Public Version

PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the Patent Act, R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF Alexion Pharmaceuticals Inc. and the medicine "Soliris"

DECISION

(Hearing on the Merits)

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Public Version

I. Summary of Decision

1. The Panel of the Patented Medicine Prices Review Board (the "**PMPRB**" or the "**Board**") seized with this proceeding has considered the evidence adduced (including expert evidence) and submissions made by Board Staff, Alexion Pharmaceuticals Inc. ("**Alexion**" or the "**Respondent**") and the intervenors,[1] and finds that the price of Soliris (eculizumab) 10mg/mL ("**Soliris**") was and is excessive under sections 83 and 85 of the *Patent Act.*[2] The Panel orders Alexion to (i) pay to Her Majesty in right of Canada an amount calculated by the parties in accordance with Schedule A to this decision, to be approved by this Panel, and (ii) lower the list price of Soliris in Canada as of the date of this decision to no higher than the lowest price in the seven comparator countries set out in the current *Patented Medicines Regulations* ("**Regulations**").[3]

II. Introduction

2. Soliris is a breakthrough drug indicated for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH), a rare and life-threatening blood disorder that is characterized by complement-mediated hemolysis (the destruction of red blood cells).

3. Soliris is also approved as a treatment for patients with atypical hemolytic uremic syndrome (aHUS), a rare and life-threatening genetic disorder characterized by "complement-mediated thrombotic microangiopathy" or TMA (blood clots in small vessels).

4. Soliris is sold in Canada by Alexion. Board Staff filed a Statement of Allegations on January 15, 2015 alleging that the price of Soliris was excessive between 2012 and 2014, and seeking an order from this Panel under section 83 of the *Patent Act* requiring Alexion to, *inter alia*, reduce the price of Soliris to a price that does not exceed the international highest price among the comparator countries, and pay $5,617,480.42 to offset the

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1 Ministers of Health, Canadian Life and Health Insurance Association Inc. and BIOTECanada.

2 RSC 1985, c P-4 [*Patent Act*].

3 SOR/94-688. These countries are France, Germany, Italy, Sweden, Switzerland, the UK and the US.

cumulative excess revenues Alexion had received during the period of January 1, 2012 to June 30, 2014.

5. On January 22, 2015, the Board issued a Notice of Hearing with respect to Board Staff's Statement of Allegations. After the filing of an Amended Statement of Allegations and numerous preliminary motions, this hearing was held on the following days in 2017: January 16 to 19, and 23 to 26; February 20 to 24, 27 and 28; March 1 to 3; and April 18 and 19. The purpose of the hearing was to determine whether, under sections 83 and 85 of the *Patent Act*, the Respondent is selling or, since 2012, has sold Soliris in any market in Canada at a price that, in this Panel's opinion, is or was excessive, and if so, what order(s), if any, should be made.

III. Interlocutory Decisions

6. Given the lengthy procedural history of this case, the Panel will summarize the main preliminary motions brought in this proceeding.

7. Alexion filed a motion on May 15, 2015 requesting that Board Staff be ordered to provide particulars of all allegations in the Statement of Allegations. This motion was heard on June 22 and 23, 2015 and granted by the Panel in an order dated June 23, 2015.[4]

8. Alexion brought a motion on August 21, 2015 raising allegations of conflicts of interest and reasonable apprehensions of bias on the part of a number of the individual counsel involved in this proceeding and the Chairperson of the Board. This motion was heard on September 16, 2015 and dismissed by the Panel in a decision dated October 5, 2015.[5]

9. At a pre-hearing conference held on October 28, 2015, the Panel heard various motions relating to procedural issues. In its decision dated November 24, 2015, the Panel:

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[4] Board Decision – *Order Regarding Requests for Particulars and Scheduling of Filing of Amended Respond and Reply* (23 June 2015), online: PMPRB <http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/OrderregardingparticularsJune23.pdf>.

[5] Board Decision – *Respondent's Motion Relating to Conflicts of Interest* (5 October 2015), online: PMPRB <http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/MotionRelatingtoConflictsofInterest-October5thdecision-Final.pdf>.

- dismissed Alexion's motion to strike certain parts of the Further Amended Notice of Appearance of the Minister of Health for British Columbia, in particular those parts related to the use of the Lowest International Price Comparator Test (or the "**LIPC**");

- dismissed Alexion's motion to strike certain parts of Board Staff's Amended Reply, in particular allegations related to section 85(2) of the *Patent Act* (but granted Alexion an option to file a Sur-reply); and

- granted Board Staff's motion to strike certain parts of Alexion's Amended Response, in particular inflammatory allegations relating to the integrity of counsel for Board Staff.[6]

10. On February 26, 2016, Alexion moved to strike certain parts of Board Staff's expert evidence. In a decision dated March 29, 2016, the Panel dismissed Alexion's motion, without prejudice to Alexion's right to challenge both the admissibility and the weight to be given to any of the expert evidence at the hearing on the merits.[7]

11. On May 20, 2016, Board Staff moved to (i) amend its Statement of Allegations to include alternate remedies in the event that the Panel finds that the price of Soliris is excessive, including *inter alia* the application of the LIPC test, and (ii) strike or require particulars of certain portions of the will-say statement of Mr. Barry Katsof. Through the requested amendments, Board Staff seeks (i) excess revenues in the range of $4,743,572.88 to $91,908,321.21, depending on the test adopted by the Panel, and (ii) an order requiring Alexion to reduce the price of Soliris to a price that does not exceed the LIPC. On June 10, 2016, the Panel granted Board Staff's motion to amend the Statement of Allegations,

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6 Board Decision – *Various Motions Related to Procedural Matters* (24 November 2015), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/SOLIRIS-PMPRBNovember24th2015decision.pdf> [Board Decision – *Various Motions Related to Procedural Matters*].

7 Board Decision – *Respondent's Motion to Strike Expert Evidence* (29 March 2016), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Solaris_Motion_to_Strike_Expert_Evidence_Decision_March_29_2016.pdf>.

and dismissed Board Staff's motion to strike portions of Mr. Katsof's will-say statement.[8] The hearing was adjourned for several months to allow Alexion to respond to the Amended Statement of Allegations.

12. At the commencement of the hearing, before the start of opening arguments and the hearing of any evidence, the Panel informed the parties that Mr. Normand Tremblay had resigned from the Panel due to personal reasons, and that the hearing would proceed with two Panel members, Dr. Mitchell Levine and Ms. Carolyn Kobernick, which is a quorum under Rule 4 of the PMPRB's *Rules of Practice and Procedure* (the "**Rules**").[9] On January 16, 2017, Alexion moved for an order requiring that the Panel be reconstituted to restore a third member for the purposes of the hearing. The Panel dismissed the motion on January 17 with reasons to follow, and these reasons were provided on February 1, 2017.[10]

13. On January 20, 2017, Board Staff moved for the issuance of subpoenas requiring Mr. Eric Lun and Mr. John Haslam to produce certain documents regarding Product Listing Agreements ("**PLAs**") negotiated between Alexion and various provinces concerning Soliris. On January 23, 2017, Alexion moved under Rule 24 of the Rules for an order requiring production of further documents from Board Staff. On January 24, 2017, the Panel granted Board Staff's motion and issued subpoenas to Messrs. Haslam and Lun, and dismissed Alexion's motion.[11]

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8 Board Decision – *Motion to Amend Statement of Allegations and Strike Certain Portions of Will-Say Statement* (10 June 2016), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Decision_Motion_to_Amend_Pleadings_and_Strike_Will_Say_Statement.pdf>.

9 SOR/2012-247.

10 Board Decision – *Motion to Reconstitute Panel* (1 February 2017), online: PMPRB < http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Panel_constitution_order.pdf>.

11 Board Decision – *Motion to Issue Subpoenas* (24 January 2017), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/DECISION_ON_SUBPOENA.pdf>; Board Decision – *Motion to Request Further Documents* (24 January 2017), online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Panel_order_production_respondent.pdf>.

IV. Fact Evidence

14. Board Staff called one fact witness: Mr. Richard Lemay. Alexion called three fact witnesses: Mr. John Haslam, Mr. Barry Katsof and Mr. Matthew George. The fact evidence is briefly summarized in this section of the decision.

(a) Richard Lemay

15. Mr. Richard Lemay is the Manager of the Outreach and Investigations Unit of the PMPRB. He joined the PMPRB in 2015 and, as at the time of his testimony, reported directly to Ms. Ginette Tognet, Director of the Outreach and Investigations Unit. Mr. Lemay's testimony focussed on the various filings made by Alexion with the PMPRB in relation to Soliris, including the sources used for the calculations of excess revenues.

16. Mr. Lemay was not involved in the preparation of most of Board Staff's documents in this case, and was not able to answer questions or provide details about various aspects of the documents filed by Board Staff. It would have been much more helpful to the Panel if Board Staff had called a witness with direct involvement in, or knowledge of, Board Staff's investigation. However, Mr. Lemay's lack of knowledge was not material to the Panel's decision in this case, except with respect to the prices to be used for the purposes of calculating excess revenues (which the Panel deals with later in this decision).

(b) John Haslam

17. Mr. John Haslam is the President and General Manager of Alexion Canada. His testimony focussed on Alexion's activities in Canada, the discussions between Alexion and Board Staff related to Soliris, and the filings made with the PMPRB in relation to Soliris.

(c) Barry Katsof

18. Mr. Barry Katsof is a PNH patient and the founder of the Canadian Association of PNH Patients. His testimony discussed his experience with PNH, the benefits of Soliris, and the activities of the association that he founded.

(d) Matthew George

19. Mr. Matthew George is a PNH patient. He testified about the debilitating nature of PNH and the positive impact of Soliris on his life.

V. Evidence of the Ministers of Health

20. On March 9, 2015, the Minister of Health for British Columbia filed a Notice of Appearance (the "**Initial Notice of Appearance**"). In the Initial Notice of Appearance, the Minister of Health for British Columbia, on his own behalf and on behalf of the Minister of Health for the Province of Manitoba, provided notice of an intention to make representations pursuant to subsection 86(2) of the *Patent Act* supporting the orders requested by Board Staff in the Statement of Allegations. This is the first proceeding before the Board where a Minister of Health has exercised this right.

21. On March 13, 2015, the Secretary of the Board wrote to the Ministers of Health for British Columbia and Manitoba advising them that they had failed to meet the requirements of Rule 21(2) of the Rules. On March 17, 2015, the Ministers requested the right to amend the Initial Notice of Appearance to provide further particulars of the material facts upon which the Ministers intended to rely and to permit them to also make representations on behalf of the Ministers of Health for Ontario and for Newfoundland and Labrador (collectively, the "**Ministers of Health**"). On March 26, 2015, the Board issued an order extending the time to allow the Ministers of Health to file an Amended Notice of Appearance (the "**Amended Notice of Appearance**").

22. On April 2, 2015, the Ministers of Health filed the Amended Notice of Appearance, along with an affidavit sworn by Mr. Eric Lun, Executive Director of the Drug Intelligence and Optimization Branch, Medical Beneficiary and Pharmaceutical Services Division of the Ministry of Health of British Columbia.

23. In a letter dated April 16, 2015, Alexion objected to the filing of the Amended Notice of Appearance and sought leave to cross-examine Mr. Lun on his affidavit. In response, the Ministers of Health sought leave from the Panel to withdraw the affidavit and, on June 23, 2015, the Panel granted the Ministers of Health's request.

24. On June 26, 2015, the Ministers of Health filed a Further Amended Notice of Appearance, where they set out their intention to make additional representations as outlined in paragraphs 1 and 3 of the Further Amended Notice of Appearance. In paragraph 1, the Ministers of Health state that they intend to make representations supporting the orders sought by Board Staff, but also make representations to request that the Panel issue the following relief pursuant to section 83 of the *Patent Act*:

> "(a) the Respondent reduce the price of Soliris to a price that does not exceed the lowest price for Soliris among all comparator countries; and
>
> (b) the Respondent offset cumulative excess revenues that it has received by paying to the federal government an amount equal to the excess revenues the Board estimates that the Respondent has generated from the sale of Soliris at an excessive price, with the Board to use the lowest price for Soliris among all comparator countries as the basis for the calculation."

25. A statement of the representations that the Ministers of Health intended to make and the material facts on which the Ministers of Health were relying were referenced in paragraph 3 and set out in detail in Appendix A of the Further Amended Notice of Appearance.

26. Alexion brought a motion to strike out paragraphs 1 and 3, and Appendix A of the Further Amended Notice of Appearance. This motion was heard on October 28, 2015, and dismissed by the Panel in a decision dated November 24, 2015.[12]

27. At the hearing, Mr. Lun testified on behalf of the province of British Columbia, as well as on behalf of the Ministers of Health of Manitoba, Ontario and Newfoundland and Labrador. Mr. Lun's testimony focussed on, *inter alia*, the provinces' approach to funding medicines, including Soliris; negotiation of the PLAs for Soliris; the costs associated with Soliris, including in comparison to the costs of other expensive drugs for rare diseases ("**EDRDs**"); and the effects of EDRDs, including Soliris, on the provincial health budget. Mr. Lun testified that, in 2015/2016, British Columbia funded 14 EDRDs

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[12] Board Decision – *Various Motions Related to Procedural Matters*, *supra* note 6.

at a total expenditure of approximately $[redacted] Soliris represented $[redacted] of that $[redacted], or almost [redacted]%. The average cost of EDRDs (including Soliris) in British Columbia was $[redacted] per patient per EDRD, an amount considerably less than the annual average cost of Soliris to treat adult patients with PNH or aHUS.[13]

VI. Expert Evidence

28. Board Staff and Alexion filed multiple expert reports on the issues in dispute in this proceeding. These reports were reviewed in detail by the Panel prior to the commencement of the hearing. During the hearing itself, the evidence of each expert was provided during an examination-in-chief[14] and was tested in thorough cross-examination by the other side. The expert evidence and the parties' submissions concerning its relevance and the weight that should be given to it were then the subject of detailed written closing submissions, as well as the subsequent oral closing submissions. The Panel has considered the evidence thoroughly and will not reproduce it in detail in this decision, but will only refer to it where salient to the Panel's determination of the issues before it.

29. Board Staff called two expert witnesses: Dr. Richard Schwindt and Dr. Sumanth Addanki. Alexion called three expert witnesses: Mr. Errol Soriano, Dr. Jonathan Putnam and Dr. Aslam Anis. Their expert evidence is very briefly summarized in this section of the decision. The Panel struck out portions of Dr. Addanki's expert report, and did not qualify Mr. Tom Brogan as an expert witness. The reasons for these decisions are also provided in this section of the decision.

30. For the most part, and except as noted in these reasons, the Panel did not find the expert evidence to be of assistance to it in determining the issues in this proceeding. The experts who testified were clearly qualified and their evidence was interesting, but a large portion of the expert evidence focussed on extraneous or tangential issues, and most of it

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13 BC Minister of Health Closing Submissions dated March 31, 2017 at paras 17–19.

14 With the exception of those portions of Dr. Addanki's report that were struck by the Panel, and the report of Mr. Brogan which was not admitted by the Panel, for the reasons expressed later in this decision. Also, Dr. MacLeod, one of Alexion's proposed witnesses, was not ultimately called to testify.

did not ultimately assist the Panel in determining whether the price of Soliris is or was excessive under sections 83 and 85 of the *Patent Act*.

(e) Richard Schwindt

31. The Panel qualified Dr. Schwindt as an expert in microeconomics and economics of industrial organization. Dr. Schwindt is an economist and a professor, and holds A.B. and Ph.D. degrees in economics.

32. Dr. Schwindt provided an opinion about the use of external reference pricing ("**ERP**") to set ceilings on prices of patented drugs. ERP, also called international reference pricing, involves a comparison of the prices in other jurisdictions to prices and price changes domestically.

33. Dr. Schwindt testified that there are numerous developed countries which impose restraints on the pricing of pharmaceutical products. In Dr. Schwindt's opinion, prices charged in other countries with similar conditions can provide a perspective on costs; in other words, if the comparator country has similar demand conditions, a conclusion can be drawn that a patentee is covering its costs and earning a normal rate of return selling at that price in that country. Overall, the tests currently set out in the Guidelines are reasonable and favourable to patentees in Dr. Schwindt's opinion.

(f) Sumanth Addanki

34. The Panel qualified Dr. Addanki as an expert in the economics of industrial organization and the economics of the pharmaceutical industry. Dr. Addanki holds a Ph.D. degree in economics and is currently the Managing Director of National Economic Research Associates, Inc.

35. Dr. Addanki provided an opinion on what economic measures, tests and considerations are appropriate for determining whether the price of Soliris in Canada is or was excessive under s. 85 of the *Patent Act*, and whether the application of these economic measures, tests and considerations indicates that the price of Soliris in Canada is or was excessive.

Dr. Addanki testified that price needs context, which can be provided by looking at median household income and Gross Domestic Product (GDP) per capita.[15]

36. After Dr. Addanki was qualified, Alexion brought a motion to exclude Dr. Addanki's expert report. The Panel granted Alexion's motion in part. The Panel did not permit Dr. Addanki to give evidence on the interpretation of section 85(1)(b)[16] of the *Patent Act* and struck paragraphs 18 to 23, 28 to 31, 34 to 44 and 46 to 50, and related exhibits from his report. In these paragraphs, Dr. Addanki proposes that the definition of "therapeutic class" should include "a class of medicines that are similar, in relevant economic respects, to the patented medicine at issue" and puts forth various comparators from an economic perspective (*e.g.*, based on an analysis of supply/demand factors, prevalence, duration of treatment, etc.) that he says should be considered by the Panel to be in the same therapeutic class as Soliris for the purposes of section 85(1)(b) of the *Patent Act*. The Panel struck these paragraphs because they are based on a concept of "therapeutic class" that is not based on clinical equivalence. As explained further below, the Panel concludes that clinical equivalence is the appropriate concept to use when defining a therapeutic class for the purposes of implementing section 85(1)(b) of the *Patent Act,* and Dr. Addanki's presentation of another definition of therapeutic class is not relevant or necessary to the Panel's determination of the issues in this proceeding.

(i) Decision to Strike Portions of Dr. Addanki's Report

37. The Panel considered the oral and written submissions of the parties, as well as the case law provided. The Supreme Court of Canada set out the basic test for the admissibility of expert evidence in *R v Mohan*.[17] To be admissible, expert evidence must be relevant, necessary to assist the trier of fact, not be subject to any exclusionary rules, and must be given by a properly qualified expert.

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15 GDP per capita is the total value of goods and services produced in Canada expressed on a per head basis; this is the measure of economic activity.

16 This factor requires the Panel to consider the prices at which other medicines in the same therapeutic class have been sold in the relevant market.

17 [1994] 2 SCR 9.

38. It is also important to note that the Rules give this Panel broad discretion with respect to the admissibility of evidence. In particular, Rules 6(1)(a) and (b) provide that the Board may "receive any evidence that it considers appropriate" and "take notice of any generally recognized scientific or technical facts, information or opinions concerning patented medicines".

39. As discussed in more detail later in this decision, section 85(1) of the *Patent Act* sets out the factors that this Panel is required to consider in determining whether the price of Soliris is or was excessive. In particular, section 85(1)(b) states that the Panel shall consider "the prices at which other medicines in the same therapeutic class have been sold in the relevant market". [emphasis added]

40. Previous panels of this Board have consistently defined therapeutic class to mean clinical equivalence, and this Panel agrees with that interpretation. For example, the panel in *Dovobet* noted that "the therapeutic class of a medicine includes those medicines that are similar to the medicine under review in ways that are relevant to the pricing of the medicine, such as the condition the medicines treat, the way the medicines are delivered to the body, their chemical compositions, and the way they work in the body."[18]

41. Further, in *Penlac*, the panel noted that therapeutic class should be defined as "clinical equivalence" and "[i]f the new medicine is not demonstrated to be comparable in efficacy and safety to existing medicines in Canada, it will not be considered to be clinically equivalent and thus there will be no therapeutic class for price comparison purposes."[19] This approach was also adopted by the panel in the *Quadracel and Pentacel* proceeding.[20]

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[18] Board Decision –*Leo Pharma Inc. and the Medicine "Dovobet"* (19 April 2006), online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=827&lang=en> [*Dovobet*], rev'd in part *Leo Pharma Inc. v Canada (Attorney General)*, 2007 FC 306 [*Leo Pharma*].

[19] Board Decision –*Sanofi-Aventis Canada Inc. and the Medicine "Penlac Nail Lacquer"* (31 January 2011) at paras 18 and 20, online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=848&lang=en> [*Penlac*].

[20] Board Decision –*Sanofi Pasteur Limited and the Medicines "Quadracel and Pentacel"* (21 December 2009) at para 68, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Quadracel-Pentacel-

42. This Panel is of the view that the concept of "therapeutic class" is within its area of expertise, and it does not require expert evidence to assist it in giving meaning to that phrase in this proceeding. The Panel concludes that clinical equivalence is the correct principle to use when defining a therapeutic class for purposes of section 85(1)(b) because it reflects the wording and intent of the *Patent Act*. Therapeutic class connotes a group of medicines that share a common feature or features. As to what that commonality should be, the Panel agrees with the panel in *Penlac* that clinical equivalence captures the intent of the *Patent Act*; section 85(1)(b), as well as 85(1)(c), deal with price comparisons and the main factors in that regard are the relative efficacy and safety of the medicines being compared.[21]

43. The Panel notes that the Guidelines are consistent with this interpretation, and concludes that this aspect of the Guidelines appropriately implements the term "therapeutic class" in section 85(1) of the *Patent Act.*[22]

44. Applying this interpretation for purposes of section 85(1), there are no medicines in the same therapeutic class as Soliris. The expert Human Drug Advisory Panel (**"HDAP"**), although not binding on this Panel, reached the same conclusion for Soliris. For this reason, the prices of medicines that are not in the same therapeutic class as Soliris are not a factor for consideration under section 85(1).[23]

45. For these reasons, the Panel did not accept Dr. Addanki's alternative interpretation of therapeutic class and its application to Soliris. Those portions of his report are neither relevant nor necessary to the Panel's determination of the issues in this proceeding. As a result, the Panel struck paragraphs 18 to 23, 28 to 31, 34 to 44 and 46 to 50, and related exhibits as they related to section 85(1)(b) of the *Patent Act*, and the Panel did not permit

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Merits-Reasons-D5-Amended-March-1-2010.pdf> [*Quadracel* (2009)], amended 1 March 2010, implemented by order issued March 16, 2010, rev'd on other grounds *Sanofi Pasteur Ltd. v Canada (Attorney General)*, 2011 FC 859.

21 *Penlac*, *supra* note 19 at paras 18, 22.

22 Canada, Patented Medicine Prices Review Board, "Compendium of Policies, Guidelines and Procedures", (February 2017) at C.8 [*Guidelines*].

23 *Penlac*, *supra* note 19 at para 86.

Dr. Addanki to give oral evidence on the interpretation of section 85(1)(b) of the *Patent Act* at the hearing.

(g) Errol Soriano

46. The Panel qualified Mr. Soriano as an expert in valuation, financial analysis and quantification of financial loss. Mr. Soriano holds an H.B.A. degree, and is qualified as a FCPA, FCA, Chartered Business Valuator and a Certified Fraud Examiner. Mr. Soriano was the Managing Director of Campbell Valuation Partners Limited, which was recently acquired by Duff & Phelps.

47. Mr. Soriano's report, among other things, provides a calculation of the Canadian price of Soliris from year to year using the CPI methodology in the Guidelines, and the additional profit that Alexion could have realized during the period under review if it had increased the price by the CPI factor year after year. Mr. Soriano further testified that although the nominal price of Soliris has not changed from 2009 to 2015, in "real dollars" the price of Soliris has decreased by 9.7% (based on inflation).

48. Mr. Soriano also proposed two alternative approaches to compare Canadian and foreign prices, that he argued would be more consistent with the principles of fairness as compared to the current Guidelines. First, a "Comprehensive Test" that compared prices based on price inflation in Canada with prices in the comparator countries – applying this test would result in excess revenues of $[redacted], which Mr. Soriano opined would be reduced to zero if certain offsets were permitted. Second, the use of Purchase Price Parity ("**PPP**") Benchmarking, which takes into account relative purchasing power in Canada and the comparator countries. Mr. Soriano testified that the application of this approach would result in the Canadian price of Soliris never being the highest among the comparator countries.

(h) Jonathan Putnam

49. The Panel qualified Dr. Putnam as an expert in economics of patents, and international trade involving patents. Dr. Putnam is the founder and principal of Competition

Dynamics LLC, a litigation and management consulting firm in Boston, and holds B.A., M.A. and Ph.D. degrees in economics.

50. Dr. Putnam's opinion focussed on the current methodologies employed by the Board, in particular the use of exchange rates to compare prices across the comparator countries. Dr. Putnam also responded to the reports of Drs. Schwindt and Addanki.

51. In Dr. Putnam's opinion, the Board: fails to employ the CPI methodology, as required under section 85(1)(d) of the *Patent Act*; then introduces foreign exchange rates to implement section 85(1)(c), even though such rates are not mentioned in section 85 and are neither necessary nor sufficient to implement s. 85(1)(c); and then avoids using exchange rates adjusted by the CPI (or any other adjustment that removes the effects of currency fluctuations on price levels). Dr. Putnam also notes that Soliris is a non-traded good, and thus, in his view, an exchange-rate converted price is not a "price" and should not be used to conduct an analysis under s. 85(1). Contrary to Dr. Schwindt, Dr. Putnam ultimately concludes that the Board's methodology as set out in the Guidelines is unreliable.

(i) Aslam Anis

52. The Panel qualified Dr. Anis as an expert in health economics and pharmacoeconomics. Dr. Anis holds Bachelors, Masters and Ph.D. degrees in economics, and holds various positions, including Professor of Health Economics at University of British Columbia, Director of the Centre for Health Evaluation and Outcomes Sciences, and National Director of the CIHR Canadian HIV Trials Network.

53. Dr. Anis responded to Drs. Addanki and Schwindt. Dr. Anis testified that the health gain from a drug is disease-specific, and the methodology used to compare the relative cost-effectiveness of various drugs is to convert their disease specific effectiveness to a common metric known as the Quality-Adjusted Life Year (QALY) Gained. Dr. Anis testified that for orphan drugs, the standard Cost/QALY approach is generally not used for various reasons, and that such drugs have to be priced at a higher level due to both

market factors and the difficulties inherent in quantifying the cost-effectiveness threshold for rare diseases.

54. Dr. Anis testified that there is an internal inconsistency in the Guidelines because patentees are asked to control prices in conjunction with exchange rates and CPI, neither of which is within the patentee's control. His opinion is that PPP exchange rates are more appropriate than market exchange rates for making more equitable comparisons to assess the financial burden of acquiring the same commodity in different countries.

(j) Tom Brogan

55. At the hearing, Mr. Tom Brogan was proffered by Alexion as an expert in Canadian drug pricing and reimbursement; market access for drug companies in Canada; and collection and interpretation of data concerning drug sales in Canada. Mr. Brogan is an independent consultant and holds a B.A. degree in economics. Mr. Brogan's expert report, which was filed prior to the hearing, focussed on issues related to compliance with, or reliance on, the Guidelines (and not on the matters in which Alexion proposed to qualify Mr. Brogan as an expert at the hearing).

56. The Panel decided not to qualify Mr. Brogan as an expert in this proceeding because he was sought to be qualified on matters outside his expert report and, in any event, his evidence was not relevant and/or necessary for the Panel's determination of the issues in this proceeding.

57. The Panel recognizes that Mr. Brogan has significant experience with domestic and international pharmaceutical companies, particularly in respect of filings with the PMPRB. As noted above, the matters in which Mr. Brogan was proposed to be qualified as an expert were not dealt with in his report. The Panel has reviewed the mandate which was provided to Mr. Brogan by Alexion, as set out in paragraph 10 of his report. In particular, Mr. Brogan was "asked to comment on the following questions:

> (a) Had you advised a company like Alexion in 2009 on the introductory price of a new drug like Soliris, what test under the Guidelines would you have indicated would apply in setting the introductory or benchmark price if the

drug was a breakthrough medicine without domestic or foreign comparators?

(b) In 2009, would you have cautioned a company like Alexion that at some future date the price of the company's medicine could be retroactively "re-set" back to the date of first sale to some other price and that the "other" price would be either a re-calculation of the median international price comparison test ("MIPC') or a new test like the so-called lowest international price comparison test ("LIPC") and that the company could be liable for any consequential excess revenues?

(c) Was there any basis in 2009 to provide advice to Alexion that the Board would change the basis for calculating "excess revenues" based on tests or price sources that were not in the Guidelines, including the so-called LIPC?

(d) Do patentees, in your experience, generally rely upon the Guidelines in setting, maintaining, or increasing the price of patented medicines?

(e) Are you familiar with any circumstances in which the Board has departed from the Guidelines to a patentee's detriment to seek increases in excess revenues based on factors or tests not found in the Guidelines? In what circumstances, to your knowledge, has the Board, or a hearing panel, departed from the Guidelines?

(f) Are you familiar with any circumstances in which the Board has held a patentee responsible for excess revenues based solely on fluctuations in foreign exchange rates?

(g) Is IMS Health data publicly available in Canada, or internationally, as you understand the term "publicly available"?

(h) In its Reply to Alexion's Supplementary Response, the Board has indicated that Alexion's relies "at its own peril" on "publications, practices, and representations of the Board" (including presumably the Guidelines) because only a hearing panel can determine "whether the price of Soliris is excessive". Does this statement reflect your understanding of how the industry, in particular patentees, regard the regulatory system?"

58. As noted above, the Panel is of the view that the matters set out in this mandate (*i.e.*, related to compliance with, or reliance on, the Guidelines) are either not relevant or not necessary to the Panel's determination of whether the price of Soliris during the relevant periods is or was excessive based on sections 83 and 85 of the *Patent Act*. What Mr. Brogan may have advised a patentee does not assist the Panel in determining whether the price of Soliris is or was excessive. As explained in the section of this decision below dealing with the role of the Guidelines, the Guidelines are not binding on this Panel, and the past practices of the Board or Board Staff are not determinative of the issues in this proceeding. Furthermore, Mr. Brogan is not qualified to opine on legal questions, such as the definition of "publicly available" or the legal status of the Guidelines.

59. For these reasons, the Panel did not qualify Mr. Brogan as an expert in this proceeding, and his report was not considered by the Panel in reaching its decision.

VII. Key Documents and Chronology

60. Given the long and rather complex factual background, the Panel provides a chronology of key events in this section of the decision.

61. On February 4, 2009, RTI Health Solutions Inc. ("**RTI**"), on behalf of Alexion, provided the PMPRB with the product monograph and Form 1 for Soliris.[24] Shortly thereafter, on March 18, 2009, RTI provided the Board with the new medicine submission for Soliris for consideration by the HDAP.[25]

62. HDAP reviewed Soliris at its May 15, 2009 meeting. HDAP's report, provided to Alexion on June 2, 2009, recommended that Soliris be classified as a category 2 new drug product.[26] Based on the then (and current) Guidelines, the highest possible price at introduction, known as the Maximum Average Potential Price or "MAPP",[27] for a breakthrough drug is the median price of the seven comparator countries set out in the

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24 Exhibit 1, Tabs 4, 5.

25 Exhibit 1, Tab 6.

26 Exhibit 1, Tab 85.

27 Under the then Guidelines, this was referred to as the Maximum Non-Excessive (or "MNE") price.

Regulations (known as the Median International Price Comparison, or "**MIPC**" test). The ceiling or maximum price for breakthrough drugs in subsequent years, referred to as the Non-Excessive Average Price or "NEAP", is the lower of (i) the price from the previous year increased by the allowable increase based on the Canadian Consumer Price Index (CPI), or (ii) the highest price in the comparator countries (known as the Highest International Price Comparison, or "**HIPC**" test). These price comparison tests and methodologies are commonly referred to as External Reference Pricing, or "ERP".

63. Soliris was first sold in Canada in June 2009. At that time, Soliris was sold in six of the seven comparator countries. The list price of Soliris in Canada at introduction was $224.7333 per unit; this is not the cost of one package, as Soliris is supplied as a 10mg/ml solution in 30ml single-use vials, and a vial (containing 30 units) of Soliris costs $6,742.[28] The product monograph sets out the dosing information for Soliris, and the maintenance dose of Soliris for PNH for an average adult costs approximately $20,000 every two weeks.[29]

64. On June 25, 2010, approximately a year after the first sale of Soliris in Canada, the PMPRB sent a letter to David Hallal of Alexion, advising him that Board Staff had commenced an investigation into the price of Soliris after reviewing the introductory price and sales data (for July to December 2009) filed by Alexion.[30] The MAPP for Soliris, calculated using the MIPC, was $217.6772, and the $224.7333 price being charged by Alexion at the time exceeded that by 3.2%. The letter indicated that Alexion had generated excess revenues of $78,322.61 during that period. Board Staff also advised that they were unable to find a public price for Soliris for Germany and France, and had found discrepancies between the public prices and the prices filed by Alexion for the United Kingdom and the United States.

65. On July 5, 2010, PDCI Market Access Inc. (previously RTI) responded to the June 25, 2010 letter (referenced above), noting that Alexion was in the process of assembling

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28 Exhibit 1, Tab 12.

29 Estimate based on dosing information in product monograph.

30 Exhibit 1, Tab 14.

source materials for prices reported in its filings, and that the method used by the PMPRB to remove the mark up in the UK is not consistent with the Board's reference publication.[31]

66. On July 13, 2010, PDCI filed Alexion's Form 2 for Soliris for January to June 2010.[32] A Form 2 contains information about the sales and prices of the drug product in Canada and the comparator countries. Patentees are required to file this pricing information with the PMPRB twice a year (for January to June and July to December of each year).

67. On August 25, 2010, PDCI provided Board Staff with the requested source materials for France (*Theriaque*) and Germany (*Medikamente-per-klick*).[33]

68. On October 21, 2010, PDCI sent Board Staff revised Block 5 data for Soliris for January 2009 to June 2010, which reflected the "correct distribution chain for [Soliris]". Block 5 data on Form 2 is the data related to sales and prices of the drug in the comparator countries. PDCI noted that the "previous reports incorrectly included wholesale and pharmacy classes for Europe" but "with the exception of Germany, Soliris is supplied directly to hospitals."[34] On November 30, 2010, PDCI corrected an error in the forms filed on October 21, 2010 – PDCI had inadvertently entered a non-hospital customer code for France (even though Soliris was supplied only directly to hospitals in Europe except for Germany).[35]

69. On February 1, 2011, PDCI filed the Form 2 for Soliris for July to December 2010.[36]

70. On June 21, 2011, Board Staff sent a letter to Alexion in regard to Board Staff's investigation into the price of Soliris that had been commenced on June 25, 2010. Board Staff accepted the amended Form 2 information filed on October 21 and November 30,

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31 Exhibit 1, Tab 16.

32 Exhibit 1, Tab 15.

33 Exhibit 1, Tab 17.

34 Exhibit 1, Tab 18.

35 Exhibit 1, Tab 19.

36 Exhibit 1, Tab 20.

2010, and noted that there were cumulative excess revenues remaining as of December 2010 of $16,946.37:

> Alexion Pharma is being given the opportunity to take a voluntary price reduction to offset the cumulative excess revenues. To offset excess revenues via a price reduction, the average price will be considered to have been reduced if it is below the previous year's national non-excessive average price (N-NEAP). The current Guidelines state that excess revenue balances below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six-month reporting periods (three years) will be expected to be offset through a Voluntary Compliance Undertaking (VCU). Alexion Pharma is expected to offset the outstanding $16,946.37 excess revenues by December 31, 2012 or it may be subject to a VCU for that amount.[37]

71. Mr. Lemay testified that this amount was eventually offset by the deadline.

72. On August 25, 2011, the PMPRB sent Alexion a Compliance Status Report ("**CSR**") for Soliris for the period January to June 2011.[38] The cover letter explained that Board Staff reviews prices on an annual basis (*i.e.*, any investigations are commenced on a review of the full-year data). In other words, although the PMPRB issues CSRs twice a year following the reporting of the relevant information by the patentee, compliance is determined on a full-year basis (and not for each reporting period individually). The N-NEAP for this reporting period was calculated at $231.6936.

73. On January 31, 2012, PDCI filed the Form 2 for Soliris for the July to December 2011 reporting period.[39]

74. On February 27, 2012, Board Staff provided Alexion with the CSR for Soliris for 2011. The N-NEAP for Soliris for 2011 was calculated at $226.5297 and the compliance status

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37 Exhibit 1, Tab 116.

38 Exhibit 1, Tab 24.

39 Exhibit 1, Tab 25.

was "Within Guidelines".[40] The cumulative excess revenues were "0" because they had been offset.

75. On July 9, 2012, PDCI filed the Form 2 for Soliris for the January to June 2012 reporting period.[41]

76. On August 2, 2012, Board Staff sent Alexion a CSR for Soliris for January to June 2012. The N-NEAP for this reporting period was calculated at $222.2143; the average price of Soliris in Canada, referred to as the National Average Transaction Price or the "N-ATP", during this time period was $224.7333, and thus was above the N-NEAP.[42]

77. On October 25, 2012, PDCI corresponded with Board Staff, referencing a telephone conversation between PDCI and Board Staff, and requesting a meeting "to discuss an emerging international price comparison / exchange rate issue concerning Soliris."[43]

78. On December 11, 2012, a meeting between Board staff, Alexion and PDCI took place. Meeting notes indicate that Alexion is expected to "have a problem in 2012 [and] possibly 2013", "certainty is important for [the] company" and Alexion is "prepared to make commitments" or "could agree to a price freeze".[44]

79. On January 30, 2013, PDCI filed the Form 2 for Soliris for July to December 2012.[45]

80. On February 25, 2013, Board Staff provided Alexion with the CSR for Soliris for 2012.[46] The investigation criteria for Soliris was triggered in 2012 because the N-ATP of Soliris ($224.7333) was above the N-NEAP for that year ($214.2568), and Board Staff asked Alexion to lower the price to the N-NEAP by December 31, 2013. The compliance status was "Investigation" and the excess revenues for the period (as well as the cumulative

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40 Exhibit 1, Tab 26.

41 Exhibit 1, Tab 28.

42 Exhibit 1, Tab 29.

43 Exhibit 1, Tab 86.

44 Exhibit 1, Tab 103A.

45 Exhibit 1, Tab 31.

46 Exhibit 1, Tab 32.

excess revenues) were calculated at approximately $1.7 million. The letter sent by Board Staff states:

> The PMPRB's policy with respect to the Highest International Price Guideline addresses situations where a drug product's price is within the Guidelines in one review period, but outside the Guidelines in a subsequent period as a result of events other than actions directly attributed to the patentee. In this situation, the patentee is notified of the commencement of an investigation and informed that it is expected to adjust the price of the drug product so that its price is within the Guidelines or be subject to a VCU and repayment of excess revenues dating back to the original excessive price. [emphasis added]

81. Alexion did not adjust the price of Soliris to the N-NEAP by December 31, 2013, nor did it enter into a VCU.

82. On March 1, 2013, Alexion received a Notice of Compliance (NOC) for Soliris for aHUS.[47] The current Guidelines do not provide for a rebenching of a price of a patented drug product in these circumstances and the price of Soliris remained at $224.733 per unit. However, the dosing regimen for aHUS is different than that for PNH. The maintenance dose of Soliris for aHUS for an average adult costs approximately $27,000 every two weeks.[48]

83. On July 25, 2013, PDCI filed the Form 2 for Soliris for January to June 2013, noting "that the Canadian average transaction price of Soliris (as reported on Block-4) has remained unchanged since introduction in 2009. As previously discussed with Board Staff, fluctuations in exchange rates and the appreciation of the Canadian dollar has resulted in the Canadian price of Soliris appearing to be higher than corresponding international prices. Alexion would like to meet with Board Staff to discuss this situation and find a resolution to this matter in an expeditious manner."[49] As noted below, Mr. Lemay testified that this (second) meeting did take place and the focus of the meeting was on certain benefits provided by Alexion, which Alexion proposed to include in its

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47 Exhibit 1, Tab 34.

48 Estimate based on dosing information in product monograph.

49 Exhibit 1, Tab 35.

Form 2 – Block 4 filings. Block 4 data on Form 2 is the data related to sales and prices of the drug product in Canada.

84. On July 26, 2013, Board Staff provided Alexion with a CSR for Soliris for January to June 2013. The N-NEAP was calculated at $214.7355; the N-ATP for Soliris during this time period was $224.7333, and thus was above the N-NEAP.[50]

85. On December 11, 2013, the second meeting between Board Staff, Alexion and PDCI took place. Meeting notes indicate that although exchange rates are the primary reason for Alexion being offside the Guidelines, a principled reason would be required to deviate from the Guidelines. The notes also reference that "no benefits filed" and Alexion "to get back to [the PMPRB] in mid-January 2014".[51]

86. On January 29, 2014, PDCI filed the Form 2 for Soliris for July to December 2013, as well as amended Block 4 information for July to December 2011, January to December 2012, and January to June 2013. The reason for the amendment, according to Alexion, was to "[include] the rebates given during that period."[52] On February 6, 2014, Board Staff advised Alexion that it requires evidence to support any revisions to Form 2 data.[53]

87. On February 12, 2014, PDCI responded to Board Staff as follows:

> Further to Alexion's meeting with Board Staff in December 2013, Alexion refiled its Form-2 Block-4 data for Soliris to include "benefits" that had not previously been reported to PMPRB (for the periods July to December 2011 through January to June 2013). The benefits in question were rebates paid to provincial drug plans under the terms of product listing agreements (PLAs).[54]

88. Board Staff responded to PDCI on February 20, 2014:

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50 Exhibit 1, Tab 36.

51 Exhibit 1, Tab 103B.

52 Exhibit 1, Tab 37.

53 Exhibit 1, Tabs 38, 39.

54 Exhibit 1, Tab 39.

> When the subject of including benefits was first raised at our meeting in December 2013, there was no mention of the fact that the benefits being referred to were in fact third party payments. Board Staff was under the impression that the benefits to be included in the anticipated re-filing of Block 4 data related directly to a sale or sales to customers.
>
> […]
>
> Although Board Staff would not typically require evidence to support the reporting of third party payments, provided they had been consistently included or excluded in their Form 2 reporting from the outset, this is not the case for data revisions. With any and all data revisions, it is mandatory to provide verifiable evidence to support the revised data. As a result, the Soliris investigation team has determined that at a minimum, the company shall be required to provide copies of the Product Listing Agreements entered into in 2011 with the provinces of Nova Scotia, Ontario and BC.[55]

89. On February 25, 2014, Board Staff provided Alexion with a CSR for Soliris for 2013.[56] The N-NEAP for this reporting period was calculated at $213.9103; the N-ATP for Soliris during this time period was $216.4597, and thus was still above the N-NEAP. The N-ATP for Soliris was not $224.7333 because the original Form 2 filed for July to December 2013 for Soliris included rebates.[57] With respect to a patentee's original Form 1, Form 2 and Form 3 filings, Mr. Lemay testified that Board Staff does not take any steps to verify the information filed by the patentee.[58] If a filing is amended, the amendment is verified by Board Staff. The compliance status for 2013 was "Investigation". The excess revenues for 2013 were approximately $572,697, and the excess cumulative revenues were approximately $2.24 million.

90. Also on February 25, 2014, PDCI advised Board Staff that "John Haslam will be in Ottawa on Tuesday March 4th and could be available to meet briefly with Board staff… Alexion will provide Board staff with an opportunity to review the PLA agreements…

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55 Exhibit 1, Tab 39.

56 Exhibit 1, Tab 41.

57 Exhibit 1, Tab 37.

58 Examination In-Chief of Mr. Lemay (Cont'd), January 17, 2017, Hearing Transcript, Vol 2 (Confidential) at p. 8, lines 5-25.

and ask any questions… it is not Alexion's intention to leave copies of these documents with Board [Staff]".[59] This meeting did not take place.

91. On April 29, 2014, Board Staff advised Alexion that it would not accept data revisions to past filings related to rebates under PLAs, and asked Alexion to refile the Form 2 for July to December 2013 removing the rebates.[60] Board Staff's letter shows cumulative excess revenues of approximately $4 million as at the end of 2013, attaches a draft VCU and states:

> Based on our review of the price and sales data for the January to December 2013 reporting period, the N-ATP of Soliris in 2013 was $216.4597. As the 2013 N-ATP is not lower than the 2012 N-NEAP, in accordance with the Board's Guidelines, Alexion is being given the opportunity to provide a Voluntary Compliance Undertaking (VCU).
>
> […]
>
> Since the N-NEAPs for 2012 and 2013 were established by the Highest International Price Comparison (HIPC) tests, Board Staff verified the Block 5 International prices filed by Alexion for Soliris for 2012 and 2103 [sic]. There appears to be discrepancies with the German price which is the highest priced country in 2012. From 2009 to 2011 and for 2013, Alexion filed a Pharmacy and a Wholesale price for Germany. For 2013, the highest priced country based on the Block 5 information submitted by Alexion is Sweden. There was no price for Sweden in Board Staff's publicly available sources. Attached is a comparison of Board Staff's publicly available prices and the Block 5 information submitted in [Alexion's] Form 2 filing for 2012 and 2013.
>
> Given the discrepancies between [Alexion's] Form 2, Block 5 international prices and Board Staff's public sources, Alexion is requested to provide an explanation of the discrepancies and copies of the source documents that the company relied upon for the Block 5 information.[61]

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59 Exhibit 1, Tab 127.

60 Exhibit 1, Tab 117.

61 Exhibit 1, Tab 117.

92. Charts attached to Board Staff's letter note that the German price filed by Alexion in 2012 (which is the highest price in the comparator countries in 2012) is $214.2588, and the German price found by Board Staff through its price verification process is $212.8455. As noted above, the N-ATP for 2012 for Soliris is $224.7333, higher than both of these prices. The highest price filed by Alexion in 2013 was the Swedish price ($213.9103).

93. On May 28, 2014, PDCI advised Board Staff that the "Canadian price of Soliris is expected to be lower than the Swedish price based on the expected 2014 exchange rates." Board Staff replied on June 25, 2014, stating, "Board Staff is not prepared to rely on forecast compliance based on expected exchange rates in order to delay compliance with the [HIPC]… [t]he price of Soliris has been the highest of the comparator countries since 2012."[62]

94. On July 30, 2014, PDCI filed the Form 2 for Soliris for January to June 2014.[63] On August 5, 2014, Board Staff sent Alexion a CSR for Soliris for that reporting period. The N-NEAP was calculated at $220.3276; the N-ATP for Soliris during this period was $224.7333, and thus was above the N-NEAP.[64]

95. On August 6, 2014, PDCI filed amended Block 4 data for Soliris for July to December 2013 reporting period, removing the rebates/benefits to the provinces, as requested by Board Staff.[65]

96. On August 20, 2014, Board Staff asked PDCI for international price sources for Germany (July to December 2012), Sweden (July to December 2013 and January to June 2014) and Italy (January to June 2014). PDCI responded the same day attaching the price sources, which included *Rote Liste* for Germany, *Apoteket* for Sweden and *Pagine Sanitarie* for Italy.[66]

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62 Exhibit 1, Tab 88.

63 Exhibit 1, Tab 43.

64 Exhibit 1, Tab 44.

65 Exhibit 1, Tab 45.

66 Exhibit 1, Tab 46.

97. On September 23, 2014, in response to the price sources provided by PDCI, Board Staff rejected the German and Italian prices (and asked Alexion to refile), and accepted *Apoteket* as a pricing source for Sweden.[67]

98. On January 15, 2015, Board Staff filed the Statement of Allegations alleging that the price of Soliris was excessive between 2012 and 2014, and seeking an order under section 83 of the *Patent Act*. On January 22, 2015, the Board issued the Notice of Hearing.

99. There is no cover e-mail or date, but Alexion filed the Form 2 for Soliris for July to December 2014.[68] Block 4 data on this form (as well as previously filed Block 4 data by Alexion) reflects two customer classes: hospital and pharmacy customers (class 1 and 2, respectively), and not wholesalers (class 3).

100. On January 29, 2015, PDCI filed amended Form 2s for Soliris for 2012, 2013 and for January to June 2014, as requested by Board Staff on September 23, 2014.[69]

101. On February 18, 2015, Board Staff provided Alexion with a CSR for Soliris for 2014. The compliance status was "Notice of Hearing" and the N-NEAP, N-ATP and excess revenues were not calculated.[70] Mr. Lemay testified that once a case proceeds to this stage (*i.e.*, a hearing before the Board), these values are not calculated by Board Staff.

102. On June 30, 2015, Board Staff wrote to PDCI about the Block 4 information for Soliris for July to December 2014, noting that it appears very different from all other reporting periods since the date of first sale, and not all sales of Soliris in this filing were reported at the list price. PDCI replied on July 2, 2015, that "[t]he lower average prices reported for the July to December 2014 reporting period accurately reflect reductions from the List Price of Soliris provided by Alexion to its wholesaler/distributor and reported as required

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67 Exhibit 1, Tab 47.

68 Exhibit 1, Tab 89.

69 Exhibit 1, Tab 49.

70 Exhibit 1, Tab 119.

under the Regulations."[71] Block 4 data for July to December 2014 (as noted above), as well as previously filed Block 4 information for Soliris reflects only two customer classes: hospital and pharmacy customers (class 1 and 2, respectively), and not wholesalers (class 3).[72]

103. During the hearing, Mr. Haslam testified that Alexion's only customer in Canada is Innomar, and put into evidence credit memos from Alexion to Innomar (two dated November 7, 2014, one dated December 16, 2014, and one dated June 16, 2015) which reflect the different prices reported in Alexion's Form 2 for 2014.[73] These credit memos and the rebates to Innomar will be addressed by the Panel later in these reasons when dealing with the appropriate order under section 83 of the *Patent Act*.

104. There is no cover e-mail or date, but Alexion filed the Form 2 for Soliris for January to June, and for July to December, 2015.[74] On February 2, 2016, Board Staff provided Alexion with a CSR for Soliris for 2015. The compliance status for 2015 was "Notice of Hearing" and the N-NEAP, N-ATP and excess revenues are not calculated.[75]

105. Form 2s for the two reporting periods in 2016 were not in evidence at the hearing, nor was the CSR for 2016.

VIII. Issues in this Proceeding

106. There are two issues for the Panel to determine:

(i) Is or was the price of Soliris excessive within the meaning of sections 83 and 85 of the *Patent Act*?

(ii) If the answer to issue (i) is yes, what order(s), if any, should this Panel make?

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71 Exhibit 1, Tabs 55.

72 Exhibit 1, Tab 89.

73 Exhibit 46; Exhibit 47.

74 Exhibit 1, Tabs 90, 91.

75 Exhibit 1, Tab 97.

IX. Analysis

(k) The correct benchmark for determining whether the price of Soliris is excessive is the LIPC test

(i) The Consumer Protection Mandate of the PMPRB

107. Amongst other things, this Board has a consumer protection mandate, which was affirmed by the Supreme Court of Canada in *Celgene.*[76] In particular, the Supreme Court of Canada in *Celgene* references the Hansard and notes:

> [27] When the *Patent Act* was further amended in 1993 (*Patent Act Amendment Act*, 1992, S.C. 1993, c. 2), the then Minister of Consumer and Corporate Affairs and Minister of State (Agriculture), the Hon. Pierre Blais, reiterated the Board's consumer protection mandate:
>
> > With Bill C-91, we also wanted to strengthen consumer protection, so that consumers can continue to obtain patented medicine at reasonable prices. I think that all Canadians are entitled to that.
> >
> > …
> >
> > … The board will thus be able to provide all Canadian consumers with even more effective price control. These new powers will authorize the board to order a reduction of prices it considers too high...
> >
> > … I am convinced that these new provisions will assure Canadian consumers, of reasonable prices, like those they have had since 1987.
> >
> > (House of Commons Debates, vol. XII, 3rd Sess., 34th Parl., December 10, 1992, at pp. 14998 and 15001)

108. The Panel recognizes and accepts that, when making its determination under section 85, it must consider the Board's consumer protection mandate – specifically, the Board's role in ensuring that all Canadians are able to obtain patented medicines at "reasonable prices"

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[76] *Celgene Corp. v Canada (Attorney General)*, 2011 SCC 1 at para 27 [*Celgene*]; see also, *ICN Pharmaceuticals Inc. v Patented Medicine Prices Review Board*, [1996] FCJ no 206 at para 24 (FC), aff'd [1996] F.C.J. No. 1065 (FCA).

and that prices of patented medicines do not rise to "unacceptable levels."[77] As noted by the hearing panel in the *Celgene* proceeding, this mandate applies to all purchasers – there is no indication in the *Patent Act* that Parliament intended the Board to leave any purchaser unprotected from the general remedial powers of the Board, whether the purchaser is a government, insurer, wholesaler or consumer.[78]

109. Alexion went to considerable efforts in the hearing to try to convince the Panel that it acted responsibly and fairly, that it did nothing wrong, and that it was a victim of forces outside of its control. It is not necessary for this Panel to decide whether Alexion has accurately described its conduct and the situation because, as set out in greater detail below, such factors are irrelevant to the Panel's determination under section 85(1). As confirmed by the Federal Court of Appeal, this Panel's focus must be on the persons who are in need of protection from excessive pricing, and not on the conduct of the patentee alleged to have excessively priced.[79] In other words, a Panel can certainly find that Canadians are in need of protection from excessive pricing of a patented medicine through an order from the Panel even where the situation is caused by forces outside of the patentee's control.

(ii) The Role of the Guidelines

110. The Guidelines were first published in 1994 and, since then, have been revised on an ongoing basis. The current version of the Guidelines was released on June 9, 2009, implemented on January 1, 2010, and last updated in February 2017. For the purposes of the Panel's decision in this proceeding, any revisions that have been made to the version of the Guidelines implemented on January 1, 2010 are not material.

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77 *Celgene*, *supra* note 76 at paras 25-28; Board Decision –*Ratiopharm Inc. and the Medicine "ratio-Salbutamol HFA"* (27 May 2011) at para 13, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/ratio-Salbutamol-HFA-Merits-Reasons-D3-May-27-2011.pdf> [*ratio-Salbutamol* (Board Decision)], rev'd on other grounds *Ratiopharm Inc. v Canada (Attorney General)*, 2014 FC 502, Federal Court decision rev'd and Board Decision aff'd *Canada (Attorney General) v Sandoz Canada Inc*., 2015 FCA 249 [*Sandoz* (Appeal Decision)].

78 Board Decision –*Celgene Corporation and the Medicine "Thalomid"* (21 January 2009) at para 23, online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=881&lang=en>.

79 *Sandoz* (Appeal Decision), *supra* note 77 at para 67.

111. The Guidelines were prepared in consultation with relevant stakeholders. Amongst other things, they advise patentees how Board Staff will approach compliance, how Board Staff reviews the prices of patented drug products, and when an investigation by Board Staff will be triggered. The Guidelines do not address how a hearing panel will apply the *Patent Act* to determine whether a price is excessive, or to impose a remedy should the hearing panel conclude that a price is excessive.

112. Board Staff applies the factors set out in section 85 of the *Patent Act* to determine if the price of a patented drug product sold in Canada is excessive, and the Guidelines are meant to provide assistance in the application of these factors. There is also a complementary *Patentee's Guide to Reporting*, which sets out technical and other details related to a patentee's reporting obligations.[80]

113. The Guidelines deal with both the introductory price and the price going forward of patented drug products. For breakthrough drugs, such as Soliris, the Guidelines adopt the MIPC test for the introductory price, and the maximum price is set as the median ex-factory price of the same strength and dosage of the drug for France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. As noted above, at introduction the price of Soliris in Canada exceeded the MIPC, and an investigation was triggered because the excess revenues were calculated at approximately $78,000 (which was above the $50,000 threshold for triggering an investigation under the Guidelines). However, Alexion amended its filings, reducing the amount of excess revenues to an amount (approximately $16,000) that was not sufficient to trigger the investigation criteria in the Guidelines (albeit the price was still above the MIPC).

114. For the price going forward, the Guidelines adopt the HIPC or CPI tests – the ceiling price for a breakthrough drug going forward is the lowest of either the HIPC test or the CPI test set out in the Guidelines.

115. The current Guidelines state at section A.5.3:

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[80] Exhibit 2, last updated July 2015.

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

116. There is no doubt that the Guidelines are advisory only and are not binding on this Panel.[81] While not binding, the Panel will give the Guidelines due consideration in light of their provenance and the role that they play in assisting patentees in the application of the provisions of the *Patent Act*.[82] There is a need to balance certainty and consistency (which the Guidelines promote) with the need to be flexible and have fact-specific solutions. In any event, this Panel cannot apply the Guidelines as if they are the law, and cannot rely on them in a manner that inappropriately limits the discretion conferred on this Panel by the *Patent Act*.[83] To the extent that the Guidelines conflict with the *Patent Act* or the Regulations, the latter must prevail.[84]

117. For this Panel to rely on the provisions of the Guidelines to reach a conclusion on whether Soliris has been or is excessively priced, it must be satisfied that the Guidelines provide an appropriate implementation of the *Patent Act* specifically in relation to Soliris. This Panel can reach that conclusion as a result of the evidence and argument provided by the participants in this proceeding, or the Panel's own expertise, or a combination of the two.[85]

118. The hearing panel in the *Adderall* case provided a helpful summary of the role of the Guidelines:

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81 *Patent Act*, *supra* note 2, s. 96(4).

82 *Dovobet*, *supra* note 18; *Quadracel* (2009), *supra* note 20 at paras 13, 14, 16; *ratio-Salbutamol* (Board Decision), *supra* note 77 at paras 57-58.

83 *Gordon v Canada (Attorney General)*, 2016 FC 643 at paras 29, 40, 41; *Thamotharem v Canada (Minister of Citizenship & Immigration)*, 2007 FCA 198 at paras 55-62, leave to appeal refused [2007] SCCA no 394 (SCC).

84 *Sandoz* (Appeal Decision), *supra* note 77 at para 75; *Teva Neuroscience G.P.-S.E.N.C. v Canada (Attorney General)*, 2009 FC 1155 at para 32 [*Teva Neuroscience*].

85 *Quadracel* (2009), *supra* note 20 at para 16; *ratio-Salbutamol* (Board Decision), *supra* note 77 at para 60.

> 15. The Guidelines were established after consultation with stakeholders, as mandated by subsection 96(5) of the Act. The Guidelines aim to provide a structure for the necessary particularization and integration of the general factors listed in section 85, to provide fairness through consistent treatment among patentees, and to give patentees guidance on the process that will be used in establishing the MNE for their medicines, both when the medicines are first introduced to a market in Canada and each year thereafter that they are sold in Canada.
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> 16. On the other hand, the Guidelines are not binding on the Board. Furthermore, situations could arise that are not contemplated by the Guidelines, or changes in medicine or the marketing of medicines in Canada could give rise to situations that are no longer covered appropriately by the Guidelines. In each case, where the review of the pricing of a medicine comes before a panel of the Board, the panel must determine whether the medicine is priced excessively within the terms of section 85 of the Act. To the extent that the Guidelines speak to this issue, the panel must determine whether the Guidelines provide for an appropriate and reasonable implementation of the factors in section 85 of the Act before establishing an MNE by the terms of the Guidelines. If the Guidelines do not result in an appropriate implementation of section 85 of the Act, the panel must depart from the Guidelines.
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> 17. Board Staff suggested in final argument that the Guidelines establish an MNE for a medicine that should be presumed by a panel of the Board, in a price review hearing, to be excessive unless the patentee can satisfy the Board otherwise. The Panel believes that this over-states the role of the Guidelines. In each case, a hearing panel must be satisfied, through evidence, argument, the application of its own expertise and judgment or a combination of all of those factors that the Guidelines provide for a reasonable implementation of section 85 of the Act. In deciding whether to reach this conclusion, appropriate weight will be given to the provenance and role of the Guidelines, but they will not be presumed to correctly implement the Act.[86] [emphasis added]

119. This is a unique case in terms of the parties' respective positions on the application of the Guidelines. Generally, in past hearings, one party (usually the patentee) argues that a certain aspect of the Guidelines should not be applied to the particular facts of the medicine at issue, and the other party (usually Board Staff) argues that the Guidelines

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[86] Board Decision –*Shire BioChem Inc. and the Medicine "Adderall* XR*"* (10 April 2008) at paras 15-17, online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=808&lang=en> [*Adderall*].

should be adhered to. In this case, both parties argue that the Guidelines should not be strictly applied, but they differ on what aspects of the Guidelines should be applied and what aspects should not.

120. Board Staff argues that the Guidelines are an appropriate implementation of the *Patent Act* except for the benchmark test that should be used to determine whether Soliris has been excessively priced and to calculate the amount of excess revenues. Board Staff argues that the LIPC test, which is not a test in the Guidelines, should be applied. On the other hand, Alexion submits that it is critical that the Panel adhere to the benchmark tests in the Guidelines (for reasons of transparency, fairness and certainty), but argues that it should be relieved from the consequences of foreign exchange rate fluctuations, which the Guidelines clearly say are the responsibility of patentees.

121. Based on a thorough consideration of the submissions of the parties and the evidence in this proceeding, and after applying its own expertise and judgment, this Panel is of the view that the Guidelines are appropriate for the application of section 85(1) of the *Patent Act* to Soliris, subject to one exception which is necessary to properly implement the *Patent Act* (through the order to be issued by this Panel).[87] The Panel has concluded that the MIPC and HIPC tests do not appropriately implement the *Patent Act* in the case of Soliris. Rather, the appropriate benchmark to determine whether the price of Soliris is excessive is the LIPC. The reasons for the Panel's decision in this regard are contained in the section of this decision dealing with the application of the factors in section 85(1), which follows this discussion of the role of the Guidelines.

122. In deciding to depart from the Guidelines on the issue of the benchmark test, the Panel is certainly aware of the important role played by the Guidelines and the fact that stakeholders generally rely on the consistent application of the Guidelines to provide certainty and predictability. However, the Panel has no choice but to deviate from the Guidelines if and to the extent they do not result, in the case of Soliris, in a reasonable implementation of the factors in section 85(1) of the *Patent Act*. In those circumstances,

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87 *Quadracel* (2009), *supra* note 20 at para 19.

the Panel must apply its own judgment to the factors in section 85, and apply them appropriately to evaluate the price of Soliris.[88]

123. Before proceeding further with these reasons, the Panel will address the position of Alexion and the intervener, BIOTECanada, that it is not open to this Panel to deviate from the benchmark tests that are set out in the Guidelines.

124. First, Alexion argues that while previous hearing panels have deviated from the Guidelines where they were found to not properly implement the *Patent Act*,[89] they have only done so in a manner that was favourable to the patentee. Whether this is true or not is of no consequence in this proceeding as this Panel must deviate from the Guidelines in the case of Soliris to the extent they are not an appropriate implementation of section 85(1) of the *Patent Act*, regardless of whether that deviation favours the position of Board Staff or the patentee.

125. Second, Alexion and BIOTECanada argue that this Panel cannot apply any benchmark test that is not in the Guidelines until the Guidelines are changed, and that the consultation process required by the *Patent Act* must occur before any changes to the Guidelines are made. The Panel disagrees – if the Panel accepted this submission, it would in effect be treating the Guidelines as binding and thus fettering the discretion afforded to it by sections 83 and 85 of the *Patent Act.* The Panel is not amending the Guidelines and the Panel's decision is applicable only to Soliris.

126. Third, Alexion places emphasis on the fact that Board Staff's ultimate position in this proceeding departs markedly from the approach it originally took in this case, and has taken in past cases (where Board Staff has advocated that the Guidelines are appropriate to determine whether a medicine is or has been excessively priced and to calculate excessive revenues). The Panel notes that Board Staff's Amended Statement of Allegations charts a markedly different course than the original allegations, as well as the position taken by Board Staff generally in other cases. However, how Board Staff

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88 *Adderall*, *supra* note 86 at para 36.

89 See for example, *Adderall*, *supra* note 86 at paras 5, 16, 34, 46.

reached its ultimate position in this case, and whether that position is consistent with Board Staff's usual or past practices or conduct, is not relevant to the Panel's determination under section 85(1) of the *Patent Act*.[90] And, while the amendments did alter this proceeding in some respects, the Panel is satisfied that Alexion was given a full and fair opportunity to respond to the amendments. As noted above, the hearing was adjourned for several months to allow Alexion to respond to the Amended Statement of Allegations.

127. Fourth, Alexion argues that the doctrine of legitimate expectations supports its argument that the Panel in this proceeding is restricted to the tests and methodologies set out in the Guidelines. The Panel disagrees. The doctrine of legitimate expectations is part of the rules of procedural fairness that govern administrative bodies – it provides that where a government official makes a clear, unambiguous and unqualified representation within the scope of his or her authority to an individual about an administrative process that the government will follow, the government may be held to its word as long as the representations are procedural in nature and do not conflict with the decision maker's statutory duty. Where it applies, the doctrine can create a right to make representations or to be consulted. The doctrine of legitimate expectations cannot create substantive rights. And, it cannot serve to fetter the discretion of the decision maker following the representations or consultation.[91]

128. There is no clear, unambiguous and unqualified representation to Alexion that the Board would apply the tests set out in the Guidelines in an excessive pricing proceeding. In fact, the *Patent Act* states the exact opposite. Section 96(4) of the *Patent Act* provides that "the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any rights holder or former rights

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90 *Dovobet*, *supra* note 18.

91 Board Decision –*Galderma Canada Inc. and the Medicines Containing "Adapalene"* (19 December 2016) at para 69, online: PMPRB <http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Galderma_Decision_December_19_2016.pdf>, citing *Canada (Attorney General) v Mavi*, 2011 SCC 30 at para 68; *Moreau-Bérubé c Nouveau*-Brunswick, 2002 SCC 11 at para 78; *Reference Re Canada Assistance Plan*, [1991] 2 SCR 525 at para 67; *Malcolm v Canada (Minister of Fisheries and Oceans)*, 2014 FCA 130 at paras 47-49 [*Malcom*]; *Sanofi-Aventis Canada Inc v Canada (Attorney General)*, 2009 FC 965 at paras 53, 54.

holder." The Guidelines do not purport to advise how a panel of the Board will apply section 85(1) of the *Patent Act* in an excessive pricing hearing. Further, even if there had been a representation that the Guidelines would be applied in a hearing concerning Soliris, it would conflict with the Panel's statutory duty to apply section 85(1) without fettering its discretion. And, even if the doctrine did apply, it only gives Alexion the right to notice and to be consulted, both of which have been provided. Alexion has always been aware that the Guidelines are not binding and that the Board may choose not to follow them in an excessive pricing hearing.[92] In fact, Alexion itself urged the Panel to deviate from the Guidelines with respect to foreign exchange rate fluctuations. Alexion has had ample notice of the alternative tests ultimately advanced by Board Staff, and a full opportunity to respond to Board Staff's position and to make its position clearly known to this Panel.

129. Lastly, BIOTECanada submitted that the doctrine of promissory estoppel precludes this Panel from deviating from the tests and methodologies set out in the Guidelines. In particular, BIOTECanada asserts that since Board Staff used the MIPC test to initially determine the MAPP, and Alexion based its initial price based on that, estoppel applies so as to prevent the Board from "changing course" and using the LIPC test to determine excessive pricing or forfeitures. The Panel also rejects this submission. Promissory estoppel requires proof of a clear and unambiguous promise made to a citizen by a public authority in order to induce the citizen to perform certain acts. The citizen must have relied on the promise and acted on it by changing his or her conduct. However, promissory estoppel cannot interfere with the proper administration of the law – it cannot be invoked to preclude the exercise of a statutory duty, or to avoid the application of a clear legislative provision.[93]

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92 The Panel notes that, in the 10-K (annual report) filed by Alexion in the United States for the year ending December 31, 2008, Alexion states that, in certain foreign countries, pricing of drugs is subject to governmental control, and Alexion may be unable to negotiate pricing on terms that are favorable to it. Similar statements are found in subsequently filed reports.

93 *Immeubles Jacques Robitaille Inc. c Quebec (Ville)*, 2014 SCC 34 at paras 19, 20; *Lidder v Canada (Minister of Employment & Immigration)* [1992] 2 FC 621 at para 17 (FCA); *Malcolm*, *supra* note 91 at paras 38, 39.

130. The Panel agrees with Board Staff that, to establish promissory estoppel, the elements of estoppel must be proven with respect to Alexion itself (and not stakeholders generally), and that no evidentiary basis was provided to establish the elements of the test with regard to Alexion. Further, even if the evidentiary basis had been provided, estoppel cannot operate to require this Panel to apply the benchmark tests set out in the Guidelines where doing so would not be an appropriate implementation of section 85(1) of the *Patent Act*, which is exactly the Panel's conclusion in this case.

131. The Panel has set out below its analysis of the various factors in section 85(1) of the *Patent Act*, resulting in the Panel's decision to apply the Guidelines in the case of Soliris, with the exception that the benchmark for determining whether the price of Soliris is excessive is the LIPC.

(iii) The price of Soliris is excessive based on an analysis of the factors in section 85(1) of the Patent Act

132. Section 85(1) of the *Patent Act* states: "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."

133. The *Patent Act* does not define "excessive" price. Further, it does not prescribe any price tests or methodology in sections 83 and 85 for determining whether the price of a medicine is or was excessive. Parliament clearly contemplated that different tests and approaches may be appropriate for different patented medicines, and it chose to give the Panel the discretion to determine what tests and approaches should be applied in an excessive pricing hearing. Parliament clearly chose not to give patentees the certainty and predictability that would come with a legislatively mandated test for determining whether a price is excessive.

134. This Panel is required to formulate an opinion as to whether the price of Soliris is or was excessive and, in doing so, it must give due consideration to all of the factors in section 85(1). Section 85(1) leaves it to the Panel's discretion to determine the relevance and weight of each factor and of all of the factors taken together.[94] In any event, the Panel is obligated to provide clear and intelligible reasons as to the consideration and weight given to each factor in reaching its decision.[95]

135. The Panel must consider the factors set out in section 85(1) according to some rationale, methodology or approach, which may be derived from the Guidelines, or it may be *ad hoc*.[96] As discussed above, there is certainly no requirement on the Panel's part to apply the Guidelines, in whole or in part.

136. If the Panel is able to make a determination by reference only to section 85(1), it is to limit itself to a consideration of the factors under that section. If not, this Panel can, under section 85(2), take into consideration the costs of making and marketing the medicine.[97] This Panel agrees with other hearing panels who have concluded that there would have to be compelling reasons to determine the issue of excessive pricing on the

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94 *Adderall*, *supra* note 86 at para 14.

95 *Teva Canada Innovation v Canada (Attorney General)*, 2013 FC 448 at para 42 [*Teva Canada*]; *Teva Neuroscience*, *supra* note 84 at para 76.

96 *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board)*, [1996] FCJ No 1112 at paras 6, 8 (FC) [*ICN*].

97 *ICN*, *supra* note 96 at para 3; *ratio-Salbutamol* (Board Decision), *supra* note 77 at paras 56, 86.

basis of the costs of making and marketing the medicine, and it is only appropriate to do so in exceptional circumstances and on the basis of clear and reliable evidence.[98]

137. Board Staff and Alexion agree that this Panel can reach a determination under section 85(1), and the Panel need not and should not resort to section 85(2). The Panel agrees – the Panel is able to reach a decision based on the factors in section 85(1), and as such, did not have regard to the factors in section 85(2). The Panel also agrees with Alexion that there is no clear and reliable evidence in the record that would allow the Panel to make a determination based on the factors in section 85(2) in any event.

138. Section 85(3) of the *Patent Act* provides: "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."

139. The evidence about research and development costs offered at the hearing was limited. Between 2010 and 2014, Alexion reported a total of approximately $[redacted] of Research and Development expenditures in its Form 3s for Soliris.[99] Mr. Haslam also testified about R&D expenditures generally in Canada (but not specifically for Soliris in Canada).[100]

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98 Board Decision –*ICN Canada Ltd. and ICN Pharmaceuticals Inc.* (26 July 1996) at pp. 11, 12, online: PMPRB <http://pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/db-95d5v-e14LGJ-492003-8710.pdf> [*Virazole*]; application for stay of board decision dismissed *ICN*, *supra* note 96; Board Decision –*Teva Neuroscience and the Medicine "Copaxone"*, (25 February 2008) at para 48, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/COPAXONE_Merits-Reasons_-_D2-_Feb_25_0838KCU-3102008-2953.pdf > set aside on other grounds in *Teva Neuroscience*, *supra* note 84.

99 Exhibit 1, Tabs 21 (2010), 27 (2011), 33 (2012), 42 (2013), 50 (2014).

100 Examination In-Chief of Mr. Haslam, February 24, 2017, Hearing Transcript, Vol 13 (Public) at p. 1839, line 23 – p. 1844, line 1.

140. R&D spend is not one of the factors required to be considered under s. 85(1) of the *Patent Act*, and the Panel has not considered it. Even if the Panel was willing to consider this factor, the Panel agrees with Board Staff that it did not receive the necessary evidence that would allow it to do so. In particular, the Panel did not receive cogent and reliable evidence of the specific R&D costs it is entitled to consider, as set out in section 85(3) of the *Patent Act*.

(A) Section 85(1)(a) – the prices at which the medicine has been sold in the relevant market

141. Board Staff submits that section 85(1)(a) is a stand-alone factor which requires the Panel to conduct a contextual analysis of the price of Soliris. Board Staff submits that the Panel should consider factors such as the annual cost of treatment, social or opportunity costs, median household income and per capita GDP. Board Staff submits that all of these factors point to the price of Soliris being excessive.

142. The Ministers of Health make a similar argument. They argue that section 85(1)(a) allows the Panel to assess the annual treatment cost of Soliris in the context of its broader effect on payors, including the opportunity costs resulting from the public funding of Soliris, the cost pressures under which public payors operate, and the rising costs of EDRDs. In particular and as noted above, Mr. Lun testified that, in 2015/2016, British Columbia funded 14 EDRDs at a total expenditure of approximately $[redacted]. Soliris represented $[redacted] of that $[redacted], or almost [redacted]. The average cost of EDRDs (including Soliris) in British Columbia was $[redacted] per patient per EDRD, an amount considerably less than the annual average cost of Soliris to treat adult patients with PNH or aHUS.[101]

143. Alexion disagrees with Board Staff's and the Ministers of Health's interpretation of section 85(1)(a). Alexion submits that the price at which the medicine has been sold in the relevant market (being Canada in this case) is based on the information filed by the patentee under the *Patent Act* and Regulations, and that price is then used as the basis for the comparisons mandated by sections 85(1)(b), (c) and (d) of the *Patent Act*. Alexion

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101 BC Minister of Health Closing Submissions dated March 31, 2017 at paras 17–19.

argues that section 85(1)(a) does not permit comparisons with factors such as GDP or median family income.

144. As confirmed by the Federal Court, a plain reading of the *Patent Act* leads to the logical conclusion that it is on the basis of the information provided by the patentee under section 80(1)(b) of the *Patent Act* that the Board will be able to determine the price at which the medicine is being sold in the relevant market.[102] This interpretation was applied by the hearing panels in both the *Penlac* and *Quadracel and Pentacel* proceedings, and the Panel agrees with this approach.

145. In *Penlac*, the panel concluded that the price at which the medicine is being sold is the starting point of the section 85(1) assessment, and that this price, which is based on information on file with the Board, is then considered in light of the other factors in section 85(1).[103]

146. In *Quadracel/Pentacel*, the patentee argued that the panel should take into account factors unique to vaccines in considering section 85(1)(a). The hearing panel rejected this argument, concluding that section 85(1)(a) required the panel to establish a means of determining the price at which a patented medicine is or has been sold in Canada, but does not direct the panel to engage in an open inquiry into the price excessiveness (or not) of a medicine. Rather, having established the price at which the medicine is sold in Canada under section 85(1)(a), the Board is instructed by the balance of section 85(1) to consider whether that price is excessive based on the other factors listed in section 85(1).[104]

147. The Regulations require patentees to file, pursuant to section 80(1) of the *Patent Act*, the average price per package or the net revenue from sales in respect of each dosage form, strength and package size in Canada, as well as the publicly available ex-factory prices in

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102 *Leo Pharma*, *supra* note 18 at para 47.

103 *Penlac*, *supra* note 19 at para 14.

104 *Quadracel* (2009), *supra* note 20 at para 48.

Canada and the comparator countries.[105] This information allows the Board to determine the first factor as listed under paragraph 85(1)(a) of the *Patent Act*, namely the price at which the medicine has been sold in the relevant market.[106]

148. For Soliris, the Panel considers the "relevant market" to be Canada, and the "prices" to be the N-ATP as disclosed in Alexion's filings with the Board. In this case, Alexion has consistently maintained that the price of Soliris in Canada has not changed since its introduction and is $224.7333 per unit (notwithstanding any rebates or discounts).

(B) Section 85(1)(b) – the prices at which other medicines in the same therapeutic class have been sold in the relevant market

149. If there is no other medicine in the same therapeutic class, this Panel should disregard s. 85(1)(b), and will (assuming changes in the CPI are not in issue) consider only the price of the medicine under review in Canada and outside Canada.[107]

150. As already noted in the reasons for striking portions of Dr. Addanki's evidence, the Panel accepts that Soliris is a breakthrough medication for which there are no other medicines in the same therapeutic class that have been sold in Canada. This factor is therefore not applicable to Soliris.

(C) Section 85(1)(c) – the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada

151. Since there are no other medications in the same therapeutic class as Soliris, the Panel is left to consider the prices at which Soliris has been sold in countries other than Canada. Section 85(1)(c) of the *Patent Act* does not prescribe how this should be done nor does it set out the list of countries that must be considered.[108]

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105 *Patented Medicines Regulations*, SOR/94-688, s 4(f).

106 *Leo Pharma*, *supra* note 18 at para 47.

107 *Penlac*, *supra* note 19 at para 21; *Virazole*, *supra* note 98 at p.7.

108 The Regulations contain a list of seven countries for which a patentee must file pricing information under s. 80 of the *Patent Act*. However, there is no requirement in the *Patent Act* or the Regulations that these are the countries that must be considered under s. 85(1)(c) of the *Patent Act*.

152. The Panel notes that the price of Soliris has been under scrutiny in countries, other than the comparator countries. For example, the Health Service Executive in Ireland has indicated that the cost of Soliris is "exorbitant" and "astronomical", and that Alexion refused to provide a reasonable and sustainable price.[109] Initially in 2013, Ireland declined to fund Soliris for PNH[110] but the National Centre for Pharmacoeconomics reviewed the matter again in 2015, and decided to cover the costs. Similarly, PHARMAC in New Zealand refused to fund Soliris for PNH in October 2013, noting that the price is "extreme" and "out of line with other comparable innovative new medicines supplied by other companies".[111] In particular, PHARMAC notes that "Eculizumab could benefit up to 20 people, at a cost of approximately $10 million per year." This translates to an annual cost of treating a PNH patient as NZ$500,000 or approximately CDN$437,000 (at market exchange rates in December 2013).[112]

153. The question for this Panel is whether the relevant sections of the Guidelines, including the MIPC and HIPC tests, are an appropriate implementation of the requirement in the *Patent Act* that the Board consider the international prices of Soliris when determining whether the price of Soliris is or was excessive in Canada. The current ERP system in the Guidelines is meant to apply section 85(1)(c) of the *Patent Act* and uses as comparators the seven countries set out in the Regulations.

154. The countries which are used for comparison under this factor are the seven countries set out in the Regulations. These seven countries were selected by Parliament in the Regulations and are the only other countries for which price information for Soliris was available in this proceeding. Furthermore, several of the seven comparator countries had a higher GDP per capita than Canada (including if adjusted for PPP) in 2009 when Soliris was introduced, reflecting that the set of comparators does not only include "poor" countries which may bias price downwards. Dr. Schwindt also testified that the "set of comparator countries used by the PMPRB… does not contain countries with significantly

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109 Exhibit 1, Tab 71(a).

110 Exhibit 1, Tab 71(b).

111 Exhibit 1, Tab 72.

112 Board Staff Written Closing Submissions dated March 24, 2017 at para 16, n 1).

lower standards of living, which could bias relative prices down, and does include countries with significantly higher per capita GDP. It is also worth noting that the set of comparators includes the U.S., a pharmaceutical market viewed as high priced amongst developed countries."[113]

155. The Panel recognizes that, in performing the comparison required under section 85(1)(c), it is limited to comparing the price in Canada with the publicly available ex-factory prices in the comparator countries (which are often subject to discounts) filed by Alexion under the Regulations.[114] No evidence regarding any rebates or discounts provided in comparator countries was filed in this proceeding, and the Panel does not know whether the publicly available ex-factory price of Soliris in the comparator countries is in fact the actual price due to any discounts or rebates.

156. Using the publicly available ex-factory price in the comparator countries filed by Alexion as the reference point allows the Panel to conduct an apples-to-apples comparison when it comes to comparing the price of Soliris in Canada to the price of Soliris in the other jurisdictions because the list price of $224.7333 in Canada does not include any discounts or rebates and, as noted above, no evidence regarding any rebates or discounts provided in comparator countries was filed in this proceeding. These are also the prices used by Board Staff in the various price tests set out in the Guidelines, and the Panel is satisfied that the use of the publicly available ex-factory price for these purposes is an appropriate implementation of section 85(1)(c) of the *Patent Act*.

157. The fact that the Board may not be comparing actual prices does not render the factor in s. 85(1)(c) unreliable or inherently deserving of less weight. As the Federal Court explained in *Teva Canada*, having enacted section 85(1)(c), Parliament is presumed to be aware of the difficulties in comparing the prices of medicines across borders and, despite

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113 Exhibit 8, pp. 11-12.

114 *Virazole*, *supra* note 98 at p.10.

this, section 85(1)(c) is a factor that must be considered. For this Panel to conclude otherwise would be to subvert the will of Parliament.[115]

158. In Board Staff's submission, 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." Board Staff submits:

> "ERP for pharmaceutical prices is used in many other countries. Professor Schwindt noted that it is used by 24 of the EU member states.
>
> […]
>
> 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."[116]

159. The Panel agrees with this submission. The Panel found Dr. Schwindt's evidence on this point helpful, in particular his reference to the article titled *"Differences in external price referencing in Europe—A descriptive overview*," which shows that price comparison tests are widely used in Europe.[117] Dr. Schwindt testified that prices in other countries demonstrate a patentee's willingness and ability to supply at that price (and assume a normal rate of return). In particular, Dr. Schwindt stated:

> Prices in other developed countries disclose the patentee's willingness to supply other, roughly comparable, markets. Presumably, these prices compensate the patentee's costs. If a patentee willingly supplied other, comparable markets at prices

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115 *Teva Canada*, *supra* note 95 at para 41.

116 Board Staff Written Closing Submissions dated March 24, 2017 at paras 92, 95.

117 Exhibit 9.

> significantly below the Canadian price, this would call for a justification of the Canadian price. Comparison with foreign prices also addresses, to a limited extent, the fact that Canadian pharmaceutical consumers cannot arbitrage across international markets as is possible in other jurisdictions.[118] [footnotes omitted]

160. Dr. Anis argued that one cannot infer a patentee's willingness to supply in a country based on price alone, and we have to consider supply and demand factors.[119] Dr. Schwindt acknowledged that price is not a perfect surrogate for estimating costs, but is reasonable.[120] The Panel agrees.

161. The Panel understands that countries may have different supply and demand characteristics, but is satisfied that ERP systems such as the one in the Guidelines are widely used in developed countries to compare prices, and are appropriate to evaluate section 85(1)(c) of the *Patent Act* in this proceeding. Although the comparison methodology (*i.e.*, the ERP system) set out in the Guidelines is appropriate, the Panel concludes after considering all of the evidence and submissions that the application of the HIPC benchmark to the price of Soliris is not an appropriate implementation of sections 83 and 85 of the *Patent Act*. Rather, for the reasons set out below and in order to fulfill the Panel's consumer protection mandate, price excessivity for Soliris should be determined by reference to the LIPC test.

162. The Panel notes that even the lowest price for Soliris among the comparator countries has been under attack for being unreasonable. The United Kingdom is the comparator country that has had the lowest international price since 2011. In 2015, the price of Soliris in the UK was approximately $188 – the Canadian list price of approximately $224 is about 20% higher. Nonetheless, the National Institute for Health and Care Excellence (NICE) in the UK noted in 2015, in the context of aHUS, that "it had not been presented with enough justification for the high cost per patient of eculizumab, or for the

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118 Exhibit 8, p. 4.

119 Examination In-Chief of Dr. Anis, March 1, 2017, Hearing Transcript, Vol 16 (Public) at p. 2026, line 25 – p. 2027, line 8.

120 Examination In-Chief of Dr. Schwindt, January 26, 2017, Hearing Transcript, Vol 8 (Public) at p. 834, line 8 – p. 835, line 14, p. 842, lines 3-16, p. 893, lines 4-18.

overall cost of eculizumab with reference to what could be expected to be reasonable in the context".[121] While this Panel cannot comment on whether the UK price of Soliris is excessive under the regime in the UK, this certainly suggests to the Panel that permitting Alexion to sell at a price up to the UK price is generous to Alexion.[122]

163. While Alexion tried to refute this fact, the evidence establishes that patented medicines are generally more expensive internationally (especially in the United States) than in Canada.[123] The House of Commons debates in 1986 surrounding the then amendments to the *Patent Act* refer to drug prices in Canada being approximately 80% of those in the United States.[124] The House of Commons debates in 1992 surrounding the subsequent amendments to the *Patent Act* refer to a (then) recent study from the United States' General Accounting Office that concluded that medicines in Canada are priced 32% lower than in the United States,[125] and refer to the PMPRB as being successful in keeping Canadian prices lower than in the US.[126] Lastly, an article in the 2016 Journal of the American Medical Association refers to prices being 10 to 15% higher in the US than they are in Canada.[127] Drs. Addanki, Schwindt and Putnam agreed that Canadian prices of pharmaceuticals are generally lower than in the United States (where prices are not regulated).

164. In light of this, one would expect the price of Soliris in Canada to have been lower than the price in the US, which it was not.

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121 Exhibit 69, p.27.

122 The Panel agrees with the principle adopted by previous hearing panels that establishing the maximum allowed price of a medicine by reference to the price of a medicine that is itself excessively priced should be avoided. See, Board Decision –*Hoechst Marion Roussel Canada Inc. and the Medicine "Nicoderm"* (9 April 2010) at para 13, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/NICODERM-Merits-Reasons-D10-April9-2010.pdf>; *ratio-Salbutamol* (Board Decision), *supra* note 77 at para 68.

123 *Penlac*, *supra* note 19 at para 88.

124 *House of Commons Debates*, 33rd Parl, 2nd Sess, Vol 1 (20 November 1986) at 1372.

125 *House of Commons Debates*, 34th Parl, 3rd Sess, Vol 10 (16 November 1992) at 13417; *House of Commons Debates*, 34th Parl, 3rd Sess, Vol 12 (9 December 1992) at 14935, 14943; *Debates of the Senate*, 34th Parl, 3rd Sess, Vol 3 (15 December 1992) at 2467.

126 *House of Commons Debates*, 34th Parl, 3rd Sess, Vol 11 (17 November 1992) at 13482.

127 Exhibit 42 at p.859.

165. When Soliris was introduced in Canada, and in 2010, the price of Soliris in the US was the lowest international price. In his report, Dr. Addanki showed that, between 2009 to 2016, the Canadian price of Soliris exceeded the US wholesale or "WAC" price when converted at the market exchange rate for most of the period (and by almost 20% as late as January 2016). He opined that this was even more remarkable given that the US WAC price was steadily increasing during this period. Professor Schwindt opined that the US price of Soliris shows Alexion's willingness to supply a market like the US at a much lower price than the Canadian price, which, Dr. Addanki argues, is useful information indicating that the Canadian price may be excessive. The Panel agrees with Drs. Schwindt and Addanki in this regard.

166. This Board's mandate, amongst other things, is to ensure that all Canadians are able to obtain patented medicines at reasonable prices. This Panel concludes, based on a thorough consideration of all of the evidence and the unique circumstances of this case, that the reasonable price for Soliris in Canada is one that does not exceed the lowest international price ("**LIP**") in the seven comparators. Based on the most recent evidence available to the Panel, the LIP is the price charged in the United Kingdom. Using the UK price as an example (because it is the current LIP), Alexion is willing to supply Soliris in the UK at the LIP. The Panel accepts Dr. Schwindt's evidence that a price charged in another country can provide a reasonable (although admittedly not perfect) perspective on costs, in that one can reasonably assume that by selling at the LIP in the UK, Alexion is covering its costs and earning a normal rate of return. No explanation or justification was provided to the Panel as to why Canadians should be paying significantly more for Soliris than comparable developed countries, including the United States and the United Kingdom.

167. In these circumstances, the Panel can see no justification why Canadians should not have the benefit of the lowest price being paid in any of the comparator countries, such as the UK (or the United States for that matter), especially considering the significant impact that the cost of Soliris is having on the provinces' health care budget even as compared (in the case of British Columbia as explained by Mr. Lun) to other EDRDs.

168. Since the date of first sale in Canada and continuing to the present, Soliris has been priced above the lowest price in the comparator countries specified in the Regulations. Accordingly, the Panel concludes that the price of Soliris is, and has been since 2009, excessive within the meaning of sections 83 and 85 of the *Patent Act*.

169. The Panel wishes to make clear that Board Staff's submission that Alexion's market power requires this Panel to apply greater scrutiny to its prices, and that this justifies the LIPC test, is rejected by the Panel and did not form any part of its decision. The Federal Court of Appeal has clearly stated that the existence of market power is not a pre-condition to the Board's exercise of its jurisdiction, nor is it relevant to the exercise of that jurisdiction.[128] This Panel also agrees with the statement made by the hearing panel in *Quadracel and Pentacel* that it is not necessary or appropriate for the Board to inquire into the existence of market power of either the patentee or the purchaser, in exercising its discretion under sections 83 and 85 of the *Patent Act*.[129]

170. In the remainder of the analysis of section 85(1)(c), the Panel will address the issues raised regarding exchange rates and the credibility of some of the data and calculations relied on by Board Staff.

Exchange Rates

171. The parties disagreed on the use of foreign exchange rates to compare prices of Soliris in the comparator countries to the Canadian price.

172. Alexion's position is that it has not changed the price of Soliris since its introduction in Canada, and the only reason it is non-compliant with the Guidelines is because of exchange rate fluctuations. Alexion submits that it should not be held responsible for forces outside its control.

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128 *ratio-Salbutamol* (Board Decision), *supra* note 77 at para 89, citing *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board)*, [1996] F.C.J. No. 1065 (FCA).

129 *Quadracel* (2009), *supra* note 20 at paras 44-47.

173. The Guidelines are clear in respect of the situation in which Alexion found itself. Schedule 6 of the Guidelines provide:

> **3. Existing Drug Products with Unusual Circumstances**
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> 3.1 The Guidelines require that patentees take appropriate action when an investigation concludes that the price of its patented drug product appears excessive. There are, however, circumstances where a patented drug product whose price does not appear to be excessive in one review period then appears excessive in a subsequent period, due to the application of the HIPC test. This could be as a result of events beyond the control of the patentee. The following are examples of three such circumstances:
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> - Exchange rate variations;
> - A foreign regulator forcing price reductions; or
> - The highest priced drug product is removed from the market.
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> Under the circumstances identified above, patentees will be notified that the patented drug product's price appears excessive and will be expected to adjust the National Average Transaction Price and Market-Specific Average Transaction Prices for the pharmacy and hospital customer classes, and for each province and territory by the end of the next two reporting periods, in which case the price will not be presumed to have been excessive. Failing this, the patentee would be requested to submit a Voluntary Compliance Undertaking (VCU) and repay any excess revenues dating back to the first period in which the price exceeded the HIPC test. If the patentee declines to submit a VCU, then the matter would be reported to the Chairperson with the recommendation that a Notice of Hearing be issued. [emphasis added]

174. The Panel notes that this section was not in the 2003 version of the Guidelines, but that fact is not material. It is clear that such a situation (*i.e.*, exchange rate fluctuations leading to breaches of the price test) could occur, even if this warning was not explicitly included. In any event, section 3.1 of Schedule 6 was contained in the Guidelines implemented on January 1, 2010, giving Alexion more than sufficient notice that Board Staff considers exchange rate fluctuations to be the responsibility of the patentee.

175. The Panel agrees that exchange rates are not within a patentee's control but, this is not relevant for the reasons already provided in the Panel's discussion of section 85(1) above.

176. In any event, Alexion was aware during the relevant time of the potential impact of currency exchange rate fluctuations on its business and has adopted business strategies to hedge against this risk. In its annual report for the fiscal year ended December 31, 2008, filed with the Securities Exchange Commission prior to the sale of Soliris in Canada, Alexion notes that its business is subject to the risk of "fluctuations in currency exchange rates".[130] In particular:

> While we attempt to hedge certain currency risks, currency fluctuations between the U.S. dollar and the currencies in which we do business have caused foreign currency transaction gains and losses in the past and will likely do so in the future. Likewise, past currency fluctuations have at times resulted in foreign currency transaction gains, and there can be no assurance that these gains can be reproduced.
>
> […]
>
> In the first quarter of 2008, we began a program to limit the foreign currency exposure of our monetary assets and liabilities on our balance sheet. In the third quarter of 2008, we commenced a program to hedge a portion of our forecasted product sales to mitigate fluctuations in foreign exchange rates. Both programs utilize forward foreign exchange contracts intended to reduce, not eliminate, the impact of fluctuations in foreign currency rates.
>
> […]
>
> We operate internationally and, in the normal course of business, are exposed to fluctuations in foreign currency exchange rates. The exposures result from portions of our revenues, as well as the related receivables, that are denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound. We manage our foreign currency transaction risk within specified guidelines through the use of derivatives. We do not use derivatives for speculative trading purposes. [131] [emphasis added]

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130 Exhibit 1, Tab 58, p. 41.

131 Exhibit 1, Tab 58, pp. 41, 76, F-24.

177. Similar statements are found in Alexion's other annual reports filed in this proceeding, making it clear that Alexion is aware of the risk of fluctuations in currency exchange rates, and has adopted practices to manage this risk.[132] For example, Alexion notes:

> We enter into foreign exchange forward contracts, with durations of up to 60 months, to hedge exposures resulting from portions of our forecasted revenues, including intercompany revenues, that are denominated in currencies other than the U.S. dollar. The purpose of the hedges of revenue is to reduce the volatility of exchange rate fluctuations on our operating results and to increase the visibility of the foreign exchange impact on forecasted revenues. Further, we enter into foreign exchange forward contracts, with durations of approximately 30 days, designed to limit the balance sheet exposure of monetary assets and liabilities. We enter into these hedges to reduce the impact of fluctuating exchange rates on our operating results.[133] [emphasis added]

178. Alexion chose not to comply with the Guidelines to address the excess revenues generated by the exchange rate fluctuations. It could have easily done so by reducing the N-ATP of Soliris. Instead, it decided to attempt to negotiate a resolution with Board Staff outside of the Guidelines. [134] Alexion was of course free to take this approach, but it did so with full knowledge that it was not complying with the Guidelines. Alexion was well aware of the appreciating Canadian dollar and the 36-month flexibility provided for by the Guidelines, as well as the risk that a hearing panel may conclude (as this Panel does) that the Guidelines' treatment of foreign exchange fluctuations is an appropriate implementation of section 85(1)(c) of the *Patent Act*.

179. Alexion also argues that this Panel should not convert international prices into Canadian dollars for the purposes of the section 85(1)(c) comparison. Relying on Dr. Putnam's evidence[135], Alexion submits that foreign exchange rate fluctuations are irrelevant to the evaluation of the price of a non-traded good like Soliris, and an exchange-rate converted price is not a "price" that should be used for comparison purposes under section 85(1)(c).

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132 Exhibit 1, Tabs 59-64.

133 Exhibit 1, Tab 64, p. 43.

134 Exhibit 1, Tabs 103A, 103B.

135 Exhibit 34, paras 41-57.

180. The Panel disagrees. The Panel concludes that foreign prices of Soliris must be converted into Canadian dollars for the purpose of conducting the comparison mandated by section 85(1)(c). This Panel agrees with the conclusion reached by the hearing panel in *Dovobet* that "[i]nternational price comparisons over time must take account of fluctuations in exchange rates in order to be appropriately accurate."[136]

181. The Panel heard evidence about two possible methods for conducting the conversion into Canadian dollars: using (i) market exchange rates, or (ii) PPP rates. As noted previously, PPP rates adjust market exchange rates for differences in local purchasing power. The Guidelines require the use of market exchange rates averaged over a 36-month period of time.[137] The Panel has considered both methods for conversion and, for the reasons set out below, the Panel concludes that the method for conversion in the Guidelines is an appropriate implementation of section 85(1)(c) of the *Patent Act* in the case of Soliris.

182. As explained by Dr. Schwindt, market exchange rates are appropriate and used in many jurisdictions that use ERP, and he was not aware of any jurisdiction that used PPP rates instead of market exchange rates. Noting that the purpose of ERP is to reflect a willingness of a patentee to supply, he explained that market exchange rates are appropriate because they demonstrate the price at which Alexion is prepared to supply Soliris, and it is fair to assume that the price in the comparator countries is set so as to cover the patentee's costs.[138]

183. Also, importantly, market exchange rates are more straight-forward to determine as compared to PPP rates. For example, there are difficulties associated with assembling the identical basket of goods in the countries being compared, and there is no clear consensus

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136 *Dovobet*, supra note 18.

137 More specifically, the Guidelines provide that the exchange rates to be used to convert international prices into Canadian dollars are the simple average of the 36 monthly average noon spot exchange rates for each country (taken to eight decimal places) as published by the Bank of Canada.

138 Examination In-Chief of Dr. Schwindt, January 26, 2017, Hearing Transcript, Vol 8 (Public) at p. 880, line 13 – p. 881, line 5, p. 882, line 6 – p. 883, line 5. Dr. Addanki was of a similar view – he believes that market exchange rates are appropriate because what should be measured is what would occur if the goods had been tradable. In other words, for example, what would Canadians have paid if they purchased Soliris in the US at the US price. See Examination In-Chief of Dr. Addanki, February 22, 2017, Hearing Transcript, Vol 11 (Public) at p. 1287, line 22 – p. 1289, line 4.

in respect of the right basket of goods for determining PPP rates. Dr. Putnam also agreed that there were issues with PPP rates.[139]

184. In addition, the 36-month period provided in the Guidelines is generous to patentees in that it irons out the volatility that can happen with market exchange rates and means that patentees are not forced to immediately adjust prices based on market exchange rates. In other words, the Guidelines provide enough time to eliminate the effects of any sudden fluctuations in exchange rates, and give patentees a reasonable period of time to monitor and react to changes in exchange rates. Dr. Schwindt testified that some jurisdictions provide for a much shorter time frame (*e.g.*, six months in Norway).[140]

185. The Panel acknowledges that Mr. Soriano and Dr. Putnam advocated various alternative approaches to conducting the comparison required by section 85(1)(c) of the *Patent Act*. The Panel was not persuaded that these alternative approaches appropriately implement that section.

186. For example, Mr. Soriano assumes that Alexion raised its price by the relevant CPI in Canada and in the comparator countries, both of which did not occur. The Panel agrees with Board Staff that this comparison of hypothetical prices is not the appropriate analysis under section 85(1)(c). The Panel also notes that Mr. Soriano used PPP rates for the purposes of his analysis. The Panel was not persuaded that Mr. Soriano's approach would lead to an appropriate implementation of section 85(1)(c) of the *Patent Act* for the following two additional reasons: first, he did not apply PPP rates consistently, but only for the years 2010 forward.[141] Second, his analysis applied the PPP rates but the prices were not constrained by the CPI methodology as set out in the Guidelines. As explained when discussing the factor in section 85(1)(d) below, the Panel is of the view that the

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139 Cross-Examination of Dr. Putnam (Cont'd), February 24, 2017, Hearing Transcript, Vol 13 (Public) at p. 1798, line 11 – p. 1799, line 19.

140 Examination In-Chief of Dr. Schwindt, January 26, 2017, Hearing Transcript, Vol 8 (Public) at p. 887, lines 11-22.

141 There was general consensus amongst the experts, and the Panel agrees, that whatever exchange rate is used, it should be used consistently. Using PPP rates from the price at introduction forward for Soliris would have made Alexion worse off in that the ceiling for the introductory price would have been set at approximately $200, as compared to the actual introductory price of $224.7333. *See* Dr. Schwindt's Expert Reports, Exhibit 8, Table 5, p. 15 and Exhibit 81, Table 1, p. 6.

Guidelines' use of the CPI as a price constraint (*i.e.*, ceiling price must be the lower of CPI and ERP benchmark) is an appropriate implementation of section 85(1) of the *Patent Act*.

187. Dr. Putnam argues that an exchange-rate converted price is not a "price" and should not be used for comparison purposes under s. 85(1)(c). Dr. Putnam's analysis also conflates subsections (c) and (d), as discussed later in these reasons when the Panel considers section 85(1)(d).

188. Alexion also appears to have accepted the appropriateness of using market exchange rates with respect to Soliris. In its negotiations with the provinces, Alexion took the position that the exchange rate methodology in the Guidelines was well-established and appropriate.[142] The Panel also notes that Alexion uses market exchange rates for its financial reporting – its financial statements are consolidated and denominated in US dollars with conversion based on market exchange rates.[143]

189. Furthermore, 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-month market exchange rate methodology was appropriate.[144]

190. Based on the considerations above, the Panel is of the view that the market exchange rate methodology set out in the current Guidelines is an appropriate implementation of section 85(1) of the *Patent Act*.

Disputes About Price Sources, Back-out Formulas and Data

191. An argument advanced by Alexion throughout the proceeding was that Board Staff had failed to meet its burden of proof. Alexion argued that Board Staff failed to adequately prove the underlying data for Board Staff's calculations of excess revenues, and provided

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142 Exhibit 23, Tab 7, p. 2.

143 Exhibit 1, Tab 61, p. F-8; Exhibit 1, Tab 64, p. F-8; Cross-Examination of Mr. Haslam, February 28, 2017, Hearing Transcript, Vol 15 (Confidential) at p.664, line 13 – p. 667, line 19.

144 Exhibit 1, Tab 109, p.3.

numerous conflicting charts showing different prices and amounts of excess revenues for 2012 to 2015, without an adequate explanation as to why the numbers differed. Alexion also argued that its inability to cross-examine those persons at the Board who were directly involved in the preparation of the charts and calculations was a denial of natural justice.

192. The Board's regulation of the prices of patented medicines is based on self-reporting. In other words, the patentee is required to file the relevant pricing information in its Form 2. The role of Board Staff is to verify the information, and it can only do so using publicly-available information (because that is the only information it has access to, unless the patentee volunteers additional information).

193. The dispute in this case largely centered on some of the sources used by Board Staff to verify the international prices, as well as the appropriateness of "back-out" formulas used to ensure the price reflected the ex-factory price. In some instances, the price source or the back-out formula used by Board Staff for Soliris was not listed on the Board's website. Alexion also strongly objected to the use by Board Staff of IMS MIDAS data for verifying prices.

194. The Panel agrees with Alexion that the various charts and calculations filed by Board Staff were unclear and, despite being repeatedly addressed at the hearing, the Panel did not receive a clear explanation of the differences in the charts. The Panel also agrees with Alexion that the confusion surrounding the use of certain foreign price sources, the relevance of back-out formulas, and the inconsistent disclosure was not adequately resolved by the evidence adduced in the hearing. Lastly, while it is certainly conceivable that in any given case Board Staff may have to look beyond its usual sources to verify foreign prices, the Panel concludes that Board Staff did not meet its evidentiary burden of establishing that the IMS MIDAS data was an appropriate source of foreign price verification in the circumstances of this case. For example, Board Staff did not call any witness who had direct and relevant knowledge of the nature and composition of the IMS MIDAS data.

195. This general state of confusion in the evidence was certainly not assisted by the fact that Board Staff's sole fact witness, Mr. Lemay, was not personally involved in the preparation of any of the relevant documents or the investigation itself, and therefore could not assist in resolving the uncertainty surrounding Board Staff's approach to foreign price verification.

196. However, it is important to note that none of the sources in dispute, including IMS MIDAS data, have any impact on the determination of whether Soliris was priced above the lowest priced comparator country – in all cases, Soliris would fail the LIPC test – which the Panel has determined is the correct benchmark. Accordingly, the confusion noted above has no impact whatsoever on the Panel's decision that the price of Soliris is and was excessive in Canada.

197. This issue is relevant in respect of the calculation of excess revenues to be paid by Alexion, which is addressed by the Panel later in these reasons. Any potential concerns that Alexion may have with the information relied on by Board Staff are, in the Panel's view, completely resolved by the Panel's requirement that the parties use only the information provided by Alexion in its Form 2s (except for any claimed rebates to the provinces or Innomar) for the purpose of calculating excess revenues.

198. The Panel rejects Alexion's submission that it has not received procedural fairness in this proceeding. The Panel concludes that Board Staff has complied with its disclosure obligations in that Alexion was advised of the case it had to meet, and was provided with all of the documents that Board Staff intended to rely on.[145] When Board Staff filed the Amended Statement of Allegations, Alexion received sufficient time to review and respond to it, including through its detailed fact and expert evidence at the hearing. Alexion's response included submissions as to why Board Staff's amended position should be rejected and why the evidence provided by Board Staff, including the inconsistencies and confusion noted above, could not be relied on. The Panel has taken

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145 *Ciba-Geigy Canada Ltd., Re*, [1994] 3 FC 425 at para 32 (FC), appeal dismissed [1994] FCJ No 484 at paras 5, 6 (FCA).

all of this (including Alexion's evidence and submissions) into account in reaching its decision, including the terms on which the excess revenues are to be calculated.

(D) Section 85(1)(d) – changes in the Consumer Price Index

199. The current Guidelines provide that the "National Average Transaction Price and the Market-Specific Average Transaction Prices of an existing patented drug product will be presumed to be excessive if they increase by more than that allowed under the Board's CPI-Adjustment Methodology, as long as this price does not exceed the HIPC test." The CPI Adjustment Methodology is set out in Schedule 9:

> 1.2 The CPI-Adjustment Methodology involves the following calculations:
>
> - Adjusting the benchmark prices of the drug product for the cumulative change in the CPI from the benchmark year to the year under review (CPI-Adjusted Price); and
>
> - Applying a cap on the maximum price increase in any one year, equal to 1.5 times the change in the latest actual lagged CPI. In periods of high inflation (over 10%), the limit will be five percentage points more than the latest actual lagged change in the CPI.
>
> 1.3 The lower of the results of both calculations will set the Non-Excessive Average Price for a particular year. (footnotes omitted)

200. Board Staff argues that section 85(1)(d) should be given less weight than section 85(1)(c) because CPI is not relevant to the introductory price of Soliris, and Alexion did not ever adjust its price in Canada based on CPI.

201. Alexion submits that the predominant consideration under section 85(1)(d) is that the price of Soliris in Canada has never increased and, in fact, has decreased by approximately 10% based on changes to the CPI.[146]

202. In the Panel's view, the methodology in the Guidelines reasonably and appropriately applies the factor in section 85(1)(d) for Soliris, except that, going forward, a price

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[146] *See*, Exhibit 40, p. 11, where Mr. Soriano calculated the 2016 inflation-adjusted price to be $199.05.

increase based on CPI cannot exceed the LIPC test (instead of the HIPC test). The Panel acknowledges that a patentee should be able to take price increases based on inflation, but at no time in the future should Canadians be paying a higher price for Soliris than the price in the lowest priced comparator country. The Panel accepts Dr. Schwindt's evidence that using the lower of the two tests provides an indication that the patentee has covered costs and is willing to supply at a certain price.[147]

203. The Panel acknowledges that the price of Soliris in Canada has not changed since its introduction and notes Mr. Soriano's evidence that in "real dollars" the price of Soliris has decreased due to inflation. The Panel found Mr. Soriano's evidence in this regard to be unhelpful as it is not based on an appropriate comparison – for example, in devising his proposed Comprehensive test in Appendix B, Table 3 of his report, Mr. Soriano adjusts the ex-factory prices in comparator countries upwards based on CPI in those countries (even if the actual price in those countries did not change but in fact decreased in "real dollars" based on the same reasoning that Alexion uses to argue that the price in Canada has decreased due to inflation), and then Mr. Soriano does not adjust the Canadian price upwards based on CPI in Canada in the same table, thus comparing the nominal price in Canada with CPI-adjusted prices elsewhere.[148] This is not an appropriate comparison in the Panel's view. Considering inflation in Canada while disregarding the effect of inflation in the comparator countries does not allow for a meaningful comparison.

204. Mr. Soriano also presents in his report an analysis of additional revenues that Alexion could have realized had it increased its price by the CPI factor each year. This analysis is not helpful to the Panel because it ignores the fact that there is no guaranteed yearly CPI increase under the *Patent Act*, and that between 2012 and 2015, a price increase by the CPI factor would not have been available to Alexion under the Guidelines.[149]

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147 Examination In-Chief of Dr. Schwindt, January 26, 2017, Hearing Transcript, Vol 8 (Public) at p. 846, line 25 – p. 847, line 24.

148 Exhibit 40.

149 The Panel also relies, by way of analogy, on the decisions of previous hearing panels that it is not appropriate for a patentee to bank price increases that were not made in a given year to be used in some fashion by the patentee in future years to justify a price. See Board Decision –*Sanofi Pasteur Limited and*

205. Dr. Putnam argued that section 85(1)(d) requires this Panel to convert the nominal price of Canadian Soliris and of international Soliris to its "real price" by applying CPI adjustments, and then compare the CPI-adjusted price. The Panel rejects Dr. Putnam's analysis because it is not supported by the wording of section 85(1)(d). Section 85(1)(d) simply requires the Panel to "consider changes in the CPI" – it does not require the Panel to apply CPI to the nominal price and then do a comparison of the Canadian price and the international prices using the CPI-adjusted price.

206. Further, as already mentioned in its discussion of section 85(1)(c), the Panel agrees with Board Staff that Dr. Putnam's analysis inappropriately conflates the consideration of the factors in sections 85(1)(c) and (d) by advocating that the international prices that 85(1)(c) requires the Panel to consider need to be adjusted by the CPI in order for the Panel to comply with 85(1)(d). Lastly, the Panel agrees with Board Staff that the wording of section 85(1) is clear that the change in CPI referred to in section 85(1)(d) is to be considered with respect to the Canadian price which is under review, not the prices in the comparator countries it is being compared against.

207. As noted above, section 85(1)(d) only requires the Panel to consider changes in the CPI. The Panel has considered that the price of Soliris in Canada did not change even though there was a positive rate of inflation between 2012 and 2015. However, the Panel notes from Mr. Soriano's report that the price in the lowest priced comparator in 2012 to 2015 (United Kingdom) also did not change, even though there was a positive rate of inflation in the United Kingdom. In fact, in 2011, 2012 and 2013, the United Kingdom had a higher CPI factor than Canada.[150]

208. In light of the above, the Panel is of the view that the current methodology in the Guidelines (adjusted to refer to the LIPC test on a go-forward basis) correctly implements this factor of the *Patent Act* for Soliris.

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the Medicines "Quadracel and Pentacel" (14 June 2012) at para 6, online: PMPRB <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=860&lang=en> [*Quadracel* (2012)].

150 Exhibit 40, Table 3, p.5, and Appendix B.

(E) Section 85(1)(e) – such other factors as may be specified in any regulations made for the purposes of this subsection

209. No regulations have been passed and this factor is therefore not applicable.

(F) Summary of Analysis under Section 85(1) of Patent Act

210. Irrespective of any discrepancies with foreign price verification sources, the price of Soliris in Canada (s. 85(1)(a)) at all times since its introduction has been above the LIPC (s. 85(1)(c)). Given that the Panel has concluded that the LIPC is the correct benchmark for Soliris, even considering changes in the CPI (s. 85(1)(d)), in respect of the first issue then the Panel finds that the price of Soliris is and was excessive for the purposes of s. 83 and 85 of the *Patent Act*. The Panel rejects Alexion's submission that Board Staff did not meet its burden of proof on a balance of probabilities.

X. Order

211. Sections 83(1) and (2) of the *Patent Act* provide this Panel with broad remedial discretion:

> **83 (1)** Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.
>
> **(2)** Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:
>
> **(a)** reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

> **(b)** reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or
>
> **(c)** pay to Her Majesty in right of Canada an amount specified in the order.

212. Board Staff argues that this Panel is entitled to calculate excess revenues under section 83(2) on a different basis than the setting of the price of Soliris going forward under section 83(1).[151] This Panel agrees that it has such discretion and has exercised it in the circumstances of this particular case.

213. The Panel has found that Alexion is selling Soliris in Canada at a price that is excessive. Based on its analysis of the factors in section 85(1) and the discretion granted to it under section 83(1) of the *Patent Act*, the Panel orders Alexion to reduce the price of Soliris in Canada to no higher than the price in the lowest priced comparator country in the Regulations as of the date of the decision.

214. The Panel has also found that Alexion was selling Soliris in Canada at a price that was excessive during 2009 to 2015 in that the price exceeded the price in the lowest priced comparator country in the Regulations, and thus generated excess revenues. Based on the discretion granted to it under s. 83(2), the Panel orders Alexion to pay to Her Majesty in right of Canada the amount calculated by the parties and approved by this Panel in accordance with Schedule A to this decision, in order to offset these excess revenues.

215. Although the Panel is of the view that the correct benchmark for Soliris is the LIPC as of the date of first sale in Canada, the Panel is not prepared to order Alexion to pay past excess revenues based on this benchmark and is only requiring Alexion to comply with the LIPC test going forward from the date of this decision.

216. In light of all of the evidence and the unique circumstances of this case, the Panel concludes that requiring Alexion to make a payment to address past excess revenues

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151 Submissions by Mr. Migicovsky, April 18, 2017, Hearing Transcript, Vol 19 (Public) at p. 2787, line 19 – p. 2788, line 20.

calculated on the basis of the HIPC test is the remedy that is appropriate, fair and consistent with the Panel's mandate. In reaching this conclusion, the Panel took into consideration the fact that the LIPC test was not proposed as the appropriate benchmark for Soliris until 2015, several years after Soliris was first sold in Canada and, up until 2015, Board Staff had consistently applied the HIPC test in the Guidelines to the pricing of Soliris. Fashioning a remedy to address past excess revenues in this particular case that is based on the lowest international price comparison test (the LIPC test) is inconsistent with an environment that encourages the supply of patented medicines at reasonable prices to Canadians.

217. Alexion submits that if any one of a number of "offsets" is taken into account, the quantum of excess revenues (calculated on the basis of the current Guidelines) is completely offset. Alexion refers to four potential offsets (discussed below).

218. First, approximately $[redacted] in rebates paid under the PLAs in 2011 to 2013. As discussed above in the factual history of Board Staff's investigation, Board Staff rejected these rebates in reliance on the *Pfizer* decision.[152] Alexion argues that Board Staff's reliance on *Pfizer* is misplaced, and conflicts with the decision in *Leo Pharma* that the distribution of free goods voluntarily reported to the Board could be taken into account.[153]

219. Mr. Haslam testified that Alexion refiled its Block 4 information as a result of the December 2013 meeting with Board Staff. He believed that a solution to Alexion being offside the Guidelines was to refile 2011 to 2013 with the provincial rebates included, as doing so would bring the ATP of Soliris down below the maximum non-excessive price for 2012 and 2013.

220. Board Staff rejected the refiled information because, in its view, the rebates were not payments to customers. Board Staff took the position that *Pfizer* stands for the proposition that rebates to third parties cannot be taken into account to reduce the ATP

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152 *Pfizer Canada Inc. v Canada (Attorney General)*, 2009 FC 719 [*Pfizer*].

153 *Leo Pharma*, *supra* note 18 at para 57.

because reporting of rebates to third parties (such as the provinces) is outside the Board's jurisdiction.

221. While disagreeing with Board Staff on its interpretation of *Pfizer*, Alexion acceded to Staff's request and refiled its Form 2s without the rebates to the provinces.

222. The Federal Court made it clear in its decision in *Leo Pharma* that the determination of the ATP of a patented medicine must take into account any reduction given in the form of rebates.[154] The Panel interprets this direction as referring to rebates given to customers.

223. The Panel notes that Alexion appears to have taken conflicting positions on the meaning of *Pfizer* during the course of this proceeding. In its closing argument, Alexion argues that *Pfizer* does not prevent the distribution of free goods (or similar benefits) voluntarily reported to the Board from being taken into account when determining the ATP. This would, of course, require this Panel to consider the relationship between Alexion and a third party (in this case, the provinces). On the other hand, in its objection to the intervention request filed by the Ministers of Health, Alexion argued that this Panel lacks jurisdiction to consider any submissions by the Ministers about the downstream arrangements for the sale of patented medicines.[155] And, in its reply closing submissions,[156] Alexion argues that *Pfizer* expressly holds that the Board's jurisdiction is subject to a constitutional limitation that does not permit consideration of contractual arrangements involving patentees and entities further down the distribution chain.

224. *Pfizer* was a case where a Board's policy requiring patentees to report rebates to third parties (in that case, provinces) was challenged. The Federal Court concluded that the Board cannot require patentees to report rebates paid to third parties because federal jurisdiction is confined to the regulation of the factory gate prices of patented medicines.

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154 *Leo Pharma*, *supra* note 18 at para 69.

155 Alexion's Reply Submissions - *Motion to Strike Portions of the Minister of Health of B.C.'s further Amended Notice of Appearance* (23 October 2015) at para 13, online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/Hearings%20and%20Decisions/Decisions%20and%20Orders/Respondent_reply_to_Board_Staff_response_to_motion_to_strike_BC.pdf>. This is summarized by the Panel in Board Decision – *Various Motions Related to Procedural Matters*, supra note 6 at para 43.

156 Alexion Reply Closing Submissions at paras 9-10.

The Court noted that the provinces never take title or possession to the medicines, are not parties to the sale at factory gate, and do not provide payment to the patentees. The Court concluded that the provinces are not customers, but more akin to public insurers.[157] The Court also clarified the meaning of "rebate" and found that to qualify as a rebate, there must be a return of a portion of money actually paid, and the payment cannot be paid to a stranger to the sale transaction.[158]

225. This Panel agrees with the comments made by the panel in the *ratio-Salbutamol* proceeding that there is some confusion as to how far the Court's decision in *Pfizer* extends.[159] This Panel does not need to resolve this confusion in order to make a decision concerning these rebates in the case of Soliris. The Panel concludes that the rebates that Alexion provided to the provinces do not qualify as rebates within the meaning of the Regulations as interpreted by the Federal Court. The provinces are not customers but akin to public insurers and were a stranger to the sale transaction (*i.e.*, not a party to the sale at factory gate since Mr. Haslam testified at the hearing that Alexion's only customer in Canada is Innomar) and therefore even if payments were made directly to the provinces by Alexion, those payments do not qualify as rebates. Further, in the end, Alexion adhered to Board Staff's request to refile the relevant Form 2s without the provincial rebates, and has always maintained throughout this proceeding that the ATP of Soliris has remained unchanged since introduction. For these same reasons, it is not appropriate for this Panel to allow Alexion to use these rebates to offset any excess revenues.

226. Second, Alexion refers to approximately $[redacted] in rebates provided by Alexion to Innomar. As discussed above in the factual history of Board Staff's investigation, Alexion filed Block 4 information for July to December 2014 showing a reduced ATP which was described as "accurately reflect[ing] reductions from the List Price of Soliris

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157 *Pfizer*, *supra* note 152 at paras 61-62, 73, 80.

158 *Pfizer*, *supra* note 152 at para 88.

159 *ratio-Salbutamol* (Board Decision), *supra* note 77 at paras 118-125.

provided by Alexion to its wholesaler/distributor and reported as required under the Regulations."[160]

227. During his testimony, Mr. Haslam explained that, technically, Innomar is Alexion's only customer and all sales go through Innomar. He explained that Innomar is either a wholesaler or a pharmacy, with the majority of sales going through Innomar as a pharmacy and, on some occasions, sales were made to hospitals. The Form 2s filed by Alexion referred to hospitals and pharmacies, and not to a wholesaler because Alexion was, according to Mr. Haslam, trying to show where the product was going. Mr. Haslam explained that the amended Form 2s reflected Alexion's decision to share with Innomar the costs of the volume discount payments made to the provinces under the PLAs, and the mechanism used to share the payments was credit notes paid by Alexion to Innomar. The credit notes were issued in 2014 and 2015, and reflected what Alexion thought would be the amount by which the ATP exceeded the HIPC for 2014 and 2015. [redacted]

228. The Panel agrees with the comments made by the panel in the *ratio-Salbutamol* case that the patentee has the evidentiary burden to provide supporting documentation of any rebate that is claimed in respect of the medicine.[161] This Panel concludes that Alexion has failed to meet its evidentiary burden to show that these credit notes justify a reduction in the ATP for Soliris for 2014 or 2015, or should be permitted to be used as an offset for excess revenues. Alexion's position that Innomar, a wholesaler, is its only customer, conflicts with the information found in the Form 2s. In these circumstances, the Panel requires some corroboration of Mr. Haslam's statements at the hearing as to what Innomar is and what role it played. No documents were produced concerning Alexion's relationship with Innomar. Photocopies of what were described as credit notes produced for the first time during Mr. Haslam's examination-in-chief are insufficient proof in the circumstances as no explanation was provided as to why these credit notes were not

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160 Exhibit 1, Tabs 55.

161 *ratio-Salbutamol* (Board Decision), *supra* note 77 at paras 111-112.

produced earlier in this proceeding, no back up documentation was provided for the credit notes and, with only photocopies of what were described as credit notes, Board Staff did not have a fair opportunity to challenge this evidence.[162]

229. Based on the consistent position taken by Alexion throughout this proceeding that the price of Soliris in Canada has not changed since introduction, the Panel is not willing to accept these credit memos to reduce the ATP of Soliris in Canada in 2014 or 2015 for the purposes of this hearing; in the Panel's view, the price of Soliris in 2014 and 2015 for the purposes of determining price excessivity is $224.7333.

230. Third, Alexion argues that if infusion costs had been taken into account in the Form 2 filings, the price of Soliris would have decreased further and offset excessive revenues. This assertion was raised for the first time during the hearing and was not contained in Mr. Haslam's witness statement. Mr. Haslam testified that Alexion's contract with Innomar covers infusion costs for Soliris for Canadian patients and those costs can range between $[redacted] to $[redacted] per infusion.[163] The only evidence provided on this point was Mr. Haslam's oral testimony, subject to one document that was prepared by Alexion and produced for the first time during the hearing. Mr. Haslam's evidence in this respect conflicts, at least in part, with other evidence adduced at the hearing. In particular, Mr. Lun testified that the public payor system covers at least some of the infusion costs.[164]

231. The Panel rejects Alexion's argument concerning infusion costs for the same reasons it rejected the argument concerning rebates paid to Innomar. No credible evidence was provided demonstrating the relationship between Alexion and Innomar, as well as the arrangement between them related to infusion costs. Alexion has failed to meet its evidentiary burden to prove that these infusion costs were in fact covered by Alexion and the amount of relevant infusion costs covered, and thus it is not appropriate for this Panel to take them into account to reduce the ATP or to offset any excess revenues.

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162 Examination In-Chief of Mr. Haslam, February 27, 2017, Hearing Transcript, Vol. 14 (Confidential) at p. 501, lines 17-21, p.513, line 20 – p.514, line 4.

163 Examination In-Chief of Mr. Haslam, February 27, 2017, Hearing Transcript, Vol. 14 (Confidential) at p. 516, line 14 – p. 517, line 4.

164 Examination In-Chief of Mr. Lun (Cont'd), February 22, 2017, Vol. 11 (Confidential) at p. 339, lines 3-15.

232. Fourth, Alexion relies on Mr. Soriano's evidence that no inflationary increases were taken by Alexion and therefore the real price of Alexion decreased. The Panel concludes that this does not justify any offset of excess revenues. Amongst other things, it incorrectly assumes that Alexion would have been permitted to take yearly CPI increases.

233. The Panel concludes that the provisions of the current Guidelines dealing with permitted offsets are an appropriate implementation of the *Patent Act* in the circumstances of this case. They provide flexibility to the patentee while, at the same time, preventing the charging of excessive prices with the elimination of excess revenues at some future unknown date at the control of the patentee (which would, if permitted, frustrate the Board's consumer protection mandate and create volatility).[165]

234. The relevant provisions of the Guidelines, dealing with offsets, are as follows:

> **B.7 Policy on the Offset of Excess Revenues**
>
> B.7.1 The Board may allow a patentee to offset any excess revenues estimated by it to have been derived from the sale of the medicine at an excessive price through either: (i) the reduction of the price of the medicine or the price at which the patentee sells another patented medicine in Canada; or (ii) a payment to Her Majesty in right of Canada.
>
> B.7.2 To offset excess revenues via a price reduction, the average price of a patented drug product will only be considered to have been reduced if it is below the previous year's Non-Excessive Average Price; not taking an allowable price increase will not be considered for purposes of offsetting excess revenues.
>
> B.7.3 Cumulative excess revenues cannot fall below zero.

235. In relation to this Panel's jurisdiction to make an order under section 83, Alexion relied on several arguments – including the law of expropriation, NAFTA and the Canadian *Bill of Rights* – to argue that it would be an error for this Panel to interpret the *Patent Act* as allowing the Panel to make an order that is based on a methodology which is not contained in the Guidelines. The Panel disagrees – the Panel does not lack the ability to make an order under section 83 that deviates from the methodologies and tests in the

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165 *Quadracel* (2012), *supra* note 149 at para 14.

Guidelines for the reasons already articulated above and for the additional reasons set out below.

236. Principles of the law of expropriation do not assist Alexion. In making an order under section 83 of the *Patent Act,* this Panel is exercising statutory regulatory authority. An exercise of regulatory authority, even if its effects are significant or retroactive, is not an act of expropriation.[166]

237. NAFTA has no application to this proceeding. The Federal Court has made it clear that NAFTA is not part of Canada's domestic law, and does not have the force of an Act of Parliament. In relevant part, NAFTA allows an investor of a NAFTA signatory to initiate a claim to determine, through international arbitration, whether another signatory state has violated the obligations set out in NAFTA. No such claim or arbitration proceeding is at issue here, nor has the evidentiary foundation for such a claim (should the Panel have jurisdiction to consider it) been provided.

238. While an international treaty, like NAFTA, may be used to assist in interpreting domestic legislation, it cannot be used to override the clear words of a federal statute and, where legislation is clear, one need not and should not look to international law to interpret its meaning.[167] Sections 83 and 85 of the *Patent Act* are clear and unambiguous, and any suggestion that the Panel should look to international law to give them meaning is rejected.

239. Even if the Panel did turn to international law to interpret sections 83 and 85, international law supports the Panel's decision in this proceeding. NAFTA arbitration panels have rejected the claims of investors affected by the domestic law of a NAFTA signatory where the domestic law was in fact regulation for a public purpose, the law was non-discriminatory and was done with due process, and the investor was not promised that the law would not apply and invested in the signatory state with its eyes wide open as

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166 *A & L Investments Ltd. v Ontario (Minister of Housing)*, [1997] OJ No 4199 at paras 29-31 (Ont CA); leave to appeal refused [1997] SCCA No 657 (SCC).

167 *Baker Petrolite Corp. v Canwell Enviro-Industries Ltd.*, 2002 FCA 158 at para 25; *Pfizer Canada Inc. v. Canada (Attorney General)*, 2003 FCA 138 at para 20, leave to appeal refused 27 C.P.R. (4th) vi (SCC).

to what the regulatory context was in the signatory state.[168] The Panel concludes that this is exactly the context of this case. As referenced above, Alexion has consistently noted the potential impact of government regulation of the price of Soliris in its annual filings with the Securities Exchange Commission in the US.

240. The Canadian *Bill of Rights* also does not support Alexion's argument. It was unclear which provision of the *Bill of Rights* – section 1(a) and/or 2(e) – Alexion was relying on to argue that the Panel's remedial powers are limited to the methodologies and tests in the Guidelines. However, this is irrelevant as neither provision supports Alexion's position in this proceeding.

241. Section 1(a) provides the right of the individual not to be deprived of the enjoyment of property except by due process of law. Corporations are not entitled to make a claim under section 1(a).[169] In any event, even if the Panel's order qualified as expropriation of Alexion's property (which it does not), section (1)(a) does not protect against the expropriation of property by the passage of unambiguous legislation like the relevant provisions of the *Patent Act*.[170]

242. Section 2(e) guarantees the right to a fair hearing before an administrative body. The Panel does not have to resolve whether or not section 2(e) applies to corporations because, even if it does, the Panel concludes Alexion did receive a fair hearing in this proceeding.

243. In any event, the Panel has ordered that any excess revenues for 2012 to 2015 be calculated based on the Guidelines and using Alexion's filed Form 2 information (without rebates to the provinces or Innomar), and thus Alexion's concerns are not relevant in

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168 *Marvin Feldman v Mexico* (16 December 2002), Case No ARB(AF)/99/1 at para 103, online: International Centre for Settlement of Investment Disputes <http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C175/DC587_En.pdf>; *Methanex Corporation v United States of America* (3 August 2005) at Part IV, Ch D, para 15, online: UNCITRAL: < https://www.state.gov/documents/organization/51052.pdf>.

169 *Smith, Kline & French Laboratories Ltd. v Canada (Attorney General)*, [1985] FCJ No 501 at para 60 (FC), aff'd [1987] 2 FC 359 (FCA), leave to appeal refused 27 CRR 286 (SCC); *R. v Colgate-Palmolive Ltd*., 5 CPR (2d) 179 at para 10 (Ont GSP Ct), aff'd 6 CPR (2d) 4 (Ont CA).

170 *Authorson (Litigation Guardian of) v Canada (Attorney General)*, 2003 SCC 39 at para 51.

respect of the calculation of excess revenues to be paid to the Crown. The required application of the LIPC to Soliris commences on the date of this decision, and Alexion now has notice that it will be subject to the LIPC test going forward. There are no issues of "notice" or "retroactivity" concerning the price of Soliris going forward.

244. The Panel wishes to reiterate that the Guidelines do not address the issue of remedy in an excessive pricing hearing, and that when a case proceeds to the hearing stage, the Panel is not restricted to remedies based on an application of the methodologies and tests in the Guidelines. The mandate of this Panel is to apply sections 83 and 85 of the *Patent Act* in accordance with the wording and intent of those provisions, as well as the Board's consumer protection mandate.

245. Lastly, the Panel wishes to address the remedy that was sought by CLHIA, an intervenor in this proceeding solely on the issue of remedy. CLHIA argued that in order for this Panel to deal effectively with past excess revenues, the price going forward for Soliris in Canada should be reduced even further (*i.e.*, below the LIPC) until those excessive revenues are wholly set off. Otherwise, CLHIA argues, private insurers will not benefit from the Panel's decision (assuming the Panel found the price was excessive and ordered a lower price). Alexion objected to this request, and argued that this Panel has no jurisdiction to make such an order.

246. Such an order would be punitive to Alexion, would be difficult to implement, and is not necessary, in the Panel's view, for it to fulfill its consumer protection mandate in this case. The Panel need not decide whether it has the jurisdiction to make the remedial order requested by CLHIA, as it has concluded that, even if it had the jurisdiction, it would not be an appropriate exercise of its discretion to make such an order in the circumstances of this case. The Panel also notes that section 83(2) specifies the payment being made to the Federal Crown, as opposed to any entity that ultimately covered the cost of the medicine at issue, reflecting Parliament's acceptance of the fact that a remedy may not "compensate" the ultimate payors of the excess revenues.

247. The Panel therefore makes the following two orders:

(i) Alexion shall reduce the price of Soliris in Canada to no higher than the price in the lowest priced comparator country set out in the Regulations from the date of this decision forward, applying the tests and methodologies in the Guidelines, except that the price excessivity benchmark to be applied is LIPC and not HIPC; and

(ii) Alexion shall pay to Her Majesty in right of Canada an amount calculated by Board Staff and Alexion, and approved by this Panel in accordance with Schedule A to this decision.

Dated at Ottawa, this 20th day of September, 2017.

Original signed by

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members

Mitchell Levine
Carolyn Kobernick

Counsel for Alexion

Malcolm Ruby
David Woodfield
Alan West

Counsel for Board Staff

David Migicovsky
Christopher Morris

Counsel for Panel

Sandra Forbes
Adam Fanaki
Badar Yasin

SCHEDULE A

1. The relevant period is 2009 to the date of this decision (the "**Relevant Period**").

2. The relevant prices are those contained in Alexion's original Form 2, Block 4 and Block 5 filings (the "**Relevant Prices**"). The Relevant Prices shall not reflect any rebates or credits provided by Alexion to the provinces or Innomar even if such rebates or credits are included by Alexion in any original Form 2 filing during the Relevant Period.

3. The methodologies and tests set out in the Guidelines to calculate excess revenues shall be applied to the Relevant Prices for the Relevant Period for purposes of calculating the payment to be made by Alexion. For greater certainty, Alexion is entitled to an offset of any excess revenues in accordance with sections B.7.2 and B.7.3 of the Guidelines, as applicable.

4. The parties shall consult and submit a joint chart setting out the calculation of the payment as specified by this Schedule A to the Panel by 4 pm on October 20, 2017. If the parties cannot agree on a joint chart, each party shall provide by 4 pm on October 20, 2017 the chart that it submits is accurate along with brief written submissions clearly and concisely setting out the differences between the parties and why their chart should be approved by the Panel.

5. A case conference will be scheduled in the event the Panel has any questions about the chart(s).

6. The Panel will review the joint chart or separate charts, as applicable, and issue a decision confirming the amount of the payment. Alexion shall make the payment within 30 days following the Panel's decision.