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 (the "Respondent")
and the medicine Cysteamine Bitartrate sold by the Respondent under the trade name Procysbi**

WRITTEN SUBMISSIONS OF BOARD STAFF

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

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PART I – OVERVIEW

1. A Board panel hearing an allegation of excessive pricing must determine the matter pursuant to the specific factors set out in s.85(1) of the *Patent Act*, RSC 1985, c.P-4 ("the Act"). It is only if the Panel cannot make a determination based on the factors set out in s.85(1) that it is then permitted to consider the factors set out in s.85(2), namely the costs of making and marketing a medicine. The Board has previously noted in numerous decisions that it will be very rare that it will need to decide a matter under s.85(2).

2. The cost of making and marketing a medicine is a relevant factor under s.85(2) of the Act. Evidence of such costs is complex and contentious.

3. Nevertheless, despite the separate and sequential scheme set out in s.85(1) and s.85(2), the Respondent, Horizon Pharma ("Horizon"), has filed the expert report of Professor Hay which *inter alia* contains detailed evidence of the costs of making and marketing the medicine at issue in this case.

4. In the unlikely event that it becomes necessary for the Panel to consider the factors set out in s.85(2) Board Staff is unable to respond to Horizon's evidence regarding the costs of making and marketing the medicine at issue without its own experts first having access to the books and records of Horizon.

5. However, such evidence is technical, highly complex, voluminous, and contentious. This is problematic for two reasons: first, as set out in the Act, a Panel can only consider such evidence if it cannot make a determination based on s.85(1); and second, Board hearings are to be dealt with in a manner that is just, expeditious and as least expensive as possible. Such a result would best be achieved in this case by bifurcation of the hearing between s.85(1) and (2). Such an approach would mean that the Panel in this case would not initially hear evidence and argument regarding the costs of making and marketing the

medicine. (Indeed it is highly likely that the Panel would not ever need to hear this evidence.)

6. In the event that the hearing in this matter is not bifurcated, then Board Staff requests that the Panel issue an order allowing its expert, Secretariat, to conduct an inspection of the original books and records of Horizon as well as being provided with relevant documentation. Without such an order, Board Staff will be unable to respond to the evidence of Professor Hay regarding the costs of making and marketing the medicine at issue in this case. As outlined below, granting Board Staff an order for inspection and production is consistent with past decisions of the Board.

PART II – STATEMENT OF FACTS

7. Board Staff alleges that Horizon is selling the medicine Cysteamine Bitartrate under the trade name Procysbi ("Procysbi") at a price that is excessive. Board Staff seeks an order under s.83 of the Act for a reduction in the price of Procysbi and repayment of excess revenues.

8. Procysbi is used to treat the disease cystinosis. The only active medicinal ingredient in Procysbi is cysteamine bitartrate. Procysbi must be taken every twelve (12) hours.

9. Cystagon is the trade name for the only other product used to treat cystinosis. Like Procysbi, it contains as its only active medicinal ingredient cysteamine bitartrate. However, unlike Procysbi, Cystagon must be taken every six (6) hours.

10. Procysbi and Cystagon both act to deplete the cystine that accumulates in the tissues of the body as a result of cystinosis. The same indications and contraindications exist for both Procysbi and Cystagon. As a result, Board Staff

alleges that there is no reliable evidence of any meaningful therapeutic advantage between Procysbi and Cystagon.

11. Horizon agrees that Procysbi is the only other treatment option for patients suffering from cystinosis. However, Horizon asserts that there is a therapeutic advantage of Procysbi over Cystagon. Horizon asserts that Procysbi is either a breakthrough, substantial improvement or at minimum a moderate improvement over Cystagon and that its price is not excessive.

12. Board Staff alleges that the annual treatment cost of Procysbi for an adult patient suffering from cystinosis is approximately $325,000 per year while the annual treatment costs of an adult patient treated with Cystagon is approximately $5,000 per year. Treatment begins as soon as a patient is diagnosed (often before the age of 2) and continues for the entire life of the patient.

13. Section 85(1) of the Act sets out the following factors to be considered by the Panel in determining whether a price is excessive:

> **85 (1)** In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
> (a) the price at which the medicine has been sold in the relevant market;
> (b) the price 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 in the Consumer Price Index;

14. In its Statement of Allegations, Board Staff asserts *inter alia* that, having regard to the factors set out in s.85(1) of the Act, the maximum non-excessive price

("the MNE") of Procysbi should be determined based on one of three different and alternative approaches. All three alternatives are based on a comparison of the price of Procysbi with Cystagon in Canada and internationally.

15. Board Staff, in its Statement of Allegations, assert that the price of Procysbi is excessive. It alleges that the proper application of the s.85(1) factors would result in the MNE of Procysbi being lowered in accordance with one of the following three approaches:

    a. The *Same Medicine Comparison*. This approach asserts that the price of Procysbi should be lowered to a price that does not exceed that of Cystagon in Canada. This approach is based on the fact that Procysbi and Cystagon are identical. They are the same medicine: they use the same sole active medicinal ingredient to treat the same disease through the same biochemical mechanism. The only difference is the delivery of that medicine: Procysbi is microencapsulated with an enteric coating, which delays release of the medicinal ingredient.
    b. The *Premium Price*. This approach is premised on the Panel accepting that the enteric coating of Procysbi, which allows it to be dosed every twelve (12) hours, rather than every six (6) hours as is the case for Cystagon, justifies a price premium. Board Staff suggests that a reasonable premium on the facts of this case would be a quarter-point (midpoint of the midpoint) between the current price of Procysbi and the price of Cystagon.
    c. The *Market Share Approach*. If the decrease in dosing schedule (from every 6 hours with Cystagon to every 12 hours with Procysbi) justifies a price premium, this approach asserts that the price of Procysbi should be lowered to a price that is calculated based on the market share of Procysbi and Cystagon in the comparator countries where Procysbi and Cystagon are sold.

16. In support of these three alternative pricing approaches, Board Staff has served Horizon with two expert reports. The first report is that of Dr. Julien Midgley, a pediatric nephrologist who treats cystinosis patients with Cystagon and Procysbi. He discusses his personal clinical experience with the relative advantages and disadvantages of the two drugs.

17. The second report is that of Professor Richard Schwindt. His report provides an expert opinion regarding the methodologies for determining an excessive price of Procysbi under s.85(1) of the Act.

18. Horizon has served Board Staff with two expert reports. The first report is that of Dr. Craig Langman, a pediatric nephrologist. His report provides information regarding cystinosis and treatment options. He opines *inter alia* on whether there are therapeutic advantages of Procysbi compared to Cystagon.

19. The second report is that of Professor Joel Hay, a professor of pharmaceutical economics. His report provides an explanation of general considerations that go into the pricing of rare disease drugs and an explanation of the price control modes in Canada, including those in the *Compendium of Policies, Guidelines and Procedures of the PMPRB*.

20. Professor Hay also opines on whether the three approaches proposed by Board Staff would allow Horizon "to recover the costs associated with commercializing Procysbi in Canada". Professor Hay provides his opinion on the losses Horizon would allegedly suffer at the prices proposed by Board Staff. The details of Professor Hay's financial analysis are contained in Appendices E, F, and G of his report.

21. Appendix F of Professor Hay's report purports to rely on business forecasts prepared by Horizon [redacted] Appendix F contains a Section A headed "Cash Flows from Procysbi based on its current ex-factory price". The following are the subheadings in section A:

    1. Cash Flows from Procysbi based on its Current Ex-Factory Price
    2. Ex-Factory Prices and Discounts on Sales of Procysbi
    3. Royalties Payable on Net Sales of Procysbi
    4. Per Unit Cost of Goods Sold for Procysbi
    5. Other Cost of Sales for Procysbi
    6. Sales and Marketing Expenditures for Procysbi
    7. General and Administrative Expenditures for Procysbi
    8. Cost of Procysbi's Development and Commercialization
    9. Forecasted Net Cash Flows from Sales of Procysbi in Canada

22. Section B of Appendix F is titled "Cash Flows from Procysbi based on Board Staff's proposed prices". In this section, Professor Hay uses the financial economic model he created to assess Horizon's return on sales of Procysbi under the prices proposed by Board Staff. The model he uses purports to compute net revenues and the allocation of sales and marketing expenses and general and administrative expenses.

23. Appendix G of Dr. Hay's report contains tables of data with the following headings:

    1. [redacted]
    2. [redacted]

3. [redacted]

24. Board Staff asserts that the information and opinions of Professor Hay regarding the costs associated with commercializing Procysbi and the accompanying financial data contained in Appendices F and G is not relevant to any of the factors contained in s.85(1) of the Act, although it might be relevant under s.85(2) of the Act. However, as expressly stipulated in the Act, s.85(2) may only be considered by the Panel if it is unable to reach a determination based on s.85(1).

25. Board Staff have retained the expert services of Howard Rosen and Julius Koo of Secretariat ("Secretariat") to assist them in the review of the report of Professor Hay. Secretariat were requested to review the financial matters underlying Professor Hay's opinions on whether Horizon would be able to recover the costs associated with commercializing Procysbi in Canada, and in particular the financial analysis set out in Appendices F and G. Secretariat have advised that, in order to test the assumptions, statements, and calculations made by Professor Hay, they require access to the books and records of Horizon as well as various documents and records. Thereafter, Secretariat may need to provide an expert report in response to Professor Hay's report.

PART III – LAW AND ARGUMENT

I. Relationship between s.85(1) and s.85(2)

26. Under the *Act*, the factors to be considered in determining whether a patented medicine is sold at an excessive price are set out in s.85(1) and s.85(2) as follows:

> **Factors to be considered**
> **85 (1)** In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (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 in the Consumer Price Index; and
> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.
>
> **Additional factors**
> **(2)** Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:
>
> (a) the costs of making and marketing the medicine; and
> (b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

27. The excessive pricing regime set out in the *Act* requires the Board to first determine whether the matter of excessive pricing can be determined pursuant to s.85(1) of the *Act,* based solely on the factors outlined in that section. It is only **if**

the Board cannot make a determination based on the factors set out in s.85(1), that the Board is permitted by the Act to consider the factors set out in s.85(2).

> ***ICN Canada Ltd., merits decision*, PMPRB-95-D5/VIRAZOLE, July 26, 1996 [Virazole]**
> ***ratiopharm Inc., merits decision*, PMPRB-08-D3-ratio-Salbutamol HFA, May 27, 2011 [ratio Salbutamol]**
> ***Alexion Pharmaceuticals Inc., merits decision (public version)*, Soliris, September 20, 2017 [Soliris]**

28. The sequential approach imposed by the Act has been recognized previously and on multiple occasions by the Board in numerous Panel decisions. For example, in *Virazole* the Board indicated that it was instructed by the *Act* to first consider whether the matter could be determined pursuant to s.85(1). Only if a determination could not be made under s.85(1) should the Board consider the factors outlined in s.85(2). The issues of making and marketing costs are not relevant to the determination under s.85(1). On this point, the Board held at page 8:

> It seems apparent to the Board, then, that it is instructed by the *Act* to first attempt to determine the matter by reference to criteria established by Parliament in subsection 85(1) of the *Act* or by regulations pursuant to that subsection, and only if that exercise is not successful should the Board consider factors such as the costs of making and marketing the medicine or other factors the Board considers appropriate pursuant to clause 85(2)(b). Accordingly the Board concludes that its deliberations pursuant to subsection 85(1) are indeed restricted to the factors set out in that subsection or in regulations passed pursuant to that subsection.
>
> It is not appropriate for the Board, in its deliberations pursuant to subsection 85(1), to consider the costs to ICN Canada Ltd. of making and marketing Virazole.

29. The Board also noted that there must be compelling reasons to consider basing an excessive pricing analysis on making and marketing costs pursuant to s.85(2) and that it would be rare to proceed on this basis. On this point, the Board noted at page 11:

> There would have to be compelling reasons for the Board to determine the MNE on the basis of a patentee's costs of making and marketing a medicine and it seems likely that the instances in which that analysis will be appropriate will be rare...

30. The Board also noted that it was likely that evidence relating to the costs of making and marketing a patented medicine would be complex and contentious, holding at page 12:

> Finally, it should be noted that, given the potentially complex and contentious nature of the financial and accounting evidence on this issue, the Board expects that the determination of a MNE by reference to the costs of making and marketing the medicine would only be possible where the Board received clear and reliable evidence on the point.

31. The Board took a similar approach to the relationship between s.85(1) and s.85(2) in *ratio Salbutamol,* noting that the Board would only look to s.85(2) if it was unable to make a determination based on s.85(1). On this point, the Board held at paragraph 86:

> vi) Subsection 85(2) of the Act
>
> In accordance with subsection 85(2) of the Act, the Panel need only take into consideration the factors set out therein if it is unable to determine whether the medicine under review is being or has been sold at an excessive price after taking into consideration the factors referred to in subsection 85(1).

32. In *Soliris*, the Board noted that, as it was able to make a determination based on the factors in 85(1), it was not necessary for it to consider the factors relevant to section 85(2). The Board held at paragraph 136:

> If the Panel is able to make a determination by reference only to section 85(1), it is to limit itself to a consideration of the factors under that section. If not, this Panel can, under section 85(2), take into consideration the costs of making and marketing the medicine. This Panel agrees with other hearing panels who have concluded

> that there would have to be compelling reasons to determine the issue of excessive pricing on the basis of the costs of making and marketing the medicine, and it is only appropriate to do so in exceptional circumstances and on the basis of clear and reliable evidence.

II. Bifurcation

33. Board Staff agrees that the report of Dr. Langman is relevant for the purpose of s.85(1). It contains evidence regarding Cystagon, which is in the same therapeutic class as Procysbi. Both s.85(1)(b) and s.85(1)(c) specifically require a Panel to have regard to medicines in the same therapeutic class.

34. Board Staff submits that while parts of the evidence of Professor Hay are relevant for the purpose of s.85(1), there are separate and distinct portions in his report that have no relevance to any of the factors set out in s.85(1). Appendices F and G of Dr. Hay's report contain detailed financial economic analysis, that is then used by Dr. Hay in support of his conclusions regarding Horizon's return on investment. This is information relating to the costs of making and marketing Procysbi. While such evidence can be relevant under s.85(2), it is manifestly not relevant under s.85(1).

35. As previously noted in the *Virazole* and *ratio-salbutamal* cases, evidence as to the cost of making and marketing a medicine is complex and contentious. This is self-evident from even a cursory review of Professor Hays' report and Appendices F and G.

36. The evidence of Secretariat provides further confirmation that the nature of the evidence required to properly assess the costs of making and marketing Procysbi is complex and will require the production and review of a substantial amount of documentation. It will also require that Secretariat have access to the original books and records of Horizon. It may also result in an additional expert report.

37. A Panel hearing an allegation that a medicine is excessively priced must begin by determining the issue under s.85(1). The evidence with respect to s.85(1) is materially different than it would be under s.85(2). Moreover, since the evidence of Professor Hay regarding the costs of making and marketing Procysbi under s.85(2) is complex and contentious, it would also necessitate reply evidence that would be complex and contentious. Board Staff submits therefore that this is an appropriate case for the Panel to bifurcate the hearing. In the event that the Panel was unable to determine the matter under s.85(1), then and only then, would the hearing be reconvened to present evidence and argument regarding the factors in s.85(2). Moreover, since 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.

38. The authority of the Board to bifurcate a hearing arises from the Act and the *Patented Medicine Prices Review Board Rules*, SOR/12-247 ("the Rules"). The Board is directed by the Act to ensure that all proceedings before it are dealt with informally and expeditiously at s.97(1), as follows:

> **Proceedings**
> **97 (1)** All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit.

39. The Board is given the power to make rules relating to the practice and procedure of the Board pursuant to s.96(2)(b) of the *Act*, as follows:

> **Rules**
> **96(2)** The Board may, with the approval of the Governor in Council, make general rules
> ...
> (b) for regulating the practice and procedure of the Board

40. Rule 5(2) provides that the Board may deal with any unanticipated procedural matter in a manner to ensure a fair and expeditious proceeding, as follows:

> **Unanticipated procedural matters**
> 5(2) Any procedural matter or question that is not provided for in the Act, in these Rules or in any regulations made pursuant to the Act that arises in the course of any proceeding may be dealt with in any manner that the Board directs in order to ensure the fair and expeditious conduct of any proceeding.

41. Analogy may be drawn to the principles applied by the Federal Court. Rule 107 of the Federal Court Rules permits severance of issues as follows:

> **Separate determination of issues**
> **107** (1) The Court may, at any time, order the trial of an issue or that issues in a proceeding be determined separately.
>
> **Court may stipulate procedure**
> (2) In an order under subsection (1), the Court may give directions regarding the procedures to be followed, including those applicable to examinations for discovery and the discovery of documents.

42. In *Eli Lilly Canada Inc. v. Novopharm Ltd.*, the matter involved an appeal from a prothonotary decision to bifurcate the issue of quantum from the issues of validity and infringement of a patent. One of the factors that the prothonotary had taken into account was the fact that bifurcation tended to be the norm in patent infringement cases. The appellant suggested that the prothonotary had inappropriately switched the onus with respect to bifurcation to the party resisting the request for bifurcation. The appellant also argued that the prothonotary should have required specific evidence of the number of days of discovery or quantification of costs that would allegedly be saved by bifurcating the issues.

***Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 1126 [Eli Lilly]**

43. The Federal Court upheld the prothonotary's decision, noting that the prothonotary took many factors into account and was satisfied on the whole of

the evidence that "severance is more likely than not to result in the just, expeditious and least expensive determination of the proceeding on the merits".

44. With respect to the fact that the prothonotary did not require evidence of the exact number days to be saved or quantification of the costs to be saved, the Federal Court noted at paragraph 6:

> Evidently, the Prothonotary was satisfied that she did not require more specific evidence in respect of the number of days of discoveries or an exact quantification of the time and expenses that would be saved in order to determine whether this would necessarily result in a saving of time and money for the Court and the parties.

45. In *Bristol-Myers Squibb Co. v. Apotex Inc.*, the Federal Court of Appeal observed that although bifurcation is the norm in pharmaceutical patent infringement matters, this was only one of the factors that the judge considered. The Court of Appeal observed that the right of a litigant to have all issues determined in one trial could be displaced upon a finding that it would be more just, expeditious and less expensive to bifurcate.

***Bristol-Myers Squibb Co. v. Apotex Inc.*, 2003 FCA 263 [Bristol-Myers] at para. 10.**

46. In *Apotex Inc. v. Pfizer Canada Inc.*, the moving party brought a bifurcation motion under Rule 107 asking that the question of entitlement to elect an accounting of profits with respect to a pharmaceutical infringement be determined separately, and prior to, any discovery relating to quantification of damages or profits. The Court noted at paragraphs 3 and 11 that severance will be granted if it is "more likely than not to result in the just, expeditious and least expensive determination".

***Apotex Inc. v. Pfizer Canada Inc.*, 2014 FC 159 (CanLII) [Pfizer]**

47. One of the factors considered by the Court was that discovery was time-consuming and could give rise to further motions. At paragraph 12, the Court stated:

> First, I accept that documentary and oral discovery is a costly and time-consuming process and may give rise to a variety of motions for further disclosure (which are also likely to result in further delays in case of subsequent appeals). Therefore, I find that an early determination of Merck's entitlement to an accounting of profits will narrow the scope of the discoveries to be conducted. If Merck is not found entitled to the remedy, further discoveries into Apotex's profits become irrelevant. On the other hand, if Merck is found entitled to the remedy, it is reasonable to permit Merck to discover Apotex or issues relating to its profits before Merck makes that request. Additionally, unless Merck elects damages, there would then be no reason for them to be submitted to discovery since, indeed, any information relevant to the extent of infringement by Apotex, and its profits made from infringement, is wholly within Apotex's knowledge.

48. On this motion, Board Staff seeks an order bifurcating the hearing, and in the alternative an order for production and inspection of various financial records of Horizon. It is of course entirely possible (and may indeed be likely) that the production and inspection of the financial records will lead to further motions. It should however be noted that if the within motion for bifurcation is granted, then the Panel need not decide upon the motion by Board Staff for production and inspection, as the Panel may well be able to determine whether or not the price of the medicine is excessive based on the factors in s.85(1). The Board has frequently noted that resort to s.85(2) will be very rare.

49. In *Pfizer*, the defendant in a pharmaceutical patent infringement action sought an order that the issue of the "start date" of liability be bifurcated and determined prior to the trial on the issues of liability and damages. The Court noted that this was not a "garden variety" request for bifurcation, which usually related to determining liability before damages. The parties offered different affidavit

evidence relating to whether determining the "start date" would lessen the complexity of the matters in dispute.

50. The Court reviewed the principles relating to bifurcation of an action. After reviewing previous case law, the Court then went on to consider issues when making a determination of whether bifurcation was appropriate. Although the Court used the terminology usually applied to liability/damages issues, we have summarized the points below in more neutral language:

- complexity of the issues;
- whether the issues are clearly separate
- whether the factual structure of the case was unique;
- whether there would be a savings of cost and time;
- whether there were factors that were extraordinary or exceptional which would favour bifurcation;
- whether it was preferable to deal with all issues at the same time to address matters of credibility;
- whether a better understanding of the matters would be achieved by hearing all matters together;
- whether the matters were so inextricably interwoven that they ought to be heard together;
- whether there are resources to hear the matters separately;
- whether there is a clear advantage to having a matter determined first;
- whether there would be a substantial savings of cost;
- whether splitting the case will save time or will lead to delay;
- whether hearing the bifurcated issue first could facilitate or lead to settlement; and,
- whether the bifurcated matter could lead to an end to the action.

51. In this case, the Court noted that although the matters to be bifurcated were usually liability and damages, the availability of bifurcation was not limited to this factual situation. After reviewing all the factors, the Court determined that bifurcation of the specific issue relating to the start date was appropriate.[1]

III. Application of bifurcation principles to the present case

52. Bifurcation of the issues based on s.85(1) and s.85(2) would be appropriate in this case for the following reasons:

a. *complexity of the issues*: The financial analysis of the cost of making and marketing Procysbi is complex. It will require expert evidence from Board Staff and Horizon. This factor favours bifurcation.

b. *whether the issues are clearly separate*: The relevant facts and issues under s.85(1) and s.85(2) are separate and distinct. According to the Act, and as repeatedly recognized by the Board in past decisions, the analysis under s.85(1) must occur first. Only if the Panel cannot determine whether the medicine is excessively priced does the Panel resort to s.85(2). This factor favours bifurcation.

c. *whether the factual structure of the case was unique*: The jurisprudence is clear. Section 85(2) will only be considered if there are compelling and exceptional factors at play. Since the evidence regarding the cost of

[1] For the sake of completeness, we note that in *Pfizer*, there was a further motion between the parties at a later date, where the defendant brought a motion to amend its defence. Since the Court found that the motion to amend expanded significantly the scope of the "start date" question, the Court allowed the motion to amend to add the additional material, but vacated the bifurcation order, as it was no longer appropriate. [see 2014 FC 876]

making and marketing Procysbi is complex and contentious and unrelated to the factors in s.85(1), this factor favours bifurcation.

d. *whether there would be a savings of cost and time*: If the present matter can be determined pursuant to s.85(1), then bifurcating the matter will save time and money. The documents sought in the inspection and production order will not be required. Further production motions will be unnecessary. Professor Hay's evidence will be limited to the factors in s.85(1). Board Staff will not be required to have Secretariat prepare a report with its own analysis of the cost of making and marketing Procysbi. This factor favours bifurcation.

e. *whether there were factors that were extraordinary or exceptional which would favour bifurcation*: As noted by the Board jurisprudence, it would only be in exceptional circumstances that s.85(2) costs would be a legitimate consideration in an excessive pricing proceeding. Furthermore, this would be the first time that a Panel of the Board would consider this issue and, therefore, this determination would likely be highly contentious and controversial. This factor favours bifurcation.

f. *whether it was preferable to deal with all issues at the same time to address matters of credibility*: Since the factors relating to s.85(1) and s.85(2) are different and distinct (with the exception of Professor Hay) it is unlikely that the same witnesses would be involved in the hearings under s.85(1) and s.85(2). Moreover, Professor Hay's evidence in the s.85(1) hearing would not overlap with his evidence in the hearing under s.85(2), should it even be necessary. This factor favours bifurcation.

g. *whether a better understanding of the matters would be achieved by hearing all matters together*: The evidence relating to s.85(1) is distinct from the evidence relevant to s.85(2). This factor favours bifurcation.

h. *whether the matters were so inextricably interwoven that they ought to be heard together*: It is clear that the factors are completely distinct and separate. This factor favours bifurcation.

i. *whether there are resources to hear the matters separately*: If the Board is unable to determine the matter under s.85(1), the hearing could continue to consider s.85(2). There are no known resource problems at the Board. This factor favours bifurcation.

j. *whether there is a clear advantage to having a matter determined first*: The advantage to having the issues relating to s.85(1) heard first is that it is possible, and indeed likely (considering prior case law), that the Board will be able to make a determination pursuant to s.85(1). The advantage is obvious – the Board will not be distracted in making its determination under section 85(1) by evidence that is clearly not relevant to the issue.

k. *whether splitting the case will save time or will lead to delay*: If the Board is able to resolve the matter pursuant to s.85(1), this will save time and resources. If the Board is unable to do so, then the Panel could reconvene to consider s.85(2) in another hearing without any undue delay. This factor favours bifurcation.

l. *whether the bifurcated matter could lead to an end to the action*: If the Board determines that it is able to come to a conclusion about excessive pricing pursuant to s.85(1), this will end the merits decision. It is only if the

Board is unable to determine the matter pursuant to s.85(1) that it would then become necessary to proceed with the evidence related to s.85(2). This factor favours bifurcation.

IV. Board powers relating to subpoena and production

53. The Board has powers set out in both the Act and the Rules to subpoena witnesses, order inspections and require production. In particular, s.96 of the Act provides the Board with broad powers, equivalent to those of a superior court, with respect to the attendance of witnesses and the production and inspection of documents. This section provides as follows:

> 96 (1) The Board has, with respect to the attendance, swearing and examination of witnesses, the production and inspection of documents, the enforcement of its orders and other matters necessary or proper for the due exercise of its jurisdiction, all such powers, rights and privileges as are vested in a superior court.

54. Rule 6(2) provides that the Board may direct a party to provide information or documents, as follows:

> **Directions — information, documents and facts**
> **6(2)** The Board may, at any time, direct
>
> **(a)** that a party provide any information or documents, in paper or electronic format, that the Board considers concerned to any proceeding;

55. Rule 24 addresses the issue of subpoenas and the production and inspection of documents.

> **Issuance of subpoena**
> **24 (1)** In any proceeding, the Board may, on its own motion or on motion by a party, issue a subpoena for the attendance of witnesses and for the production or inspection of documents.

> **Reasons for subpoena**
> **(2)** If a party applies to the Board for a subpoena, the party must provide reasons in support of the issuance of the subpoena and must identify the person and documents or information to be named in the subpoena and their relevance to the proceeding.

56. The Board has consistently held that it favours having an accurate and complete picture of all matters to be argued before it. Therefore, the Board will order a subpoena, a production order and inspections in order to have all of the information necessary to address the issues before it and to determine the correctness or reasonableness of the parties' arguments.

> ***Alexion Pharmaceuticals and the medicine "Soliris",* Reasons for Decision (motion to issue subpoenas), January 24, 2017 [Soliris Supboena Motion]**
> ***sanofi-aventis Canada Inc. and the medicine "Penlac Nail Lacquer",* PMPRB-07-D1-PENLAC, motion for production and leave to file reply evidence, August 20, 2008 [Penlac Production Motion]**
> ***ratiopharm Inc. and the medicine ratio-Salbutamol HFA,* PMPRB-08-D2-ratio-Salbutamol HFA, Reasons for Decision (preliminary motions), August 14, 2009 [ratio-Salbutamol Preliminary Motions]**

57. For example, in *Soliris Subpoena Motion*, the Panel agreed with Board Staff that it was appropriate for witnesses to be required to produce documents relating to agreements between the patentee and various provincial drug plans, where these agreements had been referred to by the witnesses. The Panel concluded that the documents should be ordered to be produced because they were relevant to an issue raised by the patentee in the proceeding, and their production would further a fair and expeditious hearing. The Board held at paragraph 7:

> The Panel concludes that the documents requested to be produced for inspection are relevant to the issues in the proceeding, and that their production furthers the fair and expeditious resolution of the proceeding. The PLAs are specifically discussed in the witness statements of both Mr. Lun and Mr. Haslam. Correspondence about the PLAs is included in Exhibit 1 and was discussed with Mr. Richard Lemay during his examination-in-chief. If the PLAs are

> going to be the subject of testimony, it is important that the Panel have an accurate and complete picture.

58. The Board issued a subpoena requiring one witness to produce agreements referred to in his witness statement as well as correspondence relevant to the negotiations referred to in his witness statements. A similar subpoena was issued to another witness requiring him to produce agreements for inspection that were referred to in his witness statement as well as correspondence relevant to negotiations referred to in his witness statement.

59. In *Penlac Production Motion*, the Board ordered that the respondent produce data and protocols used in studies that had been referred to in the proceedings. The Board did not provide specific reasoning for making this order, but sets out the order at paragraphs 1 and 2, as follows:

> *Production of Documents*
>
> 1. The Respondent shall produce to Board Staff such data and protocols used in the production of the studies referred in these proceedings as Trials 312 and 313 (the "Data") as are in the possession, power or control of the Respondent, and in this regard, the Respondent shall use its best efforts to obtain the Data from any affiliated or related entities or other persons that the Respondent might reasonably expect to have the Data in their possession, power or control.
>
> 2. The Respondent shall file an affidavit in this proceeding with respect to the Data that are in its possession, power or control, and with respect to its efforts to obtain the Data in accordance with paragraph 1 hereof.

60. In *ratio-Salbutamol Preliminary Motions*, the Board was dealing with a situation where the respondent was a reseller of the patented medicine. Board Staff brought two preliminary motions: one requesting that the pharmaceutical company that sold the patented medicine to the respondent be added as a party; the second requesting that the respondent permit Welch LLP to inspect its books

and accounts with respect to the purchase of the patented medicine. The other pharmaceutical company resisted being added as a party and argued that any information that was required from it could be obtained by the broad powers given to the Board pursuant to s.96(1), as the Board had all the powers of a superior court.

61. The Board did agree that the information sought by the Board Staff would be necessary for a finding as to whether the patented medicine had been sold at an excessive price. The Board determined that it was not necessary to add the other pharmaceutical company, given its powers under s.96(1) to require the production of documentation. The Board noted that the test of whether the information should be provided would be the relevance of the information for the proper exercise of its mandate. In the result, the Board refused to add the other pharmaceutical company as a party, but issued a subpoena to the company. The Board's reasoning on this issue is set out at paragraphs 11 and 12, as follows:

> With respect to ratiopharm's submission that it has delivered to the Board all the documents that it intends to rely on in the Pricing Proceeding, the Panel is of the view that the test of what is necessary to be provided to the Board is the relevance of the information for the proper exercise of its excessive pricing mandate and not whether it is the only information that a party intends to rely on to justify its price of a medicine.
>
> The Panel is not persuaded, however, that it is necessary to issue either the Joinder Order or the Filing Order sought by Board Staff at this time, given that the Board can, pursuant to its powers under subsection 96 (1) of the Act, require GSK to provide to Board Staff the information it has set out in the Proposed Order. Pursuant to subsection 96 (1) of the Act, and in accordance with section 25 of the Proposed Patented Medicine Prices Review Board Rules, the Board will therefore issue a subpoena to GSK requiring the production of the information sought by Board Staff.

62. Board Staff had also sought an order requiring the patentee to permit the independent accounting firm of Welch LLP to inspect its books and accounts with respect to the purchase of the patented medicine. It also requested that the patentee provide the Board with certain information and documents relating to the purchase and sale of the patented medicine. The Board determined that it did have jurisdiction to require an inspection, and held that the governing principles were that this power would be exercised as necessary to ensure that the Board had a complete record of all relevant information to complete its mandatory regulatory exercise. On this point, the Board held at paragraph 27:

> The Panel is satisfied that, pursuant to its powers under the Act, in particular in paragraph 81 (1)(c) and subsection 96 (1), it has the power to order an on-site inspection, as necessary for the production of required information. In its view, it is essential that the Board remain the judge of what production and information are necessary to ensure that it has a complete record and a full understanding of the issues at play in a proceeding. The test of 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. The test cannot be, as suggested by ratiopharm, the volume or quantity of the evidence filed or the particular evidence a party intends to rely on at a hearing.

63. The Board also noted that it was not satisfied that the information could be obtained in an effective manner by requiring further production. An inspection order was likely to result in a more expeditious process. On this point, the Board held at paragraph 31:

> Considering the history of the Pricing Proceeding, the Panel is not persuaded that the material listed in the Inspection Order can be obtained in an effective and efficient manner by requesting further production. An inspection order, in the Panel's view, is more likely to ensure, in the circumstances, a timely and thorough filing of the information required without repeated iterations and interlocutory processes. An inspection order is more likely, it has concluded, to

> ensure that the Pricing Proceeding is dealt with as expeditiously as the circumstances and considerations of fairness to all parties permit, as required by subsection 97 (1) of the Act.

64. The subpoena required the pharmaceutical company to produce annual and monthly breakdowns of prices charged and quantities sold with respect to this patented medicine. With respect to the production order, the respondent was required to produce all relevant correspondence, studies and analysis to Board Staff. With respect to the inspection order, the respondent was required to permit an on-site inspection by Welch LLP, and was required to provide access to all necessary information, outlined at paragraphs 2 and 3 of the Terms of the Inspection Order as follows:

> For the purposes of performing the inspection, Welch LLP shall have (i) access to and the right to make copies of all books, records, documents, accounts and other forms of records necessary to verify the amounts claimed by ratiopharm in respect of benefits or other costs of selling ratio-Salbutamol HFA in the Sample Period, whether paper, electronic or digital form and whether recorded and maintained in computer or storage facilities in the possession of ratiopharm; and (ii) access to ratiopharm's in-house knowledgeable staff, to respond to Welch LLP's questions regarding ratiopharm's accounting processes and documentation.
>
> ratiopharm shall take all reasonable steps to facilitate the inspection and direct Welch LLP to any document, record or information from which Welch LLP can ascertain the benefits and other costs incurred by ratiopharm in respect of its sales of ratio-Salbutamol HFA in the Sample Period.

65. In summary, the Board will issue subpoenas, require production and order inspections where a matter is relevant to an issue before the Board, and will result in a fair and expeditious hearing. It is clear that the Board favours having an accurate and complete picture of matters to be argued before it. The Board is likely to order any information that it considers necessary to properly address the issues before it.

66. In the case at bar, the expert report of Professor Hay contains his financial conclusions based on data and information supplied to him by Horizon (see paras 23, 23(a)(b)(c), 85, 88, 90(a), 93(a), 101 and Appendices E, F, and G of the report of Professor Hay). The data and the analysis by Professor Hay are being tendered by Horizon as relevant evidence to the cost of making and marketing Procysbi. The cost of making and marketing a medicine, although not a matter that the Board can consider pursuant to s.85(1) of the Act, is relevant if the Board needs to resort to s.85(2).

67. The accounting firm of Secretariat has been retained by Board Staff to provide its opinion with respect to the financial conclusions reached by Professor Hay. They are not able to provide their analysis without the Board issuing an order compelling the production of the information set out in Exhibit B to the affidavit of Mr. Rosen and allowing Secretariat access to the original books and records.

68. For these reasons, absent bifurcation of the hearing, Board Staff's motion for inspection and production is appropriate and consistent with the past decisions of the Board. Indeed, the Board in *Virazole* noted on p. 11 that given the complex and contentious nature of the financial and accounting issues, clear and reliable evidence is required on the costs of making and marketing a medicine. It is submitted that in order for this Panel to have this clear and reliable evidence, Board Staff's experts must be given access to all of the relevant financial data and analysis. This will result in the Panel then having all of the necessary evidence to determine the issues in a hearing under s.85(2).

69. In *Soliris Subpoena Motion*, the Panel granted the request for a summons and production of documents, while noting that ideally such requests should be made at a time that does not disrupt the hearing. Consequently, Board Staff in the case at bar has now brought the within motion.

PART IV – ORDER REQUESTED

70. Board Staff requests that the Panel issue the following orders:

a. An order bifurcating the hearing in this matter between s.85(1) and (2).

b. An order redacting those portions of the report of Professor Hay that relate to the cost of making and marketing the medicine.

c. In the alternative, an order allowing Secretariat to inspect the books and records of Horizon in order to determine the cost of making and marketing the medicine and an order directing the production of the relevant documentation.

d. Such further and other relief as this Panel deems just.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 28th day of November, 2019

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