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
Alexion Pharmaceuticals Inc. and the medicine "Soliris"

WRITTEN SUBMISSIONS OF BOARD STAFF

PERLEY-ROBERTSON, HILL & MCDOUGALL LLP
340 Albert Street, Suite 1400
Ottawa, ON K1R 0A5
Fax: (613) 238-8775

David Migicovsky
Tel: (613) 566-2833
Email: dmigicovsky@perlaw.ca

Christopher P. Morris
Tel: (613) 566-2802
Email: cmorris@perlaw.ca

Lawyers for Board Staff

March 24, 2017

Table of Contents

WRITTEN SUBMISSIONS OF BOARD STAFF

(I) Overview

1. The *Patent Act* requires that this Board ensure that the price of patented medicines is not excessive. The *Patent Act*, however, does not explicitly define what an "excessive price" is. Although s. 85 sets out various measures that can be used to determine whether a price is excessive, if does not specifically dictate how they should be used. The deliberate wording of s. 85 and lack of definition of "excessive" indicate a legislative choice to grant the maximum amount of leeway possible to the Board in exercising its consumer protection role. Indeed, the very structure of s. 85 shows indicates that the determination of whether any particular price is "excessive" is not a formulaic "one size fits all" analysis, but rather one that can vary greatly depending on the particular circumstances of the medicine.

2. By and large, the process outlined in the *Guidelines* appears to be efficient and generally reasonable in identifying the medicines whose price may merit more in-depth analysis which have an excessive price. There are hundreds of medicines filed with the Board every year, and only a few end up in investigations, and even less end up in hearings. The *Guidelines* achieve some of this general efficiency by being very generous to patentees.

3. The *Guidelines*, however, are not perfect. This is most evident when the Guidelines are applied to what can be termed as "exceptional" cases that the Guidelines were not designed to address. In such circumstances, the Guidelines may fail to flag prices which have an enormous potential for excessivity, such as those where the patentees have the greatest amount of "bargaining power" due to the lack of comparators, small market size, and potential for prolonging life-spans. This case is about one of those medicines – Soliris.

4. This case is about whether the price of Soliris is excessive. It is about consumer protection. It is about one of the most expensive drugs in the world. It is not about the investigation by Board Staff or whether the *Guidelines* need to be reformed. It is also not about exchange rates or whether the *Patent Act* should be re-written. This hearing is an opportunity for the Board to examine whether the price of a medicine which can have an annual treatment cost of up to $700,000 is excessive under s. 85.

(II) Introduction

(A) Background

5. Soliris is sold by Alexion Pharmaceuticals Inc. ("Alexion"), an American company headquartered in Connecticut. It carries on business in over 50 countries through wholly owned subsidiaries. Alexion holds the patent for Soliris. Soliris has two approved indications - paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS).

6. Soliris is one of the most expensive medicines in the world. The annual cost of treatment in Canada for patients with PNH is approximately $539,000. The annual cost of treatment for adult patients with aHUS is $728,000 (**Exhibit 1, Tab 98, Tables 8 and 9**).

7. Soliris was first sold in Canada in 2009. At the time Soliris was priced at an amount that exceeded the median international price of Soliris and was approximately 2.5% below the highest international price of the seven comparator countries.

8. In 2010 and 2011, the price of Soliris in Canada continued to exceed the median international price and was only slightly below the highest international price.

9. Since 2012, and continuing through 2015, Soliris was sold in Canada at a price that exceeded the highest international price in the seven comparator countries.

(B) The Price of Soliris

10. That Soliris is expensive is beyond question. Although Mr. Haslam, President and General Manager of Alexion Pharma Canada Corp., refused to agree with this statement, Alexion's 10K filings with the SEC confirm that "Soliris is significantly more expensive than traditional drug products…". The 10K filings also confirm Alexion's

awareness that the payors of Soliris may impose obstacles to coverage (**see for example Exhibit 1, Tab 58, pp. 24 and 121; Tab 59, pp. 18 and 118**).

(C) Concerns in Canada and Internationally about the Price of Soliris

11. The Common Drug Review in Canada ("CDR") (which is part of the Canadian Agency for Drugs and Technologies in Health) provides formulary listing recommendations to publicly funded drug plans. A review by CDR of Soliris for PNH recommended that it not be listed at the submitted price (**Exhibit 1, Tab 32, p. 4**).

12. The CDR also reviewed Soliris for aHUS in 2013. It recommended that it not be listed (**Exhibit 1, Tab 134**). The matter was then reviewed again by CDR in May 2015 (**Exhibit 1, Tab 135**). The Committee reaffirmed their decision and, at page 7, noted the very high cost of the medicine per patient and the need to consider the opportunity cost of decision-making and drug plan and health care system sustainability.

13. Although patient groups have lobbied the Canadian government (and others) to cover treatment with Soliris, these groups receive funding from Alexion (which can then be used to lobby governments for coverage of Soliris). The mandate of these groups is access to Soliris. Mr. Katsof who heads a patient advocacy group has stated: "Pricing is not a concern for the group." (**Exhibit 1, Tab 74, last page**)

14. The present case is the first time that the provinces have exercised their statutory right to participate in a hearing before the Patented Medicine Prices Review Board ("the Board"). The provinces are extremely concerned about the financial impact of coverage for Soliris and the high opportunity costs of coverage on provincial public drug plans.

15. Globally there has also been concern about the extreme cost of Soliris. In 2013 Ireland declined to fund Soliris for PNH. In 2015, Ireland reviewed the matter again and this time decided to cover the costs, although it described them as "inordinate" and noted that Alexion refused to provide a reasonable and sustainable price (**Exhibit 1, Tabs 71(a) and (b)**).

16. In 2013, New Zealand refused to fund Soliris for PNH. PHARMAC noted that the price was extreme and that the price being offered was higher than that charged in other countries and "out of line with other comparable innovative new medicines supplied by other companies" (**Exhibit 1, Tab 72**).[1]

17. The high cost of Soliris has also been the subject of concern in the U.K. This is of particular significance because the U.K. is one of the seven comparator countries specified in the *Patented Medicine* Regulations and the price of Soiris in the U.K. has been the lowest international price among the comparator countries since 2011.

---

[1] PHARMAC noted on p. 2 that the cost of treating 20 patients would be NZ$10,000,000. This translates to an annual cost of treating a PNH patient as NZ$500,000. At market exchange rates in December 2013, this was equivalent to approximately CDN$437,000.

(III) The *Patent Act* and the *Guidelines*

18. The only questions before this Board are whether the price of Soliris is excessive and, if it is, what the price ceiling for Soliris should be. How, when and, to a large extent, why this case came to a hearing is irrelevant to the analysis of the price of Soliris.

19. When a panel of the Patented Medicine Prices Board ("the Board") conducts a hearing into the price of a medicine under the *Patent Act* it must consider whether the evidence adduced at the hearing by Board Staff establishes, *de novo,* that the price of the medicine under review is or was excessive based on the factors in s. 85 of the *Patent Act*. The history of how Board Staff reached its conclusion that the price of the medicine was excessive or whether that conclusion was consistent with Board Staff's usual practices is not relevant to the Panel's consideration of the price of a medicine. The Panel must reach its own conclusions based solely on the evidence presented at the hearing."[2]

20. Section 85 of the *Patent Act* lists a series of factors to be considered by the Board but does not specify how the factors should be used or weighed by the Board.

21. The *PMPRB Compendium of Policies, Guidelines and Procedures* ("the *Guidelines*") *may* provide an appropriate rationale for a decision in some cases. It is

---

[2] *PMPRB–04–D2–Dovobet*, April 19, 2006 [*Dovobet]* at page 6

important to note, however, that the *Guidelines* are not binding.[3] The *Guidelines* are simply an administrative tool.

22. Moreover, if the application of the *Guidelines* conflicts with the *Patent* Act or the Regulations, the application of the *Guidelines* "cannot prevail".[4]

23. The rationale, approach, or methodology for the application of the factors in subsection 85(1) of the *Patent Act* may be *ad hoc* by a Panel of the Board after a hearing or may be derived from the *Guidelines*. This was confirmed by the Federal Court of Appeal in *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board)* [1996] F.C.J. No. 1065 [*ICN Pharmaceuticals*] at paragraph 6.

(IV) Alexion's Response to Excess Revenues

24. The application of the *Guidelines* by Board Staff during the investigation identified that excess revenues were being generated by Alexion in 2009 and consistently throughout 2012-2015. Although Alexion asserted during this hearing that it had attempted to address the excess revenue, the evidence demonstrates that no such steps were taken. At no time during the relevant period did Alexion propose to repay excess revenue or to reduce the price of Soiris going forward. This matters

---

[3] *Patent Act*, R.S.C., 1985, c. P-4
[4] *Teva Neuroscience G.P.-S.E.N.C. v. Canada (Attorney General)*, 2009 FC 1155 at para 32 [*Teva Neuroscience*]

because it rebuts Alexion's vehement (and irrelevant) assertions that it was "caught by surprise" by this hearing, that it has somehow been victimized by Board Staff or that it has always complied with the *Guidelines* and is only here because of a random technicality.

(A) 2009 Prices

25. In accordance with the requirements of the *Patented Medicine Regulations* (SOR/94-688) ("the Regulations"), in 2009, Alexion reported its revenues for 2009 and its Block 5 information. Block 5 information is the publicly available international ex-factory prices that patentees are required to file and which Board Staff then verify. Board Staff advised Alexion that based on Alexion's own Block 5 data in 2009, its average transaction price ("ATP") exceeded the maximum non-excessive price ("MNE") by 3.2%.[5] This resulted in Alexion having cumulative excess revenue of $78,000 at introduction (**Exhibit 1, Tab 14**).

26. Alexion was therefore advised that based on its own Block 5 filings (even without Board Staff verifying the Block 5 information) an investigation would be commenced into the price of Soliris.

27. Alexion's response to being advised that an investigation had been commenced was to amend its Form 2 and provide new Block 5 data (**Exhibit 1, Tabs 18 and 19**). The result of the new data for 2009 was that the investigation criteria under the

[5] The MNE was subsequently renamed as the Maximum Average Potential Price or MAPP.

Guidelines were no longer triggered since the excess revenues were now $16,000 – an amount which was below the threshold for commencing an investigation. This does not imply that excess revenues are permissible. The threshold however for commencing an investigation is based on the administrative resources required for such an investigation. [redacted]

(B) 2012 Prices

28. In July 2012, Alexion filed its Block 4 and 5 data for the first reporting period of that year (**Exhibit 1, Tab 28**). Shortly thereafter, Alexion was made aware from the compliance letter that it received (**Exhibit 1, Tab 29**) that its ATP was higher than the non-excessive average price ("NEAP"). This meant that if Alexion continued to sell Soliris for the balance of the calendar year, it would have charged an excessive amount and that such excess revenues would need to be repaid.

29. As a pharmaceutical company operating internationally, Alexion is acutely aware of international exchange rates and the impact on prices and revenues.[6] Alexion would also have been monitoring the fact that the Canadian dollar had been appreciating for several years (**Exhibit 7**). Alexion would also have been aware of the 36 month average period used for calculating exchange rates under the *Guidelines*. Notwithstanding Alexion's awareness in mid-2012 that the price of Soliris was now in excess of the highest international price, Alexion elected not to reduce its ATP for the

[6] See Alexion's 10K filings with the SEC (**Exhibit 1, Tabs 59-64**).

second reporting period of 2012. Alexion continued to sell Soliris for the same amount in Canada

30. On October 25, 2012, Alexion contacted Board Staff to discuss the fact that its 2012 price (and likely its 2013 price) would exceed the highest international price. Although Alexion suggested that it wanted to resolve the problem, the evidence demonstrated that the resolution did not involve what would have been the simplest and most obvious solution – namely, reducing the Canadian price of Soliris (**Exhibit 1, Tab 103(a)**). Indeed, Alexion could have resolved the problem that was occurring in 2012 without having to repay any of its excess revenues, since the *Guidelines* provided that it could have reduced its 2013 ATP price to an amount that would be less than its 2012 NEAP. Alexion chose not to do so.

(C) 2013 Prices

31. Although Alexion was aware in 2012 of the looming price issue for 2013, it once again chose not to take any steps in 2013 to reduce its excessive price. The result was that the price of Soliris in Canada, again, exceeded the highest international price (**Exhibit 1, Tab 36**). Alexion was again advised that Board Staff would now be investigating the 2013 price (**Exhibit 1, Tab 41**).

(D) 2014 Prices

32. After the first reporting period in 2014, Board Staff let Alexion know that its 2014 price was in excess of the highest international price. Again, Alexion had a choice to make. It could reduce its price or it could continue to sell Soliris at the same price, knowing that it was continuing to earn excess revenue. Alexion chose the latter option.

33. In 2014, Alexion attempted to "solve" the problem of its excess revenues earned in prior years through a number of different methods. None of them involved the repayment of excess revenue or the reduction in the price of Soliris to an amount that was less than the highest international price.

34. One "solution" to the problem that Alexion adopted was to simply refile its Block 4 data so as to show a reduction in its ATP. Alexion attended a meeting with Board Staff in December 2013 (**Exhibit 1, Tab 103(b)**) and mentioned that it had provided rebates. Alexion did not, however, mention that the "rebates" were not payments made by Alexion to its customers. Alexion was aware that the Board only regulates prices at the factory gate and that, pursuant to the Federal Court's decision in *Pfizer Canada Inc. v Canada (Attorney General)*, 2009 FC 719, rebates to third parties could not be taken into account to reduce the ATP. When Board Staff pointed this out, Alexion backtracked and refiled its Block 4 data to remove the rebates.[7] Thus, Alexion's first proposed "solution" to the excess revenues it had earned was to refile its data for 2012

[7] At the hearing, however, Alexion appeared to suggest that the rebates to provinces could be taken into consideration. This is inconsistent with the revised (and certified as accurate) Block 4 data submitted by Alexion after being informed of Board Staff's position. It is also inconsistent with the observation by the Panel in *PMPRB-08-D3-ration-Salbutamol HFA – Merits*, May 27, 2011 at paragraph 125 that the decision in *Pfizer* is binding in regard to rebates to the provinces.

and 2013 and to change the way it reported that data for the first reporting period in 2014.

35. It is, of course, no surprise that Board Staff did not accept that the filing of revised data for 2012 and 2013 would be effective to reduce the ATP. The new filings (**Exhibit 1, Tab 37**) were entirely inconsistent with Alexion's original filings, as well as being inconsistent with an email from Alexion in July 2013 (**Exhibit 1, Tab 33**) in which it stated that its ATP had always remained the same.

36. Once its attempt to "solve" its excess revenue by refiling its Block 4 data failed, Alexion came up with yet another "solution" to the excess revenue it had charged and the fact that its price exceeded the highest international price. Once again the "solution" did not involve repaying the excess revenue or lowering the price. Alexion now filed Block 4 data for the second reporting period of 2014, not showing any rebates, but rather showing that the ATP was now reduced from the previous reported price of $224.7333. When Board Staff inquired why the Block 4 data was so different from what had previously been submitted, Alexion's answer was non-responsive. Mr. Palmer simply reported that "The lower average prices reported accurately reflect reductions from the list price of Soliris provided by Alexion to its wholesaler/distributor and reported as required under the Regulations." (**Exhibit 1, Tab 55**)

37. This answer was illogical and inconsistent with the information previously certified as accurate on the Form 2s that Alexion had filed from 2010 to date. On all

previous filings Alexion had reported two separate customer classes – "Pharmacy" (class 2) and "Hospital" (class 1). Alexion had not reported any sales to a "Wholesaler" (class 3).[8] The requirement to specify the customer class is set out in s. 4(1)(f) of the Regulations.

38. Understandably, Board Staff was concerned and perplexed about the reporting of a new price immediately upon the heels of Alexion being informed that their last attempt to "solve" the problem of excess revenue was to refile their Block 4 data, which was also not a solution to the excess revenue.

(E) Testimony of Mr. Haslam on Pricing[9]

39. In 2016, for the very first time, Alexion, in the witness statement filed for Mr. Haslam at this hearing, asserted that it had <u>always</u> had only one customer – Innomar. If this is true, it is entirely inconsistent with <u>all</u> of the filings by Alexion during the period of 2010-2015 which always showed only two customers – neither of which was a wholesaler.[10] Alexion was aware at all times that the ATP of its medicine was an issue in this proceeding. Board Staff had no reason to believe, that Alexion had changed its unit price. It always believed, and continues to believe that the ATP for Soliris from 2009-2015 was $224.7333.

---

[8] In 2009 Alexion had reported sales to a Wholesaler (Class 3) so it was obviously aware of the distinction in customer classes and the need to accurately report same.
[9] Mr. Haslam's testimony on other matters is discussed later in this submission.
[10] It should also be noted that although Alexion had previously tried to obtain credit for "rebates" and had filed new Block 4 data, it had not changed the customer class on the new filing.

40. Disclosure dates for this hearing were set in advance. Alexion produced no documents whatsoever to demonstrate that Innomar was its customer or that Innomar was a Pharmacy.

41. In the midst of the examination in chief of Mr. Haslam, counsel for Alexion produced what purported to be photocopies of "credit memos" that Alexion had allegedly issued to Innomar (**Exhibits 46 and 47**). Mr. Haslam testified that these "credit memos were essentially the credits paid to Innomar to reduce an average transaction price below that of the anticipated average transaction price for that year" (**Transcript Vol. 14 (Combined Public-Confidential), C. 506 et seq**).

42. The Panel should not rely upon these "credit memos" for the reasons set out below:

(i) If the "credit memos" were relevant, why were they never produced until the midst of Mr. Haslam's evidence in chief? Had they been produced in advance, Board Staff would have had the opportunity to review and investigate the matter. Board Staff could also have obtained a subpoena to obtain additional information relevant to determining whether Innomar was ever Alexion's customer.

(ii) It is not possible to determine when these credit memos were actually issued. One cannot assume that the date that appears in the document is the date that the document was created.

(iii) It is not possible to relate these "credit memos" to any particular transaction or sale by Alexion to Innomar.

(iv) It is not possible to determine whether, in fact, Innomar is Alexion's factory-gate customer or whether it is simply a distributor of products on consignment.

(v) Alexion has not produced any copies of its contracts or amendments to its contracts with Innomar.

(vi) Alexion has not produced any invoices or purchase orders to Innomar.

(vii) Alexion has not produced any documentation to establish what the "credit memos" relate to.

(viii) The "credit memos" do not appear to relate to an actual payment of a rebate by Alexion to any of its customers. Rather the "credit memos" relate to vials of Soliris, all of which are shown as being priced at $6,742 (which means a unit price of $224.7333).

(ix) There is no explanation for how the amounts on the "credit memos" were calculated.

(x) There has been no explanation for why Alexion from 2010 to date has consistently reported having two customer classes (Hospital and Pharmacy) and now reports that it has only ever had one customer (reported by Mr. Palmer as a "Wholesaler", but which Mr. Ruby stated is a Pharmacy).

(xi) Given all of the above, a reasonable inference is that the transactions between Alexion and Innomar are either not at the factory-gate or that the relationship is not one that is at arms-length.

43. In *R v After Dark Enterprises Ltd.*, 1994 ABCA 360 (CanLII) the Alberta Court of Appeal dealt with a situation in which a party failed to produce the best evidence of a fact. At paragraph 6 and 7 the Court stated as follows:

> [6] As we understand it, the best evidence rule provides, first of all, what we might call an admonition that real evidence is usually more reliable than human evidence. This aspect of the matter is, as some of the authorities say, merely a wise counsel to triers of fact. It has nothing to do with admissibility.
>
> [7] In some cases, however, the real evidence is not produced and no explanation is given by the witness, or the party adducing the witness, why they fail to produce the real evidence. In cases of that sort, the question arises whether or not evidence, other than that real evidence, should be admitted to establish what could have been established by examination of the real evidence. There is some dispute in the authorities at this point whether what we might call the "substitute" evidence is admissible. Some authorities say that it is not admissible; other authorities say that it may be admissible but that, in the absence of any reasonable explanation of the failure to produce the real evidence, an adverse inference should be drawn about the reliability of the "substitute" evidence.

44. In *Conway v. Conway*, 2005 CanLII 14136 (ON SC), Justice Gordon stated as follows at paragraph 15:

> Similarly, failure to present relevant evidence, in support of a position advanced by a party, may result in an adverse inference. This, for example, pertains to disclosure not made or a necessary witness not called to testify: see, for example, Levesque v. Comeau 1970 CanLII 4 SCC [1970] S.C.R. 1010 (S.C.C.). In addition, the best evidence rule requires the production of documents which are relevant to an issue, not simply a reference to it in oral testimony.

45. Alexion's failure to present the documentary evidence in support of its position results in an adverse inference. It is not sufficient for Alexion to simply rely upon Mr. Haslam's oral testimony and the "credit notes" produced for the first time during that testimony.

46. Another proposed "solution" by Alexion for the excess revenues accumulated was suggested for the first time in its witness statement for Mr. Haslam. Alexion asserted that it had provided "free goods" totalling [redacted] dollars. However it offered no documentary evidence whatsoever, nor any details to substantiate that it had provided such goods or the value of such goods. As a matter of law, Alexion's evidence in this regard suffers from the same deficiencies as noted above. In this respect an

adverse inference should also be drawn regarding the failure to produce any documentation to substantiate this claim.

47. Alexion also asserted at the hearing (again for the very first time) that it should be given credit for the OneSource Program and the infusion costs. Once again, there was no disclosure of any documentation prior to the hearing. Indeed even at the hearing Alexion only produced a document it had created itself without producing any source documentation (**Transcript Vol. 14 (Combined Public-Confidential), c. 507 – c. 578**).

48. It is clear that the OneSource Program is a marketing tool. It ensures that individuals adhere to the treatment schedule and do not miss a dose. Although that is obviously in the best interest of the patient, it is also very much in Alexion's financial interest given that a single treatment will result in the purchase of vials of Soliris that exceed $20,000. (It should also be noted that 10K filings of Alexion at the SEC make it clear that the OneSource Program has as its purpose "to facilitate solutions for reimbursement, coverage and access" (**see for example Exhibit 1, Tab 58, p. 21**).

49. It is also important to note Mr. Lun's evidence that the public payor system covers infusion costs of Soliris. In addition, Mr. Lun noted B.C.'s concern about the fact that Alexion requires patients to supply confidential information to Alexion, which is of commercial value and to sign an agreement in order to participate in the OneSource Program.

50. Even if the above-noted attempts by Alexion to address its excessive revenue could be substantiated, it is submitted that the evidence is of no relevance to any of the factors in subsection 85(1) of the *Patent Act*.

(V) The Expert Evidence

(A) General

51. Board Staff called two expert witnesses. The first expert was Professor Schwindt who testified about External Reference Pricing (ERP) and the methodology in the *Guidelines*. Professor Schwindt concluded that Soliris was excessively priced.

52. Dr. Addanki was the second expert. He provided an economic analysis of s. 85(1) of the *Patent Act*. He also analyzed the price differential of Soliris between Canada and the U.S. Dr. Addanki concluded that Soliris was excessively priced.

53. Dr. Putnam was called as an expert by Alexion. He reviewed the price of Soliris during 2012-2014 and found that it was not excessive based on his interpretation of the various factors in s. 85(1). Dr. Putnam's analysis was focused on the comparison of the international prices and the price in Canada and the methodology in the *Guidelines*. Dr. Putnam did not analyze the price of Soilris in 2009 (and 2010). All of Dr. Putnam's opinions were rendered under the *assumption* that the price of Soliris was not excessive in 2009.

54. Dr. Anis was also called as an expert by Alexion. Dr. Anis was asked to identify other methods to show the price of Soliris was not excessive. Although disagreeing with the experts called by Board Staff, he did not identify an alternative method to determine excessivity.

55. Mr. Soriano was a chartered accountant called by Alexion. He performed various calculations to determine additional revenue Alexion would have earned had it increased prices. He also created a "test" in order to find that the price of Soliris was not excessive. This test ignored 2009 and *assumed* that Solirs was not excessively priced in that year.

(B) Weighing the Expert Evidence – Legal Principles

56. As this was a case in which both sides relied upon expert witnesses who reached differing opinions, it is useful to review the principles that apply in assessing the reliability and credibility of experts.

57. In *Moore v. Getahun*, 2014 ONSC 237 at paragraphs 253 and 254 (2015 ONCA 55) the trial judge noted the following factors as relevant in her assessment of each expert's comparative reliability and credibility:

- The expert's professional qualifications
- Actual experience
- Participation or membership in professional associations

- The nature and extent of his or her publications
- Involvement in teaching
- Involvement in courses or conferences in the field and his or her efforts to keep current with the literature
- Whether the expert has previously been qualified as an expert in the area

58. The trial judge at paragraph 255 also noted the following questions as relevant to assessing the comparative reliability and credibility of each side's expert witnesses:

- Is the witness fair and impartial in the report presented and in the evidence given?
- Is the expert's report and oral evidence consistent?
- Is the expert's opinion clearly set out in the report, including the facts and documents underpinning the opinion?
- Do the conclusions logically flow from the facts?
- Are alternative theories canvassed?
- Does the expert make concessions in the report where appropriate that may not be helpful to the party who retains him or her?
- Are the facts relied upon by the expert confirmed in the evidence at trial?
- Does the expert make reasonable concessions in his or her viva voce evidence if the facts are not as he or she assumed them to be?
- Does the witness provide balanced evidence that is neutral, or is he or she dogmatic and fixed in his or her opinion?

- Does it appear that the witness aligned with one party's position, assuming the role of an advocate, rather than act as a neutral witness with a duty to the court?
- Is there an appearance of bias, or is there evidence of actual bias?

59. In *Vescio v. Garfield*, [2007] O.J. No 2426 (ONSC) [*Vescio*], the trial judge was addressing the conflicting evidence of experts. Although addressing conflicting medical experts, the factors set out by the trial judge are useful to weigh and assess conflicting evidence of all experts. The factors referenced by the trial judge at paragraph 100 are set out below:

- The relevance of the training, experience and specialty of the witnesses to the medical issues before the Court;
- Any reason for the witness to be less than impartial;
- Whether that testimony appears credible and persuasive compared and contrasted with the other expert testimony at the trial.

60. The trial judge in *Vescio*, *supra*, expressed the view at paragraph 104 that the objectivity of one of the experts was suspect. The trial judge noted that the expert's "...objectivity has been compromised by his eagerness to persuade this court of the validity of the opinions he gave, both as to the merit of his own view...and as to his criticism of the views of other experts". At paragraph 105 the trial judge also noted during cross-examination this same expert had "...maintained rigid positions in the face of reasonable suggestions not entirely opposite to positions he had earlier espoused. On the whole he struck me as a man on a mission and that mission had rather less to

do with assisting the court toward a reasonable understanding of the technical, medical issues arising in this case than it had to do with winning a debate on his particular views."

61. The trial judge also commented on the expert evidence of another witness at paragraph 107 by noting "She too was rigid and unyielding in her views." The trial judge noted that the expert had not appeared to have made an effort to be objective. The trial judge concluded that there were many instances of partisan positioning during the course of the experts' evidence.

(C) Dr. Putnam

62. Dr. Putnam's analysis in this case was undoubtedly influenced by his opposition to the regulation of pharmaceutical prices. His views in this regard were clearly articulated in his article "*The Price We Pay for Drug Research*". In that article he notes that there is a basic impulse to regulate economic activity past the point of no return and that there is a political view that prices are too high. He indicates that the fundamental reason that pharmaceutical prices are high is because consumers are willing to pay for them directly or through taxes. (**Exhibit 36, p. 28**)

63. Dr. Putnam expresses the view that if we want to reduce prices then we should increase the rewards to suppliers and not decrease prices. While Dr. Putnam is entitled to these opinions, they do not reflect Parliament's intention in creating the Patented

Medicine Prices Review Board, which was to ensure that prices do not become excessive.

64. The Board was created with a consumer protection mandate. Dr. Putnam, however, has previously expressed the view that "protecting consumers" deprives the inventor of the full enjoyment of the monopoly conferred by the patent. He expressed the view that the purposes of the price regulation sections in the *Patent Act* are inconsistent with the purpose and effect of the rest of the *Patent Act*. His view is that the price regulation scheme protects buyers – not inventors and that the remedies in the *Patent Act* are "confiscatory and punitive" (**Transcript Vol. 12 (Combined Public-Confidential), p. 1627, Exhibits 36 and 37**).

65. Given Dr. Putnam's clearly held opinions, as well as the leading questions he was asked to answer in his report, (*"Are there other methods of comparing the Canadian price with the prices in the several comparator countries that lead to the conclusion that the Canadian price was not excessive between 2012 and 2014?"*), it is of no surprise that he reached the conclusions that he did in his report.

(D) Dr. Anis

66. In assessing the credibility of Dr. Anis' evidence, it is helpful to remember that at the commencement of his cross-examination he was asked about his familiarity with the IMS MIDAS database, which contains information about prices of drugs in other

countries. He was categorical in saying that he was not familiar with it (**see Transcript Vol. 16 (Public), p. 2050, lines 4-9**) – until he was shown **Exhibit 62** (his own affidavit in another proceeding before the Board). At page 2051 of the **Transcript** he noted "I just contradicted myself".

67. Dr. Anis was then asked to confirm that IMS is the major supplier of international data on pharmaceutical prices. His response was that he did not know. When taken to paragraph 4 of **Exhibit 62** (**see Transcript, Vol. 16 (Public), p. 2051**) he was then forced to admit that IMS is the major supplier of international data. On page 2053 at line 5, Dr. Anis was asked if he frequently used and relied upon IMS data prior to swearing his affidavit. He responded by saying "not frequently". He was then directed to paragraph 4 of his own affidavit in which he stated "During the last two decades I have frequently used and relied upon IMS data". (**Transcript Vol 16 (Public), p. 2053, line 5 to p. 2057**)

68. Although Dr. Anis was very familiar with the U.S. General Accounting Office Report ("the GAO Report") (**see Exhibit 39**) which compared Canadian and U.S. drug prices (having cited the GAO Report in several of his own papers) he refused to concede a fact that all of the other experts had agreed was true – namely that drug prices in the U.S. were generally higher than in Canada. This Panel should therefore be cautious in accepting his opinion where it conflicts with the other experts.

69. Dr. Anis' opinion as to whether Soliris was excessively priced was influenced by the partisan view he articulated in paragraph 53 of his report (**Exhibit 54**). He noted that a patentee "will not charge excessively high prices simply because of its monopoly position." Dr. Anis concludes this paragraph by noting that it is not in the interest of the monopolist to set an excessive price. The assertion of this opinion by Dr. Anis amounts to a denial of the *raison d'être* of the Board and of the reason why drug prices in Canada are regulated.

(E) Mr. Soriano

70. Mr. Soriano is not an economist. He is a chartered accountant and a chartered business valuator. He has no experience in price regulation of pharmaceuticals under the *Patent Act.* The issues he considered in his report or his testimony were not issues that drew upon his experience as a chartered business valuator or accountant. Mr. Soriano has not lectured, nor has he conducted research on the price regulation of pharmaceuticals. He cites no academic authority for his opinion.

71. Mr. Soriano was advised by Alexion's counsel "... that it is Alexion's position that in regard to Soliris, the Patented Medicine Prices Review Board's price calculations (based on the methodology in the 2010 *Guidelines*) are neither fair nor effective as those terms are used in the 2010 *Guidelines*, or in common law". In response Mr. Soriano created a test to determine if Soliris was excessive. This "test" purports to take into consideration the factors set out in s. 85(1) of the *Patent Act.* The "test" results in

Mr. Soriano concluding that there are excess revenues of $1,034,647.00. Not surprisingly, Mr. Soriano then notes that if Alexion increased the price, it would have realized a larger amount in additional revenue. At Table 2 and paragraph 39 of his report he also notes that Alexion would have had additional profit in 2010 and 2011, which could then be used as an offset (**Transcript Vol. 17 (Public), pp. 2283-2284, 2437-2440 and Exhibit 73, para. 18, FN 18**).

72. The Board has been clear in rejecting this type of offset. In *PMPRB-07-Quadracel and Pentacel-Merits,* December 21, 2009 at paragraphs 53-56 the Respondent's expert witness, a chartered accountant, proposed that excess revenues received by a patentee which had sold its medicine at prices exceeding the MNE in particular years could be offset by sales during other years in which the prices were below the MNE. The panel was then directed by Federal Court to reconsider its decision on remedy to provide an explanation.

73. The panel explained their reasoning in *PMPRB-07-D6-Quadracel and Pentacel-Reconsideration of Remedy*, June 14, 2012. At paragraph 14, the panel noted that price-averaging should take place during a one-year period. This has the advantage of providing flexibility to the patentee who can correct for unexpected revenues. It would also prevent patentees from changing excessive prices and then eliminating them at an unknown date in the future if they choose. The panel noted that such an approach would frustrate the consumer protection mandate of the Board.

(F) Professor Schwindt

74. Professor Schwindt has been an academic for almost 45 years. He has published widely and frequently been recognized as an expert in matters involving competition and parallel trade. He has been qualified as an expert witness before the Board in which he opined on the *Guidelines*. He was qualified as an expert in applied microeconomics and the regulation of industrial organizations.

75. Professor Schwindt was fair and impartial in his evidence. His report and oral evidence were consistent. He considered and rejected alternative approaches (such as purchasing power parity, which would have resulted in increased excessive revenue). He was not dogmatic and provided balanced evidence.

76. The Panel should prefer the evidence of Professor Schwindt over that of Alexion's experts where there are differences of opinion. As Justice Wilson observed at paragraph 325 in *Getahun* in preferring the evidence of one side's expert:

> [325] I reach this conclusion based on his years of experience as an upper extremity orthopedic surgeon, his extensive history of teaching and lecturing, his numerous publications, and his vast experience in Ontario and internationally as a leading surgeon in his field. In assessing Dr. Richards' credibility, I emphasize the importance of his independence and neutrality. He is abrupt and no nonsense in giving his evidence, but he makes concessions both in his written reports and in his evidence where

appropriate. He provided a consistent, fair, unbiased opinion. As well, his evidence makes sense in light of the facts of this case and is consistent with the medical literature.

(G) Dr. Addanki

77. Dr. Addanki has extensive professional qualifications and experience. He has frequently been qualified as an expert. His report and oral evidence were consistent and his conclusions flowed from the facts. He answered questions on cross-examination in a direct fashion and without bias.

(VI) The Factors Set Out in s. 85(1) of the *Patent Act*

78. Section 85(1) of the *Patent Act* provides that the Board must have regard to four factors if information relating to them is available:

> 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.

79. In *PMPRB-06-D3-Adderall XR-Merits*, April 28, 2008 [*Adderall XR*] at paragraph 14, the Board noted that it is not required to give each factor equal weight. It is recognized that each factor could lead to a different and irreconcilable conclusion. Consequently it may be necessary to give one (or more) factors primary weight. In *Teva Neuroscience*, *supra*, Justice Hughes at paragraph 47 noted the need for the Board to give consideration to each of the four individual factors in 85(1)(a)(b)(c) and (d).

80. As Soliris is a breakthrough medicine, then regard can only be had to the three factors set out in s. 85(1)(a), (c) and (d).

(A) "the price of the medicine in Canada" – s. 85(1)(a)

81. It is clear from the plain language of s. 85(1) that there are four separate factors to be considered in determining whether a medicine is being sold at an excessive price. As the opening words of s. 85(1) already refer to the "price" of a medicine, it is clear that subparagraph (1)(a) is not intended to be duplicative of the word "price" that appeared

in the opening words of Section 85(1)(a). Section 85(1)(a) must be treated as a separate factor. If subparagraph (1)(a) is simply read as referring to the "price" of the medicine, then it would be superfluous.

82. Accordingly it is relevant to consider under subparagraph (1)(a) more than the simple fact that the unit price of Soliris is $224.7333. It is also relevant to consider that the price of Soliris can be in excess of $700,000 annually.

83. Dr. Addanki noted that from an economic perspective the actual price of Soliris is a starting point in the analysis under s. 85(1)(a) and that there is information contained in that price. At a minimum, it informs the analysis even if it does not actually tell us whether the medicine is excessively priced. Dr. Addanki noted that the social cost/opportunity cost of a medicine that is priced excessively at $500,000 annually is not the same as it would be for medicines that are priced at much lower levels (**Transcript Vol. 11 (Combined Public-Confidential), pp. 1273-1275**).

84. It is necessary to conduct a contextual analysis of the price of Soliris. This means that it is useful to consider items such as median household income ($76,000 in 2013) and per capita GDP ($54,000 in 2013). Thus, if household income was $2 million dollars, Soliris, although still extremely expensive, would be more affordable (**Transcript Vol 11 (Combined Public-Confidential), pp. 1277-1278**).

85. Mr. Lun's evidence makes it clear that there are lost opportunity costs associated with provincial reimbursement of Soliris at the listed price. The Pharmacare budget for B.C. is between 6.5% and 7%. Costs used in one area have a direct impact on other parts of the budget such as health authorities, hospitals and physician services (**Transcript Vol. 11 (Combined Public-Confidential), p. 1393**).

86. Mr. Lun noted the concern of the Province of B.C. that their drug programs be sustainable for future generations as well as affordable. In particular, Mr. Lun addressed the financial impact on the budget for Expensive Drugs for Rare Diseases (EDRD) – a term that covers orphan drugs. The decision on whether to cover such drugs as "non-benefits" necessitate a consideration of the opportunity cost of the drug and whether it is affordable. The annual costs of the treatment of other EDRD are typically significantly less than the cost of Soliris. Moreover, the expenditures for EDRDs, including Soliris, have been continually growing.

87. Mr. Lun noted that there are currently 69 drugs under review in B.C. – each with a cost significantly less than Soliris and that the drug budget of the province B.C. is in a deficit situation. That means every dollar counts in deciding what drugs can be funded. He noted that the opportunity cost was critical and was faced everyday (**Transcript Vol. 11 (Combined Public-Confidential), p. 1429**).

(B) The Prices at which the Medicine is Sold in Other Countries – s. 85(1)(c) – A critical factor for Breakthrough Medicines

(1) General

88. S. 85(1) requires that the Board consider whether a medicine is being or has been sold at an excessive price. This means that the Board has a continuing mandate to regulate the price of patented medicines.

89. Accordingly, the Board must consider the prices in the seven comparator countries ("the International Prices") when the medicine is first introduced onto the Canadian market, as well as the Canadian price, and the International Prices in subsequent years. It should be noted, however, that the Board is not constrained by the *Act* on how it chooses to examine potential excessivity based on the prices in other countries: the *Act* does not dictate that prices be set at the "highest" or "median" or "lowest" of the international comparators. Instead, the *Act* leaves this determination to be made on a case by case basis, based on the particular facts of each case.

90. Since subparagraph (1)(d) refers to the "change in the CPI", this factor clearly has no appreciation to the medicine when it is first introduced onto the market. Thus, there are only two factors that can be considered by the Board when a breakthrough medicine is introduced, namely the price of the medicine in accordance with s. 85(1)(a) and the price of the medicine in other countries in accordance with s. 85(1)(c).

(2) Using External Reference Pricing is Reasonable

91. Soliris is a breakthrough drug for which there are currently no therapeutic equivalents. Consequently, the comparison under s. 85(1)(c) is of the price charged by Alexion for Soliris in Canada to the price charged by Alexion for Soliris in the other comparator countries. There is nothing unfair or unreasonable in conducting such an analysis which is referred to as ERP. There is also nothing unfair or unreasonable in conducting ERP analysis based on "nominal" prices (i.e. the actual list prices in each country) in foreign currency that is converted to Canadian currency using market exchange rates.

92. ERP for pharmaceutical prices is used in many other countries. Professor Schwindt noted that it is used by 24 of the EU member states. As foreign prices are reported in local currencies, then it is necessary to translate them into Canadian dollars in order to compare the prices. Professor Schwindt noted that market exchange rates are appropriate since they demonstrate the price at which a patentee such as Alexion is willing to supply. Moreover, it must be assumed that the price in another developed country covers the patentee's costs.

93. Additionally, as an American company, the relevant exchange rate to Alexion is the market rate. Alexion's financial statements (as noted in their 10K filings) are consolidated and are denominated in U.S. dollars with conversion based on market

exchange rates. Professor Schwindt noted that prices will be set in foreign countries so that when converted to U.S. dollars, Alexion's costs will be covered and the conversion rate will be the market rate.

94. The authors Leopold et al. in their article *Difference in External Reference Pricing in Europe – a descriptive overview* (**Exhibit 9**) (which was referenced by Professor Schwindt), adopt the definition used by the European Pharmaceutical Pricing and Reimbursement Information glossary which defines ERP at p. 51 as "the practice of using the price of a medicine in one or several countries in order to derive a benchmark or reference price for the purpose of setting or negotiating the price of the product in a given country". The authors note that ERP is a policy used throughout the world. They note at p. 59 that pharmaceutical companies in Europe and the U.S. are strategic in their pricing decisions and often launch in high price countries such as in Germany so as to have the German price as one of the benchmarks for those countries that have Germany in their basket of countries. (Significantly, Germany is one of the seven comparator countries used in Canada.)

95. Professor Schwindt noted that the use of ERP is also a substitute for the fact that pharmaceutical consumers for the most part cannot engage in arbitrage. If a market was competitive and there were no constraints on purchasing products from other jurisdictions, then the buyers would purchase their products in countries with lower prices and then import the product. (In particular, this would be the case for

pharmaceuticals with a high value to weight ratio.) Arbitrage would then take place at current market exchange rates.

96. Professor Schwindt was asked at **Transcript Volume 18 (Combined Public-Confidential), p. 2625** about whether external reference pricing necessitated comparisons between countries based on foreign exchange market rates. It was specifically suggested to him that a comparison could be done involving PPP prices between different countries. In reply, Professor Schwindt noted that although this was *hypothetically* possible, he had not found any other jurisdiction that had used external reference pricing based on purchasing power parity.[11]

97. Professor Schwindt notes in both of his reports (**Exhibit 81 at p. 16 and Exhibit 8 at p. 15**) that market exchange rates are used in other jurisdictions that use ERP. Indeed, he notes that these countries use shorter time periods to calculate exchange rates (i.e. Norway uses the previous 6 months period while Switzerland uses the monthly average for the last year. In contrast, Board Staff uses a lagged 36 month average).

98. Professor Schwindt's opinion that the price of drugs sold in countries other than Canada provides useful information is shared by Dr. Addanki. He opines that a drug which is sold for less money in other countries indicates that the manufacturer is willing to accept a lower price for that drug. (**Exhibit 17, para. 25**)

---

[11] Professor Schwindt also rejected the appropriateness of comparing international prices by PPP.

99. Dr. Addanki explained at **Transcript Vol. 11 (Combined Public-Confidential) at pp. 1299-1300** that what needs to be measured is what a Canadian consumer would have paid if, for example, they had purchased Soliris in the U.S. at the Wholesale Acquisition Cost ("WAC"). That question is answered by reference to market exchange rates because what should be measured is what would occur had these goods been tradeable. Dr. Addanki opined that this is what should be emulated when regulating prices.

100. Dr. Addanki's comparison of the price of drugs in Canada and the U.S. was also based upon market exchange rates.

101. Professor Schwindt and Dr. Addanki's opinion that ERP provides an indication of what a patentee is willing to sell its medicine for (which is an indication of whether the patentee is covering its cost and making a profit) was confirmed by Mr. Haslam. Mr. Haslam agreed that Alexion may determine not to sell Soliris in some countries if they are unable to obtain coverage, pricing or reimbursement on terms acceptable to Alexion. He agreed that Alexion has not yet had to discontinue selling its medicine in any of the comparator countries. It follows, therefore, that Alexion has always had the financial ability to sell Soliris for substantially less than the price it was sold in Canada during the relevant period.

102. Dr. Anis rejected the assertion by Professor Schwindt that foreign prices disclose a patentee's willingness to supply as he alleged that Professor Schwindt did not take

supply and demand into account. However, as Professor Schwindt noted at **Transcript Volume 18 (Combined Public-Confidential) C. 939**, supply and demand were considered by Alexion when it set its profit-maximizing price.

103. Professor Schwindt noted that Alexion's foreign prices provide insights into costs and one could reasonably assume that, in foreign markets, Alexion was at least covering its costs and not selling its product at a loss. Professor Schwindt had regard to the fact that the comparator countries were similar to Canada in terms of development.

104. Professor Schwindt also noted that the prices were determined at the factory gate door and therefore distribution costs in each country would not be relevant. Professor Schwindt noted at **Transcript Volume 18 (Combined Public-Confidential) p. 2586** that although cost to supply would not be identical in each country, there was no reason to believe that costs to supply would be significant enough to account for the price discrepancies seen between the various countries in this case.

105. As acknowledged by Dr. Schiwndt, the *Guidelines* apply ERP using a reasonable methodology which is consistent with that used elsewhere and which is supported by an economic rationale. This methodology involves a comparison between the Canadian price of a medicine and the price of the medicine in each of the seven comparator countries.

106. In order to conduct the comparisons, the foreign prices must be converted to Canadian dollars. There are two methods of doing so. Market exchange rates can be used. These are the rates determined in markets where buyers and sellers transact business or purchasing power parity rates ("PPP") in which market rates are adjusted for differences in local purchasing power (**see Exhibit 8, p. 13**).

107. The methodology in the *Guidelines* calls for the use of market rates averaged over a three year period of time, which Professor Schwindt noted was very reasonable.

108. Dr. Putnam suggested that Canadians are not interested in the price of Soliris in the U.S. since they are unable to purchase Soliris in the U.S. The evidence, however, clearly demonstrates that Canadian payors are very interested in the prices charged by Alexion in other countries.

109. The *viva voce* testimony of Mr. Haslam and Mr. Lun, as well as the documentary evidence produced in response to the subpoenas, confirms that the negotiations for the product listing agreements ("PLAs") were based entirely on the price charged by Alexion for Soliris in other countries. When Alexion referenced the reimbursement criteria used in Australia, the provinces specifically requested information about the price in that country. This information was refused (**See Exhibit 23, Tab 6**).

110. When Alexion and the provinces commenced negotiations in 2010, the price of Soliris in the U.S. was the lowest price in the seven comparator countries. The

provinces [redacted] (Part B) recipients (**see Exhibit 23, Tab 6**). Mr. Haslam confirmed that the [redacted] the price of Soliris in Canada.[12]

111. When the province's offer to purchase Soliris from Alexion at the same price as was being charged [redacted]

112. At the end of the negotiations, [redacted] the provinces and Alexion then needed to calculate the exchange rate in order to convert the price to Canadian dollars.

113. During the negotiations Alexion argued that [redacted] (**Exhibit 23, Tab 7, p. 2**).

[redacted]

114. On July 6, 2011, the British Columbia Minister of Health authored a letter to Alexion in the U.S. (copied to Mr. Haslam in Canada) setting out his expectation that the price to be charged in Canada should be comparable to the price in the U.S. The Minister specifically noted that a patient in British Columbia could "not understand why the cost of your medication is so dramatically higher in Canada, than in the United States". The Minister noted that there had been no justification for why Canadians were required to pay so much more than the U.S. price. The Minister threatened to make these concerns public (**see Exhibit 23, Tab 10**).

115. Alexion did not respond to the Minister's letter. Indeed, even at this hearing, Alexion offered no evidence as to why Canadians continued to pay more for Soliris than the price charged in all other jurisdictions between 2012-2014 (Canada was the highest in those years) or why the price in Canada was above the median international price in 2010 (Canada was the third highest), (when the Canadian price was the second highest) and in 2015 (when the Canadian price was the third highest).

116. It is also worth noting that the *methodology* Board Staff proposed should be used in this case for comparing the International Price of Soliris with the Canadian prices (which is consistent with that in the *Guidelines*) has previously been the subject of consultation. In 1993, a Working Group on Technical Issues related to the Proposed Amendments to the *Guidelines* was struck with representatives from the pharmaceutical industry and others to examine the issue of international price comparisons and in particular the methodology for converting international prices to Canadian currency

(**Exhibit 1, Tab 105**). The Working Group agreed upon the following principles, which continue to have application today:

(i) short-term volatility in exchange rates should be eliminated;

(ii) at the same time exchange rates should adequately reflect trends in currency relationships; and

(iii) the methodology should not benefit nor disadvantage consumers and patentees as a result of volatility in exchange rates (**Exhibit 1, Tab 104**).

117. Prior to 1993, exchange rates were averaged over a six month period. The period of time was then increased to 36 months as this was seen as a reasonable compromise among the three principles noted above. The increase to a 36 months period removed "the volatility of short-term exchange rates without totally insulating the international price comparisons from long-term trends in international currency relationships". This was seen as improving predictability for patentees (**Exhibit 1, Tabs 104 and 108**).

118. In 2008, a new Working Group on Price Tests concluded that the 36 months exchange rate methodology was satisfactory and that there was no need to change it to a five year period. (**Exhibit 1, Tab 109**)

119. Dr. Putnam and Mr. Soriano both agreed that the use of the 36 months average eliminated volatility in exchange rates. Consequently, patentees do not need to immediately adjust prices based on market exchange rates.

120. A review of Exhibit 7 demonstrates this point quite clearly. Although Alexion's introductory price in 2009 was only slightly below the highest international price and the Canadian dollar continued to appreciate between 2009-2011, it was only in 2012 that Alexion's price in Canada exceeded the highest international price.

121. As an American corporation carrying on business internationally, Alexion was well aware of what was happening to the Canadian dollar and its upward trajectory.

122. Indeed, Alexion's 10K filings with the SEC show that it took steps to manage currency fluctuations. Professor Schwindt noted in his evidence that Alexion substantially benefited by the appreciation of the Canadian dollar. (**See Exhibit 7**)

123. The use of a 36 month average exchange rate to calculate international prices is extremely generous to patentees. Professor Schwindt noted at page 15 of Exhibit 8 that other developed countries which use ERP systems utilize much shorter time frames.

124. In *Dovobet*,[13], the patentee and Board Staff disagreed over whether the international price comparisons over time should take into account fluctuations in

[13] The Board's determination of the MNE in that case was upheld by the Federal Court (although its calculation of the ATP of the medicine was overturned). See *Leo Pharma Inc. v Canada*, 2007 FC 306.

exchange rates. The Board concluded at page 26 that there was no reason why this should not be done.

(3) Unjustified Criticism of ERP Methodology

125. Dr. Putnam criticized the use of ERP based on the methodology proposed by Board Staff and consistent with the *Guidelines*, but he offered no real alternative on how the Board should properly implement s. 85(1)(c) of the *Patent Act*.

126. Dr. Putnam's analysis was premised on the assertion that the price of a medicine in a foreign country when converted to Canadian currency is not a "price" under s. 85(1)(c) of the *Patent Act* since a medicine is a non-traded good. For the reasons set out below this interpretation is erroneous.

127. Dr. Putnam's analysis is based on a strained definition of the word "price". As Professor Schwindt noted, however, although a Canadian purchasing something in a store in France may not be able to pay with Canadian dollars, she can go to the bank around the corner from the store and exchange her Canadian dollars for euros which she will use to purchase the product. Undoubtedly, when the Canadian consumer purchases the product in France she is interested in knowing the price she will pay and what it is in Canadian dollars. She will also be interested in comparing the French price with what the product would cost her in Canada.

128. Dr. Putnam was dogmatic in arguing that an "exchange-rate-converted medicine price" is not a "price" and that one cannot compare international prices based on converting them to Canadian currency. Notwithstanding his refusal to concede at the hearing that the price of a drug in another country when converted to Canadian dollars was not a "price", his own article used the terminology of "price" in comparing the price of medicines in Canada and the U.S. (**see Exhibit 36 at p. 28** in which Dr. Putnam noted the following, "In Canada where prices are regulated under the *Patent Act* by the Patented Medicine Prices Review Board, prices are generally lower than in the United States").

129. Dr. Putnam's assertion that Canadians are "indifferent" to the price of Soliris in other countries is specifically contradicted by the evidence of Eric Lun as well as the documentation contained in **Exhibits 23 and 50**. The price charged by Alexion for Soliris in other countries was clearly very relevant to Canadian payors. It mattered not to them whether they were able to purchase Soliris only in Canada.

130. Professor Schwindt noted that Canadians do indeed have interest in the different price of non-traded goods between Canada and the U.S. At **page 13 of Exhibit 81** he noted consumer concerns about the price differentials for tobacco, mobile telephone services, cable television, milk, cheese, etc.

131. Although Dr. Putnam asserted that Canadians are indifferent to the price of Soliris in other jurisdictions, his opinion does not reflect what s. 85(1)(c) of the *Patent*

Act requires be done – namely, to compare the price of a medicine in Canada with the price of the medicine in other countries. Dr. Putnam's analysis is an attempt to negative or minimally consider what the legislature has directed must be considered.[14]

132. Although Dr. Putnam took exceptions to using the word "price" to compare the prices of medicines in other countries with Canadian prices based on market exchange rates, Dr. Anis had no difficulty comparing Canadian prices of medicine to the price of the same medicine in other countries. In his own article at **Exhibit 38 at page 22** he too compared the "price" of drugs in Canada and the U.S. In order to engage in such an analysis it is evident that he too converted the U.S. price into Canadian dollars using market exchange rates in order.

133. Dr. Anis' article (**Exhibit 38**) also references the GAO Report comparing U.S. and Canadian drug prices. The GAO Report concluded that Canadian prices were approximately 32% lower than in the U.S., as a result of Canadian regulation by the Patented Medicine Prices Review Board.[15]

134. The GAO Report compares the U.S. WAC price with the ODB formulary price using market exchange rates (**Exhibit 39, p. 26, FN 6**).

---

[14] It is also worth noting that when the legislature was amending the *Patent Act*, there was considerable concern manifested about the impact of the changes and the effect they would have on Canadian prices compared to international prices. (See section VIII(D) of these submissions.)

[15] Dr. Anis in his testimony attempted to downplay his references to this study by saying he did not "rely" on it but merely cited it. In fact Dr. Anis repeatedly relied on this study and his repeated attempt to disassociate himself from it was sophistry.

135. Dr. Anis also confirmed that in his testimony in the *Adderall XR*, *supra*, case before the Board he compared the Canadian price of a drug to the foreign prices of other drugs using IMS data. Dr. Anis further confirmed that in order to compare Canadian and U.S. prices a conversion could be done using market exchange rates (**Transcript Vol. 16 (Public), pp. 2058 and 2071**).

(C) Purchasing Power Parity Exchange Rates are not an Appropriate Basis for Comparing International Prices

136. PPP is a method used to adjust exchange rates for different prices in other countries. Professor Schwindt explained this by reference to the "Big Mac Index" in **footnote 21 of Exhibit 8** and in more detail at **Transcript Vol. 8 (Combined Public-Confidential) at p. 851 et seq**.

137. PPP rates are based on a whole basket of goods and what its price is in each country. Professor Schwindt noted at **Transcript Vol. 8 (Combined Public-Confidential) at p. 879** that it is used when comparing the well-being between citizens of different countries. PPP compares the portion of the basket of goods that have to be given up in one country with the portion of the same basket given up in another country.

138. Professor Schwindt further noted that because the purpose of ERP is to provide insight into willingness to supply, the focus should be on market rates and not PPP rates as patentees do not set their prices based on PPP.

139. Professor Schwindt also noted at **Transcript Vol. 8 (Combined Public-Confidential), p. 883** that there are difficulties associated with compiling the PPP exchange rates based upon the difficulty in putting together the identical basket of goods in each country. There are multiple organizations and measures for doing so.

140. Dr. Putnum hinted that PPP rates may be more appropriate than market exchange rates (**see for example Transcript Vol. 12 (Combined Public-Confidential), p. 1584**). He also noted, however, that whatever method is chosen should be done consistently (**see for example Transcript Vol. 13 (Combined Public-Confidential) pp. 1757 and 1759**) and one should not flip between using market exchange rates and PPP exchange rates (**p. 1800**).

141. At paragraphs 75-77 of Dr. Anis' report (**Exhibit 54**) he suggests PPP exchange rates might be used to make international price comparisons more meaningful, but then in paragraph 75 rejects them on the basis that the financial burden to the consumer is not relevant given the existence of insurance coverage of Soliris for patients.

142. Mr. Soriano also considered the use of PPP exchange rates for comparing international prices. Mr. Soriano, however, did not articulate an economic rationale for why such rates would be appropriate. This is not surprising since Mr. Soriano was qualified as a chartered accountant and chartered business valuator. Mr. Soriano had no experience in the type of analysis required in this case.

143. Moreover, Mr. Soriano's analysis using PPP exchange rates suffers from a fundamental flaw. At Paragraph 18(b) and Table 5 of his report (**Exhibit 73**) he calculates the NEAP for Soliris in each year based on PPP exchange rates. Table 2 purports to demonstrate that in each year the NATP for Soliris would therefore be below the NEAP. However, this analysis disregards two important matters noted below.

144. Firstly, the analysis ignores the fact that had PPP exchange rates been used in 2009, the median international price would have been $200.0646 and not $223.2066. This would have resulted in Alexion's 2009 price of $224.7333 being excessive. (Professor Schwindt and Dr. Putnam were both in agreement that it would not make sense to use market exchange rates in one year and then use PPP exchange rates in another year.)

145. Secondly, under the *Guidelines*, which Mr. Soriano was attempting to mirror, the price of a medicine in each year is constrained by <u>two</u> factors – the CPI adjusted price and the highest international price comparison ("HIPC"). The allowable price is limited by the lesser of the HIPC and the CPI adjusted price. Had PPP exchange rates been used in 2009 and thereafter annually, then the price of Soliris would not have been permitted to exceed the CPI increases shown for each year. Table 3 of Appendix C of Mr. Soriano's report, however, does not reference what the PPP price would be if it had been constrained by the change in CPI each year. Thus, Table 5 of Mr. Soriano's report provides a false picture as it <u>only</u> reports the prices in 2010 using the HIPC price

determined by PPP exchange rates. It disregards the fact that if PPP exchange rates were used, rather than market exchange rates, in 2009 the median international price would have been $200.00.

146. Table 3 of Professor Schwindt's Reply Report (**Exhibit 81**) is instructive. It demonstrates the impact on Alexion's revenues if PPP exchange rates had been used on introduction and the NEAP in each year was constrained by the change in CPI annually.

147. In any event, Board Staff submits that for the reasons expressed by Professor Schwindt, there is no sound basis for comparing international prices by PPP exchange rates. To do so is to ask the wrong question under s. 85. Professor Schwindt summarizes the rationale for ERP and the use of market exchange rates on p. 11 of his Reply Report (**Exhibit 81**).

148. It is also noteworthy that in September 1993, the Board reported that it had adopted the recommendations of the Working Group in respect to matters pertaining to the conduct of international price comparisons which were based on market exchange rates (**see Exhibit 1, Tabs 107 and 108**).

149. Moreover, in the real world, companies transact international business based on market rates, not PPP rates.

150. It is also relevant to note that in July 2008, a Working Group on Price Tests that was set up by the Board specifically considered and rejected the idea that conversion of International Prices should be based on PPP rates and reaffirmed that the 36 months market exchange rate methodology was appropriate (**see Exhibit 1, Tab 109, p. 3**). The members of the Working Group (in both 1993 and 2008) included representatives from pharmaceutical manufacturers, CLHIA, government, academia and Board Staff (see p. 10).

(D) Changes in CPI – s. 85(1)(d)

151. Section 85(1)(d) directs the Board to "take into consideration" "changes in the Consumer Price Index". The requirement to take changes in the CPI into consideration should not be interpreted as legislative recognition that if the price of a medicine has not increased more than the change in the CPI, the medicine is not excessively priced.

152. To reach that conclusion would be to disregard the Board's comments in the *Adderall XR*, *supra*, decision on page 5. The Board noted that it was necessary to balance all of the factors and assess the relevance of each. It is logically impossible for each factor to be given equal weight. There are circumstances where one or more factors may have decisive weight. In the present, case the international price of Soliris and its comparison to the Canadian price should be accorded greater weight because there was no possible "change" in CPI at introduction and Alexion did not adjust its price based on CPI (or anything else) afterwards.

153. Dr. Addanki did consider changes in the CPI, but in light of the pattern he noted regarding the relative prices of Soliris in Canada and the U.S., he found that it did not provide meaningful information.

154. The pattern Dr. Addanki observed was that the Canadian prices of pharmaceuticals were substantially lower than the unregulated prices in the U.S.[16] Dr. Addanki further noted at paragraph 45 of his report (**Exhibit 17**) that, between 2009-2016 the Canadian price of Soliris exceeded the U.S. WAC price when converted at the market exchange rate for most of the period.[17,18] This is even more remarkable given that the U.S. WAC price was steadily increasing during this period. As late as January 2016, the Canadian price of Soliris was still about 20% higher than the U.S. price. Dr. Addanki described this pattern as "striking and informative".

155. Professor Schwindt noted that, on introduction Alexion priced Soliris so close to the highest international price that taking CPI increases would have caused the Canadian price to become the highest international price in 2011. He further noted that there was an economic logic to constraining prices by reference to the lower of the international price or the CPI adjusted price. Using the lower of the two prices provides an indication that the patentee has covered its costs and is willing to supply at a

---

[16] This opinion was also reached by Professor Schwindt and Dr. Putnam. Dr. Anis equivocated on this issue.

[17] It should be noted that for the period of 2009 to mid-2011 the FSS price was substantially lower than the WAC price. Using the FSS price would make the difference between the U.S. and Canadian prices even more pronounced.

[18] Professor Schwindt also noted at **p. 18 of Exhibit 8** that from a commercial perspective, current market rates are more relevant to Alexion.

particular price (**See Transcript Vol. 8 (Combined Public-Confidential), pp. 847-848 and C. 244-245**). Professor Schwindt also noted that in some jurisdictions in which ERP is used, yearly price increases are not allowed (**pp. 888-889**).

156. Given these circumstances, and the consumer protection mandate of the Board, Professor Schwindt's greater emphasis on the international price comparison over the change in CPI is logical and compelling.

157. Moreover, Board Staff submits that the price of Soliris was already excessive in 2009. Accordingly, had Alexion taken a CPI increase in subsequent years this would have meant that its price would have become even more excessive.

158. In *Teva Neuroscience*, *supra*, the Federal Court noted that s. 85(1) contains four separate factors that must be considered. In *Adderall XR*, *supra*, the Board noted at paragraph 14 that each factor could lead to a different conclusion, but that after consideration of each factor, the Board could decide to give one factor primary or decisive weight if the conclusions from each factor were irreconcilable.

159. Dr. Putnam's analysis of s. 85(1), however, conflates the factors set out in subparagraphs (a), (c) and (d). In particular, his analysis treats subparagraphs (c) and (d) as if they require the international prices referenced in (c) to be adjusted by changes in the CPI in accordance with subparagraph (d). This leads Dr. Putnam to erroneously conclude that it is necessary to compare the "real price" (as opposed to the "nominal

price" or sticker price which consumers actually pay) of Soliris in the U.S. with the "real price" of Soliris in Canada.[19]

160. Dr. Putnam's analysis of s. 85(1)(d) is premised upon reading the section as if it compelled the Board to consider the "real price". However, that is not what s. 85(1) provides. On a plain reading of the language, s. 85(1) merely requires the Board to consider the change in CPI. Having considered the matter, the Board is permitted to conclude that it is to be accorded little or no weight and that other factors are of decisive weight.

161. Dr. Putnam's opinion as to whether Soliris was excessively priced was based on an erroneous interpretation of the words "relevant market" in s. 85(1)(a), which he defines as a market of close substitutes (and on the unfounded assumption that the price of Soliris in 2009 was non-excessive). If this interpretation was accepted it would mean that the price of a breakthrough drug could not be regulated at all since there are no substitutes. Such an interpretation would frustrate the Board's ability to fulfill its consumer protection mandate. Dr. Addanki's opinion was that from an economic perspective the less competition there was, then the greater the potential for consumer harm (**see Transcript Vol. 11 (Combined), pp. 1266 and 1267**).

---

[19] In *Teva Canada Innovation v. Attorney General of Canada* 2013 FC 448 the Federal Court set aside a decision in which the Board interpreted one of the factors in s. 85(1)(a) as complementing the limits that the other factors placed on the price. At paragraph 44 the Court noted that each factor is relevant to determining whether the price is excessive.

162. Board Staff submits the words "relevant market" in s. 85(1)(a) must be read in conjunction with the phrase "in any market in Canada" in the opening words of s. 85(1). "Any market in Canada" refers to discrete markets defined by geography or classes of customer (see Board decision in *PMPRB-07-D1-Thalomid*, January 21, 2008 at paragraph 20, upheld in *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1 [*Celgene*]). Thus a "relevant market" is a subset of "any market" in Canada.

163. Moreover, Dr. Putnam's conclusion that in order to compare the U.S. price of Soliris to the Canadian price of Soliris it is necessary to use "real prices" (i.e. prices adjusted by CPI as opposed to nominal prices) does not accord with the statutory language. It is clear from the opening words of s. 85(1), which specifically references Canada, that subsections (a), (b) and (d) obviously also refer to prices in Canada. This is to be contrasted with s. 85(1)(c) which specifically references "countries other than Canada." Hence, where Parliament intended to refer to a "country other than Canada" in one of the s. 85(1) factors, it used specific language to make that clear. The absence of specific language in 85(1)(d) to the words "countries other than Canada" in s. 85(1)(d) is a clear direction that the change in CPI is only something to be considered in regard to the Canadian price that is the subject of the price review.

164. The "test" created by Mr. Soriano is also based on conflating the factors in s. 85(1)(c) and (d) as if they were a single factor. This is also not consistent with the jurisprudence which treats each factor separately. It is also not supported by any economic principles or rationale.

165. The "test" created by Mr. Soriano in Appendix B of his report does not compare the price of Soliris in Canada to the price of Soliris in other countries, as mandated by s. 85(1)(c). Rather, it compares what the price would be in all years after 2009 if Alexion had raised the price of Soliris in Canada by CPI and if Alexion had also raised the price of Soliris in foreign countries by the foreign CPI in that country. This results in a comparison of a price that is not being charged in one country (Canada) with a price that is not being charged in another country. There is nothing "real" about this test.

166. Mr. Soriano's "test" also allows a patentee to charge excessive prices in one year and then claim an offset based on price increases that were not taken in another year. There is no economic logic to such a test, and it is hard to understand how it protects consumers. Additionally, it must be recalled that Dr. Anis noted that the rational monopolist charges a profit maximizing price each year. Dr. Anis noted that if a price above the profit maximizing price was charged by the monopolist, then its overall revenues might decline since fewer products will be sold. It is logical, therefore, to assume that Alexion made a strategic and business decision to not increase its price in Canada between 2009-2015.

167. Mr. Soriano's "test" would result in volatility in the prices of medicine. It would allow patentees to gain market share by making a strategic decision to price their medicine at a price significantly below its NEAP and then allow it to significantly exceed

the NEAP in subsequent years based on offsetting the prior excess revenue by the potential revenue that could have been charged in a previous period.

(VII) Irrelevant Considerations

(A) Purchase from Ireland

168. Mr. Haslam testified that Alexion in Canada purchases Soliris from Ireland and that it pays a transfer price of 80% of the list price. This evidence from Mr. Haslam was unburdened by any documentary evidence. Board Staff submits that the price paid by one Alexion subsidiary to another Alexion subsidiary is entirely irrelevant to the determination of whether or not Soliris is excessively priced in Canada. Transfer pricing is simply a mechanism for a company with wholly owned subsidiaries to transfer profits from one jurisdiction with higher tax rate to another jurisdiction with lower tax rates.

169. This fact was specifically noted in Alexion's 10K 2013 filing in regards to Alexion's operation in Ireland. Alexion noted that government agencies and others in the countries in which they operate have focused on "base erosion and profit shifting" in which payments are made between affiliates from a jurisdiction with high tax rates to one with lower tax rates (**Exhibit 1, Tab 64, p. 56**).

170. Additionally, In Alexion's 10K filings they note that they have "designed our corporate structure and the manner in which we develop and use our intellectual

property and our intercompany transactions between our affiliates in a way that is intended to enhance our operational and financial efficiency and increase our overall profitability". Alexion further notes, "The tax authorities of the countries in which we operate may challenge our methodologies...for transfer pricing" (**Exhibit 1, Tab 64, p. 56**).

171. Simply put, transfer pricing is irrelevant. Transfer pricing is not a cost of "making and marketing" or a cost of Canadian Research and Development under s. 85(2) and cannot possibly be related to any of the factors in s. 85(1). Furthermore if such evidence was relevant, it would have been incumbent upon Alexion to have produced the best evidence available – namely copies of the contracts, surrounding documents, the communications with Canada Revenue Agency and the invoices from Alexion in Canada and Ireland. The fact that Mr. Haslam produced no documentation supports the Panel drawing an inference that the documentation would not support Alexion's position.

172. In assessing Mr. Haslam's credibility, it may also be relevant to consider his response to the subpoena, as well as the manner in which he responded in cross-examination. Although Alexion was required to comply with a subpoena requiring Mr. Haslam to produce, *inter alia*, the correspondence relevant to the negotiations of PLAs with the provinces, and although the Panel directed that such production take place no later than January 31, 2017, Mr. Haslam did not produce all of the relevant documents, nor were they produced in a timely fashion.

173. Mr. Haslam was highly selective in what he chose to present. He produced documents that did not respond to what had been requested, but which he hoped would be helpful to Alexion's case (**see for example Exhibit 50, Tab 26 and Vol. 14, c. 557-600**). He did not, however, produce any documents in connection with the execution of the PLA's by the five provinces who signed PLA's in 2012, notwithstanding that these documents were clearly relevant. He also did not produce many documents which British Columbia had produced, although the subpoena clearly obligated him to do so.

174. Notably, Mr. Haslam did not produce the letter from the Province of Ontario to Alexion dated May 18, 2011 (**Exhibit 23, Tab 6**) in which Ms. McArthur stated the following:

> "Eculizumab is one of the highest cost drugs brought forward for funding consideration in Ontario and it is widely reported as the most expensive drug in the world. Of particular note is the price you offer in the U.S."

175. Mr. Haslam also did not produce the letter of July 6, 2011 from the British Columbia Minister of Health to Alexion (**Exhibit 23, Tab 10**) in which the Minister noted in regard to a Canadian patient the following:

> "As a Canadian, he and his family cannot understand why the cost of your medication is so dramatically higher in Canada than in the U.S. I am

equally troubled that your pricing policy would discriminate against Canadians."

176. It is also of interest to note that in response to the subpoena, Alexion produced the draft letter dated November 9, 2011 which appears at **Exhibit 50, Tab 26**. This letter was not a document that was required by the subpoena. It was obviously produced in an attempt to cast the Province of B.C. in a negative light. During Mr. Lun's evidence, however, the actual letter sent by Alexion was marked as **Exhibit 30**. In addition, Mr. Lun also identified as **Exhibit 31** the response by B.C. to Alexion. (Alexion had chosen to present only one side of the issue and had obviously chosen not to produce the documentation from B.C. in response, which contained negative comments about Alexion's use of the OneSource Program).

177. Even if Alexion was repatriating its Canadian revenues to Ireland, it does not alter the fact that the Canadian dollar was also appreciating against the euro. Moreover, ultimately all revenue of Alexion was denominated on the consolidated financial statements of Alexion in U.S. dollars. This is consistent with the fact that Alexion is an American owned company with subsidiaries (including the operations in Ireland) and throughout the world.

(B) Discounted Prices

178. Alexion (and Dr. Anis) argued that because of rebates and confidential prices, it is difficult to compare international prices and that it is tantamount to comparing "sticker prices" for cars at a dealership. Board Staff rejects this argument.

179. The legislation mandates that patentees file publicly available ex-factory prices in Canada, as well as internationally. Accordingly, the legislation obviously requires the Board to regulate ex-factory prices since there is no mechanism to require patentees to disclose confidential price agreements or rebates in other countries.

180. In *Teva Canada Innovation v. Attorney General of Canada* 2013 FC 448 at paragraph 41, the Board diminished the significance of the international price comparison mandated by s. 85(1)(c) on the basis that there may be difficulties in comparing prices across borders. The Federal Court rejected this analysis on the basis that the Board was "subverting the will of Parliament which clearly saw this as a relevant factor to be accorded weight".

181. The comparison by Dr. Anis to "sticker prices" on cars at a dealership is not appropriate. Customers who buy a car at a discounted price are not prohibited from disclosing the price to others. Accordingly, it is possible to compare the actual prices of cars. Alexion, however, does not allow payors to disclose discounted prices of Soliris. Consequently, the only reliable method of comparing prices is to utilize public list prices

which are set by the patentee itself. Accordingly, the appropriate international price comparisons in this case should be to the publicly available ex-factory Block 5 prices in Canada and the seven other comparator countries.[20]

182. It is also reasonable to assume that if discounted prices are given in one country they are likely given in other countries as well. Alexion is obviously aware of the discounted prices it provides in other countries. If the Board was to consider using discount prices as the basis of the international price comparisons, it would be incumbent upon Alexion to have produced documentation to establish the discounted prices in the other countries. Alexion did not do so.

183. Moreover, the setting of a price for Soliris going forward that is based on the list price merely sets the price ceiling. The use of a price ceiling based on a list price which is higher than the confidential price is obviously generous to patentees.

184. Finally, it must be noted that, notwithstanding the existence of PLA prices, there are many payors who continue to pay the full list price of $6,742 per vial of Soliris. This is evident from the Block 4 filings of Alexion which continue to show this price in most markets in Canada. The full list price is also paid by the provinces and hospitals who cover the cost of Soliris for aHUS. (In addition some also pay a mark-up fee.) It is also the price paid by private insurers. It should be noted that in B.C. (and some other

[20] Board Staff submits that the publicly available ex-factory price of $224.7333 in Canada is also the same as Alexion's ATP of $224.7333.

provinces as well) Soliris for PNH is a "non-benefit", which means it will only be covered if the person does not have private insurance coverage.

(C) Research and Development

185. One of the reasons articulated by Mr. Haslam for the extremely high cost of Soliris was that drugs for orphan diseases were expensive to develop given limited patient populations. Mr. Haslam also mentioned that there was a very high cost associated with the research and development of Soliris. Mr. Haslam's assertion was not corroborated with any documentation.

186. It is of interest to note that the report from NICE (**Exhibit 69**) noted at page 21 that research and development only explain a small proportion of Alexion's costs.

187. In any event, research and development costs are <u>not</u> relevant to any of the factors in s. 85(1) of the *Patent Act*. When a panel is unable to determine whether a medicine is excessively priced under s. 85(1), it may have regard to s. 85(2).[21]

188. Pursuant to s. 85(2), the Board may consider matters not specifically enumerated in s. 85(1) however, when it comes to research and development costs, the legislation is very clear about what can be considered and by extension what cannot. This is clear from s. 85(2) and (3) which provide as follows:

---

[21] See *PMPRB-95-D5/Virazole-Merits*, p. 11 and 12 (application for stay dismissed *ICN Pharmaceuticals*, [1996] F.C.J. No. 1112

Additional factors

85(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.

Research costs

85(3) In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.

189. Alexion led no evidence regarding its total research costs relating to Soliris, nor of the Canadian portion of such costs calculated in proportion to the ratio of sales by Alexion of Soliris in Canada to its worldwide sales. (Alexion's costs in purchasing

Enobia and its costs related to other medicines are also not relevant to the issues in this case.)

190. Additionally, the PMPRB does monitor and report on the research and development of patentees in Canada on medicines. Section 6 of the Regulations specifically defines "research and development". The total amount of money spent by Alexion on research and development is practically nil (**Exhibit 1, Tab 21** (0); **Tab 27** [redacted] **Tab 33** (0); **Tab 42** (0); **Tab 50** (0)).

191. Professor Schwindt at **Transcript Vol. 8 (Combined Public-Confidential), p. 834 et seq** explained that the PMPRB does not directly consider costs when determining whether a medicine is excessive. Section 85(1) of the *Patent Act* however directs the Board to look at foreign prices as a source of information about costs. He explained as follows on page 834-835:

> MR. MIGICOVSKY: ...the Patented Medicine Price Review Board doesn't, you say, directly consider costs when determining whether a medicine is excessive. Can you just explain that? You're using the word "directly" versus "indirectly." Why is that?
>
> PROF. SCHWINDT: Well, if you've ever seen or been party to a hearing for a rate increase with a public utility, they essentially open their books to the regulator so that the regulator knows what costs - and there's all kinds of mechanics that go on in scrutinizing those costs.

> The Patented Medicine Price Review Board does not do that. They don't require disclosure of detailed finances. Instead, they look elsewhere. And one place they look is if there are substitutes of some sort or another in therapeutic classes, they'll look there for a comparable. I don't know the extent to which costs are actually comparable, but at least they have some comparison going. To my - in my view, when the *Patent Act* directs the Board to look at foreign prices, that this is a source of information about costs.

(D) Stability of Soliris' Price between 2009-2015

192. The Board has a consumer protection mandate to ensure that the prices of patented medicines are not excessive. In order for the Board to properly exercise its mandate, it must have a regard to the initial price of a medicine when it comes onto the market as well as the price in subsequent years.

193. If the only concern that the legislature had was the price on entry into the market, and that thereafter the Canadian price could be increased by CPI, then s. 85(1) would have made clear that subparagraph (1)(c) would not have application after the entry price was established. The legislation however contemplates that the price of the medicine in other countries should continue to be a relevant factor. This is in recognition of the fact that patentees sell their medicines internationally. Since the purpose of ERP is to provide information about a willingness to supply other

comparable markets at lower prices, then the economic logic for using international comparisons remains the same as that used when the introductory price was established (**Exhibit 8, p. 5**). (This is especially true when reviewing the price of a breakthrough medicine.)

194. It follows, therefore, that if a price of a medicine in the period after introduction has become lower in other countries (whether because of a change in exchange rates or because of a price reduction in the local currency), it demonstrates a continuing willingness by the patentee to sell its medicine at a lower price.

195. Professor Schwindt notes at **page 16 of Exhibit 8** that in some countries patentees are required to reduce their prices over time. In their 10K filing, Alexion notes that in some countries pricing reimbursements for drugs are constrained by the prices of the same drug in other countries and that this may limit Alexion's ability to maintain its anticipated pricing (**Exhibit 1, Tab 62, pp. 38 and 134**). It follows, therefore, that as a patentee operating globally, Alexion was always aware that the price of Soliris in Canada would be constrained by the price of Soliris in the other comparator countries. Therefore, it is neither unfair nor unreasonable that Alexion would have to reduce its price in Canada based on the prices in other jurisdictions.

196. The Board has previously recognized that it is possible for the price of a medicine that has not increased to become excessive because of international price comparisons. In 1993 the Board decided to amend the existing *Guidelines* (effective

1994) for new and existing medicines. The amendment provided that the price of a medicine was to be presumed excessive if it exceeded the highest price of the same medicine in other countries. The Board recognized that this provision could result in the price of some medicines in Canada now exceeding the price in all other countries, notwithstanding that the current price of the medicine complied with the current *Guidelines*. The Board addressed this situation by noting that it would generally not take action immediately if it could be satisfied that the Canadian price would comply with the *Guidelines* within a two year period. This meant that the patentee could not increase its Canadian price for two years. If, however, the Canadian price still exceeded the highest international price, then patentees were told that it would then be necessary for them to reduce their Canadian prices over the same two year period (**Exhibit 1, Tab 108, p. 3**).

197. In any event, this is not a situation where a price has become excessive over time. On the contrary, the price of Soliris was excessive from the start and has remained excessive all along.

(VIII) The Price of Soliris is Excessive and should be Capped at the Lowest International Price

(A) The *Patent Act* and the Consumer Protection Mandate of the Board

198. The Federal Court has confirmed that the "mandate of the Board includes balancing the monopoly power held by the patentee of a medicine, with the interests of purchasers of those medicines".[22] It is important to recognize that "it is not "market abuse" that the Board is required by the *Patent Act* to find, but rather an "excessive price".

199. In *Celgene*, *supra*, Justice Abella conducted a detailed analysis of the legislative history of the *Patent Act* as follows: "The Board was established in amendments contained in Bill C-22. *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, which received Royal Assent on November 19, 1987, as S.C. 1987, c. 41. Introducing the Bill for second reading, the Hon. Harvie André made the following relevant comments about the Board objectives:

> In essence, the amendments I propose in Bill C-22 will create a climate favourable to new investment in research and development by giving patent holding pharmaceutical firms in Canada a guaranteed period of protection. These changes will also ensure consumer protection by creating a drug prices review board to monitor drug prices ...

[22] *PMPRB-07-D1-THALOMID*, *supra*, at para 5 - Upheld on review, *Celgene*, *supra*.

> I humbly submit that anybody who takes an objective view of what we are proposing will see that we have in place enormous checks and balances to ensure that consumer prices of drugs remain reasonable. They should look at what we will get by way of research and development, and at the jobs this will create.
>
> Whatever the costs might be associated with this legislation will be minimal. They will not hit the consumer. [Emphasis added.]

200. In keeping with the consumer protection mandate of the Board, the Supreme Court of Canada agreed that the Board properly interpreted their jurisdiction as extending to patented medicine shipped from the U.S. to doctors in Canada and paid in the U.S. in U.S. dollars as a medicine "sold in any market in Canada". The Court found that while this interpretation of the phrase may not be in keeping with commercial law principles, the legislation should be interpreted in a manner which best implemented the consumer protection mandate of the price regulation provision.[23]

(B) The Approach and Methodology set out in the *Guidelines* is Overly Generous to Patentees in the Context of Soliris

201. The *Guidelines* provide that breakthrough medicines (Category 2) may be priced at introduction at the median international price. This is a premium price. Given the consumer protection mandate of the Board, the extremely high cost of Soliris and the purpose of ERP, an introductory MAPP and a NEAP in each year that is benchmarked

[23] See also *Canada (Attorney General) v. Sandoz Canada Inc.*, 2015 FCA 249 at para 36 [*Sandoz*]

to the lowest international price would also be reasonable and in the interest of the consumer. After all, Professor Schwindt noted that although the median price is the constraint imposed by the *Guidelines*, this does not mean that the median price is the minimal price needed to compensate Alexion.

202. It is also worth noting that in some countries using ERP, the methodology to set the initial ceiling price is based on the lowest price of the comparator countries or the average price or an average of the three lowest prices. As Professor Schwindt notes on pages 12-13 of **Exhibit 8**, these alternative methodologies would have significantly lowered the MAPP of Soliris on introduction from $223.2066 to as low as $165.2075. (In fact, the lowest price would be approximately $135.00 which was the FSS price in the U.S. which was below the WAC price).

203. The *Guidelines* also constrain the price of a medicine over time by the lower of the CPI adjusted price or the highest international price.

204. The *Guidelines* approach of benchmarking the introductory price of a medicine at the median international price and thereafter using the HIPC is also overly generous to patentees.

205. Professor Schwindt noted at **pages 16 and 21 of Exhibit 8** that there is no other country using ERP which uses the highest price among comparator countries as the

ceiling price after introduction. Some countries use the same benchmark as was used initially to set the ceiling price.

206. The use of a lagged 36 months average for calculating the market exchange rate is also very generous to patentees as it provides them with a significant period of time to observe trends in market exchange rates and it eliminates the need to continually adjust prices. Professor Schwindt noted that in other countries that use ERP there is a much shorter time period used to calculate exchange rates (**see Exhibit 8, p. 15**).

207. The use of market exchange rates as a basis of comparing international price was also of benefit to Alexion in this case compared to the alternative of PPP exchange rates which would have resulted in a much lower MAPP under the *Guidelines* under the on introduction ($200.06) and in all subsequent years (**see Exhibit 8, Table 3, p. 8**).

208. Since the comparator countries whose prices are compared to Canada are similar to Canada with respect to income, health care systems and all have developed economies, the price discrimination by Alexion in this case is not based on humanitarian grounds. It is also noteworthy that the per capita GDP of Canada was well below the average of the comparator countries (**Exhibit 8, Table 3, p. 11**).

(C) *Guidelines* Not Appropriate in the Case of Soliris

209. The *Guidelines* were developed to implement the factors contained in s. 85(1) of the *Patent Act*. They were developed prior to the prevalence of orphan drugs. According to Mr. Haslam, prior to 1983 there were only 10 drugs that would be classified as orphan drugs while today there are probably 300 – 400 (although many are not yet available in Canada). Mr. Haslam agreed that orphan drugs are a global growth market.

210. There is no doubt that orphan drugs are more expensive than other drugs. However, Dr. Addanki noted that orphan drugs in the U.S. that were similar in economic respects to Soliris were quite a bit less expensive in the U.S. There is no explanation for why Soliris is so much more expensive. This is significant because if the price of Soliris in the U.S. is so high, and the price in Canada where drugs are typically less expensive than in the U.S. is even higher, one should assume that the price of Soliris is excessive in Canada.

211. In *PMPRB-99-D10-Nicoderm-Merit*, April 9, 2010, the Board noted at paragraph 14 that it would not be logical or consistent with the objective of the *Guidelines* or s. 85 of the *Patent Act* to set the MNE of a medicine by reference to the price of another medicine that was excessively priced. If Soliris is excessively priced in other countries, it defies logic to then permit the sale of Soliris in Canada at prices that are even higher than in other countries.

212. Soliris is truly a breakthrough drug. As it is so effective in prolonging life and providing quality of life, and there are no comparable therapies available to patients with PNH and aHUS, the demand for the drug is inelastic. This gives patentees the ability to earn super competitive returns on their medicines. The inelasticity of the demand for Soliris and the market power it has been granted by its statutory monopoly call for greater scrutiny of its prices.

213. The evidence of Mr. Lun as to the effect of orphan drugs (known as Expensive Drugs for Rare Diseases or EDRD) on the budgets of provincial payors is compelling evidence as to why the Board must ensure greater scrutiny on those drugs if it is to continue to serve a role in protecting the Canadian consumer.

214. The need for greater scrutiny of the price of drugs, such as Soliris, is evident from the conclusions of Coyle, Cheung & Evonis in their article *Opportunity cost of funding Drugs for Rare Diseases: The Cost-Effectivenss of Eculizimab in Paroxysmal Nocturnal Hemoglobinuria* (**Exhibit 70**). The authors conclude that although Soliris provides substantive benefits to PNH patients, it does so at a high incremental cost and a substantive cost. The authors recommend that payors consider such cost in determining whether the manufacturer's requested price is appropriate.

215. In *Adderall XR*, *supra* at paragraph 16 the Board noted that "... situations could arise that are not contemplated by the *Guidelines* or changes in medicine ... could give

rise to situations that are no longer covered appropriately by the *Guidelines*. Where the *Guidelines* do not appropriately implement s. 85, the Panel should decline to follow the *Guidelines*".

216. In *Dovobet*, supra, the Board noted that if a Panel concludes that a provision in the Guidelines was inconsistent with any part of the *Patent Act*, either generally or as it pertained to the pricing of a particular medicine, that provision would be given no consideration and, if appropriate, the provision would be eliminated or revised to accord with the *Patent Act*.[24]

217. In deciding to depart from the Guidelines in the *Adderall XR* decision, the Panel was aware that although Board Staff and patentees may rely to some extent on the consistent application of the *Guidelines* to provide certainty and predictability in pricing and enforcement decisions, a deviation from the *Guidelines* was necessary.

218. This is one of those cases where the *Guidelines* do not appropriately implement the factors in s. 85(1). Although the methodology in the *Guidelines* for comparing international prices is a reasonable application of s. 85(1)(c), it is not reasonable for the price of Soliris to be analyzed based on the HIPC test.

219. While the Guidelines acted as the tripwire to alert Board Staff to identifying Soliris as a medicine which had an excessive price, the *Guidelines* are of limited assistance in

[24] *Dovobet*, supra, at page 11 - Upheld in part and rev'd on other grounds, 2007 FC 306. The Federal Court confirmed that the Guidelines are not binding.

determining the remedy for that excessivity. If anything, the operation of the tests in the *Guidelines* in this case demonstrates a defect in those tests as Soliris – one of the world's most expensive drugs with very inelastic demand and consequently with the highest potential for excessive pricing - came dangerously close to not triggering an investigation under the *Guidelines* and going "under the radar".

(D) Hansard Debates Demonstrate Concern that Canadian Prices Remain Lower than U.S. Prices

220. The legislative debates in 1986 regarding the amendments to the *Patent Act* which led to the creation of the Board, demonstrate the concern by Parliament about the impact of the changes on the prices of Canadian patented medicines. Honourable Harvie André noted that the Board would monitor the price of drugs (existing and new) to ensure that the market situation in which Canadian drug prices were at 80% of those in the U.S. would remain. At the time, there was considerable concern that the extension of the patent protection period in the legislation and the removal of compulsory licenses would result in higher prices (*House of Commons Debates*, vol. 1, 2nd Sess., 33rd Parl., November 20, 1986, at p. 1372).

221. In 1992, the *Patent Act* was further amended to completely abolish compulsory licensing. On second reading, the Honourable Michael Wilson (Minister of Industry, Science and Technology) on November 16, 1992 commented on the effectiveness of the Board in keeping Canadian prices below the U.S. prices. The Minister specifically

referenced the GAO Report which found that prices in Canada were 32% lower than in the U.S. (*House of Commons Debates*, vol. 10, 3rd Sess., 34th Parl., November 16, 1992, at p. 13417).

222. On November 17, 1992, during further debates about the amendments to the *Patent Act*, the Parliamentary Secretary to the Minister of Consumer and Corporate Affairs, Ms. Dorothy Dobbie, addressed the concerns about whether the amendments would lead to higher prices in Canada compared to the U.S. Ms. Dobbie attempted to alleviate these concerns by referencing the enhanced powers of the Board (*House of Commons Debates*, vol. 11, 3rd Sess., 34th Parl., November 17, 1992, at p. 13466).

223. During debate in the House of Commons on December 8, 1992, Ms. Dobbie once again referenced the effectiveness of the Board in reducing Canadian prices to amounts that were significantly below those in the U.S. (*House of Commons Debates*, vol. 12, 3rd Sess., 34th Parl., December 8, 1992, at p. 14817).

224. On December 9, 1992, Mr. Greg Thompson spoke in favour of the amendments and the fact that prices in Canada were 32% lower on average than in the U.S., citing the GAO Report. The member further noted that there were no differences in manufacturing costs and that the reason for the price difference was the Board. He noted that the amendments would strengthen and expand the powers of the Board (*House of Commons Debates*, vol. 12, 3rd Sess., 34th Parl., December 9, 1992, at p. 14935).

225. The GAO Report and the success of the Board in keeping drug prices below those in the U.S. was also addressed by Mr. Ross Belsher (Parliamentary Secretary for the Minister of Fisheries and Oceans) who spoke in favour to the amendments on December 9, 1992 (*House of Commons Debates*, vol. 12, 3rd Sess., 34th Parl., December 9, 1992, at p. 14943).

226. In the Senate Debates on December 15, 1992, Senator Keon also spoke in favour of the amendments and of the success of the Board in keeping Canadian drug prices significantly below the U.S. prices. Senator Keon also referenced the GAO Report (*Senate Debates*, vol. 3, 3rd Sess., 34th Parl., December 15, 1992, at p. 2467).

227. It is clear that Parliament intended to ensure that Canadian prices of medicines never rose to the levels of those in the U.S.

(E) The Price of Pharmaceuticals in the U.S.

228. Professor Schwindt noted in his report, as well as his testimony, that the set of comparator countries includes the U.S. which has high prices due to the largely unregulated nature of the pharmaceutical market (**Exhibit 8, p. 12**).

229. At **p. 18 of Exhibit 8**, Professor Schwindt noted the following: "Indeed from an economic perspective, the U.S. price revealed Alexion's willingness to supply a largely unregulated market at a much lower price."

230. In *PMPRB-07-D2-Penlac-Merit*, January 31, 2011 at paragraph 88 the Board noted that patented medicines, especially in the U.S., are more expensive than in Canada and that the median international price a "premium" price.

231. Dr. Addanki also noted that the price of drugs in other countries provides relevant information on whether the Canadian price of a drug is excessive. He noted, in particular, that if a lower price is found in a country which does not regulate prices (the U.S.) this would provide "useful information indicating that the Canadian price might in fact be excessive" (**Exhibit 17, para. 25**).

232. Dr. Addanki noted that the pattern of relative prices of Soliris in which the Canadian price exceeded the U.S. price during the period of 2009-2014 was "striking and informative" [25] (**Exhibit 17, para. 45**).

233. Dr. Addanki noted at paragraph 32 that one would not expect the price of Soliris to be higher in Canada given the regulated regime in this country and the unregulated regime in the U.S. Dr. Addanki also confirmed that drugs are generally more expensive

[25] In 2015 the U.S. prices only slightly exceeded the Canadian price given the depreciation of the Canadian dollar.

in the U.S. than Canada (**see footnote 32 and Exhibit 10 of Dr. Addanki's report marked as Exhibit 17**).

234. Dr. Putnam also conceded that U.S. drug prices are higher than those in Canada.

235. Dr. Anis attempted to equivocate on this issue, although many of his journal articles cited the GAO Reportn which found that U.S. drug prices were higher than those in Canada (**see Exhibits 64, 65 and 66**).

236. Although Dr. Anis in his report referenced the 2006 article by Danzon and Furukawa at **Exhibit 56** to suggest that U.S. prices were not higher than Canadian prices, the apples to apples comparison of drug prices in that article does indeed confirm that Canadian drug prices are lower than U.S. drug prices[26] (**Transcript Vol. 16 (Public), pp. 2163-2137 and Exhibit 56**).

237. The authors of the article *The High Cost of Prescription Drugs in the United States*, *JAMA*, 2016: 316(8) 858 (**Exhibit 42**), note that prices were 10-15% higher in the U.S. than in Canada. The authors note at p. 860 that drug prices are higher in the

[26] Dr. Anis at one point in his testimony attempted to suggest that it was unclear whether U.S. drugs prices were lower than Canadian drug prices given his own reference at **p. 22 of Exhibit 38** to a PMPRB study that found higher prices in Canada. Dr. Anis in his paper however noted that the PMPRB report could be interpreted as suggesting there were loopholes in the legislation that were responsible for the high prices. At p. 24 of his article and at footnote 6 he suggests that the loophole which led to the high Canadian prices was due to the fact that when the PMPRB started reviewing prices, existing drug prices were grandfathered in and accepted as non-excessive. He noted that the loopholes have since been tightened.

U.S. than in the rest of the industrialized world, because the U.S., unlike other countries, allow manufacturers to set their own prices.

238. The authors at **pages 862-863** reject the oft repeated assertion that high drug prices are attributable to the cost needed to develop and research new drugs, noting that much of the innovative work is done by academia and investment from public sources. The authors conclude that there is little evidence of an association between research and development and find that prices in the U.S. are largely based on what the market will bear.

239. At **page 865** the author suggests various ways to lower drug prices such as that used in Sweden or through the use of international ERP. At **page 867** the authors reject the notion that a new U.S. policy to reduce drug prices would hinder innovation.

240. Alexion offered no evidence or explanation for why the price of Soliris was significantly lower in the unregulated markets of the U.S. than it was in Canada. The following table compares the Canadian and U.S. price of Soliris in the period between 2009 and 2014.[27]

[27] The data source for the U.S. price is **Exhibit 4A** which shows the Block 5 price filed by Alexion. The highlighting on Exhibit 4A shows these countries where Board Staff and Alexion disagreed. There is no disagreement on the U.S. prices.

Year	CANADA	U.S. price (average of FSS and WAC prices)[28]
2009	$224.7333	$165.2075
2010	$224.7333	$162.2769
2011	$224.7333	$193.3136
2012	$224.7333	$186.8356
2013	$224.7333	$191.0372
2014	$224.7333	$204.4753

241. It should be noted the U.S. prices set out in the above table do not represent the lowest ex-factory prices in the U.S. According to Alexion's own filings between 2009 until the second reporting period of 2011, the FSS price of Soliris in the U.S. was even lower. In 2011 (prior to the increase in the FSS price), the FSS price of Soliris expressed in Canadian dollars was $133. This is to be contrasted with the price of Soliris in Canada at $224 – a price which was 40% higher than the U.S. price (**Transcript Vol. 15 (Confidential), pp. 644-655**).

242. This is a very substantial difference. The Canadian patient in 2009-2011 was paying $539,000 per year of treatment, while the American patient in the same period was paying the equivalent of CAD$323,000. The substantial difference in price is all the more remarkable given that the U.S. is an unregulated market in which prices of pharmaceuticals are generally much higher than Canadian pharmaceutical prices.

[28] Expressed in Canadian dollars according to 36 months average exchange rate.

243. Given that the ERP tells us about the willingness of a patentee to supply its medicine in a comparable foreign market, then it is entirely reasonable to assume that Alexion could also have supplied the Canadian market at a similar price.

244. Alexion chose not to present any evidence as to why there was such a significant disparity between the U.S. and Canadian prices. The evidence suggests that there is no reason why the price of Soliris in Canada should be higher than the lowest publicly available international price. After all, as Alexion noted in its 10K filing with the SEC, if they are unable to sell Soliris in a country at a price acceptable to Alexion, they can decide not to sell Soliris in that country. Given that Alexion continued to sell Soliris in other countries at prices considerably lower than the Canadian price during the period in question, it follows that Alexion should be willing and able to sell Soliris at this same price in Canada.

(F) The Significance of the Price in the U.K.

245. The price of Soliris in Canada is well above the U.K. price. In the U.K. drugs must be reviewed by NICE (National Institute for Health and Care Excellence). In 2015 NICE published its guidance on Soliris for aHUS. They noted at page 22 that it was important to be cognizant of the fact that Soliris is licensed for both PNH and aHUS and that NICE had not been presented with "sufficient justification" for the costs of Soliris in light of the manufacturing, research and development costs. The Committee noted that

Alexion's research and development only explained a small amount of the cost variance between treatment with Soliris and those medicines used for treating larger patient populations. The Committee further noted that the purported justification by Alexion that there was only a small number of patients and a higher level of financial risk and costs of clinical trials and risks of failure applied to all specialized drugs for rare diseases was not substantiated. The Committee concluded that it had not been provided with any justification for the high cost of Soliris (**Exhibit 9, pp. 22, 23 and 27**).

(G) The Price Cap for Soliris should be based on the U.S. and U.K. Prices

246. The difference and significance of the U.S. and U.K. prices for Soliris described above also suggest that, in addition to being excessive, the price of Soliris should be capped by the U.S. and U.K prices which have been the lowest international prices during the 2009-2015 period.[29]

247. Indeed, given the price concerns expressed by NICE, where Soliris is already priced at the lowest international price ($188), it would be reasonable that the lowest international price became the benchmark for the price going forward in Canada. Moreover, prior public U.S. pricing, which has been as low as $135 (2009-2011 FSS price), and prior public U.K pricing, which has been as low as $166 (Q2, 2012) also indicate that Alexion has the ability to price Soliris at a considerable discount from the current Canadian price.

---

[29] Of course the Board could also choose a specific price based on the lowest international prices and use that specific price as the ceiling price going forward.

248. Specifically, Board Staff submits that the price of Soliris going forward should be no higher than the lowest international prices Alexion has been willing to accept, namely at a price within the range unit of $135-$188. Setting this price cap would result in a decrease in the price of Soliris in Canada of between 40%-16%. This would reduce the annual cost of treatment for PNH from around $539,000 to somewhere between $317,400-$452,760, and would reduce the annual cost of treatment for aHUS from around $728,000 to somewhere between $436,000-$611,000.

(H) No Significant Hardship to Alexion from Lowest International Price

249. Alexion has always been aware that it is necessary to compare the Canadian price of Soliris with the price of Soliris sold in other countries.

250. Alexion's 10K filings with the SEC demonstrate that it is keenly aware of exchange rate fluctuations and that it takes steps to protect itself from same. The 10K filings also note that in some years, Alexion's "losses" from currency fluctuations were offset by increased gains from currency fluctuations in other jurisdictions.

251. It is undisputed that Alexion sells (and has sold) Soliris for considerably less than the publicly available list price. In fact, according to Mr. Ruby's question on page **C. 382 of Transcript Vol. 12 (Combined Public-Confidential)**, in 2016, Alexion was already selling Soliris to the provinces for a price that was below the lowest international price

(for the first half of 2016). Accordingly, no appreciable harm would be occasioned by the Board now setting the publicly available list price at the lowest international price.[30]

252. Alexion's total revenues from the sale of Soliris in Canada during 2009-2015 was in excess of [redacted] The amount of revenue earned each year has increased exponentially (the revenues for 2015 alone were in excess of [redacted]. For the first reporting period in 2016, Alexion in Canada reported revenues of just under [redacted]

253. Globally, Alexion's revenues for the last fiscal year were in excess of US$3,000,000,000. In the preceding year, the global revenues were in excess of US$2,000,000,000.

254. Alexion has provided no financial documentation for its Canadian operations. Moreover, Alexion has provided no documentation or evidence to rebut the presumption of the expert evidence that its costs in Canada are likely to be similar to costs in the comparator countries.

255. The financial information contained in Alexion's 10K filing established that Alexion's cost of sales were between 11% - 12% of product revenue. The financial statements note that the costs of sales include manufacturing costs, as well as actual expenses associated with the sale of Soliris (**see Exhibit 1, Tab 60, pp. 55 and 109**).

---

[30] In fact, the lowest international price ever was set by the U.S. in 2009-2011 at $138 and has ranged from $166-$188 in the U.K. in 2012-2015. (**see Exhibit 4A**).

To put this in perspective, for each $500,000 worth of Soliris sales, Alexion earns an incremental profit of approximately $440,000 (88% profit). Indeed, under these circumstances, Alexion's "break-even" price/unit is in the $27 range - nowhere near the $224.73 it charges in Canada.

256. Exhibit 4 sets out the Block 5 information filed by Alexion for the period of 2009-2015. The table demonstrates that there is no dispute about what is the lowest international price in each of these years.

257. Soliris is a breakthrough medicine. There are no therapeutic substitutes for Canadian patients who rely upon the medicine. The pricing scheme in the *Patent Act* is based upon comparators. In the case of Soliris in Canada the only comparator is to the price of the medicine in other jurisdictions. Throughout the period of 2009-2015, Alexion was always aware of the public listed price for which it sold its medicine. Pharmaceutical regulatory bodies throughout the world have raised concerns over the high cost of Soliris. The high cost of Soliris is of concern to all Canadians.

258. Dr. Addanki noted that the more closely a company is to being a monopoly, the greater the potential harm to consumers and the greater the need to be vigilant in monitoring the prices. This case calls for vigilance.

259. Given all of the circumstances in this case, the price of Soliris in Canada should not be allowed to exceed the lowest international price of Soliris in the comparator countries.

(IX) Excess Revenue

260. Board Staff submits that the Board should consider the issues of the appropriate price of Soliris and the quantum of excess revenue separately. Board Staff's position below is that Soliris' price should be capped by the lowest international price and excess revenue should be calculated based on that price.

261. However, recognizing that the Board may want to calculate excess revenue on a different price basis (e.g., MIPC, HIPC) even if the Board decides on a lowest international price cap going forward, Board Staff has prepared various scenarios to illustrate the methodology by which to calculate the excess revenues and the resulting amounts to 2015. Board Staff wishes to be clear, however, that the presentation of these alternative positions do not constitute an admission that Board Staff thinks that the price of Soliris going forward should be set any higher than at the lowest international price. Setting such a going forward price represents the most effective and immediate way to directly protect consumers from further excessive pricing of Soliris.

262. **Exhibit 1, Tab 112** sets out the various methods of calculating Excess Revenues in this case. Separate Tables are provided for each scenario. It is important to note

that the requirement to repay excess revenue is not intended to be punitive. It merely results in refunding money that should not have been collected by Alexion in the first place. Professor Schwindt noted that when a patentee charges an excessive price for its medicine, the revenue that was received was an amount to which the patentee was not lawfully entitled (**Transcript Vol. 8 (Combined), p. 968**).

263. Table 1 sets out the excess revenues based on the median international price as the benchmark price in 2009 with the ceiling price for subsequent years set by the lower of the HIPC test or the CPI adjusted price. The data sources are based on Alexion's Block 5 filings with the exception of those amounts which are highlighted in yellow on **Exhibit 4A** where Board Staff did not accept the Block 5 price filed by Alexion.

264. Table 2 sets out the same information and methodology as Table 1 with the same data sources, but using the lowest international price on introduction and the ceiling price for subsequent years set by the lower of the lowest international price or the CPI adjusted price.

265. Table 3 uses the same methodology as Table 2. The data, however, comes from IMS.

266. The attached Appendix A sets out the detailed calculations of Board Staff of the international prices annually in the period 2009-2015.

267. IMS data is publicly available and is used by both Board Staff and patentees. It is also reliable. This was confirmed by Mr. Lemay, Mr. Brogan and Dr. Anis.

268. Table 4 set out the excess revenues based on the median international price on introduction with the ceiling price for subsequent years by the lower of the median international price or the CPI adjusted price.

269. Table 5 sets out the same information and methodology as Table 4. The data, however, comes from IMS.

X. Section 85(2) of the *Patent Act*

270. Board Staff submits that the evidence presented clearly establishes that Soliris is excessively priced and that this determination can be made based on the factors set out in s. 85(1). Should the Board, however, be unable to determine whether Soliris is being or has been sold in any market in Canada at an excessive price, then it is necessary to consider the additional factors set out in s. 85(2). Board Staff has set out below the evidence with respect to s. 85(2) that the Board may take into consideration in concluding that Soliris is excessively priced.[31]

271. The first additional factor referred to in s. 85(12)(a) allows the Board to take into consideration the costs of making and marketing the medicine. Alexion led no evidence

[31] Some of the evidence set out below appears earlier in our Written Argument and is repeated here in the event that the Panel concludes that such evidence was not relevant under s. 85(1) of the *Patent Act*.

in this regard. There is, however, evidence on the record of the relevant cost information from Alexion's Consolidated Financial Statements. These costs were in the range of 11 to 12%.

272. Section 85(2)(b) also permits the Board to take into consideration other factors that are in the opinion of the Board relevant in the circumstances. There are a number of such factors that should be taken into account in this regard. These include the following:

(a) Soliris is one of the most expensive medicines in the world.

(b) There has been no evidence led to establish the reason for the extreme cost of Soliris or for the price discrimination between Canada and other countries.

(c) It is appropriate to take into consideration the social opportunity costs for a medicine that can cost in excess of $500,000.00 or $700,000.00 annually.

(d) The factors set out in s. 85(1) did not contemplate a world of orphan drugs. Given that orphan drugs are breakthrough medicines, on introduction the factor that would have the most relevance is the international price. Given the existence of Alexion's monopoly power and the inelasticity of the demand for its medicine, Alexion is in the position of utilizing its global monopoly to set international prices at stratospheric levels. Moreover, Alexion through its

marketing efforts and resources is able to fund patient groups to lobby public payors globally to provide coverage no matter what the costs of the medicine. Consequently, there are almost no constraints on the market prices that Alexion can charge internationally. In these circumstances, ERP may be of minimal assistance to consumers in Canada.

(e) In other countries, regulators have compared the cost of Soliris to other medicines and found that the price of Soliris is extreme. As an example, reference may be had to the situation in New Zealand (**Exhibit 1, Tab 72**). Notwithstanding that the price of Soliris would have been less in New Zealand then in Canada, Pharmac noted that the price of Soliris was "extreme" and "out of line with other comparable innovative new medicines". Similarly, in the U.K. (**Exhibit 69**), NICE noted at page 24 that the clinical experts had confirmed that if the annual treatment costs per patient was adjusted by the average weight of the patient, Soliris would be more expensive than other highly specialized technologies.

(f) Mr. Lun confirmed that the annual treatment costs for Soliris were considerably higher than those used for other EDRDs. Dr. Addanki also agreed that the cost of Soliris in the U.S. was considerably higher than the annual cost of other orphan drugs.

(g) The authors Coyle, Cheung & Evans in their article at **Exhibit 70** conducted an analysis of the opportunity cost of funding Soliris for PNH. At page 1026, the authors note that a reduction in price of 98.5% would result in Soliris being cost effective. The authors further note that before funding such expensive treatments, payors should demand that manufacturers justify such high costs. The authors note as follows: "The monopolistic power of manufactures with respect to rare diseases and the unwillingness for decision-makers to consider cost-effectiveness as a criteria with respect to reimbursement allow manufacturers a degree of control over prices. Thus, if a decision-maker is going to ignore the underlying cost effectiveness of its product, it behooves the decision-maker to carefully consider whether the cost is warranted based on a careful consideration of manufacturer's cost and return on investment".

(h) In Dr. Anis' article at **Exhibit 66**, he notes at page 524 that PMPRB pricing guidelines may have led to retaliatory measures in foreign countries in order to strategically increase foreign prices so that Canadian prices can be increased.

(i) In Dr. Anis' article marked as **Exhibit 68** at pages 9 and 12, he notes that Canadians have lower incomes which explains why drug prices are lower in Canada. No explanation is provided for why Soliris is the exception.

(j) Dr. Anis notes at page 8 of **Exhibit 68** says that historically drug companies in Canada have never taken full CPI increases. This is an indication

to Dr. Anis that the profit maximizing price of drug manufacteurs is therefore lower than the ceiling prices set under the *Guidelines*.

(k) The decisions of the CDR not recommending coverage of Soliris for both PNH and aHUS.

(l) The evidence of the PLAs confirms that Alexion can afford to sell Soliris for substantially less than the publicly listed price in Canada. Notwithstanding Alexion's ability to supply its medicine at a considerably lower price, it continues to sell Soliris at the publically listed price in Canada (see **Exhibit 26 to 29**).

(m) In the report from the Office of the Inspector General marked as **Exhibit 19**, at page 10 the author notes the concerns and debate in the U.S. because of prices for orphan drugs which can cost more than $300,000.00 annually. Soliris is priced considerably in excess of this amount.

(n) The financial impact on the budgets of the provinces and the lost opportunity costs (See **Exhibits 26 to 29**).

(o) **Exhibit 25** demonstrates the likely impact of the current pricing of Soliris on provincial budgets. The PLA discounted prices are approaching the publically listed prices. Moreover, the ability of provincial payors to leverage a better agreement in the future becomes more difficult as more patients continue to

receive treatment with Soliris. (As an example, Ontario is currently providing funding for 59 PNH patients and 17 aHUS patients. See **Exhibit 27**). The result is that the provinces are held hostage in any future negotiations with Alexion.

(p) There is no evidence that a reduction in the publicly listed price for Soliris would cause harm to Alexion.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

March 24, 2017

Perley-Robertson, Hill & McDougall LLP
340 Albert Street, Suite 1400
Ottawa, ON K1R 0A5
Fax: (613) 238-8775

David Migicovsky
Tel: (613) 566-2833
Email: dmigicovsky@perlaw.ca

Christopher P. Morris
Tel: (613) 566-2802
Email: cmorris@perlaw.ca

Lawyers for Board Staff

APPENDIX A

Appendix A

Board Staff Review of Prices of Soliris

I. 2009 Review of Soliris Price

1. On July 30, October 25, and November 30, 2010, Alexion filed its original and revised Block 5 Form 2 data for the 2009 reporting period (**Exhibit 1, Tabs 13, 18 and 19**).

2. In Alexion's Form 2 Block 5 filings for 2009, Alexion reported prices in local currency which were converted to Canadian currency based on the foreign exchange rate methodology described in Schedule 5 of the Guidelines and as published on the PMPRB website (**Exhibit 1, Tab 111, Exhibits 2, 4 and 4A**). Alexion submitted the following prices for Soliris in Canada and the comparator countries as follows (**Exhibit 4, Tab 4**):

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Date of First Sale: 12 Jun 2009			
Company Submission Prices			
Country		**(Local Currency)**	**(Canadian Prices)**
Canada	(30)	6,742.0000 (CAD)(W)	$224.7333
France	(30)	4,450.0000 (EURO) (H)	$221.1168
Germany	(30) (30)	4,672.0000 (EURO) (P) 4,600.0000 (EURO) (W)	$230.3590
Italy	(30)	4,565.7200 (EURO)(H)	$226.8668
Sweden	(30)	42,675.0000 (SEK)(H)	$225.2963

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Date of First Sale: 12 Jun 2009			
Company Submission Prices			
Country	**(Local Currency)**		**(Canadian Prices)**
Switzerland	--		--
United Kingdom	(30)	3,150.0000 (GBP)(H)	$216.1270
United States	(30) (30)	5,250.0000 (USD)(W) 3,812.8600 (USD)(FSS)	$165.2075
Median			$223.2066

3. In order to verify the ex-factory unit prices of Soliris in each of the comparator countries, Board Staff used the following sources and applied any applicable back-out formulas as follows (**Exhibit 4, Tab 4**):

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2009							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
Canada	Not Listed	--	--	--	--	--	--
France	IMS Manufacturer (2009)	4,411.0800 €	No	4,411.0800 €	30.00	1.49067500	$219.1829
Germany	Rote Liste (August 2009)	5,736.1100 €	Yes	4,672.0000 € (PP) 4,600.0000 € (WP)	30.00	1.49067500	$230.3590
Italy	Italian Medicines Agency (AIFA)	4,565.7200 €	No	4,565.7200 €	30.00	1.49067500	$226.8668
Sweden	Prislista (December 2009)	42,842.0000 Kr.	Yes	42,675.0000 Kr. (PP)	30.00	0.15838056	$225.2963
Switzerland	Not Listed	--	--	--	--	--	--
United Kingdom	MIMS (December 2009)	3,150.0000 £	No	3,150.0000 £	30.00	2.05835278	$216.1270

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2009							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
United States	Redbook (WAC) FSS (December 2009)	5,122.0000 US$ (WAC) 3,812.8600 US$ (FSS)	No	5,122.0000 US$ (WAC) 3,812.8600 US$ (FSS)	30.00	1.09374444	$162.8742

4. For the purposes of its calculation of excess revenues, Board Staff used all of Alexion's Block 5 data for the 2009 reporting period.

5. The only differences between the prices reported in Alexion's Form 2 Block 5 data and the price sources used by Board Staff relate to France and the United States. The differences do not impact Board Staff's calculation of the highest price among the comparator countries for 2009 (**Exhibit 4A**).

II. 2010 Review of Soliris Price

6. On February 1 and August 2, 2011, Alexion filed its Block 5 Form 2 data for the 2010 reporting period (**Exhibit 1, Tabs 20 and 23**).

7. In Alexion's Form 2 Block 5 filings for 2010, Alexion reported prices in local currency which were converted to Canadian currency based on the foreign exchange rate methodology described in Schedule 6 of the Guidelines and as published on the

PMPRB website (**Exhibit 1, Tab 111, Exhibits 2, 4 and 4A**).Alexion submitted the following prices for Soliris in Canada and the comparator countries as follows (**Exhibit 4, Tab 4**):

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Period: Jul10 – Dec10		
Company Submission Prices		
Country	**(Local Currency)**	**(Canadian Prices)**
Canada	(30) 6,742.0000 (CAD)(W)	$224.7333
France	(30) 4,450.0000 (EURO)(H)	$223.1148
Germany	(30) 4,787.0000 (EURO)(P) (30) 4,715.0000 (EURO)(W)	$238.2063
Italy	(30) 4,565.7200 (EURO)(H)	$228.9167
Sweden	(30) 42,675.0000 (SEK)(H)	$215.6708
Switzerland	--	--
United Kingdom	(30) 3,150.0000 (GBP)(H)	$186.6629
United States	(30) 5,250.0000 (USD)(W) (30) 3,768.9100 (USD)(FSS)	$162.2769
Median		$219.3928

8. In order to verify the ex-factory unit prices of Soliris in each of the comparator countries, Board Staff used the following sources and applied any applicable back-out formulas as follows (**Exhibit 4, Tab 4**):

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2010							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
Canada	Not Listed	--	--	--	--	--	--

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2010							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
France	IMS Manufacturer (2010)	4,450.2200 €	No	4,450.2200 €	30.00	1.50414444	$223.1258
Germany	Rote Liste (August 2010)	5,877.0600 €	Yes	4,787.0000 € (PP) 4,715.0000 € (WP)	30.00	1.50414444	$238.2063
Italy	Italian Medicines Agency (AIFA)	4,565.7200 €	No	4,565.7200 €	30.00	1.50414444	$228.9167
Sweden	Apoteket (2010)	42,842.0000 Kr.	Yes	42,675.0000 Kr. (PP)	30.00	0.15161389	$215.6708
Switzerland	Not Listed	--	--	--	--	--	--
United Kingdom	MIMS (December 2010)	3,150.0000 £	No	3,150.0000 £	30.00	1.77774167	$186.6629
United States	Redbook (WAC) FSS (December 2010)	5,250.0000 US$ (WAC) 3,768.9100 US$ (FSS)	No	5,250.0000 US$ (WAC) 3,768.9100 US$ (FSS)	30.00	1.07957778	$162.2769

9. For the purposes of its calculation of excess revenues, Board Staff used all of Alexion's Form 2 Block 5 data for the 2010 reporting period.

10. The only difference between the prices reported in Alexion's Form 2 Block 5 data and the price sources used by Board Staff relates to France. This difference does not impact Board Staff's calculation of the highest or the lowest prices among the comparator countries for 2010 (**Exhibit 4A**).

III. 2011 Review of Soliris Price

11. On August 2, 2011 and January 31, 2012, Alexion filed its Block 5 Form 2 data for the 2011 reporting period (**Exhibit 1, Tabs 23 and 25**).

12. In Alexion's Form 2 Block 5 filings for 2011, Alexion reported prices in local currency which were converted to Canadian currency based on the foreign exchange rate methodology described in Schedule 6 of the Guidelines and as published on the PMPRB website (**Exhibit 1, Tab 11, Exhibits 2, 4 4A**). Alexion submitted the following prices for Soliris in Canada and the comparator countries as follows (**Exhibit 4, Tab 4**):

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Period: Jul11 – Dec11			
Company Submission Prices			
Country		**(Local Currency)**	**(Canadian Prices)**
Canada	(30)	6,742.0000 (CAD)(W)	$224.7333
France	(30)	4,450.0000 (EURO)(H)	$214.0108
Germany	(30) (30)	4,746.3100 (EURO)(P) 4,674.3100 (EURO)(W)	$226.5297
Italy	(30)	4,565.7200 (EURO)(H)	$219.5760
Sweden	(30)	42,685.0000 (SEK)(H)	$211.0457
Switzerland		--	--
United Kingdom	(30)	3,150.0000 (GBP)(H)	$173.5513
United States	(30) (30) (30)	5,532.0000 (USD)(P) 5,532.0000 (USD)(W) 5,448.6000 (USD)(FSS)	$193.3136
Median			$212.5283

13. In order to verify the ex-factory unit prices of Soliris in each of the comparator countries, Board Staff used the following sources and applied any applicable back-out formulas as follows (**Exhibit 4, Tab 4**):

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2011							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
Canada	Not Listed	--	--	--	--	--	--
France	IMS Manufacturer (2011)	4,449.5600 €	No	4,449.5600 €	30.00	1.44276944	$213.9896
Germany	Rote Liste (August 2011)	5,827.1900 €	Yes	4,746.3100 € (PP) 4,674.3100 € (WP)	30.00	1.44276944	$226.5297
Italy	Italian Medicines Agency (AIFA)	4,565.7200 €	No	4,565.7200 €	30.00	1.44276944	$219.5760
Sweden	Apoteket (2011)	42,842.0000 Kr.	Yes	42,675.0000 Kr. (PP)	30.00	0.14832778	$210.9963
Switzerland	Not Listed	--	--	--	--	--	--
United Kingdom	MIMS (December 2011)	3,150.0000 £	No	3,150.0000 £	30.00	1.65286944	$173.5513
United States	Redbook (WAC) FSS (December 2011)	5,532.0000 US$ (WAC) 5,448.6000 US$ (FSS)	No	5,532.0000 US$ (WAC) 5,448.6000 US$ (FSS)	30.00	1.05363333	$192.8254

14. For the purposes of its calculation of excess revenues, Board Staff used all of Alexion's Form 2 Block 5 data for the 2011 reporting period with the exception of Sweden.

15. The differences between the prices reported in Alexion's Form 2 Block 5 data and the price sources used by Board Staff relate to France, Sweden and the United States. The difference between Alexion's Form 2 Block 5 data for the United States and

the price used by Board Staff for the United States does not impact Board Staff's calculation of the highest, median, and lowest prices among the comparator countries for 2011. Board Staff relied upon Alexion's Form 2 Block 5 data for France and Board Staff's verification of public sources for Sweden (Apoteket). The differences between the prices reported in Alexion's Block 5 Form 2 data for France and Sweden and the prices used by Board Staff for Sweden have no impact on Board Staff's calculation of the highest and lowest prices among comparator countries for 2011 (**Exhibit 4A**).

IV. 2012 Review of Soliris Price

16. On January 29, 2014 and January 29, 2015, Alexion filed its original and revised Block 5 Form 2 data for the 2012 reporting period (**Exhibit 1, Tabs 28 and 49**).

17. In Alexion's Form 2 Block 5 filings for 2012, Alexion reported prices in local currency which were converted to Canadian currency based on the foreign exchange rate methodology described in Schedule 6 of the Guidelines and as published on the PMPRB website (**Exhibit 1, Tab 111, Exhibits 2, 4, and 4A**). Alexion submitted the following prices for Soliris in Canada and the comparator countries as follows (**Exhibit 4, Tab 4**):

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Period: Jul12 – Dec12		
Company Submission Prices		
Country	**(Local Currency)**	**(Canadian Prices)**
Canada	(30) 6,742.0000 (CAD)(W)	$224.7333

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Period: Jul12 – Dec12		
Company Submission Prices		
Country	**(Local Currency)**	**(Canadian Prices)**
France	(30) 4,450.0000 (EURO)(H)	$193.1733
Germany	(30) 4,787.0000 (EURO)(P) (30) 4,715.0000 (EURO)(W)	$212.6455
Italy	(30) 4,600.0000 (EURO)(H)	$205.8871
Sweden	(30) 42,842.0000 (SEK)(H)	$211.0167
Switzerland	(30) 5,781.3500 (CHF)(W)	$203.9007
United Kingdom	(30) 3,150.0000 (GBP)(H)	$166.7000
United States	(30) 5,692.0000 (USD)(W) (30) 5,448.6000 (USD)(FSS)	$186.8356
Median		$203.9007

18. In order to verify the ex-factory unit prices of Soliris in each of the comparator countries, Board Staff used the following sources and applied any applicable back-out formulas as follows (**Exhibit 4, Tab 4**):

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2012							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
Canada	Not Listed	--	--	--	--	--	--
France	IMS Manufacturer (2012)	4,450.4200 €	No	4,450.4200 €	30.00	1.34274167	$199.1921
Germany	Rote Liste (August 2012)	5,877.0600 €	Yes	4,787.0000 € (PP) 4,715.0000 € (WP)	30.00	1.34274167	$212.6455
Italy	Italian Medicines Agency (AIFA)	4,600.0000 €	No	4,600.0000 €	30.00	1.34274167	$205.8871
Sweden	Apoteket (2012)	42,842.0000 Kr.	Yes	42,675.0000 Kr. (PP)	30.00	0.14776389	$210.1941

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2012							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
Switzerland	BAG (December 2012)	5,781.3500 S.Fr.	No	5,781.3500 S.Fr.	30.00	1.05806111	$203.9007
United Kingdom	MIMS (December 2012)	3,150.0000 £	No	3,150.0000 £	30.00	1.58761944	$166.7000
United States	Redbook (WAC) FSS (December 2012)	5,692.0000 US$ (WAC) 5,448.6000 US$ (FSS)	No	5,692.0000 US$ (WAC) 5,448.6000 US$ (FSS)	30.00	1.00624167	$186.8356

19. For the purposes of its calculation of excess revenues, Board Staff used all of Alexion's Form 2 Block 5 data for the 2012 reporting period with the exception of Sweden.

20. The only differences between the prices reported in Alexion's Form 2 Block 5 data and the price sources used by Board Staff relate to France and Sweden. These differences do not impact Board Staff's calculation of the highest and the lowest prices among the comparator countries for 2012 (**Exhibit 4A**).

V. 2013 Review of Soliris Price

21. On January 29, 2014 and January 29, 2014, Alexion filed its original and revised Block 5 Form 2 data for the 2013 reporting period (**Exhibit 1, Tab 37 and 49**).

22. In Alexion's Form 2 Block 5 filings for 2013, Alexion reported prices in local currency which were converted to Canadian currency based on the foreign exchange rate methodology described in Schedule 6 of the Guidelines and as published on the PMPRB website (**Exhibit 1, Tab 111, Exhibits 2, 4, and 4A**). Alexion submitted the following prices for Soliris in Canada and the comparator countries as follows (**Exhibit 4, Tab 4**):

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Period: Jul13 – Dec13		
Company Submission Prices		
Country	**(Local Currency)**	**(Canadian Prices)**
Canada	(30) 6,742.0000 (CAD)(W)	$224.7333
France	(30) 4,450.0000 (EURO)(P) (30) 4,356.4200 (EURO)(W)	$197.1627
Germany	(30) 4,787.4000 (EURO)(P) (30) 4,640.5200 (EURO)(W)	$211.0772
Italy	(30) 4,565.7200 (EURO)(P) (30) 4,151.5000 (EURO)(W)	$195.1656
Sweden	(30) 42,675.0000 (SEK)(P) (30) 41,351.7400 (SEK)((W)	$213.9103
Switzerland	(30) 5,781.3500 (CHF)(W)	$211.7446
United Kingdom	(30) 3,150.0000 (GBP)(P)	$167.3691
United States	(30) 5,834.0000 (USD)(W) (30) 5,557.0400 (USD)(FSS)	$191.0372
Median		$197.1627

23. In order to verify the ex-factory unit prices of Soliris in each of the comparator countries, Board Staff used the following sources and applied any applicable back-out formulas as follows (**Exhibit 4, Tab 4**):

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2013							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
Canada	Not Listed	--	--	--	--	--	--
France	IMS Manufacturer (2013)	4,450.0400 €	No	4,450.0400 €	30.00	1.34331111	$199.2596
Germany	Rote Liste (August 2013)	5,877.5500 €	Yes	4,787.4000 € (PP) 4,640.5200 € (WP)	30.00	1.34331111	$211.0772
Italy	Italian Medicines Agency (AIFA)	4,565.7200 €	No	4,565.7200 €	30.00	1.34331111	$204.4394
Sweden	Apoteket (2013)	42,842.0000 Kr.	Yes	42,675.0000 Kr. (PP)	30.00	0.15274444	$217.2790
Switzerland	BAG (December 2013)	5,781.3500 S.Fr.	No	5,781.3500 S.Fr.	30.00	1.09876389	$211.7446
United Kingdom	MIMS (December 2013)	3,150.0000 £	No	3,150.0000 £	30.00	1.59399167	$167.3691
United States	Redbook (WAC) FSS (December 2013)	5,834.0000 US$ (WAC) 5,557.0400 US$ (FSS)	No	5,834.0000 US$ (WAC) 5,557.0400 US$ (FSS)	30.00	1.00625000	$191.0372

24. For the purposes of its calculation of excess revenues, Board Staff used all of Alexion's Form 2 Block 5 data for the 2013 reporting period with the exception of Italy and Sweden.

25. The only differences between the prices reported in Alexion's Form 2 Block 5 filings and the price sources used by Board Staff relate to France, Italy and Sweden. The difference between Alexion's Form 2 Block 5 data for France and price used by Board Staff has no impact on Board Staff's calculation of the highest, median and lowest prices among the comparator countries. Board Staff relied upon its verification of price sources for Italy (Italian Medicines Agency (AFIA)) and Sweden (Apoteket). The

differences between Alexion's Form 2 Block 5 prices for Italy and Sweden and the price sources used by Board Staff have no impact on Board Staff's calculation of the lowest price among the comparator countries for 2013 (**Exhibit 4A**).

VI. 2014 Review of Soliris Price

26. On July 30, 2014, January 15 and 29, 2015, Alexion filed its Block 5 Form 2 data for the 2014 reporting period (**Exhibit 1, Tabs 43, 49 and 89**).

27. In Alexion's Form 2 Block 5 filings for 2014, Alexion reported prices in local currency which were converted to Canadian currency based on the foreign exchange rate methodology described in Schedule 6 of the Guidelines as published on the PMPRB website (**Exhibit 1, Tab 111, Exhibits 2, 4, and 4A**). Alexion submitted the following prices for Soliris in Canada and the comparator countries as follows (**Exhibit 4, Tab 4**):

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Period: Jul14 – Dec14		
Company Submission Prices		
Country	**(Local Currency)**	**(Canadian Prices)**
Canada	(30) 6,742.0000 (CAD)(W)	$224.7333
France	(30) 4,350.0000 (EURO)(H)	$199.1768
Germany	(30) 4,786.9977 (EURO)(P) (30) 4,640.1335 (EURO)(W)	$215.8237
Italy	(30) 4,600.0000 (EURO)(H)	$210.6238
Sweden	(30) 42,842.0000 (SEK)(H)	$222.3936

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Period: Jul14 – Dec14			
Company Submission Prices			
Country	**(Local Currency)**		**(Canadian Prices)**
Switzerland	(30)	5,763.6900 (CHF)(W)	$216.8690
United Kingdom	(30)	3,150.0000 (GBP)(H)	$175.5250
United States	(30) (30)	5,997.0000 (USD)(W) 5,746.0500 (USD)(FSS)	$204.4753
Median			$210.6238

28. In order to verify the ex-factory unit prices of Soliris in each of the comparator countries, Board Staff used the following sources and applied any applicable back-out formulas as follows (**Exhibit 4, Tab 4**):

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2014							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
Canada	AQPP (November 2014)	6,742.0000 CND$	No	6,742.0000 CND$	30.00	1.00000000	$224.7333
France	IMS Manufacturer (2014)	4,365.8700 €	No	4,365.8700 €	30.00	1.37363333	$199.9035
Germany	Rote Liste (August 2014)	5,877.5500 €	Yes	4,787.4000 € (PP) 4,640.1400 € (WP)	30.00	1.37363333	$215.8239
Italy	Italian Medicines Agency (AIFA)	4,6000.0000 €	No	4,600.0000 €	30.00	1.37363333	$210.6238
Sweden	Apoteket (2014)	42,842.0000 Kr.	Yes	42,675.0000 Kr. (PP)	30.00	0.15573056	$221.5267
Switzerland	BAG (December 2014)	5,763.6900 S.Fr.	No	5,763.6900 S.Fr.	30.00	1.12880278	$216.8690
United Kingdom	MIMS (December 2014)	3,150.0000 £	No	3,150.0000 £	30.00	1.67166667	$175.5250

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2014							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
United States	Redbook (WAC) FSS (December 2014)	5,997.0000 US$ (WAC) 5,841.4400 US$ (FSS)	No	5,997.0000 US$ (WAC) 5,841.4400 US$ (FSS)	30.00	1.04474722	$206.1363

29. For the purposes of its calculation of excess revenues, Board Staff used all of Alexion's Form 2 Block 5 data for the 2014 reporting period with the exception of Sweden.

30. The only differences between the prices reported in Alexion's Form 2 Block 5 filings and the price sources used by Board Staff relate to Germany, Sweden and the United States. The differences between the prices reported in Alexion's Form 2 Block 5 data and Board Staff's price sources in relation to Germany and the United States have no impact on Board Staff's calculation of the highest, median and lowest prices among the comparator countries. Board Staff relied upon its verification of sources for Sweden (Apoteket) for the purpose of its calculations. The difference between the price reported by Alexion for Sweden and the price used by Board Staff does not impact Board Staff's calculation of the median or lowest prices among comparator countries for 2014 (**Exhibit 4A**).

VII. 2015 Review of the Drug Soliris

31. On July 30, 2015 and February 1, 2016, Alexion filed its Block 5 Form 2 data for the January to December 2015 reporting period (**Exhibit 1, Tab 57,90 and 91**).

32. In Alexion's Form 2 Block 5 revised filings for 2015, it reported the following prices in local currency which were converted to Canadian currency based on the foreign exchange rate methodology described in Schedule 6 of the Guidelines as published on the PMPRB website (**Exhibit 1, Tab 111, Exhibits 2, 4, and 4A**). Alexion submitted the following prices for Soliris in Canada and the comparator countries as follows (**Exhibit 4, Tab 4**):

Soliris – 10 MG/Milliliter (DIN: 02322285) Verification of International Prices Period: Jul15 – Dec15			
Company Submission Prices			
Country		**(Local Currency)**	**(Canadian Prices)**
Canada	(30)	6,742.0000 (CAD)(W)	$224.7333
France	(30)	4,350.0000 (EURO)(H)	$205.6265
Germany	(30) (30)	4,786.9977 (EURO)(P) 4,640.1335 (EURO)(W)	$222.8124
Italy	(30)	4,151.5000 (EURO)(H)	$196.2433
Sweden	(30)	42,842.0000 (SEK)(H)	$224.2858
Switzerland	(30)	5,763.6900 (CHF)(W)	$233.6792
United Kingdom	(30)	3,150.0000 (GBP)(H)	$188.4788
United States	(30) (30)	6,111.0000 (USD)(W) 5,841.4400 (USD)(FSS)	$226.6764
Median			$222.8124

33. In order to verify the ex-factory unit prices of Soliris in each of the comparator countries, Board Staff used the following sources and applied any applicable back-out formulas as follows (**Exhibit 4, Tab 4**):

Updated Tables 2 – 4 of the July 3, 2015 Particulars Foreign Price Verification for Soliris 10mg/mL (DIN: 02322285) July to December 2015							
Country	**Source Used**	**Source Price (Local Currency)**	**Need to calculate backed-out Ex-factory pharmacy/wholesaler prices (where "yes" calculated below)**	**Ex-Factory Package Price (Local Currency) EX or EX average) EX average = [(IPP) + (WP)]/2 or [(WAC) + (FSS)]/2**	**Pack Size (PS)**	**Exchange Rate (ER)**	**Unit Price (UP) (Canadian Currency) (UP) = [(EX or EX average) x (ER)]/PS**
Canada	AQPP (November 2015)	6,742.0000 CND$	No	6,742.0000 CND$	30.00	1.00000000	$224.7333
France	IMS Manufacturer (2015)	4,350.0000 €	No	4,350.0000 €	30.00	1.41811389	$205.6265
Germany	Rote Liste (August 2015)	5,877.5500 €	Yes	4,787.0000 € (PP) 4,640.1400 € (WP)	30.00	1.41811389	$222.8126
Italy	L'information Farmaceutico (December 2015)	4,151.5000 €	No	4,151.5000 €	30.00	1.41811389	$196.2433
Sweden	Apoteket (2015)	42,842.0000 Kr.	Yes	42,675.0000 Kr. (PP)	30.00	0.15705556	$223.4115
Switzerland	BAG (December 2015)	5,763.6900 S.Fr.	No	5,763.6900 S.Fr.	30.00	1.21630000	$233.6792
United Kingdom	MIMS (December 2015)	3,150.0000 £	No	3,150.0000 £	30.00	1.79503611	$188.4788
United States	Redbook (WAC) FSS (December 2015)	6,111.0000 US$ (WAC) 5,841.4400 US$ (FSS)	No	6,111.0000 US$ (WAC) 5,841.4400 US$ (FSS)	30.00	1.13789167	$226.6764

34. For the purposes of its calculation of excess revenues, Board Staff used all of Alexion's Form 2 Block 5 data for the 2015 reporting period with the exception of Sweden.

35. The only differences between Alexion's Form 2 Block 5 data and Board Staff's price sources relate to Germany and Sweden. The difference between Alexion's Form 2

Block 5 data and Board Staff's price source for Sweden has no impact on Board Staff's calculation of the highest, median and lowest prices among the comparator countries. The difference between the price reported by Alexion for Germany and Board Staff's price source appears to be due to a rounding error and has no impact on Board Staff's calculation of the highest price and the lowest price among the comparator countries for 2015 (**Exhibit 4A**).

VIII. Sweden – Board Staff used Apoteket as the Source for the purposes of verifying Swedish ex-factory prices of Soliris from 2010 to 2015

36. The usual and customary price source used by Board Staff for the verification of Swedish ex-factory prices was the National Reimbursement Scheme for the Swedish Dental and Pharmaceutical Benefits Agency ("TLV"). TLV was formerly known as Prislista. Soliris was not listed on TLV after 2009. Board Staff therefore used Apoteket as the pricing source for Sweden in order to verify the ex-factory price of Soliris in Sweden from 2010 to 2015. (**Exhibit 1, Tab 111**).

37. Since the price of Soliris was not listed in the TLV after 2009, Board Staff advised Alexion that it would accept Apoteket as a pricing source for 2010 and subsequent years. As the Apoteket Formulary Price (FP) was consistent with the 2009 Prislista (TLV) formulary price. However, the TLV price in 2009 was an ex-factory price that did not require any backing out. The Apoteket price does require application of the backing-out formula. In order to derive and verify the ex-factory unit price of Soliris in Sweden

using Apoteket as a source, the Apoteket formulary price must be backed-out as described in the foreign price verification tables (**Exhibit 4, Tab 4**).

38. On September 23, 2014, Joel Weber advised Neil Palmer that Board Staff accepted the 2013 Apoteket pricing source provided for Sweden since Soliris was available in Sweden but was not included in the TLV in 2013. (**Exhibit 1, Tab 47**). The Apoteket pricing source is found at **Tab 79 K of Exhibit 1**.

IX. Italy – Board Staff used the Italian Medicines Agency (AIFA) as the source for the purposes of verifying the Italian ex-factory prices of Soliris

39. The usual and customary source used by the Board staff to verify ex-factory prices for Soliris in Italy is L'informatorie Farmaceutico ("CODIFA"). CODIFA only listed a hospital price for Soliris. Hospital ex-factory prices are usually not provided in national formularies and cannot be derived like other ex-factory prices (ie. pharmacy and wholesale prices). Board Staff used the Italian Medicines Agency ("AIFA") as an alternative pricing source for Italy as it is a publicly available pricing source and provides an ex-factory price for Soliris. In 2009, 2010, 2011, 2012, 2014 and 2015, Alexion's Form 2 Block 5 prices for Soliris in Italy matched Board Staff's prices that it used from AIFA. (**Exhibit 1, Tab 111, Table 1, Footnote 2 and Exhibit 4A**).

40. On September 23, 2014, Joel Weber advised Mr. Palmer that Board Staff was not willing to accept an Italian price for Soliris filed by Alexion which was higher than the

maximum ex-factory price of 4,600 euros as provided in the AIFA source. At that time, Board Staff therefore asked Alexion to re-file its Italian Block 5 price for 2014. At the hearing, Board Staff produced the Italian Pharmaceuticals Agency Regulations concerning certain medications for human use (**Exhibit 3**). Article 3 of the Italian Regulations confirmed that the "price to the public" and "price from the factory" or "prezzo ex-factory" is 4,600 euros for one 30 ml vial of Soliris for the treatment of PNH. [1]

[1] Pages 133-136 of the transcripts from the Hearing