

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 PLC (the “Respondent”)
and the medicine Cysteamine Bitartrate sold by the Respondent under the trade
name PROCYSBI®**

WRITTEN SUBMISSIONS OF THE RESPONDENT

(in Response to Board Staff’s Motion for Production of Documents)

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PART I – OVERVIEW

1. These submissions are made further to the Panel’s order that the parties’ experts meet-and-confer to resolve the document requests that remain in dispute. As a result of this process, and as reflected in the parties’ joint memorandum submitted to this Panel on April 3, 2020, the parties have narrowed the dispute to two main issues:

(1) Mr. Rosen’s refusal (without explanation) to accept that certain documents do not exist; and

(2) Mr. Rosen’s request for transfer pricing documents which are not relevant to this proceeding.

2. On the eve of filing the experts’ joint memorandum, Mr. Rosen raised new issues (including a new broad document request) that were not identified in his earlier affidavits, not raised at the meet-and-confer, nor detailed in any previously exchanged drafts of the parties’ joint memorandum. Mr. Rosen baldly states that he needs these new documents either to respond to Dr. Hay’s report or to develop his own methodology. But Mr. Rosen provides no explanation for his new methodology or why the documents are required for that purpose. Horizon cannot respond to these new issues without the opportunity to understand the basis for these new requests.

3. This lack of clarity reinforces the need for an oral hearing, which will allow the Panel to hear Mr. Rosen explain his rationale and afford Horizon an opportunity to provide an informed response to these vague, late-breaking requests. Further, and in any event, the issues in dispute relate to complex concepts that are best explained by the experts at an oral hearing. An oral hearing will not only allow the Panel and Horizon to probe the new issues raised by Mr. Rosen, but it will also give the Panel the benefit of having access to the experts to ask them questions about these complex concepts. Horizon is prepared to propose practical alternatives to an in-person oral hearing in view of the current COVID-19 situation.

PART II – FACTS

Background to the production dispute

4. This section briefly describes the factual background to the production dispute between the parties.

5. *The proceeding.* In this proceeding, Board Staff alleges that Horizon is selling or has sold the patented medicine, PROCYSBI[®], at an excessive price. Board Staff put forward three models that, if accepted, would deeply discount the price of PROCYSBI[®]. Under these models, the maximum non-excessive price of PROCYSBI[®] would be reduced by 71% to 98% of its current price (the “Proposed Prices”).¹

6. *The Hay Report.* In response, Horizon retained Dr. Joel W. Hay, a pharmaceutical economist at the University of Southern California. Part of Dr. Hay’s mandate was to evaluate Board Staff’s alternative pricing models and to provide his opinion on whether Board Staff’s Proposed Prices are reasonable from an economic perspective (the “Hay Report”).²

7. To evaluate Board Staff’s proposed methodologies, Dr. Hay assessed the aggregate global profit generated by Horizon on sales of PROCYSBI[®] in Canada at each of the Proposed Prices. His results demonstrate that, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]³

¹ Statement of Allegations of Board Staff, at paras. 67-68 [Statement of Allegations]

² Hay Report, para. 17, Horizon’s Responding Motion Record (HRMR), Tab 1C, pp. 35-36

³ Hay Report, para. 23, HRMR, Tab 1C, pp. 38-4

8. ***Board Staff's motion for bifurcation and production.*** In Fall 2019, Board Staff brought a motion asking the Board to bifurcate the hearing and to strike portions of the Hay Report. In the alternative, Board Staff sought an order for the inspection of Horizon's books and records and for the production of various documents requested by its expert, Howard Rosen.

9. Horizon retained Andrew Harington, a Chartered Professional Accountant, Chartered Financial Analyst, and a Chartered Business Valuator at The Brattle Group, to provide his opinion on the reasonableness of Mr. Rosen's request for production and inspection. Mr. Harington concluded that: (1) Mr. Rosen's request for an on-site inspection was excessive and unnecessary; (2) several of Mr. Rosen's document requests were neither relevant nor necessary to his mandate; and (3) the remaining document requests were reasonable. For those requests deemed reasonable, Mr. Harington noted that his opinion should not be taken as an indication that Horizon had the document in its possession or was able to make production of that document.⁴

10. The Panel dismissed Board Staff's motion to: (i) bifurcate the proceeding; (ii) redact portions of the Hay Report; and (iii) inspect Horizon's books and records.

11. The Panel ordered Horizon to produce documents in response to the requests identified as "reasonable" in Mr. Harington's affidavit. The Panel also ordered the parties' experts to meet-and-confer to endeavour to come to an agreement on the document requests that Mr. Harington identified as not reasonable.

12. Horizon has produced all documents in its possession responsive to Mr. Rosen's requests (a total of 113 documents). These documents contain the underlying source data for each component of Dr. Hay's analysis as well as additional information which can be used to test and verify Dr. Hay's conclusions.

⁴ Affidavit of Andrew Harington, sworn December 13, 2019, at para. 20 ("First Harington Affidavit"), HRMR, Tab 1, p. 6

13. ***The meet-and-confer and experts' joint memorandum.*** In accordance with the Panel's order, the experts held their meet-and-confer on February 21, 2020, following which the experts exchanged several drafts of the joint memorandum ordered by the Panel. The parties submitted the joint memorandum on April 3, 2020. The joint memorandum summarizes the issues discussed during the meet-and-confer, identifies the document requests that remain in dispute, and summarizes the status of each request.

14. ***New request for documents.*** The *day before* the deadline to file the joint memorandum, Mr. Rosen raised a new request for documents that had not been raised before. This new request was not identified in his previous affidavits, was not discussed at the meet-and-confer, and was not detailed in any preceding draft of the joint memorandum. In this new request, Mr. Rosen asks "Horizon to provide any financial documents used by Horizon management to review or assess the actual financial performance (revenues, costs and profits) of Horizon's Canadian operations on an annual basis from 2015 to the current fiscal year."⁵

15. It appears that this broad, unspecified request is made as an alternative to Mr. Rosen's request for certain financial statements, which Horizon has repeatedly advised do not exist. Mr. Rosen was made aware of this fact as early as February 19, 2020. But, for reasons unknown to Horizon, Mr. Rosen did not raise this new request until April 2, 2020. In any event, Horizon has already provided extensive productions, which are responsive to Mr. Rosen's new request (as reflected in the joint memorandum). Without knowing what it is, specifically, that Mr. Rosen is seeking, and an explanation of why these documents are necessary (when plentiful production has been made), Horizon does not understand the basis for this late-breaking additional request.

⁵ Experts' Joint Memorandum dated April 3, 2020 [Experts' Joint Memorandum], p. 6

16. *New issues raised by Mr. Rosen.* In his final comments on the joint memorandum, Mr. Rosen also asserted, for the first time, that he requires additional “documents” for “the purposes of his own analysis, which is not necessarily a replication of what Dr. Hay has done in his report.”⁶ Again, Mr. Rosen has not provided any explanation or particulars of the “analysis” he intends to provide or why these documents are necessary for that analysis.

17. Horizon cannot respond to these issues in the absence of details, information, and an explanation for the basis of Mr. Rosen’s new requests. Given that the meet-and-confer was intended to culminate in a “hot-tubbing” of the experts to assist the Panel in reaching a decision, an oral hearing is, in Horizon’s view, necessary to allow the Panel and Horizon to probe these late-breaking issues and for Horizon to respond accordingly.

PART III – ISSUES

18. There are three production issues that remain in dispute:

- A. **Documents that do not exist:** Horizon has produced all relevant documents in its possession. However, Mr. Rosen does not accept that certain documents do not exist.
- B. **Documents related to transfer pricing:** Documents related to transfer pricing are not relevant to this proceeding and need not be produced.
- C. **No additional documents required:** The information provided by Horizon is sufficient for Mr. Rosen to analyze, test and verify the conclusions in the Hay Report.

⁶ Experts’ Joint Memorandum dated April 3, 2020 [Experts’ Joint Memorandum], pp. 8-11, 13

PART IV – ARGUMENT

Horizon has produced all relevant documents

19. Further to the Panel’s order, Horizon has conducted a thorough investigation and has produced all documents in its possession that were identified as “reasonable” in Mr. Harington’s affidavit.

20. Throughout the course of its investigation, Horizon advised Board Staff and Mr. Rosen – both in writing and at the meet-and-confer – that certain documents do not exist because Horizon does not prepare such documents in the ordinary course of business. For reasons that remain unclear, Mr. Rosen “does not accept Horizon’s confirmation that such documents do not exist.”⁷ He has not explained the basis for this (baldly) stated position.

21. Mr. Rosen’s assertion amounts to an allegation that Horizon is concealing documents in its possession. This allegation is unfounded. Horizon has explained why the documents do not exist: Horizon does not prepare these documents in the ordinary course of business. There is no basis to suggest that Horizon is deceiving both Board Staff and this Panel about the documents in its possession.

22. Specifically, there are two categories of documents that Mr. Rosen “does not accept” do not exist:

- A. Annual Financial Statements of Horizon Pharma’s Canadian subsidiary, HZNP Therapeutics Canada Limited (“Horizon Canada”).
- B. Additional documents relating to expense items (beyond the extensive detail already produced).

⁷ Experts’ Joint Memorandum, pp. 6, 11-12

A. Annual Financial Statements

23. As stated in the joint memorandum, Horizon has confirmed that neither audited nor unaudited financial statements exist, as Horizon does not prepare financial statements for Horizon Canada.⁸

24. Although this has been repeatedly expressed, Mr. Rosen does not accept this fact. His position appears to be based solely on his view that local corporate reporting entities “typically” prepare financial statements on an annual basis for purposes such as (i) internal management reporting, (ii) consolidation of a subsidiary into a parent entity, and (iii) local statutory tax reporting.

25. Mr. Rosen’s position is speculative and without merit. He ignores the fact that some companies – especially small, orphan drug manufacturers like Horizon Canada – do not prepare such documents in the ordinary course of business. Moreover, according to Mr. Harington, the preparation of financial statements is not required for the purposes identified by Mr. Rosen. Specifically:

- i. internal management reporting can be undertaken without the preparation of financial statements, especially for entities with very limited operations, such as those that existed for Horizon Canada prior to July 2019;
- ii. in Mr. Harington’s experience, financial statements are not prepared for the purpose of consolidation of a subsidiary into a parent entity; and
- iii. while financial statements are typically prepared for local statutory tax reporting for larger entities, this is not always the case for small companies.⁹

⁸ Experts’ Joint Memorandum, p. 6 (Request #1)

⁹ Experts’ Joint Memorandum, p. 6 (Request #1)

B. Documents relating to expense items

26. The second category of documents that Mr. Rosen “does not accept” do not exist are documents relating to Horizon’s expenses. Mr. Rosen’s original request contained two parts: (1) documents explaining what each line item relates to; and (2) documents explaining how each item should be allocated to PROCYSBI® sold in Canada.¹⁰

27. *Documents explaining line item expenses.* Horizon has produced all documents relevant to the first part of this request, including its general ledgers. The general ledgers reflect the most particularized level of detail that exists for each expense item. These include an itemized list of every expense from salaries and insurance to taxis, meals, postage, and printing. Despite Horizon confirming that this is the most particularized level of detail that exists, Mr. Rosen baldly asserts that he “does not accept Horizon’s confirmation that additional documents do not exist.”¹¹ Mr. Rosen has not explained why he “does not accept” that additional documents do not exist or specified the “additional documents” he is looking for and why those documents are necessary.

28. *Documents explaining how each item should be allocated.* Mr. Rosen also “does not accept” that documents explaining how each expense item should be allocated to PROCYSBI® sold in Canada do not exist.¹² Mr. Rosen’s position on this issue is particularly confusing, given that Horizon does not allocate expenses to PROCYSBI® sold in Canada, an issue that was thoroughly canvassed in the Hay Report.

29. The Hay Report explains that Horizon tracks expenses [REDACTED]
[REDACTED]
[REDACTED]

¹⁰ Experts’ Joint Memorandum, pp. 11-13 (Requests #5 and #6)

¹¹ Experts’ Joint Memorandum, pp. 11-13 (Requests #5 and #6)

¹² Experts’ Joint Memorandum, pp. 11-13 (Requests #5 and #6)

[REDACTED]

A. **Other Cost of Sales:** [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

B. **Sales and Marketing Expenditures:** [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

C. **General and Administrative Expenditures:** [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

D. **Ongoing Research and Development:** [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

30. The allocation of expenses to PROCYSBI® sold in Canada is a matter of expert opinion. To the extent that Mr. Rosen disagrees with Dr. Hay's methodology, he may develop his own methodology. But, he does not require any further

¹³ Hay Report, Appendix F, para. 16, HRMR, Tab 1C, p. 209

¹⁴ Hay Report, Appendix F, para. 19, HRMR, Tab 1C, p. 210

¹⁵ Hay Report, Appendix F, para. 21, HRMR, Tab 1C, p. 211

¹⁶ Hay Report, Appendix F, para. 24, HRMR, Tab 1C, p. 212

documents to undertake this exercise. Horizon has provided Mr. Rosen with the underlying source data for each component of the profit analysis in the Hay Report *as well as* information which allows him to analyze, test and verify the conclusions in the Hay Report. Even if the documents were to exist – and they do not – there is no reason to request additional documents (nor has Mr. Rosen identified one).

31. ***No additional documents required.*** Mr. Rosen’s approach to date has been to ignore that certain documents do not exist and instead insist that Horizon produce documents it does not have. This approach is not productive. To the extent Mr. Rosen is attempting to bolster his position by making *new* document requests and asserting that (unspecified) “documents” are required for “his own [unspecified] analysis” (both of which came on the eve of the deadline to file the joint memorandum), this approach is not productive either.

32. Horizon has confirmed that it conducted a thorough investigation and has produced all relevant documents. In any event, Mr. Rosen has had every opportunity throughout the meet-and-confer process, the exchange of documents, and the preparation of the joint memorandum to provide some explanation of what additional “documents” he is looking for and why those documents are necessary. He has failed to do so. Horizon cannot be expected to respond to a vague request for unspecified documents, especially considering the extensive information already provided.

Transfer Pricing Documents Are Not Relevant

33. The transfer pricing documents requested by Mr. Rosen are not relevant to these proceedings. In assessing the profit generated by Horizon on sales of PROCYSBI® in Canada, Dr. Hay looked only at the global profits earned by Horizon on sales of PROCYSBI® in Canada. As explained below, Horizon’s global profit – which is an aggregate of the profits earned in each of the respective profit centres – is not affected by transfer pricing arrangements between Horizon entities.

34. Moreover, by assessing Horizon’s global profits ([REDACTED])
[REDACTED]

[REDACTED] As explained below, this is because Horizon Canada [REDACTED]
[REDACTED]
[REDACTED] By looking at Horizon's global profits, Dr. Hay [REDACTED]
[REDACTED] This approach has the effect of [REDACTED]
[REDACTED]
[REDACTED]. Incorporating transfer pricing arrangements will only [REDACTED]
[REDACTED]
[REDACTED] as estimated in the Hay Report.

35. ***Transfer pricing explained.*** As explained in Mr. Harington's reply affidavit, transfer pricing rules apply where (i) a multi-national company, such as Horizon, operates in more than one income tax jurisdiction, and (ii) where transactions occur between the entities in each jurisdiction. Generally, transfer pricing rules are intended to prevent companies from maximizing after-tax profitability by setting prices such that the profits will be earned in the jurisdictions with the lowest income tax rates. To guard against this, transfer pricing rules require that related entities trade with one another at prices reflecting those that would exist if the parties were acting at arm's length. [REDACTED]
[REDACTED]

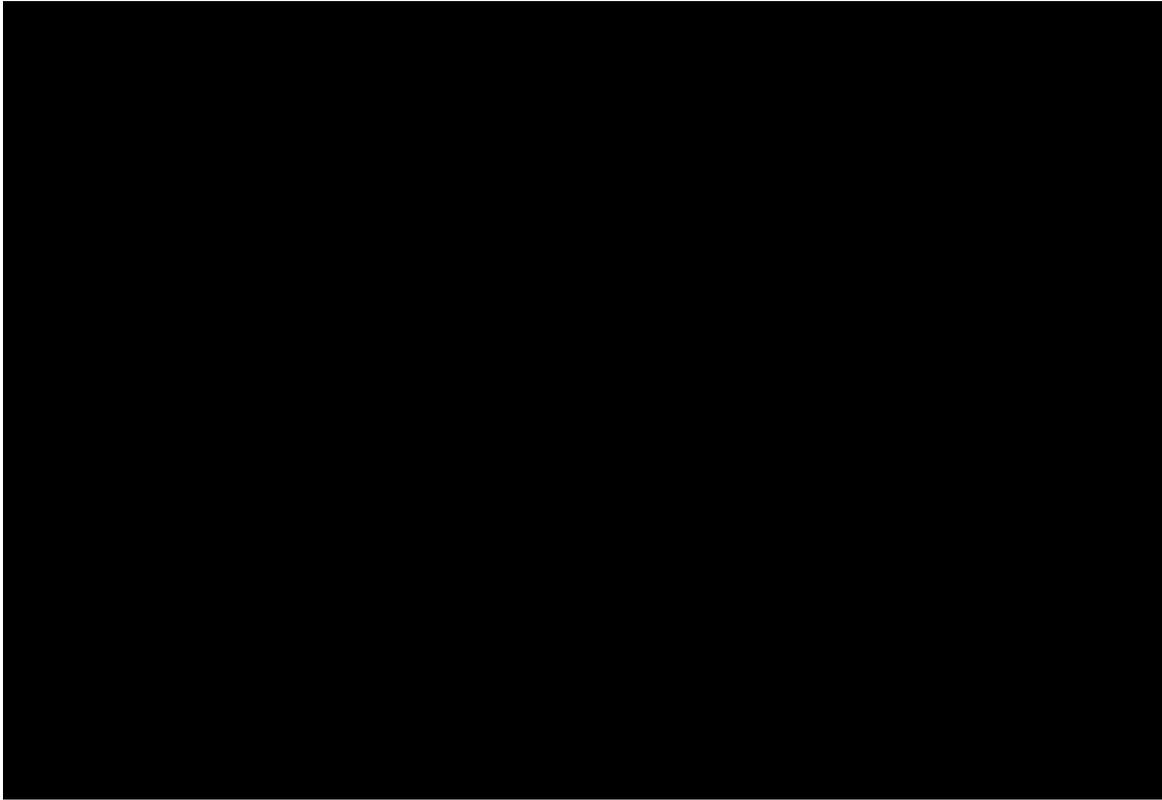
36. By regulating the prices at which goods and services are sold, the transfer pricing rules require that a company's total global profits be shared to reflect each entity's contribution. This means that if an entity earns less revenue, it will similarly earn less profit. This is because the profits that each entity earns must reflect that entity's contribution, and under the arm's length principle, one entity cannot expect to incur losses to subsidize another entity. It also means that each entity will, by definition, earn less than the company's total global profit: the profits represent one global pie, and no single entity can earn an amount greater than the whole.

37. *Dr. Hay's methodology is most favourable to Board Staff.* By looking only at Horizon's global profits, as opposed to the profits earned by Horizon's Canadian entity [REDACTED] [REDACTED] This is because, as explained above, the price paid by [REDACTED] [REDACTED] By looking only at Horizon's global profits, Dr. Hay [REDACTED] [REDACTED] [REDACTED]

38. Moreover, because Horizon's global profits must be shared in a way that reflects each entity's contribution, and [REDACTED] [REDACTED] [REDACTED] [REDACTED]

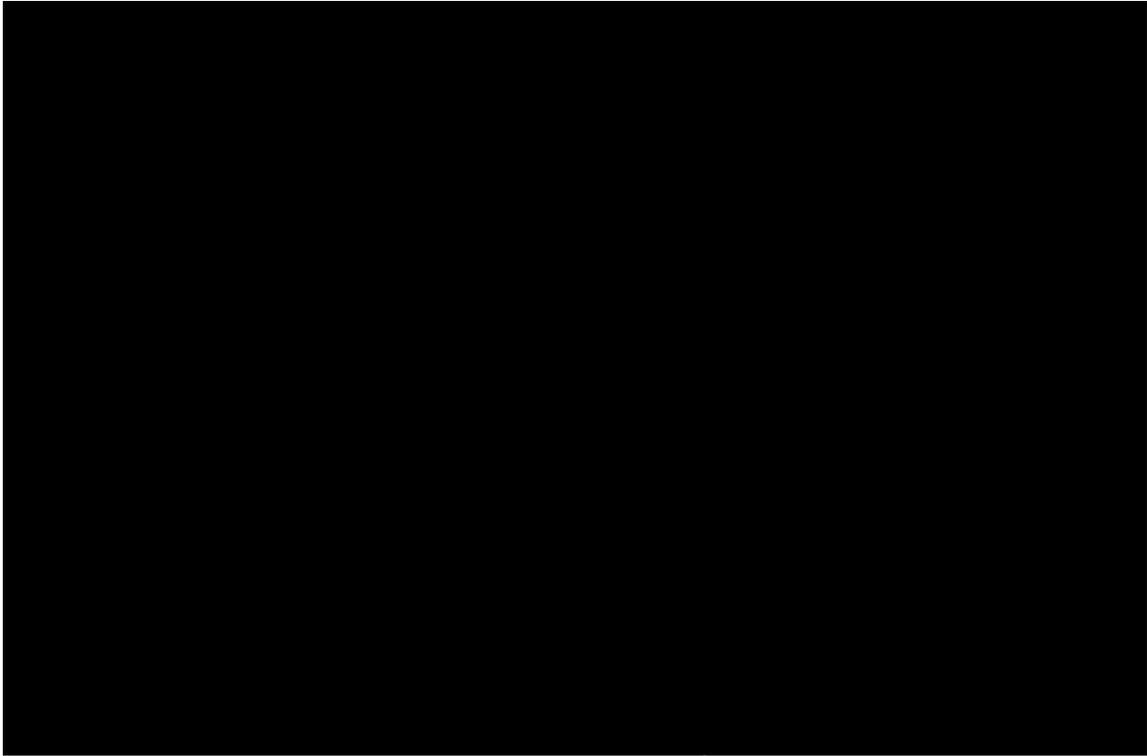
39. The effect of Horizon's transfer pricing is illustrated by the following diagrams. The columns on the left represent the respective profit pictures in Horizon Ireland (where the product is made) and Horizon Canada (through which the product is sold in Canada) if one were to consider the transfer pricing system and focus only on the profit made in Canada, as Mr. Rosen suggests. The right-hand column represents the aggregate profit of Horizon Global, as undertaken by Dr. Hay.

40. The first diagram represents Horizon's profitability at the current prices. The top right corner (the blue square on the right) shows that Horizon's global profit (as would be estimated by Dr. Hay under his approach) comprises [REDACTED] [REDACTED]



41. The diagram below illustrates the scenario addressed in the Hay Report (i.e., reflecting the lower prices proposed by Board Staff). The column on the right, which reflects Dr. Hay's approach, shows [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



42. As these diagrams show, had Dr. Hay considered only the profits generated by Horizon's Canadian entity on sales of PROCYSBI® in Canada, his calculations would result [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

43. Simply put, the transfer pricing documents requested by Mr. Rosen are not relevant to this proceeding: [REDACTED]

[REDACTED]
[REDACTED]

44. *Documents related to Horizon Canada are irrelevant.* Other categories in dispute, including (i) purchase orders and invoices for purchases made by Horizon Canada from other Horizon entities, and (ii) Income Tax Returns and Schedules (Requests 2 and 3 in the experts' joint memorandum) are irrelevant for the same

reasons that transfer pricing documents are irrelevant: they relate to the intercorporate relationships between Horizon entities, [REDACTED]
[REDACTED]

Oral Hearing Required

45. Although the parties have managed to narrow their production disputes to a handful of key issues, those issues relate to complex concepts that are best explained by the experts. The parties have significantly benefitted from the views exchanged by the experts at the meet-and-confer and, in Horizon's view, the Panel would similarly benefit from having access to the experts to ask them questions about these complex concepts.

46. Further, Mr. Rosen's final revision of the joint memorandum raised new issues. The basis for these bald assertions, explained above, requires further explanation from Mr. Rosen to enable the Panel and Horizon to understand these new requests and to allow Horizon to respond. For those reasons, and because of the importance of the issues to be addressed, Horizon requests an oral hearing. Given this was the structure originally contemplated by the Panel, and given the late-breaking document requests raised by Mr. Rosen, fairness dictates that Horizon be given an opportunity to have its expert heard. Horizon is prepared to propose alternative methods to facilitate an oral hearing in view of the current COVID-19 crisis. To assist the Panel, Horizon has proposed to Board Staff the protocol appearing at Appendix "A" for the conduct of the oral hearing.

PART V – ORDER SOUGHT

47. Horizon requests that the Panel refuse Mr. Rosen’s outstanding requests, detailed at pages 6-13 of the experts’ joint memorandum.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 15th day of April, 2020.



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APPENDIX "A"

1. The parties will proceed issue by issue (timing suggestions below are intended to be guidelines only).
2. On each issue, the witnesses will explain what is being sought to be produced and its relevance:
 - (a) Mr. Rosen will proceed first (for up to 5 minutes), ensuring he addresses the question: what is the point of difference of opinion between the two experts?
 - (b) Mr. Harington will respond (for up to 5 minutes), ensuring he addresses the question, what is the point of difference of opinion between the two experts?
3. Counsel for Board Staff may ask questions of either witness, but this is not intended to be an examination-in-chief or a cross-examination. It is to cover areas that the witnesses have overlooked;
4. Counsel for Horizon may ask questions of either witness, but this is not intended to be an examination-in-chief or a cross-examination. It is to cover areas that the witnesses have overlooked;
5. The panel members will be asked whether they have any follow-up questions for the witnesses; these will be asked and answered by the witnesses.
6. Counsel for Board Staff and then counsel for Horizon may ask supplementary questions arising from Item 5.
7. Items 3 through 6 should take no longer than 15 minutes.
8. The parties will move to the next issue.
9. Once the issues have been completed, counsel for Board Staff will make short submissions (up to 30 minutes). Counsel for Horizon will respond (for up to 40 minutes). Counsel for Board Staff will make reply submissions (for up to 10 minutes).