stated in US dollars unless otherwise noted.

E. Restrictions

- 1.8. This reply report is not intended for general circulation or publication, nor is it to be reproduced, referred to, or used without my or Secretariat’s written consent, for any purpose whatsoever other than for the purpose referred to above. Secretariat and I shall not assume any responsibility or liability for losses occasioned to any party as a result of the circulation, reproduction, reference to, or use of this reply report contrary to the provisions of this paragraph.
- 1.9. I believe that the analyses in this reply report must be considered in its entirety and that selecting portions of the analyses, without considering all factors and analyses together, could result in the misinterpretation of the comments and analyses concerning the quantum of financial loss. The preparation of such a report is a complex process and the components cannot be viewed in isolation. Any attempt to do so could lead to undue emphasis on any particular factor or analysis.
- 1.10. I reserve the right, but am under no obligation, to review the analyses of this reply report, and if considered necessary by me, to revise the analyses in light of any information which becomes known after the date of this reply report.

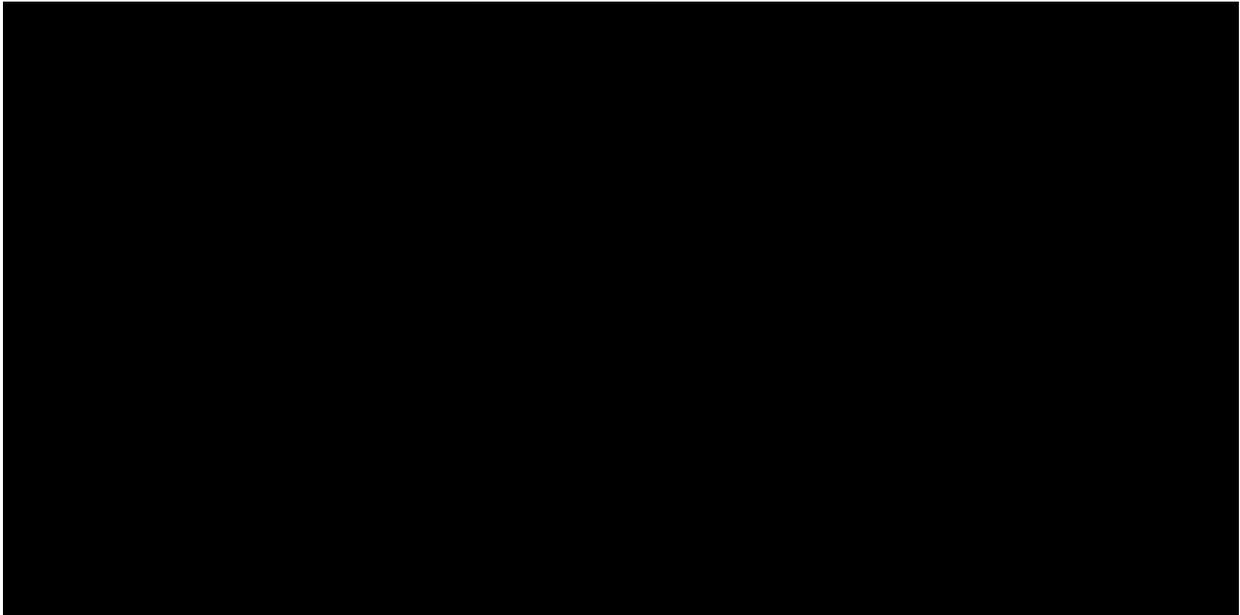
F. Scope of Review

- 1.11. In the preparation of this reply report, I have relied on the documents set forth in Appendix 3 of the Rosen Report and in Appendix 1 of this reply report.

2. SUMMARY OF THE HAY RESPONDING REPORT

- 2.1. A summary of the undiscounted profits from the sale of PROCYSBI in Canada under a 47% price reduction scenario as computed in the Hay Responding Report based on [REDACTED] [REDACTED] (compared to the profits under the other scenarios from the Hay Report) is provided below.

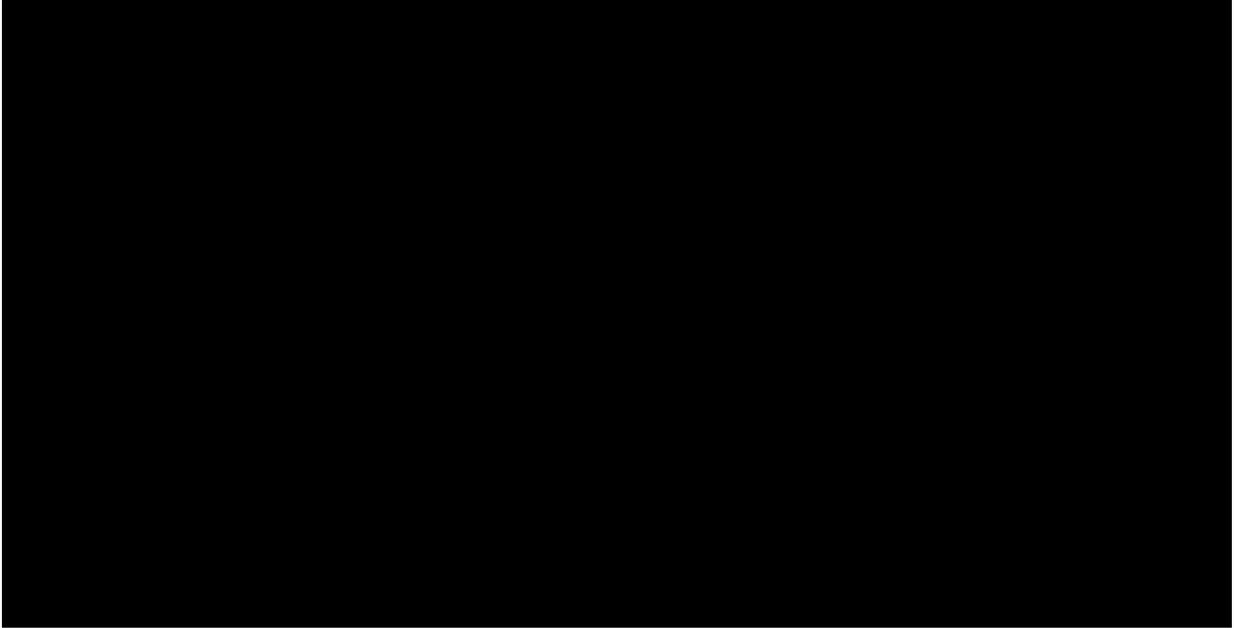
Figure 1: Summary of Undiscounted Profits – Hay Report and Hay Responding Report – Canada’s Share of Patients



- 2.2. A summary of the undiscounted profits from the sale of PROCYSBI in Canada under a 47% price reduction scenario as computed in the Hay Responding Report based on [REDACTED] [REDACTED] (compared to the profits under the other scenarios from the Hay Addendum) is provided below.

² The Hay Responding Report, Schedule 4.
³ The Hay Responding Report, Schedule 4S.

**Figure 2: Summary of Undiscounted Profits – Hay Addendum⁴ and Hay Responding Report
– Canada’s Share of Unit Sales**



⁴ The Hay Addendum, Schedule 1S to 3S.
Please note that Dr. Hay did not provide the profits calculation at Horizon’s ex-factory prices (Exhibit G of the Hay Report) in the Hay Addendum. Therefore, for illustrative purposes, I have calculated the profits at Horizon’s ex-factory prices by updating the difference between the Hay Report and the Hay Addendum, i.e. the allocation of the Raptor Acquisition Cost and ongoing R&D expenses (see Schedule 10 of the Rosen Report).

3. CALCULATION AND ANALYSIS OF PROFITS

A. Calculation of Profits

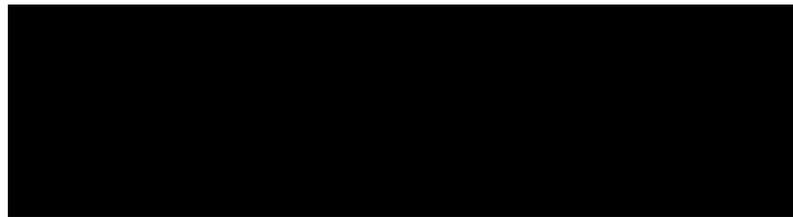
3.1 In this section, I provide my calculation and analysis of the expected net operating profits from the sale of PROCYSBI in Canada from the perspective of Horizon Canada and the Horizon Group under a 47% price reduction scenario, using the same methodology set out in Section 6 of the Rosen Report.

3.2 To compute the expected net operating profits for Horizon Canada from the sale of PROCYSBI in Canada during the period from 2017 to [REDACTED] (Schedules 1 and 2), I have made the following assumptions:

3.3 For sales volumes, gross and net sales prices, I have adopted the following assumptions used by Dr. Hay:

- a) Horizon would sell [REDACTED]
- b) Horizon would sell PROCYSBI in Canada through to [REDACTED]
[REDACTED] As such, I have adopted the following prices to compute expected cash flows:

Figure 3: Summary of Sales Prices Under a 47% Price Reduction



- c) Rebates and discounts at the rate of [REDACTED] of gross revenues.

3.4 For cost of goods sold (Schedules 5, 11, and 12), I have assumed:

- a) Fully loaded standard costs computed by Horizon from 2017 to 2020 (Figure 19 of the Rosen Report); and
- b) Thereafter, cost of goods sold increasing at the rate of 3% per annum up to [REDACTED]

3.5 For royalties, I have adopted Dr. Hay's assumption that Horizon would be required to pay 5.5% of net revenues to the University of California under the License Agreement.

3.6 I have also adopted Dr. Hay's estimates for sales and marketing expenses to be incurred by Horizon for its Canadian operations, except for the unidentified cost item that he included for 2017 as described in Section 5D of the Rosen Report. Further, I have allocated sales and

- marketing expenses to PROCYSBI on a pro-rata basis according to its share of total Horizon net revenues in Canada from 2017 to [REDACTED] (Schedule 6).
- 3.7 For the cost of PROCYSBI's development and commercialization, I have adopted Dr. Hay's estimates of R&D expenses incurred by Horizon globally, but as detailed in Section 5E of the Rosen Report, I disagree with Dr. Hay's allocation of the Raptor Acquisition Cost to PROCYSBI in Canada, [REDACTED]
- [REDACTED] In my view, the Raptor Acquisition Cost and ongoing R&D expenses should be allocated to PROCYSBI in Canada based on the economic benefits derived from the sale of PROCYSBI, which should be measured by the ratio of revenue reported by Horizon from the sale of PROCYSBI in Canada to the total revenue earned by Horizon from the sale of PROCYSBI globally. However, disclosure in Horizon's financial statements do not provide the breakdown of revenues from the sale of PROCYSBI in Canada and across the rest of the world from 2016 to 2019. Absent this information, and as a proxy, I have allocated the Raptor Acquisition Cost (Schedule 7) and ongoing R&D expenses (Schedule 8) to PROCYSBI in Canada on a pro-rata basis based on the average of revenues for all products reported by Horizon from rest of the world relative to the total revenue for all products earned by Horizon globally over the past four years, with an average rate of [REDACTED] (Schedule 7).
- 3.8 My allocation based on revenues is consistent with the methodology adopted in the KPMG Valuation of Identifiable Subject Assets and Liabilities in Connection with the Acquisition of Raptor, dated October 24, 2016, which allocated the value based on expected cash flows from each region over PROCYSBI's patent period, as detailed in Section 5E of the Rosen Report. My allocation also reflects the fact that the US was and continues to be the highest revenue generating region, with the US contributing over 90% of revenues reported by Raptor Pharma until 2015,⁵ and by Horizon of 98%-99% in 2018 and 2019.⁶
- 3.9 I have excluded other cost of sales and general and administrative expenses when computing net operating profits for Horizon Canada. I have included these costs while computing profits from the sale of PROCYSBI in Canada from the perspective of Horizon's business globally.

⁵ RR-6 – Raptor Pharmaceutical Corp. Form 10-K for the fiscal year ended December 31, 2015, Page 139.

⁶ RR-10 – Horizon Therapeutics Public Limited Company Form 10-K for the fiscal year ended December 31, 2019, Page 99.

- 3.10 For other cost of sales, I have adopted Dr. Hay's estimates, but these costs are allocated on a pro-rata basis according to the number of units sold in Canada to the number of units sold worldwide in the fourth quarter of 2019 (Schedule 9).
- 3.11 For general and administrative expenses (Schedules 10 and 13), I have only deducted costs relating to key support functions such as human resources, finance, legal, business development, and information technology that may be attributed to Horizon's day to day operations in Canada. [REDACTED]
[REDACTED]
[REDACTED]
- 3.12 Based on the assumptions discussed above, my calculation of the expected net operating profits to Horizon Canada and the Horizon Group from the sale of PROCYSBI in Canada for the period 2017 to [REDACTED] under a 47% price reduction scenario⁷ (compared to the profits under the other price scenarios from the Rosen Report) is summarized as follows.

Figure 4: Summary of Profits to Horizon Canada and the Horizon Group from the Sale of PROCYSBI in Canada



⁷ Schedule 2.

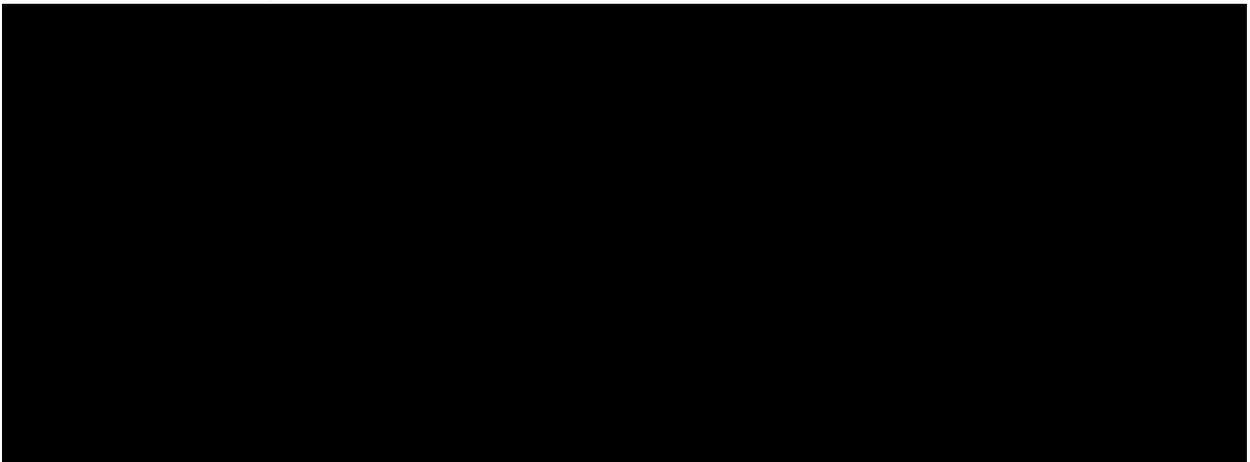
B. Calculation of Internal Rate of Return

3.13 In the Hay Responding Report, Dr. Hay concludes that:⁸

*“the results show that, under a 47% price reduction – and using the prime business loan rate⁹ as an extremely conservative **lower bound** on Horizon’s cost of capital –* [REDACTED]

3.14 As discussed in Section 5 of the Rosen Report, in my view, Dr. Hay has over-allocated the amount of the Raptor Acquisition Cost (i.e. the portion of the investment) and other expenses incurred by Horizon globally (which Horizon has acknowledged that it does not allocate to Canada)¹⁰ toward the sale of PROCYSBI in Canada. Further, in my view, the profits associated with the sale of PROCYSBI in Canada should be computed separately at the level of Horizon Canada and at the level of the Horizon Group globally. Therefore, based on my comments and analysis in Section 5 of the Rosen Report, and my calculation of the profits of Horizon Canada and the Horizon Group in Section 3A above, I have calculated the IRR under a 47% price reduction scenario¹¹ (compared to the IRR under the other scenarios from the Rosen Report), summarized as follows:

Figure 5: IRR from Sale of PROCYSBI in Canada Under Various Scenarios



⁸ The Hay Responding Report, Paragraph 22.

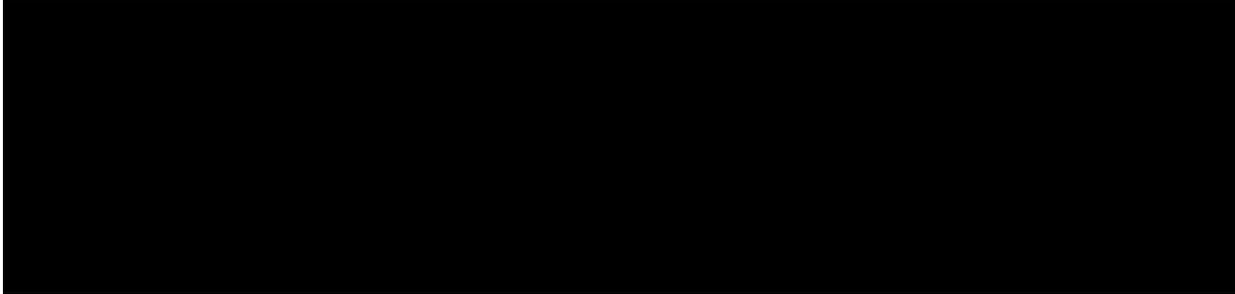
⁹ The Hay Responding Report, Paragraph 25 – Dr. Hay used the Bank of Canada prime business loan rate in October 2016 of 2.7%.

¹⁰ Joint Expert Memo, Part III - Requests that Remain in Dispute, Horizon’s Position for Document Request #5 and #6.

¹¹ Schedule 2.

3.15 While Dr. Hay has not calculated the IRR based on his profit analysis using ex-factory prices or under a 47% price reduction scenario, I have used the same methodology set out in the Rosen Report to compute the IRR implied by his profit analysis for Horizon from the sale of PROCYSBI in Canada at ex-factory prices and under a 47% price reduction scenario,¹² the results of which are presented as follows:

Figure 6: IRR from Sale of PROCYSBI in Canada Implied by Dr. Hay's Profit Analysis



3.16 As indicated above, Dr. Hay's profit analysis implies that Horizon would have expected to earn a return of between [REDACTED] (based on the Hay Addendum) to [REDACTED] (based on the Hay Report) through the sale of PROCYSBI in Canada based on ex-factory prices until [REDACTED], and a return of [REDACTED] based on the Hay Responding Report under a [REDACTED] price reduction scenario based on [REDACTED]

3.17 Based on my calculations of profits and IRR from the sale of PROCYSBI in Canada for the period 2017 to [REDACTED] I observe the following impact of a [REDACTED] price reduction of PROCYSBI:

- a) Based on my allocation of the Raptor Acquisition Cost and other expenses to Horizon Canada, and my calculation of profits and IRR thereon, at a [REDACTED] price reduction, Horizon Canada and the Horizon Group would earn profits of [REDACTED] and [REDACTED] respectively, representing an IRR of [REDACTED] and [REDACTED] respectively.
- b) This level of IRR is [REDACTED] than the IRR (ranging between [REDACTED] calculated at Section 6B of the Rosen Report) implied by Dr. Hay's profit analysis that Horizon expects to earn through the sale of PROCYSBI in Canada based on ex-factory prices until [REDACTED]
- c) This level of IRR is [REDACTED] than the IRR of [REDACTED] implied by Dr. Hay's profit analysis that Horizon expects to earn through the sale of PROCYSBI in Canada under a [REDACTED] price reduction scenario [REDACTED]

¹² Schedules 3 and 4.

4. EXPERT DECLARATION

- 4.1 I, Howard Rosen, resident of Toronto, in the province of Ontario, declare that:
- a) I have been retained by Perley-Robertson, Hill & McDougall LLP to provide evidence 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;
 - b) It is my duty to provide evidence in relation to this proceeding as follows:
 - i) to provide opinion evidence that is impartial;
 - ii) to provide opinion evidence that is related only to matters that are within my area of expertise; and
 - iii) to provide any additional assistance that the Board may reasonably require to determine a matter at issue.
 - c) 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 at Toronto, Ontario this 3rd day of November, 2020.



Howard Rosen
Managing Director
Secretariat

APPENDIX 1 – SCOPE OF REVIEW

Reference Number	Description
<u>Filings with the PMPRB</u>	
	The Responding Expert Report of Dr. Joel Hay dated October 6, 2020

