Patented Medicine Prices Review Board Canada
Conseil d'examen du prix des médicaments brevetés Canada

Box L40, Standard Life Centre
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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

REASONS FOR DECISION ISSUED JANUARY 17, 2020
(Board Staff's Motion to Bifurcate, Strike Evidence and for the Production and Inspection of Documents (the "Motion"))

1. On January 15, 2020, the panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**Board**") seized with this proceeding heard the Motion which sought the following relief:

(a) An order bifurcating this hearing between subsections 85(1) and 85(2) of the *Patent Act*[1] (the "**Act**");

(b) An order redacting those portions of the Hay Report that relate to the cost of making and marketing Procysbi;[2] and

(c) In the alternative, an order allowing Secretariat International to inspect the books and records of Horizon in order to determine the cost of making and marketing Procysbi and an order directing the production of certain documents.

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1 R.S.C. 1985, c.P-4.

2 Board Staff's Notice of Motion originally sought an order "striking" these portions of the Hay Report. However, in Board Staff's Written Submissions and during the hearing of the Motion on January 15, 2020, Board Staff amended its request to an order "redacting" these portions.

2. After carefully considering the materials filed and the oral submissions made by the Parties, the Panel issued its Decision in respect of the Motion on January 17th, 2020, with Reasons to follow. The Decision is attached as Schedule "A".

3. The following are the Panel's Reasons.

A. BACKGROUND

4. This Motion arises in the context of a proceeding commenced by Board Staff where it is alleged that the Respondent is selling the medicine Cysteamine Bitartrate under the trade name Procysbi ("**Procysbi**") at a price that is excessive under section 83 of the Act.

5. Board Staff submits that the maximum non-excessive price of Procysbi should be reduced in accordance with one of three alternative pricing models which Board Staff describes as: (1) the same medicine comparison; (2) the premium price approach; and (3) the market share approach.

6. In response to Board Staff's allegations, the Respondent retained a pharmaceutical economist, Dr. Joel W. Hay, to evaluate the impact of Board Staff's three alternative pricing models (the "**Hay Report**").

7. Board Staff takes issue with portions of the Hay Report that it alleges contain detailed evidence of the cost of making and marketing Procysbi. Board Staff brings this Motion seeking various forms of relief that will, in essence, either defer consideration of this evidence to a later stage of the hearing if necessary or, alternatively, ensure that Board Staff is given access to the relevant information underlying the analysis in the Hay Report so that it may respond to that analysis.

B. THE REQUEST FOR BIFURCATION AND REDACTION

(i) Relevant Legislative Context

8. In determining whether the price of a medicine is excessive under section 83 of the Act, the Board must undertake the following sequential analysis set out in section 85 of the Act.

9. First, the Board must consider the following factors enumerated in subsection 85(1) of the Act:

> (a) the prices at which the medicine has been sold in the relevant market;
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> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
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> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
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> (d) changes in the Consumer Price Index; and
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> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.

10. If, after considering the factors enumerated in subsection 85(1), the Board is unable to determine whether the price of a medicine is excessive, then the Board may consider the additional factors listed in subsection 85(2) of the Act; namely, the cost of making and marketing the medicine.

(ii) Submissions of the Parties

11. Given the sequential consideration of the factors enumerated in section 85 of the Act, and the significant time and resources required to present evidence and argument related to the cost of making and marketing Procysbi, Board Staff submits that bifurcating this proceeding will result in the just, expeditious and least expensive determination of this proceeding on the merits.

12. Under Board Staff's approach, the Panel would only hear evidence and argument on whether the price of Procysbi is excessive based on a consideration of the factors listed in subsection 85(1) of the Act. If after this first phase of the hearing the Panel is unable determine the matter, then the hearing would be reconvened so that the Parties may present evidence and argument with respect to the factors identified in subsection 85(2) of the Act; namely, the cost of making and marketing Procysbi.

13. If the Panel adopts this approach, Board Staff submits that the portions of the Hay Report related to the cost of making and marketing Procysbi should be redacted and not considered during the first phase of the hearing because they are not relevant to the factors enumerated in subsection 85(1) of the Act.

14. The Respondent submits that granting the relief requested by Board Staff would deprive the Respondent of a fair opportunity to present evidence and argument that goes to the ultimate issue in this proceeding: whether the price of Procysbi is excessive under section 83 of the Act. The Respondent submits that, contrary to Board Staff's submissions, the portions of the Hay Report sought to be redacted are not being submitted to justify the price of Procysbi under subsection 85(2) of the Act. Rather, the Hay Report was provided in response to Board Staff's allegations. In particular, the analysis in the Hay Report was conducted to provide the Panel with information on whether Board Staff's proposed pricing alternatives (submitted by Board Staff under subsection 85(1) of the Act) are reasonable.

15. Moreover, the Respondent submits that bifurcation artificially truncates the proceeding in a way that requires this Panel to make a decision on the merits in a "vacuum" without the full evidentiary context. Therefore, the Respondent submits that bifurcating this proceeding is neither efficient nor preferable.

(iii) The Applicable Law

16. This Panel has the power to bifurcate a proceeding pursuant to Rule 5(2) of the Patented Medicine Prices Review Board Rules[3] (the "**PMPRB Rules**") and subsection 97(1) of the Act:

(a) Rule 5(2) of the PMPRB Rules grants the Board broad discretion to address any unanticipated procedural matters "in any manner that the Board directs in order to ensure the fair and expeditious conduct of any proceeding"; and

(b) Subsection 97(1) of the Act requires all proceedings before the Board to be "dealt with as informally and expeditiously as the circumstances and considerations of fairness permit".

17. The Parties were not able to identify any prior decision by a Panel of this Board on the issue of bifurcating a hearing. The Parties did provide the Panel with jurisprudence from the Federal Court on the issue of bifurcation. The vast majority of the Federal Court cases relied on by the Parties involved a request to sever the consideration of two separate legal issues, normally liability from damages. In contrast, in the Motion, Board Staff seeks to sever the consideration of one issue (e.g. whether the price of Procysbi is excessive under section 83 of the Act) into two hearings, based on the factors set out as relevant to that issue in subsections 85(1) and (2) of the Act.

18. While the Federal Court cases were decided on very different facts and in different legislative regimes, the Panel did find them helpful in identifying the relevant principles to consider when determining whether to grant a bifurcation request.

19. In determining whether to exercise its discretion to bifurcate a proceeding, the Panel starts from the proposition that it is the basic right of a party to have all issues in

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[3] SOR/12-247.

dispute resolved in one hearing.[4] It is then for the moving party to justify the departure from the usual practice by demonstrating on a balance of probabilities that, in light of the evidence and all of the circumstances of the case, bifurcation will more likely than not result in the just, expeditious and least expensive determination of the proceeding on the merits.[5]

20. In making this determination, the Panel considers the following non-exhaustive and to some extent over-lapping list of factors to be potentially relevant:

(a) the complexity of the issues;

(b) whether the issues are clearly separate;

(c) whether the factual structure upon which the action is based is so extraordinary or exceptional that there is good reason to depart from normal practice requiring the single hearing of all issues in dispute;

(d) whether a better understanding of the matters would be achieved by hearing all matters together;

(e) whether the issues are inextricably interwoven;

(f) whether there is a clear advantage to having a matter determined first;

(g) whether there will be a substantial saving of costs;

(h) whether bifurcating the case will save time, or will lead to unnecessary delay; and

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4 *South Yukon Forest Corp. v. R*., 2005 FC 670 at para. 3; *Bristol-Myers Squibb Co. v. Apotex Inc*., 2003 FCA 263 at para. 7.

5 *Bristol-Myers Squibb Co. v. Apotex Inc*., 2003 FCA 263 at para. 10; *Unwin v. Crothers*, 2005 CarswellOnt 2811 at para. 79 (S.C.J.); *H-D Michigan Inc. v. Berrada*, 2007 FC 995 at para. 5; *Apotex Inc. v. Pfizer Canada Inc*., 2014 FC 159 at para. 42; *Teva Canada Ltd. v. Janssen Inc*., 2016 FC 318 at para. 5; *T-Rex Property AB v. Pattison Outdoor Advertising Limited Partnership*, 2019 FC 1004 at para. 19.

(i) whether the bifurcated matter could lead to an end to the proceeding.[6]

(iv) Analysis

21. The Panel has considered all of the relevant factors and concludes that Board Staff has not satisfied it that, in the circumstances of this case, there is reason to depart from the general rule requiring the single hearing of all issues in dispute. For the reasons that follow, the Panel is of the view that bifurcation will not result in the just, expeditious and least expensive determination of this proceeding on the merits.

(a) The Sequential Nature of Section 85 of the Act

22. As a preliminary matter, the Panel wishes to address Board Staff's submission that this is an appropriate case for bifurcation because section 85 of the Act imposes a sequential approach to the consideration of the factors enumerated in subsections 85(1) and 85(2) of the Act.

23. The sequential approach to the consideration of subsections 85(1) and 85(2) has been recognized by the Board on numerous occasions and is not in dispute.[7] However, *consideration* of evidence and argument should not be confused with *receiving* that evidence and argument.

24. While section 85 of the Act requires a sequential approach to the *consideration* of the factors enumerated in subsections 85(1) and 85(2), there is nothing in the Act or the

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6 *H-D Michigan Inc. v. Berrada*, 2007 FC 995 at para. 5; *Apotex Inc. v. Pfizer Canada Inc*., 2014 FC 159 at para. 42; *Teva Canada Ltd. v. Janssen Inc*., 2016 FC 318 at para. 6; *T-Rex Property AB v. Pattison Outdoor Advertising Limited Partnership*, 2019 FC 1004 at para. 19.

7 See for example Board Decision – *ICN Canada Ltd. and ICN Pharmaceuticals Inc.* (July 26, 1996) at p. 8, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/db-95d5v-e14LGJ-492003-8710.pdf>; Board Decision – *ratiopharm Inc. and the medicine "ratio-Salbutamol HFA"* (May 27, 2011) at para. 86, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/ratio-Salbutamol-HFA-Merits-Reasons-D3-May-27-2011.pdf>; Board Decision – *Alexion Pharmaceuticals Inc. and the Medicine "Soliris"* (September 20, 2017) at para. 136, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/soliris_decision_public_version.pdf>, affirmed *Alexion Pharmaceuticals Inc. v. Canada* (Attorney General), 2019 FC 734.

jurisprudence to suggest that the Board should only *receive* evidence and argument on subsection 85(2) if it cannot make a determination based on subsection 85(1).

25. In ordinary circumstances, the Board will receive evidence and argument on both subsections 85(1) and 85(2) at the hearing on the merits, and the Panel will not have regard to the evidence related to subsection 85(2) unless it is unable to decide the issue under subsection 85(1). Indeed, the Board expressly adopted this approach in *Soliris*:

> 75. Section 85 contemplates the potential of a dual-stage review by the Panel consisting of an initial examination of the factors listed in subsection 85(1) and where necessary, an examination of the additional factors listed in subsection 85(2). In terms of the hearing procedure for each of these stages, one option would be to receive evidence and submissions on whether the price of Soliris is excessive based on a consideration of the factors listed in subsection 85(1) of the *Patent Act*. If the Panel is unable to determine the issue on the basis of the subsection 85(1) factors, then the Panel would receive evidence and arguments with respect to the factors identified in subsection 85(2) of the *Patent Act*.
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> 76. In the Panel's view, dividing or "splitting" the case between the factors in subsections 85(1) and 85(2) in this manner is not an efficient or preferable way to proceed. Rather, the Panel should **receive** evidence and submissions regarding the factors listed in both subsections 85(1) and 85(2), to the extent relied upon by either party. Where a party submits evidence relating to the factors listed in subsection 85(2), the Panel **will not have regard** to such evidence unless it is unable to decide this matter based on a consideration of the factors listed in subsection 85(1) alone.
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> 77. This manner of proceeding is consistent with the approach taken by the Board in prior cases. For example, in 2011, the PMPRB conducted a hearing into whether ratiopharm Inc. ("**ratiopharm**") had sold a medicine known as ratio-Salbutamol HFA at an excessive price under sections 83 and 85 of the *Patent Act*.
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> 78. In addition to introducing evidence regarding the factors listed in subsection 85(1), ratiopharm also provided evidence under subsection 85(2) regarding the cost of making and marketing the medicine. The Panel ultimately determined that it did not need to have regard to the evidence submitted with respect to subsection 85(2) on the basis that the Panel could determine the issue through a review of the factors outlined in subsection 85(1) alone [...]
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> 79. Clearly, evidence regarding both subsections 85(1) and 85(2) of the *Patent Act* is admissible in this proceeding. Indeed, at the hearing, Alexion acknowledged the relevance of evidence under subsection 85(2). The Panel therefore anticipates that the parties will make representations and adduce

> evidence with respect to the factors listed in subsections 85(1) and 85(2) of the Patent Act.[8]

26. While *Soliris* was not decided in the context of a bifurcation motion, it is instructive in this case because the Panel indicates its desire to hear all submissions and evidence on both subsections of the Act, fully recognizing that the Panel cannot have regard to the factors enumerated in subsection 85(2) unless it is unable to decide the matter under subsection 85(1).

27. Moreover, the Board has broad discretion to admit "any evidence that it considers appropriate",[9] and has previously confirmed that evidence relating to *any* of the section 85 factors is "clearly" admissible when making a determination under section 83 of the Act.[10]

28. Therefore, despite the sequential nature of the consideration of the factors enumerated in subsections 85(1) and 85(2) of the Act, this Panel is clearly permitted to receive evidence and argument on both subsections during the hearing on the merits. This is the procedure in the ordinary course. The sequential nature of the section 85 analysis is not, in and of itself, sufficient to warrant bifurcation. The moving party must satisfy the Panel that the circumstances of the case justify splitting the evidence and argument concerning whether the price of a medicine is excessive between subsections 85(1) and 85(2) of the Act, and that doing so would result in the just, expeditious and least expensive determination on the merits.

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8 Board Decision – *Alexion Pharmaceuticals Inc. and the Medicine "Soliris"* (November 24, 2015) at paras. 75-79, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/SOLIRIS-PMPRBNovember24th2015decision.pdf> [Emphasis added, footnotes omitted].

9 *Patented Medicine Prices Review Board Rules of Practice and Procedure*, SOR/12-247, s. 6(1).

10 Board Decision – *Alexion Pharmaceuticals Inc. and the Medicine "Soliris"* (November 24, 2015) at para. 79, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/SOLIRIS-PMPRBNovember24th2015decision.pdf>.

(b) Efficiency and Cost Savings

29. The Panel recognizes that the evidence regarding the cost of making and marketing a patented medicine is potentially complex and contentious, and that gathering evidence and preparing arguments on this issue may require significant time and resources. However, the Panel is not satisfied that, in the circumstances of this case, bifurcating this proceeding will ensure the most cost efficient and expeditious determination of this proceeding.

30. First, the Panel places little weight on Board Staff's submission that this proceeding will very likely be determined solely on the basis of subsection 85(1), and therefore bifurcation will obviate the need to prepare evidence and argument on factors that ultimately will not be considered by the Panel when making its final determination.

31. At this stage in the proceeding and without the benefit of a full evidentiary record and argument, the Panel is not in a position to assess the likelihood that it will be able to base its decision on the factors enumerated in subsection 85(1) of the Act. This Panel cannot engage in an assessment of the relative merits of the Parties' case in the context of a bifurcation motion and in the absence of a full evidentiary record.[11] The fact that the Board has not in previous cases relied on the factors in subsection 85(2) to determine whether a price is excessive and that it would be a rare case for the Board to do so may be true but it is not determinative of whether this Panel will engage in an analysis of subsection 85(2) in this case.

32. Second, considering the evidence known to the Panel to date and the positions taken by the Parties, Board Staff has not satisfied the Panel that the evidence relevant to subsection 85(1) is clearly separate and distinct from the evidence relevant to subsection 85(2). If the Panel bifurcated this proceeding, there will likely be a significant overlap of evidence, fact witnesses and expert witnesses in both phases of the hearing. Board Staff's Motion to redact portions of the Hay Report itself demonstrates that a single expert may be viewed as providing an opinion that goes to both subsections

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[11] *Alcon Canada Inc. v. Apotex Inc*., 2016 FC 898 at para. 12.

85(1) and 85(2) of the Act. This overlap increases the risk of significant duplication and wasted resources.

33. Third, bifurcation will likely give rise to further disputes over the admissibility of evidence on the grounds that the evidence relates to subsection 85(2), rather than 85(1). Hearing and determining such motions in the context of a bifurcated section 85(1) hearing will not promote efficiency and expediency and, even more importantly, puts the Panel in the impossible position of being asked to decide what evidence is relevant to a subsection 85(1) analysis as opposed to a subsection 85(2) analysis in the absence of the full evidentiary context.[12] This is not a hypothetical concern in this case considering that the Respondent submits that the Hay Report is a response to Board Staff's position in respect of subsection 85(1), while Board Staff is adamant that the portions of the Hay Report it seeks to redact are only relevant to an analysis under subsection 85(2).

(c) A Just and Fair Determination on the Merits

34. This Panel must determine whether the Respondent is selling or has sold Procysbi in any market in Canada at a price that, in the Board's opinion, is or was excessive under section 83 of the Act. The Panel is of the view that, in the circumstances of this case, a just and fair determination of this issue on the merits is best achieved by hearing all evidence and argument related to both subsections 85(1) and 85(2) of the Act at a single hearing.

35. First, a single hearing ensures due process and procedural fairness. The Respondent will have the opportunity to meaningfully respond to each of the allegations made against it in the manner it sees fit by presenting evidence and argument relating

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[12] This position is consistent with this Board's decision in *Soliris*, where the Panel expressed its reluctance to determine the admissibility of evidence at an early stage in the proceeding. See Board Decision – *Alexion Pharmaceuticals Inc. and the Medicine "Soliris"* (March 29, 2016) at para. 63, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Solaris_Motion_to_Strike_Expert_Evidence_Decision_March_29_2016.pdf>.

to all factors that may be considered by the Panel when making a determination under section 83 of the Act.[13]

36. Second, given the complexity of the issues raised in this case, the Panel is of the view that it would achieve a better understanding of this matter by hearing evidence and argument related to subsections 85(1) and 85(2) during a single hearing, recognizing the fact that it cannot consider subsection 85(2) unless it is unable to make a determination under subsection 85(1). Furthermore, as discussed above, having the full evidentiary context will assist the Panel in assessing whether evidence is relevant to subsections 85(1) or 85(2) of the Act.

37. For all of these reasons, Board Staff's Motion to bifurcate this proceeding is denied. It follows that Board Staff's Motion to redact those portions of the Hay Report that it alleges are related to the cost of making and marketing Procysbi is also denied. The Panel's denial of the requested redaction is limited to the particular context of Board Staff's request for bifurcation. For clarity, it does not preclude the ability of Board Staff to raise objections to the Hay Report on grounds of relevance or weight at the hearing on the merits.

C. THE REQUEST FOR PRODUCTION AND INSPECTION

(i) Submissions of the Parties

38. In the event that the request for bifurcation was denied, Board Staff requested that this Panel order the inspection of the Respondent's books and records related to the cost of making and marketing Procysbi, and order the production of various documents set out in Exhibit "B" to the Affidavit of Howard Rosen, sworn November 28, 2019.

39. Board Staff submits that this relief is necessary in the circumstances of this case because it will ensure that this Panel has clear and reliable evidence on the complex

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[13] *South Yukon Forest Corp. v. R.*, 2005 FC 670 at para. 3; *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2003 FCA 263 at para. 7.

accounting and financial issues associated with assessing the costs of making and marketing Procysbi.

40. In response to Board Staff's request for production and inspection, the Respondent retained Andrew Harington of the Brattle Group to review and provide an opinion on the reasonableness of Mr. Rosen's request for production and inspection.

41. Mr. Harington concluded that: (1) Mr. Rosen's request to conduct an on-site inspection is 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.

42. During oral argument on January 15, 2020, the Respondent confirmed that it accepts that it ought to produce the categories of documents that Mr. Harington identified as "reasonable" in Exhibit "C" to his Affidavit sworn January 10, 2020 (the "**Harington Affidavit**").[14]

43. With respect to the document requests that remain in dispute, both Parties stated during oral argument that they do not oppose having Messrs. Rosen and Harington meet and confer to discuss the scope of relevant documents that should be produced.[15]

(ii) The Applicable Law

(a) Production and Inspection

44. The Board has broad powers under subsection 96(1) of the Act and Rules 24(1) and 6(2) of the PMPRB Rules to order the production and inspection of documents:

(a) Subsection 96(1) of the Act grants the Board "all such powers, rights and privileges as are vested in a superior court" with respect to "the production and inspection of documents";

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[14] Hearing Transcript (January 15, 2020), at p. 210, line 24 – p. 211, line 2.

[15] Hearing Transcript (January 15, 2020), at p. 167, line 20 – p. 168, line 7; p. 222, lines 10-15; p. 223, lines 20-24.

(b) Rule 24(1) of the PMPRB Rules provides that the Board may, in any proceeding, order "the production or inspection of documents"; and

(c) Rule 6(2)(a) of the PMPRB Rules confirms that the Board may direct "that a party provide any information or documents" that it considers relevant to the proceeding.

45. The Panel in *ratio-Salbutamol* described the test for ordering the inspection of documents as follows:

> The test for the proper exercise of its discretion in this regard must be the relevance of the information sought to the discharge of its legislated pricing mandate, in light of the circumstances of each case, including the evidence filed and the issues raised.[16]

46. In *ratio-Salbutamol* the Panel granted an inspection order because in the circumstances of that case, it was "not persuaded that the material listed in the Inspection Order can be obtained in an effective and efficient manner by requesting further production".[17]

(b) Expert Conferences and Panels

47. This Panel has the power to order experts to meet and confer pursuant to Rule 5(2) of the PMPRB Rules, which grants the Board broad discretion to address any unanticipated procedural matters "in any manner that the Board directs in order to ensure the fair and expeditious conduct of any proceeding".

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16 Board Decision – *ratiopharm Inc. and the medicine "ratio-Salbutamol HFA"* (August 14, 2009) at para. 27, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/ratio-Salbutamol-PreliminaryMotions-Reasons-Aug1409.pdf> [Emphasis added].

17 Board Decision – *ratiopharm Inc. and the medicine "ratio-Salbutamol HFA"* (August 14, 2009) at para. 31, online: <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/ratio-Salbutamol-PreliminaryMotions-Reasons-Aug1409.pdf>.

48. When ordering experts to meet and confer, this Panel has regard to the principles set out in the Federal Court Rules[18] that govern expert conferences and panels:

> **Expert conference**
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> **52.6 (1)** The Court may order expert witnesses to confer with one another in advance of the hearing of the proceeding in order to narrow the issues and identify the points on which their views differ.
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> **Presence of parties and counsel**
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> **(2)** Subsection (1) does not preclude the parties and their counsel from attending an expert conference but the conference may take place in their absence if the parties agree.
>
> **Presence of judge or prothonotary**
>
> **(3)** The Court may order that an expert conference take place in the presence of a judge or prothonotary.
>
> **Joint Statement**
>
> **(4)** A joint statement prepared by the expert witnesses following an expert conference is admissible at the hearing of the proceeding. Discussions in an expert conference and documents prepared for the purposes of a conference are confidential and shall not be disclosed to the judge or prothonotary presiding at the hearing of the proceeding unless the parties consent.
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> …
>
> **Expert witness panel**
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> **282.1** The Court may require that some or all of the expert witnesses testify as a panel after the completion of the testimony of the non-expert witnesses of each party or at any other time that the Court may determine.
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> **Testimony of panel members**
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> **282.2 (1)** Expert witnesses shall give their views and may be directed to comment on the views of other panel members and to make concluding statements. With leave of the Court, they may pose questions to other panel members.
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> **Examination of panel members**
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> **(2)** On completion of the testimony of the panel, the panel members may be cross-examined and re-examined in the sequence directed by [the] Court.

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[18] SOR/98-106.

(iii) Analysis

(a) Inspection

49. At this stage of the proceeding, the Panel is not satisfied that an inspection order is necessary to ensure the production of relevant documents in an effective and efficient manner.

50. In these circumstances, Board Staff's Motion for an order permitting Secretariat International to inspect the books and records of the Respondent was denied. However, the Decision is without prejudice to Board Staff's ability to renew its request for an inspection after its review of the documents referred to in paragraph 52 below. Any renewed request for an inspection should include detailed reasons as to why an inspection is necessary and appropriate in the circumstances.

(b) Production of Agreed Upon Documents

51. During oral argument on January 15, 2020, the Respondent confirmed that it accepts that it ought to produce the categories of documents that were identified by their expert as "reasonable" requests in Exhibit "C" of the Harington Affidavit.[19]

52. Therefore, the Panel ordered the Respondent to produce all requested documents that are identified as "reasonable" in Exhibit "C" of the Harington Affidavit as soon as possible.

(c) Meet and Confer to Address Remaining Disputed Documents

53. With respect to the document requests that remain in dispute, the Panel ordered Messrs. Rosen and Harington to meet and confer as soon as possible to endeavour to come to an agreement on the remaining document requests that are not identified as "reasonable" in Exhibit "C" to the Harington Affidavit. The Decision also sets out a process to be followed after the meet and confer, including a joint memorandum by the experts and their attendance at a hearing in the event any disputes remain.

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[19] Hearing Transcript (January 15, 2020), at p. 210, line 24 – p. 211, line 2.

54. The Panel is of the view that the process set out in the Decision will ensure that the remaining document disputes are resolved in the most expeditious, fair and cost-effective manner possible in the circumstances, and that the relevant information necessary to address the issues before the Panel will be available for purposes of this proceeding.

D. DISPOSITION

55. See the Panel's Decision, attached to these Reasons as Schedule "A".

Dated at Ottawa, this 28th day of February, 2020.

Original signed by Carolyn Kobernick

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Signed on behalf of the Panel by
Carolyn Kobernick

Panel Members

Carolyn Kobernick
Mitchell Levine

Counsel for Board Staff

David Migicovsky
Christopher Morris
Courtney March

Counsel for the Respondent

Sheila Block
Andrew Shaughnessy
Rachael Saab
Stacey Reisman

Counsel for the Panel

Sandra Forbes
Megan Percy

SCHEDULE A
DECISION WITH REASONS TO FOLLOW (JANUARY 17, 2020)

Please see attached.

Patented Medicine Prices Review Board Canada
Conseil d'examen du prix des médicaments brevetés Canada

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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

DECISION WITH REASONS TO FOLLOW
(Motion to Bifurcate, Strike Evidence and for the Production and Inspection of Documents (the "Motion"))

Decided by the panel (the "**Panel**") of the Patented Medicine Prices Review Board seized with this proceeding on the basis of written and oral submissions.

1. The Panel has reviewed and considered the materials filed and the oral submissions made by Board Staff and the Respondent in respect of the Motion. This is the Panel's decision on the Motion, with reasons for the decision to follow.

2. Board Staff's motion to bifurcate this proceeding is denied.

3. Board Staff's motion to redact those portions of the report of Professor Joel Hay that relate to the cost of making and marketing Procysbi is denied.

4. Board Staff's motion for an order permitting Secretariat International to inspect the books and records of the Respondent is denied, without prejudice to Board Staff's ability to renew its request for an inspection after its review of the documents referred to in paragraph 5(a) below. Any renewed request for an inspection should include detailed reasons as to why an inspection is necessary and appropriate in the circumstances.

5. Board Staff's motion for production of documents requested by Secretariat International as set out in Exhibit "B" of the Affidavit of Howard Rosen sworn November 28th, 2019 is granted in part. In this regard, the Panel makes the following orders:

(a) The Respondent shall produce all requested documents that Andrew Harrington identified as "reasonable" in Exhibit "C" to his Affidavit sworn January 10, 2020 (the "**Harrington Affidavit**") as soon as possible.

(b) Howard Rosen and Andrew Harrington shall meet and confer as soon as possible to endeavour to come to an agreement on the remaining document requests that were not identified as "reasonable" in Exhibit "C" to the Harrington Affidavit. The meet and confer shall take place in the presence of counsel for the Parties, unless the Parties agree otherwise. The Panel trusts that the Parties will make best efforts to ensure that the meet and confer is as productive as possible. Following the meet and confer, Mr. Rosen and Mr. Harrington shall prepare, and the Parties shall file with the Panel, a joint memorandum that identifies the requests that have been resolved and the requests that remain in dispute, if any.

(c) If any of the document requests remain in dispute following the meet and confer session, a one day hearing shall be scheduled, with Mr. Harrington and Mr. Rosen in attendance, so that they are available to answer any questions that the Panel may have. The Panel will also receive brief submissions from counsel in respect of the remaining document requests in dispute. The Panel is available to hold this hearing on one of the following dates:

(i) March 16, 2020;
(ii) March 17, 2020;
(iii) March 18, 2020;
(iv) March 19, 2020;
(v) March 23, 2020;
(vi) March 24, 2020; or
(vii) March 25, 2020.

The Parties shall confer and advise the Board Secretary by February 1, 2020 which of the above dates are preferred for the one day hearing, should it be necessary. The Parties shall also hold February 25, 2020 at 2:00 p.m. for a pre-hearing telephone case conference.

Dated at Ottawa, this 17th day of January, 2020.

Original signed by Carolyn Kobernick

Signed on behalf of the Panel by
Carolyn Kobernick

PANEL MEMBERS:

Carolyn Kobernick
Mitchell Levine

COUNSEL / REPRESENTATIVES:

For Board Staff:

David Migicovsky
Christopher Morris
Courtney March

For the Respondent:

Sheila R. Block
Andrew M. Shaughnessy
Rachael Saab
Stacey Reisman