

**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**

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**WRITTEN SUBMISSIONS OF BOARD STAFF  
(Motion for the Inspection and Production of Documents)**

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April 15, 2020

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## I. BACKGROUND

1. The respondent retained Dr. Joel Hay, who is a professor of pharmaceutical economics. In his report<sup>1</sup>, Professor Hay offered his opinion on whether the maximum non-excessive price which Board Staff submitted was appropriate would allow Horizon to recover the costs associated with commercializing Procysbi in Canada. Professor Hay [REDACTED]. Professor Hay's financial analysis is found at Appendices E, F, and G of his report. Professor Hay stated that [REDACTED]. In order to prepare his report, Professor Hay had access to certain individuals at Horizon who provided him with information and also gave him access to various financial documents.

2. Board Staff retained Howard Rosen as its expert to analyze, test, verify, and potentially respond to the assumptions, calculations, and conclusions of Professor Hay. Mr. Rosen is a chartered professional accountant and chartered business valuator.

3. Mr. Rosen has indicated that he required access to various financial documents in order to complete his assignment.<sup>2</sup>

4. The respondent retained Andrew Harington, who is also a chartered professional accountant. Mr. Harington provided his opinion on whether or not Mr. Rosen needed the documents which he had requested in order to fulfill his mandate.<sup>3</sup> Mr. Harington agreed that Mr. Rosen did need *some* of the documents that Mr. Rosen had requested, but that there were other documents that Mr. Rosen did not require in order to complete his assignment ("the Disputed Documents"). Mr. Rosen filed a supplementary affidavit explaining why he needed the Disputed Documents in order to conduct his analysis.<sup>4</sup>

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<sup>1</sup> Report of Professor Hay, Motion Record of Board Staff, Tab 4(B)

<sup>2</sup> Affidavit of Howard Rosen, Motion Record of Board Staff, Tab 2

<sup>3</sup> Affidavit of Andrew Harington, Responding Motion Record of the Respondent, Tab 1

<sup>4</sup> Supplementary Affidavit of Howard Rosen, Supplementary Motion Record of Board Staff, Tab 1

5. The Panel directed the experts to “meet and confer” and prepare a joint memorandum on the outstanding request for documents. The meeting resulted in the preparation of the Joint Memorandum of Howard Rosen and Andrew Harington, as well as Exhibit A to that memorandum (“the Joint Memorandum” and “Exhibit A”) which was filed with the Board on April 3, 2020.

6. These submissions address the six (6) categories of documents that remained in dispute after the “meet and confer” of the experts. Particulars regarding each party’s position is set out in Part III of the Joint Memorandum. These submissions therefore should be read in conjunction with the Joint Memorandum. We begin these submissions with reference to general principles and our submissions on why the Panel should direct the production of the Disputed Documents (set out in Part III of the Joint Memorandum) which Mr. Rosen says are necessary. Following these submissions, we will then review each of the six (6) categories of documents separately.

## II. GENERAL PRINCIPLES

7. Board Staff submits that in considering this matter, it is important to keep in mind that it is Mr. Rosen alone who is now being asked to provide an opinion on whether or not [REDACTED]

[REDACTED] This analysis requires him to look at the cost of making and marketing Procysbi. This is a complex calculation. The *Patent Act*, RSC 1985, c-P-4 provides no guidance on the appropriate methodology for performing the calculation, other than the notation in s.85(3) regarding research costs.

8. Professor Hay has provided his opinion on this issue. His opinion was based on the information given to him by individuals at Horizon as well as the financial records they gave to him. There is no evidence regarding whether or not Professor Hay conducted an analysis of the financial information he was provided or whether he

sought additional information. Significantly, Professor Hay did not file an affidavit on the motion by Board Staff to respond to the requests for documents made by Mr. Rosen.

9. Instead, the Respondent relied on the affidavit of Mr. Harington, who was not asked to conduct a financial analysis of Horizon, or any analysis on the cost of making and marketing Procysbi. Rather, Mr. Harington was only retained to provide an opinion as to the information that Mr. Rosen – a third party – indicated that he required to complete his assignment.

10. With respect, the only party whose opinion is relevant as to whether or not certain financial information is necessary in order to provide his opinion, is that of Mr. Rosen. If Mr. Rosen is prevented from getting all of the financial records he needs, his opinion will of necessity have to be qualified by virtue of the fact that he has not had access to all of the necessary documents.

11. The assertion by Mr. Harington that certain financial information requested by Mr. Rosen is not necessary, is largely premised upon the argument that the information sought by Mr. Rosen is not relevant to the analysis done by Professor Hay. But, as Mr. Rosen notes, his mandate is not simply to replicate what Professor Hay has done.

12. The fact that Professor Hay chose to calculate the cost of making and marketing Procysbi and the profitability of the respondent in a particular manner, does not mean that this approach is the only acceptable approach. If the Panel decides that the cost of making and marketing Procysbi is a relevant factor in this case, they will have to determine whether the methodology, assumptions, and conclusions of Professor Hay are appropriate or whether an alternative methodology is more appropriate. It is not however appropriate at this stage for the Panel to determine which methodology is correct.

13. Mr. Rosen should be allowed to provide the Panel with an alternative methodology. At the end of the day, the Panel will then have to decide whether one approach is better suited to determining the issue. By refusing to provide Mr. Rosen

with the Disputed Documents, Board Staff's expert will be limited to testifying only as to whether the data provided to Professor Hay supports his conclusions.

14. The issue to be decided on this motion should not be whether the information which Mr. Rosen says he requires is relevant to the conclusions or approach of Professor Hay. Rather, the issue is whether the information sought by Mr. Rosen is necessary for him to fulfill his mandate. The best person, and the only person able to answer that question is Mr. Rosen.

15. As we noted in paras 53 et seq of the Written Submissions of Board Staff filed prior to this motion, the Panel has the authority to direct the production of documents. Consequently, the proper issue to be determined on this motion is whether the documents which Mr. Rosen seeks are arguably relevant to his financial analysis of the respondent and to the cost of making and marketing Procysbi. Given that all the documents which Mr. Rosen is seeking provide financial information, they are clearly relevant. This is not a situation in which Board Staff is seeking information from a patentee that is irrelevant.

16. Importantly, the respondent has not advanced any rationale for why the financial information sought by Mr. Rosen is irrelevant to the analysis that Mr. Rosen will be undertaking. Rather, the arguments are directed at why the information is not relevant to the analysis performed by Professor Hay.

17. The jurisprudence supports the principle that it is not for an opposing party to determine what the other party's expert does and does not need for their analysis. Where an expert has requested documents to aid in their analysis and can show that the documents are relevant, either to fill in gaps in their analysis or to take a different approach, a court will order the production.

*Sa Majesté la Reine c. Rothmans Inc. et al*, 2019 CarswellNB 194 (QB) [Rothmans]

*Walsh v. TRA Company Limited*, 2019 CarswellNfld 368 (SC) [Walsh]

18. In *Air Canada*, the court evaluated two motions. In one motion, WestJet requested an order requiring Air Canada to deliver a further and better affidavit of documents. In the other motion, Air Canada requested an order requiring WestJet to produce various documents that it had refused to produce. Both motions were granted.

19. In the underlying action, Air Canada alleged that, over a certain period of time, WestJet accessed a website that Air Canada operated and retrieved confidential information regarding passenger loads and route information. Air Canada further alleged that WestJet relied on the information to alter its business plans to more effectively compete with Air Canada.

20. At paragraph 17, the court found that Air Canada should not decide what WestJet's expert did or did not need. The court held:

In terms of Mr. Smith's views, it does not lie within the purview of Air Canada to decide what information WestJet's experts do or do not need. It is also not determinative of what documents are producible that Air Canada may believe that WestJet's experts are proceeding on faulty assumptions or erroneous theories. Air Canada will have its opportunity in the fullness of time to challenge the findings of WestJet's experts. At this stage, however, as long as the documents that WestJet's experts seek have an appearance of relevance to the issues raised in the action, then WestJet is entitled to have production of those documents, albeit within reasonable parameters.

21. *Rothmans* arose in the context of claims against tobacco companies by the provincial government of New Brunswick. The defendants asked both for information that was relied upon by the government expert as well as additional information that was not relied upon by the government expert, but would be of assistance to the defence and their expert. The New Brunswick Court of Queen's Bench ordered

disclosure both of information relied upon, and information not relied upon. The court noted that disclosure of the information not relied upon would contribute to trial fairness, and that the relevance of information could not be based solely on the assertion of the adverse party as to whether or not it was relevant, holding at paragraphs 122 and 125 - 127:

122 I am satisfied that Moving Defendants 1 have established a basis for the production of a “statistically meaningful sample” of all provincial administrative databases, both “relied upon” and not, and as identified in their motion. While there is disagreement between the experts, I find that the requested databases are, at least, a “statistically meaningful sample” of the total of all provincial health data that is otherwise blocked by the provisions of subsection 2(5)(b) of the *Act*.

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125 While there is also disagreement in the affidavit evidence before me, as to the possible redundancy of some of the databases beyond those “relied upon” by Dr. Harrison, it would seem that such redundancy or duplication is not entirely, nor absolutely, the case. For example, whereas Dr. Harrison and John Boyne for the Province had previously denied the additional databases to contain *any* “smoking” information on individual insured persons, it has been discovered that this is not necessarily the case (see paragraph 13 of Dr. Wecker’s supplemental affidavit dated January 23, 2019).

126 This friction underlies a key aspect of the parties’ disagreement on production; namely whether the defendants should be entitled *only* to the same information found in the “relied upon” data as being sufficient or relevant. I have already ordered production of the “relied upon” databases. I am of the view that trial fairness requires the production of the additional requested sample databases as well. This motion is for discovery. We are not yet at the trial stage. The scope of documentary discovery cannot fall to be determined only upon the assertions of one of the parties concerning either the “likely” redundancy or “possible” usefulness of some of the requested information.

127 I am satisfied that the sample databases “not relied upon” by Dr. Harrison and requested by the Moving Defendants 1 likely contain some information that may allow for Dr. Wecker to conduct an assessment as to Dr. Harrison’s methodology and analysis, including analysis that Dr. Harrison might *not* have undertaken. In other words, such information may have a meaningful use to the defendants. Presumably this is why subsection 2(5)(d) of the *Act* allows for the defendants to make such a

request for a sample in the first place, and which would go beyond the necessary production of “relied upon” documents and records under subsection 2(5)(b). [Emphasis added.]

22. *Walsh* involved a commercial dispute with respect to provision of products to Sobey's grocery stores. The plaintiff requested a number of years of Sobey's Departmental Analysis (SDAs). Sobey's expert had referred to certain years of SDA's, but the plaintiff requested prior years as well. The Newfoundland Supreme Court noted that it was not up to Sobey's to determine whether documents were relevant to the plaintiff's case. On this point, the court noted at paragraph 8)

The Court of Appeal in *Carter v. Municipal Construction Ltd.*, 2001 NFCA 58 (Nfld. C.A.), aff'ing (2001), 204 Nfld. & P.E.I.R. 112, 107 A.C.W.S. (3d) 750 (Nfld. T.D.) at paragraph 9 states that the determination that documents “relate” to the matter is to be undertaken by the party and solicitor. It is not for Sobey's, its expert or counsel to determine whether they consider the SDAs to relate to the matters in issue. The Plaintiffs and their counsel upon reviewing the documents must determine whether the material contained in the SDAs is of aid to them. Further, Faour, J. at paragraph 15 of *Donovan* references the decision of *GRI Simulations Inc. v. Oceaneering International Inc.*, 2010 NLTD 85 (N.L. T.D.) where Hoegg, J. noted, “**parties are presumed to be entitled to documents relating to matters in issue without providing justification**”. [Emphasis added.]

23. The court noted that the plaintiff's expert wished to review the additional SDA's in order to analyze the report and to determine whether it should take a different approach to the matter. On this point the court held at paragraph 30:

Counsel for the Plaintiffs stressed in submissions that data for the SDAs was too limited for the expert to use such methodology, and it is further evidence as to why the records would have been required to enable the expert for the Plaintiffs to approach it in a different method.

24. In the result, the court ordered the material to be disclosed in order to fairly dispose of the matter, holding at paragraph 33:

The evidence therefore supports the necessity of the Plaintiffs requiring the documents to dispose fairly of the issues in the proceeding.

### III. REQUESTS THAT REMAIN IN DISPUTE

#### 1. Annual Financial Statements of HZNP Therapeutics Canada Limited (“Horizon Canada”)<sup>5</sup>

25. The production of these documents was discussed by the experts at the “meet and confer”. Although there is a column on the Joint Memorandum that is headed “Horizon’s Position”, there is no sworn evidence from Horizon on the motion indicating that financial statements do not exist. Mr. Rosen’s position as noted in the Joint Memorandum is that financial statements are typically prepared. Mr. Rosen also noted that if such documents do not exist, then the respondent should be required to provide the financial documents used by management to assess actual financial performances from 2015 onwards.

26. As Mr. Harington is not an employee of the respondent, he is of course not able to shed any light on whether or not financial statements exist. In fact, Mr. Harington specifically noted that if there are financial statements, they would only provide partial financial information. The fact that the financial statements do not provide the complete financial picture should not excuse the respondent from having to produce them.

27. Mr. Harington also notes in the Joint Memorandum that Horizon has already provided Mr. Rosen with some documents that were used by Horizon management to review and assess the actual financial performance of Horizon from 2015 to the current fiscal year. Mr. Harington then lists the documents that fall into this category. Again, the fact that some documents have been provided does not constitute a basis for refusing to provide all of the financial documents. Significantly, Mr. Harington has not

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<sup>5</sup> Joint Memorandum, pp. 5-8 and Exhibit A(2)(3) and (4)

stated that the documents provided constitute all of the financial documents used by Horizon management to assess the actual financial performance of Horizon from 2015 to the current fiscal year.

28. Board Staff notes that the request for financial statements corresponds to Exhibit A – A(2), (3) and (4). As was noted by Mr. Harington in his affidavit of December 13, 2019, this request by Mr. Rosen was a “reasonable request”. The decision by the Panel of January 13, 2020 specifically directed the respondent to produce all documents identified as reasonable.

## **2. Income Tax Returns and Schedules<sup>6</sup>**

29. It is trite to observe that income tax returns are clearly documents that may provide very relevant information regarding a company’s financial status and profitability. The income tax returns can be used by Mr. Rosen to verify the income/profits reported in Canada and can be compared to the profits calculated globally in the report prepared by Professor Hay. The fact that Professor Hay did not consider the profits of Horizon in Canada does not mean that the information is not relevant to the mandate of Mr. Rosen, particularly in view of the fact that he is entitled to undertake and offer the Panel an alternative methodology to that of Professor Hay.

30. It is also noteworthy that the respondent has not been consistent in asserting that financial information regarding the Canadian operations of Horizon is not relevant in light of the fact that Professor Hay calculated profit generated by Horizon globally. In this respect, it is worth noting Horizon’s response to another category of documents which Mr. Rosen was seeking. Item C18 on page 12 of Exhibit A was a request for “documents which support Horizon Pharma’s impairment tests relating to Procysbi”. Mr. Harington’s response to that request was,

“It is not clear whether this request relates to Horizon Pharma Canada or Horizon Pharma globally. This is a reasonable request only as it relates to Horizon Pharma Canada, as the documents are relevant only to the extent of

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<sup>6</sup> Joint Memorandum, pp. 8-9 and Exhibit A – A(10)

impairment relating to Canadian related assets of PROCYSBI. To the extent this request relates to Horizon Pharma globally, it is not a reasonable request.”

Although Mr. Rosen was only seeking information under this heading relating to Horizon Pharma Canada, his observation regarding the inconsistency of Horizon’s position is set out below:

“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 aggregate profit generated by Horizon globally or profit for Horizon as a whole.”

### **3. Purchase orders and invoices for purchases by Horizon Canada from other Horizon entities or third parties<sup>7</sup>**

31. Professor Hay’s report specifically addresses the expenses for Procysbi. The Joint Memorandum notes that the documents sought under this heading fall into Category C. That category is described as “Documents Relating to Procysbi Expense”. Given that the requested documents therefore relate to expenses associated with Procysbi, they are relevant and ought to be produced.

32. The respondent’s sole objection to the production of these documents is that Professor Hays’ conclusions relate to the global profit of Horizon. For the reasons previously advanced, Mr. Rosen does however require these documents and notes that his analysis is not necessarily going to be a replication of what Professor Hay has done. As noted earlier, he is entitled to undertake and offer the Panel an alternative methodology.

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<sup>7</sup> Joint Memorandum, p. 9; Exhibit A – C (4)

#### **4. Transfer Pricing Documents<sup>8</sup>**

33. The documents in the category were the subject matter of disagreement between Mr. Rosen and Mr. Harington. While the “meet and confer” was of assistance in providing some clarification on the nature of the transfer pricing documents that exist, the experts remained apart on their views regarding the production of these documents. For the reasons set out by Mr. Rosen in the Joint Memorandum and Exhibit A, as well as those advanced in the supplementary affidavit from Mr. Rosen<sup>9</sup> and the arguments found in the transcript from the hearing on January 15, 2020 (pages 99 *et seq*), it is submitted that these documents are relevant and ought to be produced.

34. At the hearing of the motion, the only reasons advanced for not producing the documents in this category was that it was “redundant” and speculation from counsel that “the production would be massive”. Notably, these assertions are not contained in the Joint Memorandum, nor is there any evidence to substantiate these statements. Accordingly, the documents in this category should be produced.

#### **5. Documents explaining what the following line items relate to and how each item should be allocated PROCYSBI sold in Canada<sup>10</sup>**

35. The documents sought by Mr. Rosen fall into Category C of the Joint Memorandum – “Expenses related to Procysbi”. As previously noted, documents relating to expenses of Procysbi are clearly relevant. Moreover, Mr. Harington agreed that Mr. Rosen’s request for documents in this category were “reasonable”.

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<sup>8</sup> Joint Memorandum, pp. 9-11; Exhibit A – D (2) (4) (12) (13) (14) (15) (16) and E(3)

<sup>9</sup> Supplementary Affidavit of Howard Rosen, Supplementary Motion Record of Board Staff, Tab 1

<sup>10</sup> Joint Memorandum, pp. 11-12 and Exhibit A – C (10) (11) (12) and (13)

36. Board Staff notes that in the Joint Memorandum, Mr. Harington has not expressed any position regarding Mr. Rosen's request for documents in this category. It follows therefore that the documents requested by Mr. Rosen should be produced.

#### **6. Documents that detail the nature of [certain] expenses<sup>11</sup>**

37. The request for documents in this category was noted by Mr. Harington to be "reasonable". These documents should therefore be produced.

### **IV. CONCLUSION**

38. The respondent will be leading evidence at the hearing regarding the cost of making and marketing Procysbi. Mr. Rosen requires financial information from the respondent in order to provide the Panel with his own expert opinion on the cost of making and marketing Procysbi. Mr. Rosen is best situated to determine the financial records he requires for his analysis. The Panel should have the benefit of hearing evidence from both sides on this issue.

39. In balancing the interests of the parties in this case, it is submitted that fairness dictates that Mr. Rosen should be provided the documents requested. Such an order would ensure that the Panel has all of the evidence it needs to fairly determine the issues. Granting the order sought does not cause any prejudice to the respondent.

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<sup>11</sup> Joint Memorandum p. 12-13 and Exhibit A – E (5) (6) (7) and (8)

**ALL OF WHICH IS RESPECTFULLY SUBMITTED** this 15<sup>th</sup> day of April, 2020

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