REDACTED PUBLIC VERSION

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

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

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PART I – OVERVIEW

1. Whether framed as a motion to strike or a motion to bifurcate, Board Staff's motion, if granted, would have the effect of depriving Horizon of its right to make its case and lead evidence that goes to the core issue in this proceeding: whether the price of PROCYSBI is excessive under section 83 of the *Patent Act*.

2. The Board is authorized to receive *any* evidence that it considers appropriate. It has ruled that all evidence under the section 85 factors should be received in a single hearing, following which arguments can be made as to what evidence goes to what factor. The Board has held that severing cases in the manner requested by Board Staff in this case is neither efficient nor preferable. Indeed, far from being efficient, Board Staff's motion, if granted, may preliminarily force the matter into the courts so that Horizon can maintain the right to lead evidence vital to its defence.

3. There is no basis to strike Horizon's evidence. None of Board Staff's evidence or arguments are directed to the standard required to strike evidence – that Horizon's evidence is "obviously irrelevant" or that there is a risk of "irreparable prejudice."

4. Board Staff's request for bifurcation is akin to a motion to strike in that, if granted, it would have the effect of preventing the Board from receiving relevant evidence. Bifurcating the hearing such that only subsection 85(1) is litigated, with the effect that subsection 85(2) may never be, is not only unprecedented, it is contrary to the jurisprudence of this Board. While the analytical framework of section 85 may suggest a sequential approach to the consideration of the factors under section 85, this is only after all the evidence has gone in. It is not correct to say that the Board must first prejudge whether evidence is relevant to subsection 85(1) and make a determination under that subsection before it can receive evidence under subsection 85(2). The Board in *Soliris* considered this very approach and rejected it.

5. In any event, the contested evidence is not being submitted under subsection 85(2). The Hay Report was tendered in *response* to Board Staff's allegations and proposed pricing proposals, which Board Staff has put forth under section 85(1).

Each model yields a drastic price reduction. At these massive price drops (71% to 98% *reductions* in the price), the Board is mandated to inquire as to whether these prices are reasonable – or, to borrow from Board Staff's expert, Prof. Schwindt, whether the prices "cover the patentee's costs which would include a competitive profit level" and "adequately rewards the patentee." The sections of the Hay Report that Board Staff is seeking to strike are responsive to these section 85(1) issues; they were not tendered as affirmative evidence to somehow *justify* the current price of PROCYSBI under section 85(2).

6. The effect of this motion would be to have the Board make an important determination on a rare, life-altering patented medicine in a vacuum. It would be manifestly unfair and a denial of due process to allow Board Staff to raise allegations and propose price reductions without allowing Horizon a fair opportunity to respond. This approach is also not in the public interest. The Board must make this determination after a hearing on the merits, in the context of a full evidentiary record.

7. To the extent that Board Staff require production of documents to test the assumptions in the Hay Report, Horizon has, throughout, advised that it would be amenable to provide information that is reasonable and relevant.

PART II – FACTS

The Proceeding

8. PROCYSBI is a patented medicine containing a delayed release formulation of enterically-coated, microspherized beads of cysteamine bitartrate. It is indicated for the treatment of cystinosis – an extremely rare genetic disorder that, if left untreated, leads to significant morbidity and premature death. Although an immediate-release form of cysteamine bitartrate called Cystagon has been used to treat cystinosis since the 1990s, PROCYSBI's therapeutic advantages have revolutionized the treatment of patients suffering from cystinosis.

9. This motion arises in the context of a proceeding commenced by Board Staff alleging that Horizon is selling or has sold PROCYSBI at a price that is or was excessive, and that the maximum non-excessive price of PROCYSBI is approximately 71% to 98% of its current price (the "Proposed Prices").[1]

10. Board Staff has alleged that the price of PROCYSBI is excessive on the basis of three tests, each identified under a heading entitled "Application of the s. 85(1) Factors,"[2] which are based on the allegations that the price of PROCYSBI:

(1) exceeds the list price of Cystagon;[3]

(2) exceeds a so-called Market Share Price "based on an analysis of the market share of PROCYSBI and Cystagon in the Comparator Countries where competitive forces are operative;"[4] and

(3) exceeds the price that results in a "reasonable premium … to account for the potential additional benefit of the addition of an enteric coating."[5]

The statutory framework

11. The Board's mandate under the *Act* is to ensure that Canadians can obtain patented medicines at prices that are "reasonable" or "non-excessive."[6]

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

[2] Statement of Allegations, at para. 31-34.

[3] Statement of Allegations, at para. 32.

[4] Statement of Allegations, at para. 33 (emphasis added).

[5] Statement of Allegations, at para. 34 (emphasis added).

[6] Board Decision – Alexion Pharmaceuticals Inc. and the Medicine "Soliris" (September 20, 2017) at para. 108 [*Soliris Decision on the Merits*], Horizon's Book of Authorities [BOA] Tab 1; affirmed in *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2019 FC 734 at paras. 78-79 [*Alexion*], BOA Tab 2, citing *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1 at paras. 27-28 [*Celgene*], BOA Tab 3.

12. Section 85 of the *Act* sets out the factors to be considered in determining whether the price of a medicine is excessive.

13. ***Section 85(1) – "Factors to be considered"***. In making a determination under section 83, the Board must consider the factors in subsection 85(1):

> (a) the prices at which the medicine has been sold in the relevant market;
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
> (d) changes to the Consumer Price Index;[7] and
> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.[8]

14. It is worth noting that two of Board Staff's proposed models (dealing with market share and reasonable premiums) involve considerations that fall outside of section 85(1).

15. ***Subsection 85(2) – "Additional factors"***. If the Board is unable to determine whether a medicine is being or has been sold at an excessive price using the factors in subsection 85(1), it may consider additional factors under subsection 85(2), including the costs of making and marketing the medicine and any other factors the Board deems relevant in the circumstances.

16. Board Staff has also alleged that the grounds in the Statement of Allegations listed in support of the section 85(1) factors are also relevant to section 85(2).[9]

17. ***Subsection 85(3) – "Research costs"***. In determining under section 83 whether a medicine is being or has been sold in Canada at an excessive price, the

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[7] Changes in the Consumer Price Index are not applicable in this case.
[8] To date, no additional factors have been specified by regulation.
[9] Statement of Allegations, at para. 66.

Board may consider the Canadian portion of the world costs related to the research pertaining to the medicine or to the development and commercialization of the medicine at issue. It should be noted that subsection 85(3), unlike subsection 85(2), does not contain language limiting its application to those situations where the Board is unable to make a determination of non-excessive price.

18. ***The Guidelines***. The Board's *Compendium of Policies, Guidelines and Procedures* establishes the appropriate methodologies for applying the factors in subsection 85(1) (the "Guidelines").[10] One of these methodologies is the Median International Price Comparison ("MIPC") test. The MIPC test is used to determine whether the price of a drug is excessive relative to international prices; it compares the ex-factory price of the drug in Canada to the median ex-factory price of the drug across France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States (the "PMPRB7").[11] Under the Guidelines, a drug that is a breakthrough or a substantial improvement is not excessively priced if its Canadian price does not exceed the Median International Price.

19. Since its introduction, the price of PROCYSBI is below the Median International Price; indeed, the Canadian price is one of the lowest prices in the world.[12]

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[10] Canada, Patented Medicine Prices Review Board (PMPRB), "Compendium of Policies, Guidelines and Procedures," Part A – Legal Framework, s. A.5.3 [*Guidelines*].

[11] *Guidelines*, Part C – Guidelines and Procedures; Schedule 5: Median International Price Comparison Test.

[12] Affidavit of Andrew Harrington, sworn December 13, 2019 [Harrington Affidavit], Exhibit C, Expert Report of Joel W. Hay at paras. 64-67 [Hay Report], Respondent Motion Record ["RMR"] pp. 58-59.

Board Staff departed from the Guidelines

20. Board Staff urges this Board to depart from the Guidelines. It alleges that the tests under the Guidelines are not appropriate because of "unusual circumstances" in this case.[13]

21. As stated above, Board Staff has created three alternative pricing methodologies to establish the non-excessive price of PROYCSBI: (i) the Same Medicine Comparison Test, (i) the Market Share Comparison Test, and (iii) the Premium Comparison Test.[14] These pricing models – none of which appear in the Guidelines and none of which has ever been applied – would reduce the price of PROCYSBI by approximately 71% to 98% of its current price.[15]

Horizon's response to Board Staff's allegations

22. In its response to Board Staff's allegations, Horizon denied that this case requires a departure from the Guidelines. Indeed, it pleaded that the proper application of the Guidelines shows that the price of PROCYSBI is non-excessive.[16]

23. Horizon also pleaded that the determination of whether the price of a patented medicine is excessive must be made in accordance with sections 83 and 85 of the *Act*.[17] Specifically, it pointed to several factors that show that the price of PROCYSBI is non-excessive, including:

(1) the factors set forth in section 85 of the *Act* and the PMPRB's Guidelines. This includes <u>all</u> the section 85 factors – not just those in subsection 85(1);

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[13] Statement of Allegations, at paras. 22, 35.
[14] Statement of Allegations, at paras. 42-61.
[15] Hay Report, at para. 23, RMR pp. 38-40.
[16] Horizon's Response to Statement of Allegations of Board Staff, at para. 61 [Horizon's Response].
[17] Horizon's Response, at para. 41.

(2) pricing in other jurisdictions;

(3) formulary listing agreements with the provinces, territories, and various federal programs;

(4) the non-excessive return on investment for Horizon; and

(5) Horizon's commitment to ensuring that all patients who are prescribed PROCSYBI can access it, regardless of their ability to pay.[18]

24. 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").[19]

25. Dr. Hay concluded that, to the extent there is any basis for departing from the Guidelines, Board Staff's alternative methodologies do not provide economically rational alternatives.[20]

26. Dr. Hay found that none of Board Staff's alternative models are consistent with the economic principle that the price of a new drug product should enable the manufacturer to recover the costs associated with developing and commercializing the new drug – a principle with which Board Staff's expert, Prof. Richard Schwindt, agrees.[21]

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[18] Horizon's Response, at para. 40.

[19] Hay Report, at para. 17, RMR pp. 35-36.

[20] Hay Report, at paras. 22, 101, RMR pp. 38, 75.

[21] Hay Report, at paras. 37-44, 101, RMR pp. 46-49, 75; Expert Report of Professor Richard Schwindt, dated September 6, 2019, pp. 2, 5, 15 [Schwindt Report], Board Staff Motion Record ["BSMR"] Tab 3A.

27. Prof. Schwindt admits that the "equilibrium market price" includes a "normal return for entrepreneurial effort (i.e., profit)."[22] He also admits that the MIPC test is valuable because the price charged in other jurisdictions discloses the patentee's willingness to supply, which "suggests that the price is covering the patentee's cost which would include a competitive profit level."[23] According to Prof. Schwindt, the appropriate price should adequately reward the patentee.[24]

Board Staff's Proposed Prices result in significant financial loss

28. To evaluate Board Staff's proposed methodologies, Dr. Hay assessed Horizon's anticipated returns from PROCYSBI in Canada at each of the Proposed Prices. [redacted]

29. Specifically, Dr. Hay explained that:

(a) The Same Medicine Comparison Test ignores the therapeutic benefit offered by PROCYSBI by setting the price of PROCYSBI as the price of Cystagon, which would reduce the price of PROCYSBI by 96% to 98% of its current price. If PROCYSBI were priced at a 96% discount, [redacted].

(b) The Market Share Comparison Test sets PROCYSBI's price based on the weighted average price of each of PROCYSBI and Cystagon, with weights based on their respective market shares in the PMPRB7. This model would reduce the price of PROCYSBI by 80% to 92% of its

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[22] Schwindt Report, pp. 2-3, BSMR Tab 3A.
[23] Schwindt Report, p. 5, BSMR Tab 3A.
[24] Schwindt Report, p. 15, BSMR Tab 3A.
[25] Hay Report, at para. 23, RMR pp. 38-40.
[26] Hay Report, at paras. 23(a), 87-90, RMR pp. 38, 65-68.

current price. If PROCYSBI were priced at an 80% discount, [redacted][27]

(c) The Premium Comparison Test arbitrarily sets the price of PROCYSBI as the price of Cystagon plus a twenty-five percent premium, which would reduce the price of PROCYSBI by 71% to 73% of its current price. If PROCYSBI were priced at a 71% discount, [redacted]

Board Staff's motion

30. On November 28, 2019, Board Staff brought this motion asking the Board to bifurcate the hearing between subsections 85(1) and 85(2). It also seeks an order striking (unidentified) portions of the Hay Report.[29] As stated in the Overview, the effect of this motion, if granted, would be to prevent the Board from seeing Dr. Hay's evidence in full.

31. In the alternative, Board Staff seeks production through the form on an inspection – to allow its expert, Howard Rosen, to inspect Horizon's books and records.

32. In response to this motion, Horizon retained Andrew Harington, a Chartered Professional Account, Chartered Financial Analyst, and a Chartered Business Valuator at the Brattle Group. Mr. Harington reviewed Mr. Rosen's request and identified certain categories of information that, in his opinion, are neither relevant nor necessary to Mr. Rosen's mandate.[30] Mr. Harington also concluded that Mr. Rosen's request to conduct an on-site inspection is excessive and unnecessary.[31]

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[27] Hay Report, at paras. 23(c), 94-98, RMR pp. 39-40, 70-75.

[28] Hay Report, at paras. 23(b), 91-93, RMR pp. 39, 68-70.

[29] Board Staff is seeking an order to redact some as yet unidentified portions of the Hay Report. See Written Submissions of Board Staff, at para 70.b.

[30] Harington Affidavit, at paras. 18-19, RMR pp. 5-6.

[31] Harington Affidavit, at para. 21, RMR p. 6.

33. Horizon has advised Board Staff that it is willing to provide information that is reasonable and relevant (to the extent it is available) and believes that the parties can work together to efficiently resolve the scope of production. To that end, Horizon has proposed that Merssrs. Rosen and Harington meet and confer to discuss the scope of relevant documents that should be produced (to the extent those documents are available).[32]

PART III – ISSUES

34. Whether framed as a motion to strike or a motion to bifurcate, the result of granting Board Staff's motion is clear: it will prevent Horizon from adducing evidence in response to Board Staff's allegations and proposed price reductions. Thus, the only issue on this motion is whether the Board should deny Horizon due process and the fair opportunity to respond to Board Staff's allegations. Horizon submits that the answer is no.

PART IV - LAW & ARGUMENT

Board Staff does not meet the threshold to strike evidence

35. The motion to strike is easily dealt with. It is not supported in the written submissions. More importantly, the Board has confirmed in its jurisprudence that, when making a determination under section 83 of the *Act*, evidence relating to *any* of the section 85 factors is relevant and admissible.[33]

36. Whether framed as a motion to strike or as a motion to bifurcate, Board Staff's argument is based on the "relevance" of Horizon's evidence. Even though Board Staff has attempted to cast Dr. Hay's evidence as "not relevant to any of the

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[32] Affidavit of Sandra Koomen, sworn December 13, 2019 [Koomen Affidavit] at para. 2, RMR p. 279.

[33] Board Decision – Alexion Pharmaceuticals Inc. and the Medicine "Soliris" (March 29, 2016) at para. 30 [*Soliris Decision on Motion to Strike Expert Evidence*], BOA Tab 4.

factors contained in s. 85(1) of the Act,"[34] Dr. Hay's evidence goes to the heart of the three proposed pricing models which are tendered under a section 85(1) analysis.

37. It is premature to determine the admissibility of parts of the proposed evidence at this stage. The evidence on this motion fails to meet the high threshold to strike. Expert evidence should only be struck before a hearing on the merits if it is *prima facie* irrelevant to the issues in dispute.[35] This is especially true where the issue is one of relevance.[36]

38. The Board has broad discretion to admit evidence.[37] The Board may receive "any evidence that it considers appropriate."[38] This includes expert evidence in respect of any issue raised in the pleadings or in the expert evidence.[39] Both requirements are met. The Hay Report responds to allegations made by Board Staff in its evidence and to the new pricing methodologies pleaded in its Statement of Allegations, and it deals with the very same points raised by Prof. Schwindt – namely, whether the proposed prices adequately reward the patentee.

39. This Board recently confirmed that a determination of admissibility at an early stage should only be made in the "rarest of cases" where the evidence is

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[34] Written Submissions of Board Staff, at paras. 24, 34.

[35] *Soliris Decision on Motion to Strike Expert Evidence* at paras. 63-65, 67, BOA Tab 4; *Merck & Co v. Canada (Minister of Health)*, 2003 FC 1511 at para. 6 (rev'd on other grounds), BOA Tab 8.

[36] *Mayne Pharma (Canada) Inc. v. Aventis Pharma Inc*., 2005 FCA 50 at para. 13 [*Mayne Pharma*], BOA Tab 5, citing *P.S. Partsource Inc. v. Canadian Tire Corp*., 2001 FCA 8 [*P.S. Partsource*], BOA Tab 6.

[37] The threshold required to strike evidence at this stage is dictated by the case law and by this Board's own jurisprudence. Although the rules of evidence that apply to courts do not apply to administrative tribunals, the Board regularly considers case law for guiding principles on this issue. See *Soliris Decision on Motion to Strike Expert Evidence* at para. 62, BOA Tab 4. See also *Vancouver Airport Authority v. Commissioner of Competition*, 2018 FCA 24 at para. 23, BOA Tab 9.

[38] *Patented Medicine Princes Review Board Rules of Practice and Procedure*, SOR 2012-247, s. 6(1) [Board Rules].

[39] Board Rules, s. 8(1).

"obviously irrelevant" and there is a risk of "irreparable prejudice."[40] The Panel in *Soliris* stated that evidence regarding both subsections 85(1) and 85(2) of the *Act* is "clearly" admissible.[41] The admissibility and weight to be assigned to expert reports should be decided at the hearing on the merits in the context of the full evidentiary record.[42]

40. There is no basis on which to strike Horizon's evidence. The impugned portions of the Hay Report are not obviously irrelevant, and there are no exceptional circumstances raised or cited which would warrant the striking of expert evidence.[43]

This is not an appropriate case for the extraordinary order of bifurcation

41. As with striking evidence before a hearing on the merits, bifurcation is an extraordinary form of relief. It is a narrowly circumscribed power that should be used only in the rarest of cases. It is the exception, not the rule.[44] Bifurcation is only granted when it is likely to result in the just, expeditious, and least expensive determination of the issues.[45] None of these objectives are met in this case.

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[40] *Soliris Decision on Motion to Strike Expert Evidence* at paras. 63, BOA Tab 4; *Mayne Pharma* at para. 13, BOA Tab 5, citing *P.S. Partsource*, BOA Tab 6; *Merck & Co, Inc. v. Canada (Minister of Health)*, 2003 FC 1242 at paras. 2-3 [*Merck* 2003 FC 1242], BOA Tab 10.

[41] *Soliris Decision on Motion to Strike Expert Evidence* at para. 30, BOA Tab 4.

[42] *Soliris Decision on Motion to Strike Expert Evidence* at para. 60, BOA Tab 4.

[43] *Soliris Decision on Motion to Strike Expert Evidence* at para. 67, BOA Tab 4; *Merck*, 2003 FC 1242 at paras. 2-3, BOA Tab 10.

[44] *H-D Michigan Inc. v Berrada*, 2007 FC 995 at para. 4, BOA Tab 11; Roger T. Hughes, Arthur Renaud & Trent Home, *Canadian Federal Courts Practice 2019* (Toronto: LexisNexis Canada Inc., 2019) at 609, BOA Tab 12.

[45] *Unwin v. Crothers*, 2005 O.J. No. 2797 (Sup. Ct. J.) at para. 79, BOA Tab 13; *T-Rex Property AB v. Pattison Outdoor Advertising Limited Partnership*, 2019 FC 1004 at para. 19, BOA Tab 14; *Teva Canada Ltd. v. Janssen Inc.*, 2016 FC 318 at para. 6, BOA Tab 15; *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2003 FCA 263 at para. 10 [*Bristol-Myers*], BOA Tab 16; *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FC 159 at para. 42, BOA Tab 17.

42. Board Staff has filed no evidence that bifurcation will be fair or that it will suffer prejudice if bifurcation is not ordered.[46] Board Staff has only provided an opinion from an expert accountant that he may require more information to test Dr. Hay's assumptions – i.e., to determine that issue on its merits. Bifurcation would be the rule and not the exception if it could be used to sever a proceeding because determining a point properly on a full record was inconvenient.

A. Bifurcation will not result in a just determination of the issues

43. As explained below, bifurcating the hearing between sections 85(1) and 85(2) will cause serious prejudice to Horizon by denying Horizon the opportunity to respond to Board Staff's allegations. This is not a fair or just result. Nor is it expeditious – such a ruling would force an application for judicial review to preserve Horizon's right to defend itself against these allegations.

All issues should be resolved at one hearing

44. A litigant has a basic right to have all the issues in dispute resolved at one hearing.[47] Litigation by installment is to be avoided.[48] Indeed, when used appropriately, bifurcation is intended to sever a determinative or "threshold" issue, such as liability and damages. It is not a vehicle to exclude evidence that goes to an ultimate issue – i.e., whether the price of PROCYSBI is excessive. Nor is it a vehicle to exclude evidence that *responds* to allegations on the ultimate issue – i.e., Board Staff's proposed price reductions.

The threshold issue is excessiveness

45. Board Staff's request for bifurcation rests on a single, flawed premise: that a determination under section 85(1) is a "threshold" issue. It is not. There is only one

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[46] *Bristol-Myers* at para. 10, BOA Tab 16.

[47] *South Yukon Forest Corp v. R.*, 2005 FC 670 at para. 3, BOA Tab 18; *Bristol-Myers* at para. 7, BOA Tab 16.

[48] *Garland v. Consumers' Gas Co.*, 2004 SCC 25 at para. 90 [*Garland*], BOA Tab 19.

threshold issue: whether the price of PROCYSBI is excessive under section 83 of the *Act*. Although section 85 sets out the factors that may be relevant under section 83, excessiveness is the issue to be determined.

46. The section 85 issues in this case are intertwined. In any event, as explained below, this Board has ruled that all section 85 issues should be admitted in a single hearing.

This Board has expressly rejected bifurcating section 85

47. Bifurcating the hearing between sections 85(1) and 85(2) is unprecedented. Bifurcation is not likely to result in an expeditious or least expensive determination of the issues, and this Board has expressly declined to follow this approach.

48. Recognizing that the factors under section 85 are not watertight compartments, the Panel in *Soliris* rejected the "splitting" or "dividing" of the case between the factors in subsections 85(1) and 85(2) on the basis that it is "not an efficient or preferable way to proceed."[49]

49. Yet, Board Staff's argument has the effect of portraying the analytical steps as discrete issues, suggesting wrongly that the Board must make a determination under subsection 85(1) before it can receive evidence under subsection 85(2). The Board in *Soliris* considered and rejected this approach.

50. This Board's decision in *Soliris* is instructive. In concluding that evidence relating to any of the factors in section 85 of the Act was relevant and "clearly" admissible, the Panel in *Soliris* provided clear instructions on the proper procedure:

> [T]he 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

[49] Board Decision – Alexion Pharmaceuticals Inc. and the Medicine "Soliris" (November 24, 2015) at para. 76 [*Soliris Decision on Procedural Matters*], BOA Tab 20.

> unable to decide the matter based on a consideration of the factors listed in subsection 85(1) alone [emphasis added].
>
> […]
>
> 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*.[50]

51. The Panel confirmed that this manner of proceeding is consistent with the approach taken by the Board in prior cases.[51] There is nothing in either the *Act* or the jurisprudence to suggest that the Board can only receive evidence on subsection 85(2) if it cannot make a determination based on subsection 85(1).[52]

The Hay Report responds to Board Staff's pleadings and evidence

52. Board Staff's attempt to create a rigid distinction between evidence relating to subsections 85(1) or 85(2) has no merit. It is based on an artificial distinction that focuses solely on the content of the evidence (i.e., costs), while ignoring the purpose for which the evidence was put forward.

53. Board Staff uses this approach to position portions of the Hay Report as evidence "regarding the costs associated with commercializing PROCYSBI" under

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[50] *Soliris Decision on Procedural Matters* at paras. 76, 79, BOA Tab 20.

[51] *Soliris Decision on Procedural Matters* at para. 77, BOA Tab 20.

[52] To be clear, in *Soliris*, Board Staff made arguments similar to those that Horizon is now making. There, the Respondent, Alexion, brought a motion to strike Board Staff's evidence relating to subsection 85(2). In opposing Alexion's motion, Board Staff argued the following: (1) There is only one cause of action in this proceeding, "whether Alexion is selling Soliris at an excessive price under the Patent Act" and Alexion has been aware of this allegation from the outset; and (2) Board Staff is merely confronting Alexion's allegation that the price of Soliris is not excessive by pleading additional facts relating to Alexion's costs and such other factors to "demonstrate that the excessive price of Soliris cannot be justified." As stated above, the Panel admitted evidence under all the section 85 factors. See *Soliris Decision on Procedural Matters* at para. 65, BOA Tab 20.

subsection 85(2).[53] This is incorrect. The Hay Report was tendered in *response* to Board Staff's allegations. It was not tendered as affirmative evidence to *justify* the price of PROCYSBI under section 85(2). Put simply, the analysis was conducted to provide the Panel with critical information on whether the Proposed Prices are reasonable. The evidence goes directly to the issues pleaded by the Parties (and put in play by Board Staff) and is responsive (if not consistent with) portions of Prof. Schwindt's Report.

The Board must consider all evidence when determining the maximum non-excessive price

54. The onus is on Board Staff to prove that the price of PROCYSBI is excessive and that ultimate burden never shifts.[54] The Board must consider all the evidence to determine whether the maximum non-excessive price proffered by Board Staff is reasonable. This is the case Board Staff must meet and Horizon is entitled to meet that case with evidence of its own.

55. For example, in the ultimate hearing on the merits in *Soliris*, the Board considered Prof. Schwindt's evidence of whether a patentee was "covering its costs and earning a normal rate of return."[55] On judicial review, the Federal Court upheld the Panel's consideration of this evidence, noting that "a panel is required to consider drug pricing on a case-by-case basis and to consider the statutorily prescribed factors in light of the circumstances of the drug before it. Just as the *Act* and Regulations cannot be read as excluding a particular result, they cannot be read as excluding a particular test."[56] Indeed, the evidence in Prof. Hay's report goes to the very issue that was found to be lacking in the Soliris case:

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[53] Written Submissions of Board Staff, at para. 24.

[54] *Leo Pharma Inc. v. Canada (Attorney General)*, 2007 FC 306 at para 27, BOA Tab 21; Board Decision – sanofi-aventis Canada Inc. and the medicine "Penlac Nail Lacquer" (January 31, 2011) at para. 82, BOA Tab 22.

[55] *Alexion* at para. 38, 82, BOA Tab 2.

[56] *Alexion* at para. 61, BOA Tab 2.

> I am also not persuaded that the Panel erred in noting Dr. Schwindt's evidence to the effect that the price charged in one comparator country can allow one to conclude that the patentee is covering costs and earning a normal rate of return. In Alexion's view, the Panel essentially considered the costs of making and marketing Soliris under subsection 85(2) of the Act, when the Panel had stated it would not have regard to that factor. I disagree. This appears to be a common sense conclusion that falls well short of a consideration of the costs of making and marketing medicine as contemplated at subsection 85(2). [emphasis added][57]

56. The Federal Court, as did the Panel whose decision was under review, concluded that the pricing issues raised by Prof. Schwindt were not section 85(2) issues – as Horizon argues here.

57. Thus, the Board is not restricted to the factors that it may consider when determining the maximum non-excessive price of a drug. The Board is required to consider the statutory factors, but it is not limited to them. The sequential framework under section 85 applies only to the Board's determination of excessiveness, once all of the evidence has gone in.[58]

B. Bifurcation is not in the public interest

58. The Board must be satisfied that bifurcation will result in a just determination of the issues. This is not limited to a just determination of the issues as between the parties – there are important public interest issues that must be considered.

59. The Board's consumer protection mandate has long been recognized. In *Celgene*, the Supreme Court of Canada affirmed that, when making a determination under section 85, the Board must consider its consumer protection mandate – specifically, its role in ensuring that all Canadians are able to obtain patented medicines at "reasonable prices" and that the prices of patented medicines do not rise to "unacceptable levels."[59] "Reasonable prices" and "unacceptable levels" have to be

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[57] *Alexion* at para. 82, BOA Tab 2.

[58] *Soliris Decision on Motion to Strike Expert Evidence* at para. 60, BOA Tab 4.

[59] *Celgene* at paras. 26-28, BOA Tab 3; *Soliris Decision on the Merits* at para. 108, BOA Tab 1; *Alexion* at paras. 31, 78-79, 84, 89, BOA Tab 2.

considered in relation to the public and to Horizon, as the scheme of the *Act* cannot contemplate the provision of patented medicines at prices that, in Prof. Schwindt's language, do not adequately reward the patentee. As suggested by Prof. Schwindt, the appropriate price is not one where Horizon sells at a loss. For obvious reasons, this is not in the public's interest.

60. The Board's role is not to determine the lowest possible price, and the Board should not exercise its powers in a way that impairs or restricts the ability of Canadians to access drugs. It is a balancing exercise. Evidence which bears on the commercial viability of a drug in Canada is clearly relevant to discharging that mandate.

61. The Board must consider whether a perverse result flows from the case presented by Board Staff. Evidence on the impact of proposed price reductions is therefore necessary for the Board to fulfill its mandate of ensuring that Canadians have access to patented medicines at reasonable prices.[60]

62. Bifurcating the hearing and preventing the Board from hearing this evidence is not in the public interest, and it will not result in a just determination of the issues.

Bifurcation will not result in an expeditious determination of the issues

63. Bifurcation carries with it inherent and significant duplication and delay.[61] It creates the risk of a multiplicity of proceedings and a multiplicity of appeals, the risk that preliminary steps would deny a litigant the opportunity to make its case and respond to Staff's pleadings and evidence, and the risk that a decision will be made without the full evidentiary context.[62] The consequences could delay the Board's process while the due process issues are addressed by the courts.

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[60] *Soliris Decision on the Merits* at para. 108, BOA Tab 1; affirmed in *Alexion* at paras. 78-79, BOA Tab 2, citing *Celgene* at paras. 27-28, BOA Tab 3.
[61] *Alcon Canada Inc. v. Apotex Inc.*, 2016 FC 898 at para. 12 [*Alcon*], BOA Tab 23.
[62] *Harrop (Litigation Guardian of) v. Harrop*, 2010 ONCA 390 at para. 2, BOA Tab 7

64. *Soliris* confirmed that bifurcation is neither efficient nor preferable, and there is no basis on which to depart from this ruling. The Board often receives evidence that is technical and complex from medical, scientific, economic, and sociological perspectives.[63] These are not exceptional circumstances that warrant a departure from the general rule that litigants have a right to one hearing and that "litigation by installment" should be avoided.[64]

65. If the legislature intended that the Board receive evidence on subsection 85(2) only after considering subsection 85(1), it would have said so. This Board has never bifurcated the hearing between subsections 85(1) and 85(2), and it should not do so now.

Bifurcation must not depend on the merits

66. Board Staff repeatedly states that the Board will likely be able to determine the matter based on the factors under section 85(1). According to Board Staff, because "it is exceedingly rare for a Panel to be unable to decide a matter under s. 85(1), it is likely that it will not be necessary for the hearing to be reconvened."[65]

67. The Board should disregard these bald assertions. The Federal Court has warned that a determination of contested motions for bifurcation should not turn on an assessment of the relative merits of the parties' case or an evaluation of which party is most likely to prevail.[66]

68. Rather, procedural fairness dictates that parties have a meaningful opportunity to respond to allegations made against them.[67] It would be manifestly

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[63] Board Decision – Shire BioChem Inc. and the medicine "Adderall XR" (April 10, 2008) at para. 2, BOA Tab 24.

[64] *Garland* at para. 90, BOA Tab 19.

[65] Written Submissions of Board Staff, at para. 37.

[66] *Alcon* at para. 12, BOA Tab 23.

[67] *Canadian Recording Industry Assn. v. Society of Composers, Authors & Music Publishers of Canada*, 2010 FCA 322 at paras. 15, 27, BOA Tab 25.

unfair to allow Board Staff to raise allegations and ask this Board to impose price reductions without allowing Horizon a fair opportunity to respond. This is not a fair or just result.

Board Staff's request for production and inspection is overbroad

69. Board Staff's request for production and inspection is overbroad. Although the Board has powers under the Rules to order production and inspection, this power must be exercised in accordance with the principle of proportionality. Fishing expeditions are prohibited.[68]

70. The test of whether information should be provided to the Board is the "relevance of the information for the proper exercise of its excessive pricing mandate."[69] In cases where the Board has ordered inspection, Board Staff has provided evidence of exceptional factors to justify its request. In the case of *ratio HFA*, for example, Staff alleged suspicious circumstances surrounding the manufacturer's Form 2 filings that justified additional production.[70] No such circumstances are present in this case.

71. Horizon's expert, Mr. Harington, assessed Board Staff's request for production and inspection. Mr. Harington concluded that, while Board Staff's request is generally reasonable, certain categories of documents are neither relevant nor necessary for Mr. Rosen to test, verify, and respond to the Hay Report.[71] Mr. Harington also concluded that an inspection is not necessary in these circumstances, as there is no reason to doubt the accuracy of the documents that Mr. Rosen has

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[68] *Intel Corp. v. 339583 Canada Inc.*, 2004 FC 218 at paras. 20, 22-23, BOA Tab 26; *Burnaby Machine & Mill Equipment Ltd. v. Berglund Industrial Supply Co.* (1984), 81 C.P.R. (2d) 251 (F.C.), at paras. 5, BOA Tab 27; *Crestbrook Forest Industries Ltd. v. R.*, [1993] 3 F.C. 251 at para. 37, BOA Tab 28.

[69] Board Decision – ratiopharm Inc. and the medicine "ratio-Salbutamol HFA" (August 14, 2009) at para. 11, BOA Tab 29.

[70] Board Decision – ratiopharm Inc. and the medicine "ratio-Salbutamol HFA" (May 27, 2011) at paras. 54-55, 97-98, BOA Tab 30.

[71] Harington Affidavit, paras. 18-19, RMR pp. 5-6.

requested, and Horizon's operations are not so unique as to require an on-site inspection.[72]

72. Horizon has advised Board Staff that it is willing to provide information that is reasonable and relevant (to the extent it is available) and believes that the parties can work together to efficiently resolve the scope of production. To that end, Horizon has proposed that Merssrs. Rosen and Harington meet and confer to discuss the scope of relevant documents that should be produced (to the extent those documents are available).[73]

PART V - ORDER SOUGHT

73. Horizon requests that this motion be dismissed.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 13th day of December 2019.

[72] Harington Affidavit, at para. 21, RMR p. 6.

[73] Koomen Affidavit, at para. 2, RMR p. 279.

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SCHEDULE A

TABLE OF AUTHORITIES

1. *Alcon Canada Inc. v. Apotex Inc.*, 2016 FC 898
2. *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2019 FC 734
3. *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FC 159
4. Board Decision – Alexion Pharmaceuticals Inc. and the Medicine "Soliris" (November 24, 2015)
5. Board Decision – Alexion Pharmaceuticals Inc. and the Medicine "Soliris" (March 29, 2016)
6. Board Decision – Alexion Pharmaceuticals Inc. and the Medicine "Soliris" (September 20, 2017)
7. Board Decision – ratiopharm Inc. and the medicine "ratio-Salbutamol HFA" (August 14, 2009)
8. Board Decision – ratiopharm Inc. and the Medicine "ratio-Salbutamol HFA" (May 27, 2011)
9. Board Decision – sanofi-aventis Canada Inc. and the Medicine "Penlac Nail Lacquer" (January 31, 2011)
10. Board Decision – Shire BioChem Inc. and the Medicine "Adderall XR" (April 10, 2008)
11. *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2003 FCA 263
12. *Burnaby Machine & Mill Equipment Ltd. v. Berglund Industrial Supply Co.* (1984), 81 C.P.R. (2d) 251 (F.C.)
13. *Canadian Recording Industry Assn. v. Society of Composers, Authors & Music Publishers of Canada*, 2010 FCA 322
14. *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1
15. *Crestbrook Forest Industries Ltd. v. R.*, [1993] 3 F.C. 251
16. *Garland v. Consumers' Gas Co.*, 2004 SCC 25
17. *H-D Michigan Inc. v. Berrada*, 2007 FC 995

18. *Harrop (Litigation Guardian of) v. Harrop*, 2010 ONCA 390

19. *Intel Corp. v. 339583 Canada Inc.*, 2004 FC 218

20. *Leo Pharma Inc. v. Canada (Attorney General)*, 2007 FC 306

21. *Mayne Pharma (Canada) Inc. v. Aventis Pharma Inc*., 2005 FCA 50

22. *Merck & Co, Inc. v. Canada (Minister of Health)*, 2003 FC 1242

23. *Merck & Co v. Canada (Minister of Health)*, 2003 FC 1511

24. *P.S. Partsource Inc. v. Canadian Tire Corp*., 2001 FCA 8

25. Roger T. Hughes, Arthur Renaud & Trent Horne, *Canadian Federal Courts Practice 2019* (Toronto: LexisNexis Canada Inc., 2019)

26. *South Yukon Forest Corp v. R.*, 2005 FC 670

27. *T-Rex Property AB v. Pattison Outdoor Advertising Limited Partnership*, 2019 FC 1004

28. *Teva Canada Ltd. v. Janssen Inc.*, 2016 FC 318

29. *Unwin v. Crothers*, 2005 O.J. No. 2797 (Sup. Ct. J.)

30. *Vancouver Airport Authority v. Commissioner of Competition*, 2018 FCA 24

SCHEDULE B

LEGISLATION

Canada, Patented Medicine Prices Review Board (PMPRB), "Compendium of Policies, Guidelines and Procedures"

A.5 Price Regulation Factors

A.5.1 Subsection 85(1) of the Act stipulates those factors that the Board, during the course of a hearing, must take into consideration when determining whether a patented medicine is being sold or has been sold at an excessive price in any market in Canada by a patentee or former patentee. These factors are:

- The prices at which the medicine has been sold in the relevant market;
- The prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- Changes in the Consumer Price Index; and
- Such other factors as may be specified in any regulations made for the purposes of this subsection.

A.5.2 If after considering the above factors, the Board is unable to determine if a price is excessive, subsection 85(2) of the Act stipulates that it may consider the costs of making and marketing the medicine, as well as other factors which can be specified by regulations or that the Board considers relevant in the circumstances.

A.5.3 The Board, following considerable deliberation and consultation with all stakeholders, pursuant to subsection 96(5) of the Act, published the PMPRB's Guidelines pursuant to subsection 96(4) of the Act. Although the Guidelines are not binding on the Board or the patentee, they establish an approach and methodology in applying the factors set out in subsection 85(1) of the Act.

Part C – Guidelines and Procedures

Preface

The following Guidelines and procedures represent direction from the Board, to patentees and Board Staff, in order to provide assistance on how to comply with the *Patent Act* and the *Patented Medicines Regulations*. Please note:

These Guidelines are not binding on patentees nor the Board in the context of a hearing.

The Guidelines are organized as follows:

The Scientific Review Process: An evidence-based process that assesses the level of therapeutic improvement of a patented drug product and recommends, where appropriate, the drug products to be used for comparison purposes and the comparable dosage regimens.

The Price Review Process: The level of therapeutic improvement of a patented drug product is used to determine the Maximum Average Potential Price at introduction. Following introduction, the price of an existing patented drug product is reviewed according to the relevant price tests to establish the National and Market-Specific Non-Excessive Average Prices.

Investigations: The approach used and procedures undertaken when a price appears to exceed the investigation criteria (see Schedule 11).

Schedules: All Schedules form part of the Guidelines.

Schedule 5 – Median International Price Comparison Test

1. Median International Price Comparison (MIPC) Test

1.1 The median of the ex-factory prices of the same strength and dosage form of the same patented drug product for each country listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States) will set the Maximum Average Potential Price for a new patented drug product when the Median International Price Comparison test is the pivotal introductory price test.

1.2 When the Median International Price Comparison test is being conducted and the new patented drug product is sold in an even number of countries, the median will be the simple average of the middle two prices.

1.3 When the new patented drug product is sold in fewer than five countries at the time it is first sold in Canada, the median international price will be calculated on an interim basis. At the end of three years or when the same patented drug product with the same strength and dosage form is sold in at least five countries, whichever occurs first, Board Staff will re-determine the median international price. Whenever this occurs, the drug product's Non-Excessive Average Price will be the lower of:

a. The re-determined median international price, and

b. The Non-Excessive Average Price derived from the ordinary application of the CPI-Adjustment Methodology (see Schedule 9).

1.4 Where the re-determined median international price establishes a drug product's Non-Excessive Average Price pursuant to section 1.3 above, the patentee is expected to reduce its National Average Transaction Price and Market-Specific Average Transaction Prices to the level of the Non-Excessive Average Price calculated in accordance with section 1.3 within the next two six-month reporting periods. If the patentee complies with this timeframe, its price will not be presumed to have been excessive.

2. Indirect International Price Comparison

2.1 When a direct international price comparison of the drug product under review is not possible because the drug product is only sold in Canada, the most similar strengths of comparable dosage forms (as per Schedule 2) of the same patented drug product may be considered.

3. Exchange Rates

3.1 To calculate the Median International Price Comparison test for a new patented drug product, the exchange rates used are the simple average of the thirty-six monthly average noon spot exchange rates for each country (taken to eight decimal places) as published by the Bank of Canada for the thirty-six months ending four months before the date of the first sale of the drug product.

e.g., if the new patented drug product under review was first sold in October 2009, the exchange rates used are for the months of June 2006 through May 2009.

3.2 Exchange rates are published on the PMPRB website on a monthly basis.

***Patented Medicine Prices Review Board Rules of Practice and Procedure*, SOR 2012-247**

Procedure and Evidence

Board powers

6 (1) In relation to any proceeding, the Board may

(a) receive any evidence that it considers appropriate;

(b) take notice of facts that may be judicially noticed and of any generally recognized scientific or technical facts, information or opinions concerning patented medicines;

(c) add parties at any stage of the proceeding;

(d) permit the amendment of any document filed with the Secretary; and

(e) decide any question of procedure.

Expert Witnesses

Admissibility of expert evidence

8 (1) Expert witness evidence is not admissible in a proceeding before the Board in respect of any issue unless the issue has been raised in the pleadings or in a pre-hearing conference order or the expert witness evidence is called for the purpose of rebutting the evidence of an expert witness introduced by another party.