PATENTED MEDICINE PRICES REVIEW BOARD

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

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

WRITTEN ARGUMENT OF ALEXION PHARMACEUTICAL INC. (7 APRIL 2017)

OVERVIEW

1. The case advanced by Board Staff is fundamentally flawed. An essential element, the basis for selection of foreign source prices and back-out formulae, was not proven. The Board's only fact witness, Richard Lemay, had no knowledge of the issue. He testified that the Policy Branch of the Board was responsible for the process; no witness from the Policy Branch was called. Furthermore, Board Staff led no reliable evidence quantifying alleged excessive revenues; the evidence advanced was inconsistent, conflicting, and based on unreliable hearsay.

2. In any event, Alexion clearly rebutted the "presumption" of "excess revenues". The evidence was uncontested that foreign currency exchange rate variations triggering the investigation were beyond Alexion's control. The price of Soliris has not increased since the product was introduced on the Canadian market in June 2009 and the introductory price was deemed compliant in 2010 and 2011. The price, in fact, has decreased by about 10% given the ordinary effects of inflation. Soliris is a "non-traded" good, meaning that any temporary appreciation in the Canadian dollar had no impact on Canadian consumers, who could not purchase Soliris outside Canada with Canadian dollars. Furthermore, the price of Soliris in the comparator countries did not decrease in the relevant period, meaning that Canadian purchasers were not deprived of any advantage of declining prices elsewhere. In the circumstances, the foreign exchange rate variations did not harm Canadian consumers and there was no patent abuse. The *Guidelines* raise rebuttable presumptions, and do not create a regime of absolute liability.

3. Board Staff's request that the Panel ignore the *Guidelines* to impose newly-invented liability tests retroactively to increase confiscatory liability offends basic principles of statutory interpretation, fairness, natural justice, and international law. Reliance on these new rules reveals the weakness of Board Staff's case under the *Guidelines*. The jurisprudence of the Board and Federal Court have only permitted departures from the *Guidelines* in circumstances where application of the *Guidelines* would result in unfairness to a patentee. The Board cannot abandon the rules it urges patentees to follow to single out Alexion in this case.

4. Even if liability to excess revenues was established in theory, which is vigorously denied, any such theoretical liability can be offset in several ways. Rebates were paid under confidential agreements with the provinces, whether by Alexion or its distributor Innomar, that exceed alleged excess revenues. Alexion's coverage of home and clinic infusion costs also offsets alleged excessive revenues. Furthermore, declines in the price of Soliris based on inflation created savings to purchasers that exceed theoretical excessive revenues alleged in the relevant years.

5. Board Staff's case should therefore be dismissed.

Company History and Development of Soliris

6. Alexion Pharmaceuticals Inc. ("Alexion") was established in New Haven Connecticut in 1992. The principal founder was Dr. Leonard Bell, a Yale-trained cardiologist.[1] With the support of by a venture capital fund,[2] Alexion's original objective was to develop "pexelizumab", a "complement blocking" monoclonal antibody intended for use in coronary artery bypass surgery.[3] Pexelizumab went through phase 1 and phase 2 clinical trials but, in 1996, failed to meet its "primary endpoint" in phase 3 clinical trials, leading the company to stop development of that product.[4]

7. While many biotechnology companies close their doors after a primary candidate drug fails to pass clinical trials,[5] Alexion persevered and was fortunate to have in development eculizumab, a monoclonal antibody "sibling" to pexelizumab.[6] Eculizumab, also a complement blocker,[7] was of interest to an English physician, Dr. Peter Hillmen, who wanted to explore use of eculizumab in treatment of paroxysmal nocturnal hemoglobinuria (or "PNH"), an ultra-rare blood disorder in which uncontrolled complement leads to hemolysis, or the destruction of red blood cells.[8]

8. Development of eculizumab, or Soliris, for PNH took place between the mid-1990s and 2007.[9] The first clinical trials occurred between 1996 and 1998.[10] At the time, there was no effective treatment for PNH and a high percentage of patients died within 5 years of diagnosis.[11] A pilot study with Soliris was conducted by Dr. Hillmen, who published the results in 2005 in the *New England Journal of Medicine*.[12]

9. The United States Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA") approved Soliris for treatment of PNH in 2007.[13] Both regulatory bodies conducted expedited reviews because Soliris "had a significant impact on the patient population" in circumstances "where there was a significant unmet need."[14]

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[1] Transcript, P1815.
[2] Transcript, P1817.
[3] Transcript, P1816.
[4] Transcript, P1817.
[5] Transcript, P1817.
[6] Transcript, P1817-P1818.
[7] Transcript, P1818.
[8] Transcript, P1818; Joint Book, Tabs: 6 (pg.2); 10 (pg. 2); 11 (pg. 2); and 132 (pg. 2).
[9] Transcript, P1819.
[10] Transcript, P1819-P1820.
[11] Joint Book, Tab 6, pg. 2.
[12] Transcript, P1822-P1823.
[13] Exhibit 43; Transcript, P1824.
[14] Exhibit 43; Transcript, P1824.

10. In 2008, Soliris was first used to treat another ultra-rare complement-mediated disease, atypical hemolytic uremic syndrome (or "aHUS").[15] and approved in 2011 by both the FDA and EMA for pediatric and adult use for that indication.[16] In 2011, Alexion provided free product to address a public health crisis in Germany involving a disease similar to aHUS.[17]

11. Alexion was awarded a Prix Galien in the United States in 2008 and a Prix Galien in France in 2009 for the company's innovative efforts to develop Soliris.[18] The Prix Galien is the highest international recognition for pharmaceutical research and development and is considered the equivalent of the Nobel Prize in pharmaceutical research.[19]

12. While Soliris may be a success story for Alexion, the company has also seen its share of disappointments throughout its history. In addition to pexelizumab, a number of other products, like SBC-103 for treatment of Muccopolysaccharidosis Type IV, have failed late stage phase 3 clinical trials. Moreover, clinical trials exploring the use of Soliris for other indications, including delayed graft function and myasthenia gravis, did not meet primary endpoints.[20]

Introduction of Soliris in Canada

13. Alexion obtained a Notice of Compliance ("NOC") from Health Canada for Soliris on 28 January 2009.[21] Shortly thereafter, on 4 February 2009, Alexion notified the Board of its intention to sell Soliris in Canada by filing a Form 1 "Medicine Identification Sheet", which attached a copy of the Product Monograph for Soliris. The Form 1 was filed on Alexion's behalf by RTI Health Solutions Inc. (later re-named PDCI), an Ottawa consulting company that assists the Canadian pharmaceutical industry with Board filings.[22]

14. On 18 March 2009, RTI provided the Board with Alexion's submission to the Human Drug Advisory Panel ("HDAP") seeking Category 2 "breakthrough" status for Soliris.[23] The Board also submitted to HDAP its own expert report, prepared by the Board's Drug Information Centre ("DIC"), which concluded that there were no comparators for Soliris for treatment of PNH.[24] On 15 May 2009,

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[15] Exhibit 43; Transcript, P1824.
[16] Exhibit 43; Transcript, P1827-P1828.
[17] Exhibit 43; Transcript, P1826-P1827.
[18] Exhibit 43; Transcript, P1825-P1826.
[19] See: http://www.galienfoundation.org/index.php/prix-galien

[20] Transcript, P1838-P1839.
[21] Joint Book of Documents ("Joint Book"), Volume 1, Tab 3; Health Canada's Summary Basis of Decision for granting the NOC was released on 20 to July 2009: See Joint Book at Tab 11.
[22] Joint Book, Volume 1, Tabs 4 and 5.
[23] Joint Book, Volume 1, Tab 6.
[24] Joint Book, Volume 1, Tab 10.

the HDAP reviewed the submissions and "recommended that Soliris (eculizumab) be classified as a Category 2 new drug" or breakthrough product.[25]

15. Alexion's submission to HDAP, delivered 18 March 2009, specifically mentioned the Board's then "Excessive Price Guidelines" and application of the *Guidelines* then in effect to Category 2 new medicines. The then *Guidelines* (published in 2003) provided that the introductory price of a Category 2 new drug product would be based on "the median of the international prices identified in an International Price Comparison Test (*Schedule 3*)".[26]

16. Alexion Pharma Canada Corp. ("Alexion Canada")[27] was incorporated in April 2009. John Haslam, who joined Alexion Canada in mid-April 2009,[28] was the Canadian company's first employee and only employee until June 2009.[29]

17. The first sale of Soliris in Canada took place in June 2009 while the Canadian patent for Soliris was still pending.[30] The "package price" for a 300mg vial of Soliris was $6,742 and the unit price, 10mg/mL, was $224.7333. The introductory price was determined after consultation with Mr. Neil Palmer, of PDCI, who confirmed that the *Guidelines* then in effect called for application of a median international price test for breakthrough medicines.[31] Soliris was already sold in 6 of the 7 comparator countries and Mr. Haslam understood that calculation of the median price among those countries was a "straightforward" exercise.[32]

18. Calculating the annual cost of Soliris for a PNH patient, about $539,360 in the first year and $525,876 in subsequent years, was also straightforward. The "Consumer Information" section of the Product Monograph, originally provided to the Board in early February 2009, described the "usual dose" of Soliris for a PNH patient as "600 mg of Soliris every 7 days for the first 4 weeks", followed by "900 mg of Soliris for the fifth dose 7 days later", and then "900 mg of Soliris every 14 days thereafter."[33] The same dosing information was repeated in the Board's own DIC report dated 5 March 2009,[34] in Alexion's HDAP submission delivered on 16 March 2009[35], and in Health Canada's Summary Basis for Decision issued on 22 July 2009.[36] In a document published in February 2010, CADTH's Common Drug

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[25] Joint Book, Tab 85, pg. 1.
[26] Joint Book, Volume 1, Tab 6, pgs. 7 of 9.
[27] Alexion Canada and Alexion will be referred to collectively in these submissions as "Alexion".
[28] Transcript, P1814.
[29] Transcript, C400.
[30] Transcript, C398-C399; Joint Book, Volume 1, Tab 12.
[31] Transcript, P1875.
[32] Transcript, P1876.
[33] Joint Book, Volume 1, Tab 4, p. 36; Lemay at P395.
[34] Joint Book, Volume 1, Tab 10, p. 3; Lemay at P415-P416.
[35] Joint Book, Volume 1, Tab 6, p 4; Lemay at P399-P340.
[36] Joint Book, Volume 1, Tab 11, pp. 1, 2, 5, 11, and 13.

Review specifically stated that "the annual cost of eculizumab is $539,360 in the first year and $525,876 in subsequent years."[37] A document produced by the Board entitled "Annual Cost of Treatment based on 2009 Median International Price" calculated cost of treatment in the first year at $535,695.84.[38]

19. Soon after the Canadian patent issued on 13 April 2010,[39] Alexion began filing Form 2 reports with the Board.[40] The first Form 2 reports, for the periods January to June 2009 and June to December 2009, which included full Block 4 and Block 5 information relating to Canadian and foreign country pricing, were emailed to the Board on 11 May 2010.[41]

20. In his evidence, Mr. Haslam testified that "technically", Alexion's only customer in Canada is Innomar. Innomar is "either a wholesaler or a pharmacy." In Form 2 filings, Alexion attempted to "show where the product was going." Mr. Haslam explained that while "the majority of" Alexion's sales "are pharmacy and would be through the Innomar Pharmacy", there were "occasions were some sales would be ... from Innomar into a hospital."[42] All sales of Soliris in Canada no matter the ultimate destination, are made through Innomar.

21. Mr. Haslam also explained in his evidence that one aspect of the contractual relationship between Alexion and Innomar involves coverage of infusion costs of Soliris for Canadian patients. Infusion services are delivered by Innomar under the distribution contract with Alexion. Mr. Haslam explained that infusions are typically performed either in Innomar's clinics or in the patient's home. Infusion in a clinic typically involves nursing time and infusion materials. For home infusions, additional time is required for the cost of a nurse to travel to and from the patient's home. Infusion costs can range anywhere from [redacted] per infusion. Infusion costs in a given year would be based upon the total number of infusions multiplied by cost of infusion either in an Innomar clinic or in a patient's home.[43]

2010 Investigation of Introductory Price

22. On 25 June 2010, Alexion received a letter from Ginette Tognet, the Board's Director, Regulatory Affairs and Outreach Branch. The letter stated that an investigation had been commenced in "accordance with the Board's then Guidelines" into the introductory pricing of Soliris for the period between July and December 2009. The investigation revealed that the July to December 2009

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[37] Joint Book, Volume 10, Tab 132, pp. 1, and 4; Lemay at P568-P570.
[38] Joint Book, Volume 7, Tab 98 (10); Transcript, P571-P572.
[39] Joint Book, Volume 1, Tab 2, p.2.
[40] Joint book, Volume 1, Tab 13.; Transcript, P1876-P1878.
[41] Joint Book, Volume 1, Tab 13.
[42] Transcript, P1889.
[43] Transcript, C508, C514-C518; P1478-P1479.

introductory price of $224.7333 "exceeded the maximum non-excessive (MNE) price of $217.6772 by 3.2%" and generated "excess revenues of $78,322.71 during that period."[44]

23. Ms. Tognet's 25 June 2010 letter also raised questions about international prices for Soliris contained in Block 5 of the Form 2 documents filed on Alexion's behalf by PDCI in May 2010. She said Board Staff were "unable to find a public price for Germany or France" and also raised potential "discrepancies" with U.K. and U.S. prices when compared with prices from "Board Staff's public sources." Alexion was asked to deliver copies of source documents used for Block 5 filing information and to provide an explanation for the discrepancies.[45]

24. Ms. Tognet's 25 June 2010 letter was forwarded by Alexion to Mr. Palmer, of PDCI, who was instructed by Mr. Haslam to comply with all of Board Staff's requests and provide appropriate information.[46] Additional information was delivered to the Board in August 2010.[47] In October 2010, based on the new information provided, Alexion filed amended Form 2 Block 5 information with the Board.[48]

25. In a letter dated 21 June 2011, Ms. Tognet informed Alexion that based "on the company's amended Form 2, Block 5 data and Board Staff's Verification of International Prices, the price of Soliris 10 mg/mL no longer trigger[ed] the investigation criteria."[49] She indicated, nonetheless, that there were "cumulative excess revenues remaining as of December 2010 of $16,946.37." Alexion was "expected to offset the outstanding amount" by December 31, 2012."[50] Mr. Haslam and Mr. Lemay both testified that the $16,946.37 amount was in fact offset before the end of 2011; their evidence is confirmed by several exhibits filed before the Panel.[51] Indeed, Mr. Lemay confirmed in his evidence that, as of 2011, the amount had been "offset" and Alexion had a "clean slate."[52]

Compliance Status in 2010 and 2011

26. A table appended to Ms. Tognet's 21 June 2011 letter entitled "Calculation of Excess Revenues As of First Date of Sale (June 2009)" summarized Alexion's compliance status for 2010. The table, which employed terminology from the former 2003 *Guidelines*, showed "Excess Revenues" of $16,946.37 for the "Reporting Period" June 2009 to December 2009. There were no excess revenues

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[44] Joint Book, Volume 1, Tab 14; Transcript, P1892-P1893.
[45] Joint Book, Volume 1, Tab 14.
[46] Transcript, P1878-P1879; Transcript, P1890.
[47] Transcript, P1890-P1891; Joint Book, Volume 1, Tab 17.
[48] Transcript, P1891; Joint Book, Volume 1, Tabs 18-19.
[49] Joint Book, Volume 7, Tab 99.
[50] Transcript, P1892-P1893; Joint Book, Volume 7, Tab 99.
[51] Transcript, P1893-P1894; Transcript, P1893-P1894.
[52] Transcript, P657-P658.

whatsoever for the period January to December 2010 because the Average Transaction Price (or "ATP") of Soliris, $224.7333, was below the Non-Excessive Average Price (or NEAP) of $227.2243 for the 2010 reporting period.[53]

27. On 27 February 2012, Alexion received correspondence from the Board attaching a Compliance Status Report for the two reporting periods between January and December 2011. The Report, which employed terminology from the current 2010 *Guidelines*, showed that the National Average Transaction Price of Soliris (or "N-ATP") of $224.7333 continued to be below the National Non-Excessive Average Price (or "N-NEAP") of $226.5297. There were no "Excess Revenues" for 2011 and no "Cumulative Excess Revenues" (because the $16,946.37 had been offset). The CPI-adjusted 2011 price for Soliris, $233.973, was almost $9 higher than the N-NEAP. The overall "Compliance Status" was "Within Guidelines."[54]

Negotiation of PLAs with Ontario and the Other Provinces

28. In early January 2011, Alexion and eight provinces, including Ontario and British Columbia, began confidential negotiations over Product Listing Agreements (or "PLAs") relating to the funding of Soliris for use in treating PNH patients.[55] The negotiation was part of a new process known as the pan-Canadian Pricing Alliance which later changed its name to pan-Canadian Pharmaceutical Alliance (or pCPA).[56] The "lead" province in the negotiations was Ontario, whose principal negotiator was Diane McArthur, an Assistant Deputy Minister in Ontario's Ministry of Health and Long-Term Care.[57] Alexion's David Hallal led the negotiations with Ontario on behalf of Alexion, assisted by Mr. Haslam. Once the details of the template agreement with Ontario were worked out, Mr. Haslam was principally responsible for negotiating the PLAs with British Columbia and other provinces.[58]

29. [redacted]

[53] Joint Book, Volume 9, Tab 116; Transcript, C407-C408; Transcript P657-P658.
[54] Joint Book, Volume 1, Tab 26; Transcript, C411-C412; Transcript, P662-P665; P668-P669.
[55] Transcript, C456.
[56] Joint Book, Tab 39, pg. 2.
[57] Exhibit 24(5); Transcript, C457-C458.
[58] Transcript, C455-C457.
[59] Transcript, C458-C459; Exhibit 23(5);
[60] Transcript, C460; Exhibit 23 (8) and 23(9).

30. [redacted]

31. [redacted]

32. [redacted]

33. [redacted]

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[61] Transcript, C460-C462.
[62] Exhibit 23 (9); Transcript, C459-C460
[63] Exhibit 23 (11); Transcript, C376-C378.
[64] Exhibit 23 (1), Schedule B.

[redacted]

Emerging Foreign Exchange Problem

34. In early August 2012, Alexion received a Compliance Status statement for the January to June 2012 reporting period showing that the N-ATP for Soliris, which at $224.7333 had never changed, was above the N-NEAP at $222.2143.[66] The difference between the N-ATP and the N-NEAP was attributable to fluctuations in foreign exchange rates, particularly the value of the Canadian dollar in relation to the euro and the Swedish kroner.[67] Alexion recognized the "emerging international price comparison exchange rate issue" and asked PDCI to set up a meeting with Board Staff to discuss the matter.[68] In Mr. Haslam's words, Alexion "wanted to get out in front" of the issue and "identify what options" were "at [their] disposal to address" the problem.[69] Alexion wanted to avoid accumulation of excess revenues before the end of the next two reporting periods.[70]

First Meeting to Discuss Investigation Based Upon Foreign Exchange Issue

35. [redacted]

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[65] Transcript, C378.
[66] Joint Book, Volume 1, Tab 29; Transcript, C413-C414.
[67] Transcript, P1895-P1896.
[68] Transcript, P1896; Transcript, at P674-P677.
[69] Transcript, P1896;
[70] Transcript, P1897-P1898.
[71] Joint Book, Tab 103A; Transcript, C420-C428.
[72] Transcript, C422.
[73] Transcript, C423-C424; C427.
[74] Transcript, C424-C425.

[redacted]

Compliance Correspondence in 2013

36. On 25 February 2013, Alexion received correspondence from the Board regarding compliance status for 2012. The letter indicated that Alexion's filings had "triggered the investigation criteria in 2012 and were now the subject of investigation." The letter further stated that the price of Soliris in Canada was the "highest of the IPC test" and the company was asked to "reduce price to the 2012 N-NEAP of $214.2568" by 31 December 2013. The letter acknowledged that the Board'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, but outside the *Guidelines* in a subsequent period as a result of events other than actions directly attributed to the patentee." Alexion was notified that it was "expected to adjust the price" of Soliris "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."[77]

37. A Compliance Status Report for the period January to December 2012 was attached to the 25 February 2013 letter. The report repeated the N-NEAP of $214.2566 and indicated that "Excess Revenues", and "Cumulative Excess Revenues", of $1,666,392.09 had accrued in 2012. The CPI adjusted price was still higher than the ATP: $231.9248 based upon forecast rates and $229.9022 based upon actual CPI.[78]

38. On 25 July 2013, when filing the Form 2 for the January to June reporting period of 2013, PDCI included a note to the Board as follows:

> Please note 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 in the appreciation of the Canadian dollar [have] 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 the situation and find a resolution to this matter in an expeditious manner. We will be following up to arrange [a] date and time for a meeting.[79]

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[75] Transcript, C426.
[76] Transcript, C428.
[77] Joint Book, Volume 1, Tab 32.
[78] Joint Book, Volume 1, Tab 32.
[79] Joint Book, Volume 1, Tab 35; Transcript, C437-C438.

39. The interim Compliance Status Report for 2013 was received the next day on 26 July 2013. The Report listed an N-NEAP of $214.7355.[80]

Second Meeting to Discuss Investigation Based Upon Foreign Exchange Issue

40. Through Mr. Palmer of PDCI, Alexion made further attempts in July 2013 to "reach out" to Board Staff to arrange a second meeting.[81] In September 2013, Ms. Tognet and Michelle Boudreau, the Board's former Executive Director, made a presentation to the Board of BIOTECanada. After the meeting, they met Mr. Haslam and acknowledged the need for a meeting as "soon as possible" to discuss the investigation. Mr. Haslam characterized the need for a meeting as "an urgent issue."[82] Mr. Haslam later learned that Ms. Boudreau left employment with the Board the day after the BIOTECanada meeting. In further attempts to arrange the second meeting, Mr. Haslam was told that a meeting would have to await appointment of Ms. Boudreau's successor, who turned out to be Mr. Doug Clark. Mr. Haslam testified that he would have preferred the meeting before the end of 2013 so that Alexion could "understand what our options were" to find a resolution.[83]

41. The second meeting did not occur until 11 December 2013, a year to the day from the first meeting on 11 December 2012.[84] This time, the current Executive Director, Mr. Clark, was in attendance. [redacted]

42. [redacted]

[80] Joint Book, Volume 1, Tab 36.
[81] Transcript, C439-C440.
[82] Transcript, C440.
[83] Transcript, C440.
[84] Joint Book, Volume 7, Tab 103B.
[85] Transcript, C443.
[86] Transcript, C443-C444.

[redacted]

43. [redacted]

Re-Filing of Form 2 Documents for 2011 to 2013 to Reflect Provincial Rebates as Benefits

44. On 29 January 2014, Alexion re-filed Form 2 Block 4 information for Canadian sales from 2011 to 2013 that reflected the rebates paid to the provinces under the various PLAs. On each refiled form, under "Net Revenue" the rebates were expressed either in parentheses or as negative numbers. The class of customer was listed as "4", "other", to reflect the payments to the provinces. On the same date, Alexion also filed its original Form 2 information for the second half of 2013.[92] The refiled information was acknowledged by Board Staff on 6 February 2014.[93]

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[87] Transcript, C446-C447.
[88] Transcript, C444-C445.
[89] Transcript, C446.
[90] Transcript, C447.
[91] Transcript, C450-C453.
[92] Joint Book, Volume 1, Tab 37; Transcript, C464-C468; Transcript, P699-P701.
[93] Joint Book, Volume 1, Tab 38; Transcript, C468.

45. On 6 February 2014, Board Staff's Anna Chodos contacted John Haslam by email requesting "evidence to support any revisions to Form 2 data."[94] Mr. Palmer followed up on behalf of Alexion by email on 12 February 2014. In his note, Mr. Palmer indicated that he had recently had a "discussion with Ginette concerning the Soliris Block-4 refilings." Mr. Palmer explained that the refiled documents included the rebates to the provinces, which Alexion believed were "benefits" that "had not been previously reported to the PMPRB (for the periods July to December 2011 through January to June 2013.)" Mr. Palmer explained that the PLAs were confidential, and varied slightly by province, but all PLAs involved rebates as a [redacted] A table appended to Mr. Palmer's email showed that rebates exceeding [redacted] had been paid to the provinces under the PLAs between 2011 and the first reporting period of 2013.[95]

46. Mr. Haslam subsequently offered to come to the Board's offices to meet with Board Staff to explain the provincial rebates. Board Staff had requested copies of the PLAs and Mr. Haslam had explained that the documents were confidential and could not be copied. Mr. Haslam nonetheless informed Board staff that he would be willing, assuming he could get approval from the provinces, to attend at the Board and show them copies. Board Staff declined the offer without explanation.[96]

47. On 25 February 2014, Alexion received the Compliance Status Report for 2013. The 2013 Report showed an N-NEAP (and "Highest IPC") for 2013 of $213.9103 and an N-ATP of $216.4597. The forecasted CPI adjusted price was $220.6845 and the actual CPI was $217.2564. The excess revenues showing for 2013 were $572,697.22 and the cumulative excess revenues showing were $2,239,089.31. The "projected NEAP" was $220.3276.[97] Board Staff provided no explanations for how they arrived at the inflation-adjusted prices.[98]

Board Staff's Rejection of PLA Rebates as "Benefits"

48. On 29 April 2014, Alexion received a formal response from Ms. Tognet in response to the refiling of the Form 2 documents claiming, as benefits, rebates to the provinces under the PLAs. The letter: summarized previous correspondence; referred to the 11 December 2013 meeting; made reference to subsequent communications regarding the nature of the benefits claimed; and confirmed Alexion's offer to show Board Staff the PLA agreements. Ms. Tognet indicated that, after consultation with "Legal Counsel", Board Staff had concluded based on the Federal Court's decision in *Pfizer*[99] "that the reporting of payments or rebates to third party provinces is outside the PMPRB's jurisdiction."

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[94] Joint Book, Volume 1, Tab 39;
[95] Joint Book, Tab 39, pg. 3; Transcript, C469-C472.
[96] Transcript, C476-C477.
[97] Joint Book, Tab 41; Transcript, C472-C475.
[98] Transcript, C475.
[99] *Pfizer Canada Inc. v. Canada (Attorney General)*, [2009] F.C.J. No. 82.

Accordingly, it was "Board Staff's position at this time...that it would be inappropriate for Board Staff to consider the PLA agreements as part of the investigation into the price of Soliris." A request was made that Alexion "refile the July to December 2013 Form 2, Block 4 information to remove the information relating to the PLA agreements."[100]

49. Ms. Tognet's letter went on to state that Board Staff's "review of price and sales data" for the January to December 2013 reporting period showed an N-ATP of $216.4597, the same number included in the 2013 Compliance Status Report received by Alexion with the 25 February 2013 letter. Alexion was asked to provide a VCU and a draft was enclosed with the letter together with a table calculating alleged excess revenues.[101] The table calculated "Excess Revenues" for 2012 of $1,666,392.09 and $2,431,278.72 for 2013 with total "Cumulative Excess Revenues" totalling $4,097,670.81.[102] The draft VCU asked Alexion to: agree that the N-NEAP was $214.2568 for 2012, $213.9103 for 2013, and $220.3276 for 2014; pay Her Majesty $4,097,670.81; and provide notice to customers of a price reduction for Soliris as a result of an undertaking to the PMPRB.[103]

50. Finally, Ms. Tognet's letter pointed to possible "discrepancies" with Block 5 information filed in Alexion's Form 2 information in 2012 and 2013. She pointed out a possible problem with the German price in 2012. She also observed that there was "no price for Sweden in Board Staff's publicly available sources" for 2013. Alexion was asked to "provide an explanation of the discrepancies and copies of the source documents that the company relied on for the Block 5 information."[104]

51. In his evidence before the Panel relating to Ms. Tognet's letter, Mr. Haslam testified that it was his understanding that the *Pfizer* decision gave Alexion the option of reporting rebates under the PLAs as benefits and that it was the company's "choice to do so."[105] Alexion disagreed with Board Staff's interpretation of the *Pfizer* decision but nonetheless complied with Ms. Tognet's request to refile Form 2 information for the applicable time periods without including the rebates paid by Alexion to the provinces under the PLAs.[106]

[redacted]

52. [redacted]

[100] Joint Book, Volume 9, Tab 117, pgs. 1-2.
[101] Joint Book, Volume 9, Tab 117, pg. 2.
[102] Joint Book, Volume 9, Tab 117, pg. 4.
[103] Joint Book, Volume 9, Tab 117, pg. 8.
[104] Joint Book, Tab 117, pgs. 2-3.
[105] Transcript, C481.
[106] Transcript, C481-C482; Joint Book, Volume 1, Tab 45.

[redacted]

53. [redacted]

54. [redacted]

Further Reporting and Board Staff Responses

55. In August 2014, PDCI, on Alexion's behalf, provided Board Staff with price source information for Germany and Sweden.[116] The 2012 German Rote-Liste price for Soliris was listed at €5877.06.[117] The Swedish Apoteket price for Soliris was listed at 42,842 kroner.[118]

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[107] Transcript, C486.
[108] Transcript, C378.
[109] Joint Book, Tab 86.
[110] Joint Book, Volume 2, Tab 55; Joint Book, Volume 8, Tab 111; Transcript, P769-P772.
[111] Joint Book, Volume 8, Tab 112, Table 5.
[112] Joint Book, Volume 8, FN 12; Transcript, P773-P778.
[113] Transcript, P776-P779.
[114] Exhibits 46 and 47; Transcript, C489-C490.
[115] Transcript, C506-C507; Exhibits 46 and 47.
[116] Joint Book, Volume 1, Tab 46.

56. On 23 September 2014, Mr. Joel Weber, on behalf of the Board, wrote to Mr. Palmer, of PDCI, noting that the 2012 German price for Soliris was a hospital price and that the Board's Foreign Price Verification review process required a match to an ex-factory Pharmacy and Wholesaler price. Alexion was therefore asked to re-file Block 5 prices for 2012 to match the Board's 2012 Foreign Price Verification.[119]

57. In relation to the Swedish price, Mr. Weber stated that "Board Staff accepts the 2013 Apoteket pricing source provided for Sweden" and that "Board Staff is willing to accept Apoteket as an appropriate pricing source in this instance." Mr. Weber also noted that there was no price for Soliris in the source relied on by Board Staff, the TLV, but that "historically" Apoteket and TLV had "the same prices." Nothing in Mr. Weber's email suggested that any type of back-out formula or deductions would be applied by Board Staff to the Apoteket price.[120]

58. On 29 January 2015, PDCI, filed revised Form 2 Block 5 information on Alexion's behalf for 2012, 2013, and the first reporting period of 2014.[121] The Swedish price on all re-filed documents was 42,842 krona.[122]

59. Alexion never received any correspondence from Board Staff indicating that a back-out formula would be applied to the Swedish price. In fact, the 2015 document published by the Board on "Recognized Sources for Foreign Price Verification and Formulas" states that there is "no need to "back-out" prices from Sweden if TLV is used: the AIP price corresponds to an ex-factory pharmacy price."[123]

Losses on Foreign Currency Transactions

60. Mr. Haslam testified that because two-thirds of Alexion's sales are outside of the United States, the company attempts "to limit their exposure [to currency fluctuations] through hedging practices."[124] He explained that Alexion buys foreign currency "to limit the swing in revenues that could happen as a result of change in currencies." He further testified that the purpose of the hedging strategy was "simply to reduce and maintain the risk of the impact of foreign currencies on [Alexion's] revenue." Dr. Putnam noted that companies use hedging strategies to mitigate the effects of currency fluctuations "so that

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[117] Joint Book, Volume 1, Tab 46 (last pg.).
[118] Joint Book, Volume 1, Tab 46 (pg. 9).
[119] Joint Book, Volume 1, Tab 47.
[120] Joint Book, Volume 1, Tab 47.
[121] Joint Book, Volume 1, Tab 89.
[122] Joint Book, Volume 1, Tab 49.
[123] Joint Book, Volume 7, Tab 94.
[124] Transcript, P. C531.

business operations aren't blown about by the winds of foreign exchange rate movements."[125] Based upon an analysis of foreign currency gains and losses presented by Prof. Schwindt[126] Mr. Haslam was able to conclude that "the company lost US $10 million" "cumulatively" from "2009 to 2016..."[127] on Canadian sales of Soliris.

Impact of Soliris on Patients

61. Two PNH patients, Matthew George and Barry Katsof, testified at the hearing about how Soliris had affected their lives.

a) Matthew George

62. Mr. George, now 36, manages G & B Masonry, Inc., a construction company in Kitchener, Ontario with 26 employees.[128] He was diagnosed with PNH in 2004 when he was 24.[129] The symptoms of the disease emerged when he was 20 years-old. One morning he saw blood in his urine and felt fatigued and nauseated.[130] His family doctor diagnosed a kidney infection and he was treated with antibiotics. About 10 days later, however, the symptoms recurred and he was referred to a urologist.[131] The urologist conducted several tests including cystoscopy and x-rays. In the meantime, the symptoms of "painful" fatigue, spots on his eyes, jaundice, severe acne, and nausea persisted. He was prescribed antibiotics and pain killers to deal with the symptoms.[132]

63. During a Caribbean vacation with friends in 2004 Mr. George again experienced blood in his urine, vomiting, and pain throughout his body. The pain worsened and he had difficulty breathing. He testified that had he the strength to get out of bed, he "would have thrown [himself] off the balcony." The experience was "extremely painful... mentally and physically."[133] Upon returning to Canada, Mr. George visited the Emergency Department at St. Mary's Hospital. The emergency room doctor recommended that Mr. George see a tropical disease specialist who in turn referred Mr. George to a gastroenterologist. The gastroenterologist ordered blood tests and, in a follow-up appointment, referred Mr. George to a hematologist, Dr Saeed. Dr. Saeed diagnosed Mr. George with PNH. She told him "it

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[125] Transcript, P. P1589-P1590.
[126] Transcript, P. C242.
[127] Transcript, C 533-C534.
[128] Transcript, P1934.
[129] Transcript, P1935.
[130] Transcript, P1936.
[131] Transcript, P1935-P1936.
[132] Transcript, P1937-P1938.
[133] Transcript, P1938-P1939.

was a very dangerous disease." All she could do was recommend regular visits every 4 months, rest, and to drink water.[134]

64. After the PNH diagnosis, Mr. George's health steadily continued to decline. During some episodes, there were large amounts of blood in his urine and he was in bed for 2 to 3 weeks at a time, requiring help even to get to the bathroom. While he worked when he could, the quality of his life was very poor. He conducted his own research on PNH and Dr. Saeed referred him to Dr. Brian Leber, a specialist at McMaster University in Hamilton. Dr. Leber informed Mr. George about the possibility of bone marrow transplants but told him it was "extremely risky" and he could die if the transplant did not work. Dr. Leber also informed Mr. George that he had only a 15% chance of living another 20 years and that there was very little that could be done.[135]

65. Mr. George sought yet another specialist opinion and was referred to Dr. Ian Chin-Yee at the London Health Sciences Centre. Dr. Chin-Yee was well-informed about PNH and could explain the impact the disease was having. Mr. George was comfortable seeing him.[136] After being called by Dr. Chin-Yee's office in late 2010 or early 2011, Mr. George attended an appointment and was told a new medication, Soliris, had been approved by Health Canada. Mr. George was asked about whether he had private health insurance and Dr. Chin-Yee said he would put Mr. George in touch with the "One-Source" program. Private health insurance was available to Mr. George through his partner Jeff, who worked for the Waterloo Region District School Board. It took approximately 4 weeks for Mr. George to get his first treatment at an Innomar infusion clinic in Burlington, Ontario in late February or early March 2011.[137]

66. While Mr. George was initially apprehensive, he testified that the first infusion turned out to be "the most important day of my life so far." Mr. George said that within 10 minutes of receiving the infusion "I got my life back." He could feel relief almost immediately. His fatigue lightened: "It felt like someone pulled the plastic bag off of my face." After the first infusion, his urine wasn't dark anymore. His appetite returned. After further infusions, his "body [began] to repair itself", and he saw "improvements in all of my symptoms as well as the way I felt." The fatigue went away, he gained weight, the jaundice disappeared, and his life returned to normal.[138] Currently, Mr. George receives home infusions every 14 days. He is not charged for the infusions.[139]

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[134] Transcript, P1940-P1945.
[135] Transcript, P1945-P1947.
[136] Transcript, P1947-P1948.
[137] Transcript, P1948-P1949.
[138] Transcript, P1950-P1953.
[139] Transcript, P1953-P1954.

67. After his successful treatment with Soliris, Mr. George has volunteered his time to work in the rare disease community. He believes that people with rare life-threatening diseases are often overlooked. He wants them to know whether there are answers for them, as there were for him.[140]

68. When asked about the cost of Soliris, or whether it is "expensive" or "high-cost", Mr. George responded as follows:

> I can appreciate that there is a high cost for this medication but for what this medication has done for me and what that is, it has saved my life.
>
> And I can certainly say that if I had not received this drug when I did that I would not be here today, and not only not be here today but living a fantastic life. I'm living the dream. I am running a business. I'm employing people. I have a great relationship with my partner. I have a great family and great friends.
>
> I can do basically everything that anybody else that has a normal life can do, and that they take -- a lot of people take for granted.
>
> So when I'm asked about that, I certainly can say that, yes, there is a high cost to it but, in my opinion, it certainly is a bargain.[141]

69. Mr. George was not cross-examined on his evidence.[142]

b) Barry Katsof

70. Mr. Barry Katsof, now 69, is retired. In his business life, he founded a company that specialized in electronic security and money processing equipment for financial institutions. After retirement, Mr. Katsof founded the PNH Patients Association of Canada ("Association") in 2009. He is currently the president of the Association.[143]

71. The Association educates PNH patients about the disease and advocates for patient access to treatment. The Association conducts regular information sessions across Canada and provides support to PNH caregivers. Most recently, the Association sponsored a meeting in Montréal which included patients from Québec and Atlantic Canada. A PNH specialist addressed the meeting. Individual PNH patients told their individual stories and experiences with the disease. Furthermore, the Chief Medical Officer of Ra Pharma, a company that is developing a biosimilar treatment to Soliris, spoke at the

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[140] Transcript, P1952-P1953.
[141] Transcript, P1954-1955.
[142] Transcript, P1955.
[143] Transcript, P2191-P2192.

meeting.[144] Mr. Katsof receives no personal compensation for his activities with the Association and, in fact, donates his own time and that of his part-time office staff to the Association.[145]

72. As president of the Association, Mr. Katsof keeps himself current on alternative treatments for PNH currently being developed in the industry. He testified that Ra Pharma, Keryx, Apellis Pharma, and Amgen are all working on alternative treatments. The Association currently receives unconditional grants, in roughly equal amounts, from Alexion and two of the other companies, Ra Pharma and Apellis.[146]

73. Mr. Katsof himself suffers from PNH. He began experiencing symptoms in 2001 and was diagnosed approximately 2 years later in 2003.[147] In his own words, Soliris "gave me my life back." Before he began showing symptoms, Mr. Katsof participated in a 500 mile, 5-day, bicycle ride from Montréal to Portland, Maine. "A few years later" after being diagnosed, he "was no longer able to get on" his bicycle. After treatment with Soliris, he is able to "do 25 or 30 km at a fairly good clip."[148]

74. Mr. Katsof does not pay for Soliris. The Québec government covers the costs. Because a Canadian patient cannot purchase outside of Canada, when he travels, Mr. Katsof, like other patients, obtains an advance supply of Soliris with the payer's approval. Mr. Katsof, or any other PNH patient travelling with Soliris, is required to prearrange infusions and to pay infusion costs wherever the medicine is infused outside Canada. Physicians prescribing Soliris prepare letters for airport security, customs, etc.[149]

75. Mr. Katsof, who assists other PNH patients to obtain funding from insurers for Soliris treatment, typically asks insurers to look at objective criteria in determining whether to fund treatment in individual cases. In particular he urges insurers to look at LDH levels, measure of "hemolysis, the breaking up of the red blood cells in the system." If LDH levels return to normal after treatment with Soliris, then funding should continue: if LDH levels do not respond to treatment, then treatment can be stopped.[150]

76. In cross-examination, Mr. Katsof testified that the price of Soliris would not be considered expensive to some people. In his words:

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[144] Transcript, P2192-P2193.
[145] Transcript, P2200.
[146] Transcript, P2193-P2195; P2206.
[147] Transcript, P2196.
[148] Transcript; P2197.
[149] Transcript, P2197-P2199.
[150] Transcript, P2202-P2203.

> "If you can define how you put a price on a human life, then maybe we can say the drug is expensive or not. But we're talking about a human life. How do you put a price tag on a human life."[151]

77. Mr. Katsof, and other witnesses including Mr. Lun and Mr. Haslam, testified that only 1.5 or 2% of the total annual drug cost to governments goes to drugs used to treat rare diseases.[152]

Research and Development and Related Activity in Canada

78. In late 2011, Alexion spent $1.1 billion to purchase Enobia, a Montréal company involved in research and development of asfotase alfa (or Strensiq), a drug used to treat hypophosphatasia, a rare genetic disorder that impairs bone development.[153] In Parliament, the Standing Committee on International Trade, when addressing R&D under the *Patent Act*, was informed by a witness that:

> [Enobia] took their drug to a point and they sold it to Alexion...for $1.1 billion. That money is in Canada, and it will get reinvested in other start-ups.
>
> That's the kind of ecosystem that's taking place. I think that's something we would like to keep in this country.

79. While it may not strictly qualify under the reporting provisions of the *Act*, Alexion has engaged in substantial research and development in Canada through the company's global research facility.[154] The challenges of conducting clinical trials for ultra-rare disease medicines means the company must locate patients in 25 to 30 different countries, including Canada, to obtain sufficient numbers of clinical trial participants to determine whether a medicine has a meaningful impact for a particular rare disease.[155] Since 2009, Alexion has conducted significant research and clinical trials in Canada in relation to Strensiq (for hypophosphatasia), Soliris (for myasthenia gravis, neuromyelitis optica, and delayed graft function), and Kanuma (for lysosomal acid lipase deficiency, or "LLAD"). In addition, Alexion has conducted first in human trials for other products, including Alexion 1101 and 1501, using research facilities located in Montréal.[156] The total amount spent on clinical trials and research in Canada is about $20 million.[157]

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[151] Transcript, P2224-P2225.
[152] Transcript, C888, P2224.
[153] Exhibit 43; Transcript, P1829.
[154] Transcript, P1840-P1841.
[155] Transcript, P1840-P1841.
[156] Transcript, P1841-P1843.
[157] Transcript, P1885; C916-C919.

Evidence of Richard Lemay

80. Board Staff initially delivered the witness statement of Ginette Tognet, the Board's Director of Regulatory Affairs and Outreach Branch, in early May 2016.[158] Ms. Tognet was involved in the investigation from the beginning and was the author of several key letters and emails from the Board to Alexion delivered between 2010 and 2015 relating to the pricing of Soliris.[159] Ms. Tognet also participated in two meetings between Alexion and Board Staff that dealt with the investigation and attempts to resolve pricing issues.[160]

81. On 15 November 2016, Board Staff delivered a witness statement of Mr. Richard Lemay. In the cover letter, Board Staff counsel stated that Ms. Tognet was "no longer available to give evidence as a witness at the upcoming hearing due to her impending retirement."[161]

82. At the commencement of Mr. Lemay's evidence in chief, however, it became apparent that Ms. Tognet still held the Director's position.[162] On the record, Mr. Morris refused to provide any explanation for why Ms. Tognet was "unavailable" to give evidence. He also represented to the panel, inaccurately, that no representations had been made about Ms. Tognet's retirement.[163]

83. Despite objections, Mr. Lemay was essentially led through, and asked to read from, various documents in the Joint Book of Documents. A cursory review of the transcript of Mr. Lemay's evidence in chief reveals that dozens of questions Mr. Morris asked were suggestive of the answers he hoped to obtain from Mr. Lemay.[164] Indeed, on several occasions, Mr. Morris even corrected answers given by Mr. Lemay.[165]

84. In his cross-examination, it was revealed that Mr. Lemay was a career civil servant, having held several previous positions, none of which involved price regulation or anything similar. He had difficulty recalling specific job duties performed in his previous positions.[166]

85. Mr. Lemay joined the Board in April 2015, three months after the Statement of Allegations was issued. It became apparent early in the cross-examination that apart from reviewing some tables

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[158] Witness Statement of Ginette Tognet.
[159] For example, see Joint Book, Volume 1, Tab 14; Volume 2, Tab 55; Volume 9, Tab 116; and Volume 9, Tab 117.
[160] Joint Book, Volume 7, Tab 103(A) and 103(B).
[161] See correspondence Guillaume Couillard from David Migicovsky dated 15 November 2016 with attached witness statement of Richard Lemay.
[162] Transcript, P161-P163.
[163] Transcript, P164-P165.
[164] Transcript, P170; P174; P178-P180; P182; P191; P193-P194; P200; P224-P-225; P227-P229; P231; P-233-P234; and P235: C27-C28; C31; C34-35; C37; C40; C41; C45; C61; C64; C73; C78; C79; C80-C81; C90; C92; C99; C101; C105-C106; C108; C109; C112; C117-C118; C127; C128-C129; C142; C150; C154; C155-C156; C160; C163- C164; C165; C166; C167-C168; C171; C172; C173; and C176.
[165] Transcript, P176-P177; P193; P225; C46-C47; C79; C172-C173.
[166] Transcript, P362.

relating to Soliris prepared by other Board Staff members, Mr. Lemay had almost no involvement, or knowledge, of the Soliris investigation.[167] Mr. Lemay never read the original Statement of Allegations or the Confidential Appendix A to the original Statement of Allegations.[168] He was generally unaware of the intervention by the B.C. Minister in the proceeding.[169] Mr. Lemay could not specifically remember what tables he reviewed or when he began to review tables.[170] He initially refused to identify individual Board Staff members who had prepared the tables, referring only to "Board Staff"; his evasive answers were supported by counsel.[171] It took a specific direction from the Panel before Mr. Lemay would name individual Board Staff members involved in the investigation.[172]

86. Mr. Lemay did not become aware he would be a witness until November 2016, about 8 weeks before the hearing commencement.[173] After becoming aware that he would be a witness, Mr. Lemay "went over the records", including Board documents relating to Soliris that were not produced to Alexion or the Panel.[174]

87. Mr. Lemay had limited or no knowledge of basic facts about the Board's operation. For example, he could not provide even basic information about the Board's automated filing system whether historically or currently.[175] He was not familiar with the initial communications between Alexion, or PDCI, and the Board.[176] Mr. Lemay was not generally familiar with documents and records obtained and maintained by the Board.[177] Nor was Mr. Lemay aware whether any Board Staff member outside HDAP read the product monograph for Soliris: he testified that he has never read a product monograph or DIC report himself in relation to any drug and was uncertain whether Ms. Lombardo, an experienced Board manager with a "science" function who worked on Soliris before she left the Board, had read the Soliris product monograph.[178] Mr. Lemay was not aware of communications between the Board and CADTH, whether a Board Staff member had been a member of a CADTH committee, or whether the Board received CADTH Common Drug Review reports.[179] Mr. Lemay was not immediately familiar with

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[167] Transcript, P368-P369; P378-P379.
[168] Transcript, P654.
[169] Transcript, P707-P708.
[170] Transcript, P372.
[171] Transcript, P373.
[172] Transcript, P370-P376.
[173] Transcript, P378.
[174] Transcript, P380-P383.
[175] Transcript, P389; P561-P563.
[176] Transcript, P390.
[177] Transcript, P550-P551.
[178] Transcript, P391-P392; P414.
[179] Transcript, P565-P567.

customer class codes used on Form 2 documents designating hospital and pharmacy customers.[180] Nor was he familiar with the designation "FSS" in relation to one U.S. price source.[181]

88. Without being referred to a document, Mr. Lemay was not immediately aware that Soliris came in a 300 mg single-use vial,[182] or familiar with how the standard unit of measurement used for Soliris—"10 mg/mL solution" was arrived at or used.[183] Despite having a background in finance, he was unwilling to multiply 30 times 10 to arrive at the number of milligrams of Soliris in a 300 mg vial.[184] He had difficulty identifying specific terms used by the Board or mentioned in the *Guidelines* and was not aware whether Board Staff had conducted its own research in relation to Soliris before the DIC submission was made to the HDAP.[185] Mr. Lemay had little familiarity with the concept of an Anatomic Therapeutic Class Classification (or "ATC") used in the *Guidelines* and HDAP review process.[186] In the course of working on the case, Mr. Lemay did not investigate or research the two health conditions—PNH and aHUS—that Soliris is used to treat.[187] Mr. Lemay had no familiarity with the previous *Guidelines*,[188] and, apart from being aware that an NOC is mentioned in a Form 1,[189] was not familiar with the process under which Health Canada issues an NOC or assigns a DIN.[190] Mr. Lemay had never cross-referenced the Forms filed by patentees with the requirements under the *Regulations*.[191]

89. Mr. Lemay claimed to have no knowledge of how Soliris was dosed for a PNH patient.[192] When taken to "recommended dose and dosage adjustment" in the product monograph for Soliris, however, Mr. Lemay acknowledged that it was the "type of information that the Board pays attention to."[193] In a series of questions, Mr. Lemay acknowledged that documents in Board Staff's possession, including the original product monograph, submissions to HDAP, CDR reviews, and internal calculations, would have made Board Staff aware of the annual cost of treatment of Soliris for a PNH patient and later for an aHUS patient.[194]

90. Mr. Lemay agreed that one of the primary objectives of the *Guidelines*, and indeed of Board Staff, was to "ensure that patentees are aware of policies, *Guidelines*, and procedures" that inform a

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[180] Transcript, C31.
[181] Transcript, C175.
[182] Transcript, P396-P397.
[183] Transcript, P549; P555.
[184] Transcript, P556-P560.
[185] Transcript, P407-P408.
[186] Transcript, P410-P411; P417-P418.
[187] Transcript, P412.
[188] Transcript, P529-P532.
[189] Transcript, P550.
[190] Transcript, P548.
[191] Transcript, P575.
[192] Transcript, P401-P402; P557.
[193] Transcript, P394.
[194] Transcript, P394-P396; P400-P401; P415-P419; P570-P573.

patentee "when a price appears to be excessive".[195] He also agreed that Board Staff had an obligation to uphold "principles of fairness, transparency, openness, and predictability" and that the principles were important and observed and applied by Board Staff.[196]

91. Mr. Lemay agreed that the "only factor" that triggered the investigation in 2012 leading to the current proceedings was "variations in currency [exchange] rates that made it appear that the price of Soliris [in Canada] was higher than the 7 comparator countries" as found in Schedule 6 of the current Guidelines."[197] He acknowledged that this sole factor was confirmed in correspondence to Alexion dated 25 February 2013, which referred to the apparent violation of the HIPC as the "trigger" for the investigation.[198]

92. Mr. Lemay explained that he had "no input" in the process of selecting or applying sources for foreign prices; selection of alternative sources is conducted entirely by the "Policy Branch" of the Board.[199] For example, in 2016, the Board changed the foreign source for Germany from the Rote-Liste to another foreign source, the Lauer-Taxe: Mr. Lemay testified that he did not "have the rationale behind why" the change was made.[200] He acknowledged that the change in foreign source could have a significant impact on a patentee.[201] Board Staff in the Policy Branch confer directly with governmental officials and others in foreign countries about the alternative sources.[202]

93. In his witness statement and evidence in chief, Mr. Lemay mentioned "discrepancies" and the consequences if Block 5 information filed by a patentee was "not correct."[203] It was implied that "discrepancies" involved inaccurate reporting by Alexion of foreign prices.[204] When Mr. Lemay was taken to a table prepared for the litigation (but not by Mr. Lemay[205]) it became apparent that, in the majority of cases, discrepancies involved Board Staff finding *higher* prices in their foreign sources than the prices reported by Alexion.[206] Between 2012 and 2014, 7 of 9 "discrepancies", or differences, between Alexion and Board Staff foreign prices were favourable to Alexion (in that Board Staff's foreign

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[195] Transcript, P522-P524.
[196] Transcript, P524-P525.
[197] Transcript, P541.
[198] Joint Book, Tab 32; Transcript, P544-P546; P614.
[199] Transcript, P594-P595; P597.
[200] Transcript, P616-P617.
[201] Transcript, P616-P617.
[202] Transcript, P599-P600.
[203] Transcript, C14 (17 January).
[204] Transcript, C25; C99-C100; C118; C123; C128; (18 January).
[205] Transcript, P648-P649.
[206] Transcript, P619-P622.

Soliris prices were higher than the prices reported by Alexion).[207] At no time did Board Staff disclose or reveal to Alexion the higher prices for Soliris that they found.[208]

94. It became apparent from Mr. Lemay's cross-examination that Board Staff's letter of 3 July 2015 delivered in response to the Panel's June 2015 Order for Particulars ("Disclosure Letter"), Board Staff counsel had made several representations to Alexion that were inaccurate, untrue, or incomplete. In particular, the Disclosure Letter stated that a comparison of prices reported by Alexion on Block 5 and foreign source prices found by Board Staff either "matched" or "matched with minor discrepancies."[209] When cross-examined, however, Mr. Lemay acknowledged that: (a) several prices represented by Board Staff counsel as "matching" did not "match"; (b) most "minor discrepancies" favoured Alexion;[210] and (c) Board Staff had failed to disclose several material discrepancies in Alexion's favour.[211] More specifically:

(a) **No Match**—The Table on page 6 of the Disclosure Letter states that the 2013 price reported by Alexion for Sweden "matched Board Staff's prices." This statement was false. The 2013 Swedish price found by Board Staff was $217.2790, $3.37 *higher* than the Swedish price of $213.9103 reported by Alexion.[212] Similarly, page 6 of the Disclosure Letter stated that Board Staff's prices and Alexion's reported prices for the United States "matched...with minor discrepancies due, in part, to rounding from to the fourth decimal place." This statement was also false: the 2014 price found by Board Staff for the United States was $1.66 *higher* than the price reported by Alexion (significantly *higher* than a rounding to the fourth decimal place.)[213]

(b) **Minor Discrepancies Favour Alexion**—The "minor' discrepancies for France for 2012 and 2014, and German for 2014, favoured Alexion.[214]

(c) **Discrepancies in Alexion's Favour Not Disclosed**—The Disclosure Letter did not disclose a 2013 Italian price found by Board Staff that was $9.27 *higher* than the price found by Alexion .[215] Nor did the Disclosure Letter disclose that Board Staff's 2013 price for France was about $2.20 *higher* than the price reported by Alexion.[216]

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[207] Transcript, P649-P651.
[208] Transcript, P621; P623; P631-P633; P638; P641; In Exhibit 4A, a document prepared in January 2017 days before the hearing, Board Staff included a footnote suggesting that higher prices discovered by Board Staff did not have an "impact" on excess revenues.
[209] Joint Book, Tab 111, pg. 6; Transcript, P624;
[210] Transcript, P620-P621;
[211] Transcript, P620-P622
[212] Transcript, P636-P638; Exhibit 4A.
[213] Transcript, P639-P640; Exhibit 4A.
[214] Transcript, P620, P623 (France); P628 (Germany); Exhibit 4A.
[215] Transcript, P629-P631; Exhibit 4A.
[216] Transcript, P620-P622; Exhibit 4A.

95. In his evidence, Mr. Lemay acknowledged that, from his review of the file, the meetings between Alexion and Board Staff in December 2012 involved "an exchange rate issue" that "no one can control."[217]

96. Mr. Lemay was taken to various tables, none of which he had prepared, detailing alleged excess revenues. He agreed that a table found at Tab 98(1), delivered by Board Staff in early May 2016, showed a 2017 N-NEAP of $217.27, which reduced excess revenues for 2013 by several hundred thousand dollars, thereby reducing total alleged excess revenues for the period between January 2012 and December 2014 to $4.743 million.[218] Mr. Lemay attributed the reduction to a "refile" by Alexion, as recorded in a document found in the Joint Exhibit Book at Tab 83.[219] Mr. Lemay was then taken to a chart prepared by Board Staff in late May 2016, when Board Staff sought amendments to the Statement of Allegations, showing an N-NEAP for 2013 of $215.62 and total alleged excess revenues of $4.743 million.[220] A table delivered by Board Staff in December 2016 showed an N-NEAP for 2013 of $215.62 with excess revenues decreasing to $4.378 million.[221] Ultimately, Mr. Lemay could not explain why the alleged excess revenue numbers in the different tables had changed.[222] He did acknowledge, based on the first reporting period for 2016, the N-NEAP had increased to $225.11 and that no excess revenues had accumulated to the end of June 2016.[223]

97. When taken through the *Guidelines*, Mr. Lemay acknowledged that the MIPC test applies to the introductory price of a Category 2, breakthrough, medicine. He agreed that there was nothing in Schedule 5 of the *Guidelines* suggesting that a patentee should establish a buffer or set the introductory price lower than the MIP.[224] He also acknowledged that there was no mechanism in the *Guidelines* for re-setting an introductory price (if the new drug is sold in more than 5 countries) and that the *Guidelines* contained no lowest international price comparison test (or "LIPC").[225]

98. Mr. Lemay acknowledged that IMS MIDAS data is not mentioned in the *Guidelines* and that IMS data, to the extent it is mentioned in the *Guidelines* is not from IMS MIDAS only used for comparator drugs in the same therapeutic class, and would not apply to a breakthrough drug where there are no comparators.[226] While the possibility of using foreign IMS data when a drug is not listed on a recognized

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[217] Transcript, P695.
[218] Transcript, P717.
[219] Transcript, P717-P720.
[220] Transcript, P721-P722; Joint Book, Volume 8, Tab 112, Table 1.
[221] Joint Book, Volume 8, Tab 113, Table 3.
[222] Transcript, P724-P725.
[223] Transcript, P725-P726; Joint Book, Volume 8, Tab 113, Table 3.
[224] Transcript, P736-P737.
[225] Transcript, P440-P441.
[226] Transcript, P741-P743.

foreign source was mentioned, IMS MIDAS in not included in the *Guidelines*, the Patentee's Guide to Reporting, or in any document on the Board's website dealing with foreign price verification.[227]

99. Mr. Lemay could not point to any other instance where the Board has dealt an instance of the HIPC being triggered based on foreign currency variations, described as "unusual circumstances" in Schedule 6 of the *Guidelines*. He could point to no VCU or decision raising the point. Moreover there is no guidance on the Board's website dealing with the issue.[228]

Failure to Prove Foreign Price Verification and Back-Out Formulae

100. In his report, Mr. Soriano expressed concerns about the formulae used by Board Staff to "back-out" amounts to "arrive at ex-factory prices for the purposes of the review."[229] Mr. Soriano commented that the Board had "not explained its methodology/analysis undertaken to determine the formulae, and the methodology" was "not apparent" to him. He further observed that about $2 million in excess revenues were attributable to application of the formulae and that the formulae "changed from year to year."[230]

101. Mr. Soriano also addressed the "back-out" formulae in his testimony before the Panel. His testimony was predicated on the overarching premise that "the analysis and methodology" must be "fair" "from a financial perspective".[231] He observed that the approach of the PMPRB was "very high-level and did not have the granularity that would allow someone to properly assess the underpinnings of their calculations."[232] Mr. Soriano pointed out that "the basis for the inputs" of the Board's "mechanical calculations, were not explained."[233] The problem was compounded because the formulae used by Board Staff changed from year to year. Overall, the appropriate detail a financial expert would normally expect was absent from Board Staff's calculations based on the back-out formulae.[234]

102. Mr. Soriano further testified that it was difficult to determine the "veracity of the inputs" to "backing out formulas" and that he did not "understand the basis for...adjustments that had been made in these mechanical calculations."[235] The price sources were also a concern because there were "different pricing sources for different years."[236] Mr. Soriano testified that he was "unable to agree with

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[227] Transcript, P745-P747.
[228] Transcript, P767-P769.
[229] Exhibit 73, pg. 8-9.
[230] Exhibit 73, pg. 8-9.
[231] Transcript, P2272-P2273.
[232] Transcript, P2273.
[233] Transcript, P2273.
[234] Transcript, P2274.
[235] Transcript, P2292-P2293
[236] Transcript, P2293;Transcript, P2295-P2294.

those back-outs because" he was not presented with "information to assess them properly."[237] Pointing to the Swedish prices and the apparent change in the methodology of applying sources in that country, Mr. Soriano described the "opaqueness...in terms of what they're actually doing with these back-outs." In cross-examination, Mr. Soriano repeated that he "was not clear on the basis for the inputs to the formulas."[238]

103. At several points in the cross-examination, it was suggested to Mr. Soriano that Mr. Lemay's evidence provided an explanation sources and the back-out formulae.[239] In his evidence, however, Mr. Lemay merely pointed to the website as the origin of the sources and formulae; he provided no evidence on "inputs", how the formulae were arrived at, or why formulae were changed. [240] Indeed, Mr. Lemay had no knowledge on the topic and acknowledged that the "Policy Branch" was responsible for that aspect of the Board's operation.[241]

104. During cross-examination, Mr. Soriano was taken to a document prepared by Board Staff after Mr. Soriano delivered his expert report in mid-April 2016. Initially, Board Staff counsel attempted to mislead Mr. Soriano by suggesting that the document had been available before Mr. Soriano's report was delivered. The document, a table found at Tab 98 (7) of the Joint Book, delivered in early May 2016 showed a purported rejection by Board Staff of the Swedish Apoteket price in Form 2 documents.[242] The table at Tab 98 (7) is directly contrary to an email Alexion received from Mr. Weber of the Board on 23 September 2014 stating that "Board Staff accepts the 2013 Apoteket pricing source." Other than the internal Board document, there was no evidence that the Board had ever communicated to Alexion that Board Staff had "not accepted" the re-filed Apoteket price.[243]

Non-Traded Goods

105. A traded good can be freely imported or exported between countries.[244] A non-traded good cannot be imported or exported for any one or more of a number of reasons.[245] In Canada, The *Food and Drugs Act,* prevents medicines like Soliris from being imported into Canada by individual purchasers.[246] The *Food and Drugs Act and Regulations*, prohibits drug importation into Canada. Section A.01.040 of the *Food and Drugs Regulations* provides:

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[237] Transcript, P2295.
[238] Transcript, P2404.
[239] Transcript, P2404-P2405; P2411;
[240] Transcript, C120-C124.
[241] See para. 90; Transcript, P594-P595; P597.
[242] Joint Book, Tab 98 (7); Transcript P2420.
[243] Transcript, P2420-P2421.
[244] Transcript Putnam, P1531.
[245] Transcript Putnam, P1531.
[246] Transcript, P1531-1532.

> "Subject to s.A.01.044, no person shall import into Canada for sale a ...drug the sale of which in Canada would constitute a violation of the *Act* or these Regulations.

None of the exceptions applies to an individual purchaser.[247]

106. Medicines are, therefore, "non-traded goods".[248] Non-traded goods are treated as "unique goods". Even though Soliris is sold in other countries, it is not "Canadian Soliris", which is a "unique good".[249]

107. Because Soliris is a non-traded good, the only relevant market in Canada is for patients with PNH and aHUS and the only product is ('Canadian') Soliris.[250]

108. The relative price of the Canadian dollar compared to other currencies is irrelevant to the calculations made by a consumer in Canada or any other purchaser or body that reimburses the cost of Soliris in Canada (a private insurance company or publicly-funded drug benefits agency).[251] Because Soliris cannot lawfully be imported into Canada, it makes no difference whether in theory it could be imported more cheaply into Canada from the U.S. or any other market because Soliris simply cannot be lawfully imported.

109. Because medicines including Soliris are non-traded goods and cannot lawfully be purchased from outside Canada (at any price) and imported into Canada, a consumer or other purchaser in Canada is neither worse nor better off as the Canadian dollar fluctuates in value relative to the currencies of other jurisdictions in which the medicine is also sold.[252] Accordingly, there is no impact on a Canadian purchaser whether the Canadian dollar increases or decreases relative to the foreign currency because that purchaser cannot lawfully acquire the non-traded good and import it into Canada. Depending on exchange rates, at any given time a purchaser could, in theory, get a better deal at some times and a worse deal at other times. But this is only a theoretical proposition because no real transactions occur and there is no point to any such transaction: the medicine from outside of Canada cannot be (lawfully) imported into Canada.[253]

110. When a good is non-traded, like Soliris, one must consider the price in the relevant market, for example, in Canada, and in some other country, not the price of Soliris in the other country converted to Canadian dollars. No consumer actually pays that 'converted' price for the very reason that Soliris is a non-traded good. In short, a resident of Canada cannot be in a worse position as the result of

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[247] *Food and Drugs Regulations*, A.01.040, A.01.044, C.01.003, C.01.014(1), C.08.002(1).
[248] Putnam Report, Exhibit 34, para. 18(d).
[249] Transcript, P1531.
[250] Transcript, Putnam P1531.
[251] Transcript, Putnam P1562-P1563.
[252] Transcript, Putnam P1564.
[253] Transcript, Putnam P1564.

fluctuations in exchange rate of the Canadian dollar against foreign currencies because Soliris from another jurisdiction is not within a group of goods that residents of Canada may potentially consume.[254]

Evidence of Jonathan Putnam

111. In Dr. Putnam's opinion, the price of Soliris is not excessive within the meaning of the *Patent Act*.[255] The price has remained constant from its introduction on the market in Canada in 2009 until today.[256] In fact, the price of Soliris in Canada has actually fallen in real terms since its introduction in because of the effects of inflation from 2009 to today.[257]

112. The effect of the decline in price of Soliris means that a Canadian consumer's position has actually improved since the drug was introduced.[258] Soliris is costly, but as the Board Staff itself recognized after Soliris' introduction to the market in Canada, its price was not excessive in 2010 and 2011.[259]

113. As an economist, Dr. Putnam's opinion was that it is impossible to conclude that the price of Soliris was excessive between 2012 and 2014 if the price was not excessive between 2010 and 2011 because the price in Canada did not increase (in fact, in real terms it decreased) and the price did not decrease in other countries.[260]

114. In Dr. Putnam's view, Board Staff have identified a problem with the price of Soliris where none exists.[261] The only reason Board Staff conclude that the price of Soliris is excessive is that their methodology takes into account specific foreign currency exchange rate fluctuations relative to the Canadian dollar. Foreign exchange rate fluctuations are irrelevant to the evaluation of the price of a non-traded good. If that good cannot be lawfully imported in to Canada, then the currency differential must, as a matter of simple logic, be irrelevant.[262] As foreign currencies fluctuate in relation to the Canadian dollar, the positions of consumers or purchasers of Soliris in Canada does not change at all, either in absolute terms or relative to the position of consumers in other countries.[263]

115. Dr. Putnam's opinion is that the test methodology employed by Board Staff is unreliable. Sometimes the test arrives at the correct answer and sometimes it does not. He accepts the results of

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[254] Transcript, Putnam, P1734.
[255] Report, para. 10.
[256] Report, para. 10.
[257] Report, paras. 11 and 14.
[258] Report, para. 11.
[259] Report, para. 14; Transcript, Schwind, P962-P963.
[260] Report, para. 11; Transcript, Putnam, P1629.
[261] Report, para. 14.
[262] Report, para. 10.
[263] Report, para. 10.

the HIPC test (applying the currency exchange rate methodology) for the years 2010 and 2011 but says that alleged violations in later years do not demonstrate that Alexion did anything wrong; rather, it demonstrates that the Board's test is simply unreliable.[264]

116. Board Staff's two economist experts try to avoid the conclusion that exchange rate fluctuations are irrelevant to the price of a non-traded good by two methods: (1) Dr. Addanki constructs a "relevant market" test that does not actually include medicines in any relevant market, or in any market that the *Patent Act* recognizes or that any economist would recognize.[265] He compares the price of 'Canadian' Soliris to the price of 'U.S.' Soliris converted to Canadian dollars. This confuses the price of U.S. Soliris—a good that is unavailable to residents of Canada—with the value of the U.S. dollar;[266] and (2) while Prof. Schwindt recognizes that Soliris is a non-traded good, he uses nominal exchange rates to compare the price of Soliris in Canada to the price of Soliris in other countries just as Board Staff have done, and thereby reaches the same erroneous conclusion.[267]

117. Dr. Putnam specifically considers the two major rationales for price regulation: (1) potential harm to consumer welfare (in this case including parties who pay for a medicine); and (2) potential harm to competition.[268] He concludes that neither of these harms exist in this case. His analysis is conducted applying the factors specified in s. 85(1) of the *Patent Act*[269] and he concludes that:

> (a) The relevant market is products approved by Health Canada for the treatment of PNH and aHUS;
>
> (b) Soliris is the only medicine in that market (because it has no close substitutes);
>
> (c) The relevant geographic market is Canada (because Soliris is a non-traded good);
>
> (d) Soliris as sold in Canada and Soliris as sold in other countries are not the same good and are, therefore, not substitutes for each other (precisely because it is unlawful to import Soliris as sold in other countries into Canada);
>
> (e) The "price at which the medicine has been sold in the relevant market" (as specified in s. 85(1)(a)) is the nominal price of 'Canadian' Soliris sold in Canada;
>
> (f) The price that is subject to the Board's oversight is the *real* price of Canadian Soliris, sold in Canada. This is so because s. 85(1)(d) directs the Board to take into consideration the Canadian Consumer Price Index (CPI). The CPI converts the nominal

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[264] Transcript, P1643-P1645.
[265] Report, para. 12.
[266] Report, para. 85.
[267] Report, para. 13.
[268] Report, para. 15.
[269] Report, para. 17 and following.

price of Canadian Soliris sold in Canada to the real price of Canadian Soliris sold in Canada.[270]

118. Dr. Putnam also concludes that in considering the prices at which Soliris is sold in countries other than Canada (as required by s. 85(1)(c)), the relevant prices are the price of U.S. Soliris in the U.S., the price of U.K. Soliris in the U.K., and so on, all of which occur at nominal prices in their respective geographic markets and which may only properly be expressed in the units in which the exchanges actually occur.[271] Because the Board is directed to take CPI into consideration, it must convert the nominal price of Canadian Soliris to its real price—as a matter of logic and fact, only by so doing can it actually "take into consideration" the CPI.[272]

119. It would be "economically illogical" to compare the *real* price of Canadian Soliris to the *nominal* price of U.S. Soliris, U.K. Soliris, etc., because to do is to fail to compare like with like. Dr. Putnam reasons that one should also convert the price at which: U.S. Soliris is sold in the U.S.; U.K Soliris is sold in the U.K.; and so on (each expressed in units of their own respective local currencies), to *real* prices of U.S. Soliris, U.K. Soliris, etc., expressed in local currencies. In other words, it is logically necessary to take into account CPI adjustments in each of the comparator countries to comply properly and fully with the direction to the Board set out in s. 85(1)(c).[273]

120. The methodology used by Board Staff to determine that the price of Canadian Soliris exceeded the maximum non-excessive price does not comply with the direction in s.85(1)(c) because the methodology does not compare the price at which Canadian Soliris is sold in Canada (expressed in Canadian currency) to the price at which non-Canadian Soliris is sold in each of the comparator countries (expressed in local currency). Instead, Board Staff compared the price at which Canadian Soliris is sold in Canada (expressed in Canadian dollars) to the price at which non-Canadian Soliris is sold in each of the comparator countries (expressed in Canadian dollars). In so doing, the Board Staff converts the foreign currencies to Canadian dollars at prevailing foreign exchange rates.[274] By doing this, however, Board Staff are simply calculating the rate at which one currency is traded for another and the market which determines those prices is the global currencies market. They are not calculating the price of U.S., U.K., Swedish, Swiss, etc., Soliris in Canadian dollars because there is no market in Canada for those goods.[275]

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[270] Report, para. 18(f).
[271] Report, paras. 19-22.
[272] Report, paras. 22-23.
[273] Report, paras. 22-23; Transcript, Putnam, P1561; P1662, P1664.
[274] Report, para. 25.
[275] Report, para. 26.

121. Moreover, as Dr. Putnam noted both in his report and in his evidence[276] foreign exchange rates are not even mentioned in the *Patent Act*. Foreign exchange rates are not prices of a patented medicine but rather of a currency in relation to the Canadian dollar, and foreign exchange rates (like the prices of other assets) fluctuate randomly and cannot be predicted from currently available information.

122. Of greater significance is that exchange rate-converted 'prices' of Soliris are simply not prices. As Dr. Putnam observes at para.28 of his report:

> "If one begins with an actual transaction price...expressed in U.S. currency and [which] arose from the sale of a medicine in the U.S. and converts that price to Canadian currency, the result does *not* yield or represent "the price at which the medicine has been sold in the U.S."[277]

The resulting amount is a number of exchange rate-converted currency units. That is *not a price*, because no one has traded those currency units for that medicine at that rate in any relevant market. This important distinction matters for a non-traded good (like Soliris) which cannot be exported from one country and lawfully imported into Canada.[278]

123. Canadian consumers do not and cannot purchase U.S. Soliris and there is no transaction that can or does occur in which the purchaser in Canada takes account of the Canada-U.S. exchange rate. Dr. Putnam observes that it is equally erroneous to convert prices from transactions that occur in the U.S. into Canadian dollars because the resulting exchange rate-converted currency units do not reflect a rate of exchange for Soliris in the U.S. As Dr. Putnam notes, such exchange rate-converted currency units do not and cannot imply that the nominal price of Canadian Soliris has increased nor that Canadians are paying more for Canadian Soliris.[279]

124. Dr. Putnam's position is that a more relevant question is whether Canadians pay more for Canadian Soliris in relation to other goods that Canadians buy than Americans pay for U.S. Soliris in relation to other goods that Americans buy.[280] To answer this a more meaningful comparison would be to the nominal prices of all medicines in Canada and the U.S. Dr. Putnam notes that while this approach is conceptually correct, there is no statutory authority for such a comparison.[281]

125. The only statutory authority for a comparison is found in paragraph 85 (1)(d) of the *Act*, in which the Board is directed to consider the price of all goods consumed by Canadians (i.e., the CPI. In short,

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[276] Report, para. 27; Transcript, Putnam, P1523-P1535.
[277] Report, para 28.
[278] Report, paras. 29-30.
[279] Report, para. 32.
[280] Report, para. 37.
[281] Report, para.38.

the statute requires the price of Canadian Soliris to be evaluated relative to the overall Canadian 'price level'. These relative prices are referred to by economists as "real prices".[282]

126. Dr. Putnam's view is that a 'fundamental point' is that consumers in Canada are no worse off today or at any time than they were in 2009 when Soliris was introduced.[283] In fact, consumers in Canada are better off because the real price of Soliris has fallen and this conclusion is inescapable.[284] As Dr. Putnam phrased it, to reach any other conclusion is to 'fetishize' the *Guidelines* over both the *Patent Act* and economics to come to the conclusion that consumers in Canada and provinces who pay for Soliris are worse off when, in fact they are better off.[285]

127. As Dr. Putnam stated both in his report and in his evidence[286] the Board Staff's claim of excess revenue rests entirely on its comparison of the nominal price of Canadian Soliris (expressed in Canadian dollars) to the nominal prices of non-Canadian Soliris (expressed in local currencies) and converted into Canadian dollars.[287]

128. Dr. Putnam clearly summarized the conceptual errors that this approach embodies:

> (a) Exchange rate-converted currency units (as described above) do not represent a 'price' because no one in either Canada or in any of the comparator countries exchanged currency for medicine at the rates the Board Staff use in any relevant market (thus failing to implement the directive to the Board contained in paragraph 85(1)(c) of the *Act).*
>
> (b) Nominal prices in Canada are not *real* prices and the Board's methodology fails to take into consideration the CPI. This omits an essential statutorily-mandated element.[288] Because the CPI is omitted, Board Staff do not compute the *real* price of Canadian Soliris and thereby fail to give effect to the directive contained in paragraph 85(1)(d) of the *Act.*
>
> (c) Nominal foreign prices are not *real* foreign prices and because 85(1)(d) mandates consideration of *real* prices the only meaningful way to compare prices of Canadian Soliris to the prices of Soliris in foreign countries is to use their *real* prices (which the Board does not compute).[289] These failures make it impossible to assess whether the *real* price of Canadian Soliris to consumers in Canada is higher or lower than the *real* price of foreign Soliris to consumers in each of the mandated comparator countries.
>
> (d) Nominal exchange rates are not real exchange rates and the Board Staff's methodology fails to take into account inflation (or deflation for that matter) in each of the comparator countries. For example, if inflation is higher in the domestic country than in the foreign country, then each unit of the domestic currency buys less of the foreign

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[282] Report, para.39.
[283] Transcript, P1524.
[284] Transcript, P1524.
[285] Transcript, P1524.
[286] Report, para. 41; Transcript, P1538 and following
[287] Report, para. 41.
[288] Report, para. 46; Transcript P1524, P1533-P1534; P1537-P1539; P1560-P1560-P1561; P1574; P1586.
[289] Report, para. 49; Transcript, P1561.

> country's goods. In short, the exchange rate must depreciate to reflect the diminished value of the domestic currency. Even employing foreign currency exchange rates, and knowing the statute takes into consideration Canadian CPI, this requires also taking into consideration the CPI in the foreign country. This in turn requires use of real exchange rates. The Board Staff's methodology however, employs only nominal exchange rates.[290]

129. In short, Dr. Putnam's opinion is that the price of Soliris is not excessive because it was not excessive when it was introduced, its price did not change and the only change was due to foreign exchange rate changes.[291] What appears to be a fluctuation in price is actually a fluctuation in currency rates.[292]

130. Dr. Putnam summarizes the flaws, methodological inconsistencies, and conceptual errors of Board Staff as follows. Board Staff:

> (a) failed to employ the CPI (as required under s.85(1)(d));
>
> (b) introduced foreign exchange rates to implement s.85(1)(c) even though foreign exchange rates are not mentioned in s.85 and are neither necessary nor sufficient to implement the requirements of s.85(1)(c); and
>
> (c) enforced a rule that requires Alexion to reduce the price of Canadian Soliris to maintain some notion of 'parity' to foreign prices, while not permitting Alexion to symmetrically *increase* the nominal price of Canadian Soliris when the Canadian dollar weakens against foreign currencies.

131. As to harm to consumer welfare in Canada, Dr. Putnam concludes that a consumer in Canada is unaffected by the U.S. currency-based price of U.S. Soliris.[293] As Dr. Putnam observed, a New York City subway ticket, whether its price is expressed in U.S. currency or Canadian currency, is irrelevant to the welfare of a consumer in Canada because a New York City subway ticket cannot be used on any subway in Canada. That conclusion applies equally to U.S. Soliris which, whether its price is expressed in U.S. or Canadian currency, is irrelevant because it cannot be brought into Canada and used by a patient in Canada.[294] Accordingly, where the price of Soliris (expressed in Canadian dollars) has never changed but where inflation has occurred (as in Canada), the price of Soliris has actually decreased in real terms and it defies logic to conclude that there has been any harm to Canadian consumer welfare. Just as consumers in Canada are not made worse off when the exchange rate-converted price of U.S.

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[290] Report, paras. 51, 52 and 53.
[291] Transcript, P1629.
[292] Transcript, P1636.
[293] Report, paras.71 through 77; Transcript P1563-P1564; P1574.
[294] Report, para. 72.

Soliris increases so too, Americans are not made better off either.[295] In short, where there has been no price increase in Canada there has been no harm to any consumer in the Canadian marketplace.[296]

Evidence of Prof. Aslam Anis

132. Prof. Aslam Anis is a health economist at the University of British Columbia. He has expertise in several aspects of the pharmaceutical industry especially at the interface between government regulation and corporate behaviour and is familiar with federal and provincial regulatory regimes.[297] Dr. Anis was asked whether he agreed with the conclusions of Dr. Addanki and Prof. Schwindt that the price of Soliris in Canada was "excessive." He was also asked whether there were other approaches, or methods, of comparing the price of Soliris in Canada with the prices of the drug in the 7 comparator countries.[298]

133. In his evidence, Dr. Anis observed that high-cost medicines in Canada, and most developed countries, were covered by public or private health insurance.[299] Cost-effectiveness evaluations of new drugs are based upon costs, of which price is one component, and effect, including health gain. Often a metric known as the Cost Quality-Adjusted Life Year (or Cost/QALY) is used, which is based upon a threshold price that differs across jurisdictions.[300]

134. The Cost/QALY approach is not used for drugs used to treat orphan conditions because of the low prevalence of the diseases and small market size. It is recognized that drugs used to treat orphan diseases have to be priced at a higher level based on market factors and the difficulties inherent in quantifying the cost-effectiveness threshold for rare diseases.[301] Some countries, like the United States, have developed special legislation that provides incentives for the development of rare disease drugs.[302] Other countries, like the United Kingdom, have developed special methodologies distinct from the Cost/QALY approach for reviewing cost-effectiveness of orphan drugs.[303] While some provinces have set up processes to assess the reimbursement of orphan drugs, Canada does not have orphan drug legislation and no Canadian entity, including CADTH, has established a specialized review and approval process to deal with the cost-effectiveness of orphan drugs.[304]

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[295] Report, para.76.
[296] Report, para.77; Transcript, P1574-P1574;
[297] Anis Report, paras. 1-15;Transcript, P1962-P1972.
[298] Anis Report, para. 16; Transcript, P1993-P1994.
[299] Transcript, P1994-P1997.
[300] Anis Report, paras 20-26; Transcript, P1997-P2002.
[301] Transcript, P2002-P2004.
[302] Transcript, P2003.
[303] Transcript, P2005.
[304] Anis Report, paras. 27-32; Transcript, P2006-P2007.

135. Prof. Anis expressed caution about making generalized, or "blanket" statements that U.S. drug prices are generally higher than in Canada.[305] He cited studies showing that costs of some drugs, including biologics, can be higher in Canada than in the United States.[306] He said it was very difficult to engage in a true "apples to apples" comparison of international drug prices, including prices in Canada and the United States.[307]

136. Prof. Anis also expressed caution about making generalizations that patentees, who enjoy a statutory monopoly, will automatically charge excessive prices. He observed that prices in other countries reflect "the interaction of demand and supply conditions in that market", which can include the number of patients in a particular country, regulatory policy, and listing policies.[308]

137. Prof. Anis stated that "per capita GDP", "standard of living", and "the median household income" were not informative in assessing whether the price of Soliris in Canada was excessive because public and private insurers pay for Soliris, not individuals or households.[309] In Canada and elsewhere, drugs are not approved based upon median household income, but instead upon Cost/QALY calculations, and insurance budgets: "it is the budget of the insurance plan that determines whether [a] drug will be covered or not, not the median household income."[310]

138. International comparisons based upon publicly available list prices raise challenges. In particular, pricing regulations, or laws requiring mandatory discounts, can affect published prices in other countries. Moreover, public payers in Canada and other countries negotiate discounts on behalf of provincial drug plans. While the extent of discounts may be known in some instances, the magnitude of discounts is most often confidential.[311]

139. Dr. Anis testified that there was "asymmetry" in the application of the CPI and exchange rate constraints on drug prices because firms could be required to decrease prices in times of currency appreciation yet would be constrained by CPI from increasing prices to make up for decreases caused by currency fluctuations.[312] This asymmetry meant firms were faced with a "catch 22" when attempting to be compliant with "dual yet simultaneously applicable constraints on their pricing behaviour."[313]

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[305] Transcript, P2012-P2013.
[306] Transcript, P2014-P2019.
[307] Anis Report, paras. 43-49.
[308] Anis Report, paras. 56; 60; Transcript, P2025-P2027.
[309] Anis Report, paras. 59.
[310] Anis Report, paras. 39, 59; Transcript, P2009-P2011; P2030-P2031.
[311] Anis Report, paras. 63-67; Transcript, P2012-P2013; Transcript, P2032-P2033.
[312] Anis Report, paras. 68-72; Transcript, P2036-P2041.
[313] Anis Report, paras. 74.

140. Dr. Anis also pointed out that "standard contracting practices" involve commitments binding over time that cannot be continuously adjusted in response to exchange rate fluctuations.[314] For example, companies have binding commitments to governments with budgets and enter into long-term contracts at fixed prices. "You can't just change your price based on the weather or based on the exchange rate...You can't have... a catch of the day situation."[315]

141. In his testimony, Dr. Anis stated that there was "an internal inconsistency" in the way the *Guidelines* "are asking pharmaceutical companies to behave." The inconsistency "arises because firms "are asked to control their prices in conjunction with changes in the exchange rate as well as changes in the CPI": "They only control their prices, they do not control the exchange rate, do not control the CPI."[316] The Guidelines provide "internally inconsistent instructions in some instances."[317]

142. Dr. Anis ultimately concluded that the methods used in the *Guidelines* based upon international price comparisons were "inadequate to enable one to conclude that the price of Soliris in Canada was excessive."[318]

Evidence of Errol Soriano

143. Mr. Soriano is an experienced chartered accountant and business valuator. Since 1991, his practice has focused on valuations, quantification of financial loss, and related financial analysis. He has testified in court and international arbitration proceedings on at least 50 occasions. Mr. Soriano has been appointed as a court-appointed inspector under the Ontario *Business Corporations Act* and has received honourary designations from the Canadian Institute of Chartered Professional Accountants and the Canadian Institute of Business Valuators. Mr. Soriano has also has prepared reports that form the basis for fee guides and pricing.[319] The Panel qualified Mr. Soriano as an expert witness in valuation, financial analysis, and quantification of financial loss.

144. Mr. Soriano prepared a financial analysis conforming to the PMPRB's "founding principles" (including fairness, predictability, and transparency).[320] He concluded that:

> (1) Alexion could have realized approximately $278,000 in additional revenue within the Guidelines for sales of Soliris the years 2010 and 2011[321];

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[314] Anis Report, paras. 72-73, Transcript, P2041-P2042.
[315] Transcript, P2041-P2042.
[316] Transcript, P2038.
[317] Transcript, P2039-P2041.
[318] Anis Report, para. 78.
[319] Transcript, P2253.
[320] Transcript, P2253.
[321] Transcript, P2269.

(2) Had Alexion increased the price of Soliris consistent with the CPI between 2012 and 2015, the increases in total incremental revenue would have been about $23,363,000[322];

(3) Board Staff's approach was not fair[323] because (a) foreign price sources and back-out formulae were not properly explained, meaning Mr. Soriano was prevented from conducting an informed analysis of the suitability or fairness of the formulae,[324] (b) excess revenues were based only on foreign currency fluctuations[325] and not changes in actual prices in Canada or the comparator countries[326]; and (c) the combination of the CPI calculation and HIPC test imposed a one-sided risk, or "ratchet" provision, on Alexion for foreign currency fluctuations; and

(4) Two alternative approaches were available to compare Canadian and foreign country prices that would be more consistent with principles of fairness. First, a "Comprehensive Test" comparing prices based on price inflation in Canada and the 7 comparator countries would produce total excess revenues in 2012 and 2013 of only [redacted] which could be reduced to zero if set off were permitted. [327] Second, an approach based on purchasing power parity (or PPP) taking into account relative purchasing power in Canada and the 7 comparator countries[328], which would result in no excess revenues because the Canadian price would never be the highest using PPP exchange rates. [329]

145. In addition to addressing the specific mandates in his report, Mr. Soriano also provided commentary on Board Staff's calculations based on his perspective as a financial expert:

(a) Some of the financial rationale outlined in the *Guidelines* runs contrary to what would be reasonable from a financial perspective. For example, Mr. Soriano cited concerns over the fairness of Board Staff's requirement that Alexion must reduce its price immediately to fall within an acceptable N-NEAP if there is an upward currency fluctuation but that it is only allowed to increase its price on a gradual basis, using CPI, over time if there is a downward fluctuation. He described this requirement as a "ratchet provision" and explained that it amounts to a "one-way currency risk" and observed that the asymmetry in the approach was unfair from a financial perspective.[330]

(b) There was insufficient information from Board Staff about why different pricing sources and methodologies were used, no reconciliation to permit an understanding of what Board Staff were measuring, and no explanation as to why Board Staff used different methodologies and made different adjustments (both between different countries and in different years). He expressed concern that there was no information provided as to why certain sources were considered comparable and why Alexion could not claim an offset to the excess revenues in the years where it charged less than the N-NEAP. From an excess revenue point of view, he testified that "it would seem financial common sense to me that there would be an offset" as "the Canadian consumer is benefitting by the fact that the prices haven't been going up".[331]

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[322] Transcript, P2271.
[323] Transcript, P2262.
[324] Transcript, P2273-P2274.
[325] Transcript, P2282-P2283.
[326] Transcript, P2276.
[327] Transcript, P2284.
[328] Transcript, P2285-P2286.
[329] Transcript, P2288-P2289.
[330] Transcript, P2293.
[331] Transcript, P2294.

(c) Board Staff's use of back-out formulas and the lack of information setting out how Board Staff derive these formulas is not transparent. For example, Mr. Soriano noted specifically with respect to the Swedish price that Board Staff "had not explained how they derive the formula or why the formula is not applied to the 2015 prices". He noted that Board Staff adjusted the excess revenues from "$6+ million to $4.2 million" apparently as a result of Mr. Soriano's observation in his report that there was a back-out formula applied to Sweden in the years 2013 and 2014 but not in 2015.[332] He concluded that if that formula had not been used then the excess revenues would be reduced by $1,995,101. Board Staff seem to accept this premise in their 15 December 2016[333] letter, which reduced excess revenues.[334]

Evidence of Prof. Schwindt

146. Prof. Schwindt, currently an emeritus professor at Simon Fraser University in British Columbia, was trained at the University of California Berkeley.[335]

147. Prof. Schwindt has previously testified in proceedings before the Board on behalf of Board Staff.[336] He has also had consulting engagements with the Board.[337] In some instances, he is a paid consultant to the Board and in other cases he testifies on behalf of Board Staff.[338]

148. Prof. Schwindt was taken to the *Guidelines* applicable at the time Soliris was introduced on the Canadian market. He acknowledged that the previous guidelines applicable in 2009 when Soliris was introduced did not contain the same warning about foreign currency exchange rates as the current *Guidelines*.[339]

149. In his Report and in his original testimony in chief, Prof. Schwindt agreed on the importance of predictability in the regulatory process.[340] In his words, "predictability enhances the operation of markets."[341] When a foreign company comes into Canada, it is important that the company be aware of the regulatory process and that the rule of law enhances predictability.[342] He also agreed that retroactive application of new rules impairs investment.[343] Prof. Schwindt also acknowledged that if the

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[332] Transcript, P2295-P2297.
[333] Joint Book, Tab 113.
[334] Transcript, P2307.
[335] Transcript, P803.
[336] Transcript, C290.
[337] Transcript, C290-C291.
[338] Transcript, C291; Exhibit 8.
[339] Transcript, C274-C275.
[340] Transcript, C275-C277.
[341] Transcript, C277.
[342] Transcript, C278; P934-P935.
[343] Transcript, P937.

Board wanted to change the rules so that a company product could not exceed the lowest international price "they should certainly warn the industry that there's this fundamental sea-change in policy."[344]

150. Prof. Schwindt testified that payment for Soliris came from "insurance companies, whether public or private."[345] He agreed that, practically or legally speaking, an insurer or individual cannot buy Soliris outside Canada and that it is therefore a non-traded good.[346]

151. Prof. Schwindt also agreed that the price of Soliris did not change from 2009 to the present.[347] He said that "the deflated price of Soliris has gone down, yes, there is no question."[348] He had no dispute with the Soriano report that the decline in price was about 10% as of 2016.[349] This meant that "insurers who actually pay" for Soliris "are paying 10% less now than they were in 2009."[350]

152. When asked about the trigger, or "tripwire", for the investigation, Prof. Schwindt agreed that it was the HIPC test.[351] He also agreed that foreign exchange rates were not within any individual or company's control.[352]

153. Prof. Schwindt acknowledged that revenue taken from Alexion in the process before the Board goes to Her Majesty and that Alexion is seeking relief against that remedy in the proceeding.[353]

154. Prof. Schwindt also acknowledged "asymmetry" in the application of CPI increases. That is, if the price of a product decreased based upon the HIPC test, a company may be impaired in their ability to make up the difference in a period of depreciation of the Canadian dollar. He said that it was "definitely true, and it's probably true currently because of the very significant decline in the Canadian dollar and the very limited inflation we have in this country." He agreed that if the Canadian dollar depreciated against other currencies, a company would be constrained by the Board's CPI methodology from price increases.[354]

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[344] Transcript, P944-P945.
[345] Transcript, P863.
[346] Transcript, P962-P963.
[347] Transcript, P263.
[348] Transcript, P964.
[349] Transcript, P964.
[350] Transcript, P965.
[351] Transcript, P965-P966.
[352] Transcript, P966.
[353] Transcript, P970-P971.
[354] Transcript, P990-P992.

Evidence of Dr. Addanki

155. Dr. Addanki was asked by Board Staff counsel to ignore the *Guidelines*. When examined, he could not remember whether he had even read the *Guidelines*. Dr. Addanki was not asked to, and did not, read the *Regulations*.[355]

156. When asked about foreign legislation governing orphan drugs, Dr. Addanki acknowledged that Canada had no similar legislation. He agreed the foreign legislation deals with "various economic incentives...to develop and sell medicines for rare conditions." He was not aware of "any explicit pricing component" in the foreign legislation.[356]

157. Documents concerning the U.S. *Orphan Drug Act* cited by Dr. Addanki in his report were introduced through him as exhibits. Dr. Addanki generally agreed with statements in these documents, including a report prepared by the U.S. Department of Health and Human Services.[357] In particular, he agreed that the U.S. legislation was "intended to remove disincentives to develop medications for rare diseases because of the small target patient populations, the low incidence or prevalence."[358] Dr. Addanki could point to no amendments in the U.S. legislation to deal with concerns over high costs of some new drugs created under the legislation.[359] Price control was not mentioned in either exhibit introduced through Dr. Addanki in cross-examination.[360]

158. Dr. Addanki agreed that infusion costs were probably not covered by the U.S. price.[361] Based upon hypothetical questions put to him, Dr. Addanki was prepared to concede that if infusion costs were part of the price of Soliris in Canada, the purchaser would get "something more", in terms of "a feature or benefit" than what a U.S. purchaser would get.[362]

159. Like Prof. Schwindt and all other witnesses, Dr. Addanki assumed that insurers covered the costs of purchasing Soliris and not individuals.[363] He agreed with the proposition that "Soliris that is used to treat Canadian patients is purchased in Canadian dollars in Canada."[364]

160. Dr. Addanki was prepared to agree that if the annual cost of a medicine exceeded median family income or per capita GDP, it did not necessarily lead to a conclusion that the price was "excessive".[365]

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[355] Transcript, P1304-P1305.
[356] Transcript, P1305-P1306.
[357] Exhibit 19; Transcript, P1306-P1309.
[358] Transcript, P1309.
[359] Transcript, P1311.
[360] Exhibits, 19 and 20.
[361] Transcript, P1337.
[362] Transcript, P1338-P1339.
[363] Transcript, P1339.
[364] Transcript, P1339-P1340.

Dr. Addanki was also prepared to assume that the total cost of orphan drugs was a "small percentage" of "total drug spend in Canada or in any province."[366]

LAW

Patent Act and Patented Medicines Regulations

161. Section 85(1) of the *Patent Act* lists the "factors" THE Panel "shall take into consideration" in determining whether the price of a medicine is "excessive" to "the extent that information on the factors is available to the Board." The pertinent factors in this case are: "(a) the prices at which the medicine has been sold" in Canada; "(c) the prices at which the medicine [has] been sold in countries other than Canada; and "(d) changes in the Consumer Price Index."

162. If the Panel "is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price" based on the factors in s. 85(1), the Panel "may" then consider the "additional factors" described in subsection 85(2), which include "the costs of making and marketing the medicine" and "such other factors are in the opinion of the Board, relevant in the circumstances."

163. When interpreting s. 85(1), the Panel must be mindful of the reporting requirements established by the *Act* and *Regulations*, which are an essential component of the "information on the factors available to the Board" mentioned in the opening words of the section. Section 80(1) of the *Act* lists the categories of information that must be reported "in accordance with the regulations." To date, the *Regulations* under the *Act* address the reporting requirements under: sections 80(1)(a) and 80(2)(a) of the *Act* (in section 3 of the *Regulations*); sections 80(1)(b) and 80(2)(d) of the *Act* (in section 4 of the *Regulations*); and section 88 (1) of the *Act* (in section 5 of the *Regulations*). Section 80(1)(b) of the *Act* relates specifically to: "the price at which the medicine is being or has been sold in any market in Canada and elsewhere".

164. Section 4 of the *Regulations*, which is directly addresses reporting requirements under s. 80(1)(b) addresses the following price information:

> 4. (1) For the purposes of paragraphs 80(1)(b) ... of the Act, information identifying the medicine and concerning the price of the medicine shall indicate
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> ...
>
> (f)(i) the quantity of the medicine sold in final dosage form and either the average price per package or the net revenue from sales in respect of each dosage form, strength and

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[365] Transcript, P1340.
[366] Transcript, P1342.

package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory,

(ii) the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory, and

(iii) if the medicine is being sold in one or more of the countries set out in the schedule, the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold to each class of customer in each of those countries.

...

(4) For the purposes of subparagraph (1)(f)(i),

(a) in calculating the average price per package of medicine, the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of the federal sales tax shall be used; and

(b) in calculating the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue after any reduction in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of federal sales taxes shall be used.

...

(7) For the purposes of subparagraph (1)(f)(iii), the price at which a medicine was sold in a country other than Canada shall be expressed in the currency of that country.

...

(9) For the purposes of this section, publicly available ex-factory price includes any price of a patented medicine that is agreed on by the patentee or former patentee and the appropriate regulatory authority of the country in which the medicine is sold by the patentee.

165. The Schedule to the *Regulations* lists the 7 comparator countries used for reporting purposes:

SCHEDULE

(Subparagraph 4(1)(f)(iii))

1. France
2. Germany
3. Italy
4. Sweden
5. Switzerland
6. United Kingdom
7. United States

166. Subsections 83(1) and (2) of the *Act* spell out the remedial powers the Panel may employ in the event the price of a medicine is found to be "excessive" which include price reductions, offsets of excess revenues, and payments "to Her Majesty in Right of Canada":

The *Guidelines*

167. Creation of the Board's *Guidelines*, and the requirement of consultation before the *Guidelines* can be changed, are addressed in s. 96 The *Act*:

> Guidelines
>
> (4) Subject to subsection (5), the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any patentee.
>
> Consultation
>
> (5) Before the Board issues any guidelines, it shall consult with the Minister, the provincial ministers of the Crown responsible for health and such representatives of consumer groups and representatives of the pharmaceutical industry as the Minister may designate for the purpose.

168. While the *Guidelines* are not binding, and must yield to the *Act* or *Regulations* in the event of a conflict[367], the *Guidelines* contain a detailed "approach and methodology" for applying the s. 85(1) factors. The *Guidelines* are meant to provide "predictability" and contain assurances to patentees of "fairness" and "transparency." The *Guidelines* "ensure" that patentees are "aware" of the Board's approach and serve the important purpose of providing patentees with notice of how the Board interprets, implements, and applies the factors in s. 85(1) of the *Act* when excessive pricing issues arise. The *Guidelines* cannot be ignored, and entirely new tests or considerations cannot be created, let alone applied, without notice to, and consultation with, the industry and other stakeholders.

169. This understanding of the *Guidelines* is amply supported by the wording of the *Guidelines,* the Board's annual reports, jurisprudence of the Board, and decisions of the Federal Courts.

170. The *Guidelines* state:[368]

> The Patented Medicine Prices Review Board (PMPRB) is committed to making the price review process more open and transparent to all stakeholders.
>
> One of the primary objectives of the COMPENDIUM OF POLICIES, GUIDELINES AND PROCEDURES (Compendium) is to ensure that patentees are aware of the policies, guidelines and procedures under which Board Staff reviews the prices of

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[367] See *ICN Pharmaceuticals Inc. v. Canada*, [1996] F.C.J. No. 112 at para. 6 (FC); *Teva Neuroscience G.P.-S.E.N.C. v. Canada* (Attorney General), [2009] FC 1155 at paras. 30-32 (FC).
[368] PMPRB *Guidelines*, Preamble and para. A.5.3.

> patented drug products sold in Canada, and the procedures normally undertaken in the scientific and price review processes and when a price appears to be excessive.
>
> From time to time, the PMPRB finds it necessary to update the Guidelines under which it operates to ensure that they remain relevant and appropriate, as well as uphold the principles of fairness, transparency, openness, and predictability. When considering Guidelines amendments, the PMPRB consults with its stakeholders through its Notice and Comment process.
>
> ...
>
> A.5.3 The Board, following considerable deliberation and consultation with all stakeholders, pursuant to subsection 96(5) of the Act, published the PMPRB's Guidelines pursuant to subsection 96(4) of the Act. Although the Guidelines are not binding on the Board or the patentee, they establish an approach and methodology in applying the factors set out in subsection 85(1) of the Act. [Emphasis added.]

171. The Board publishes Annual Reports containing statements that the *Guidelines* are to be consulted by patentees to ensure that a price is not excessive. The 2012 Report states that the "Compendium of Policies, guidelines, and Procedures" "details the price tests used by Board Staff to determine whether the price charged by a patentee falls within the maximum allowable price." The 2012 Report also contains a statement that the "Regulatory Affairs and Outreach Branch...encourages patentees to comply voluntarily with the Board's Guidelines."[369]

172. Decisions of previous panel's of the Board have stressed the importance of the *Guidelines* in ensuring fairness, consistency, and predictability. For example, in *Dovobet* the panel stated:[370]

> First, it is essential that the pharmaceutical industry and health care stakeholders be aware of the tests that will be applied by Board Staff to the pricing of patented medicines. It would be quite unworkable and likely unfair to attempt to make individual determinations as to the manner in which the generalities of section 85 would be applied to each of the medicines under the Board's jurisdiction.
>
> Second, the Board considers it important, as a matter of fairness, that all patentees be treated consistently and that there be stability in the principles governing the pricing of patented medicines. The Guidelines are always open to revision and interpretation, and the result of a hearing might be to depart from or add to their articulated principles if they are determined to be inapplicable or inconsistent with the Act, but the Guidelines play an important role in ensuring fair and consistent treatment of patentees.
>
> Accordingly, (and as it was obliged to do by section 96 of the Act) the Board consulted (and continues to consult) extensively with the pharmaceutical industry and health care stakeholders and experts when developing guidelines for the application of the factors stipulated by section 85. Needless to say, there were and have been differing views on how the factors in section 85 should manifest themselves in the Guidelines. After these consultations and after deliberation on the representations of the pharmaceutical industry

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[369] Annual Report, Exhibit 49, pp. 6, 10.
[370] PMPRB-04-D2-DOVOBET, pp. 10-11.

> and other stakeholders, the Board published the Guidelines, which are part of its Compendium of Guidelines, Policies and Procedures (the "Compendium"). The Compendium was part of the record of this proceeding and relied on, albeit with differing conclusions, by both LEO Pharma and Board Staff.
>
> The Guidelines have been in place and relied on by Board Staff, the pharmaceutical industry and other health care stakeholders for almost 20 years. From time to time and in the course of ongoing consultations, the Board issues updates to inform the industry and other stakeholders of interpretive clarifications or policies that bear on the Guidelines.
>
> Given these considerations, the Board in its review of a particular medicine and the representations of its patentee will be cognizant of the fact that the Guidelines were developed with principled compromises after the receipt and balancing of much broader representations than those of Board Staff and the patentee in question. The Board, while never bound by the Guidelines, will give them due consideration in light of their provenance and the role that they play in assisting the pharmaceutical industry, other stakeholders and the Board in the application of the provisions of the Act. [Emphasis added.]

173. The appropriate test was further described in the *Adderall XR* decision:[371]

> 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. [Underlining added.]

174. The role of the *Guidelines* was further described on *Quadracel and Pentacel*:[372]

> 14. ... the Board's pricing guidelines (the "Guidelines") set out the parameters within which the reduction of excessive revenues can take place: sales within a calendar year. The Guidelines are not binding on any panel of the Board. However, they provide certainty and predictability for patentees. [Underlining added.]

175. In *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, [1994] 3 FCR 425, the Federal Court noted that the *Guidelines* were adopted "in order to encourage and facilitate compliance by patentees."[373] In *Leo Pharma Inc. v. Canada (Attorney General)*, 307 FC 306, the court characterized the purpose of the *Guidelines* as "provid[ing] patentees with parameters and information that can help them establish prices that may be presumed not to be excessive."[374] In *Celgene*, the Supreme Court of Canada quoted a passage from the Federal Court of Appeal decision in *ICN Pharmaceuticals Inc. v. Patented Medicine Prices Review Board* (1996),]1997] 1 F.C. 32 (C.A.)

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[371] April 10, 2008 Decision: PMPRB-06-D3-ADDERALL XR, at paras 15 and 16.
[372] June 14, 2012 Decision: PMPRB-07-D6-QUADRACEL and PENTACEL, at para. 14.
[373] *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, [1994] 3 FCR 425.
[374] At para. 19.

describing the *Guidelines* as "detailed guidelines that patentees and Board Staff use to ensure that the prices of patented medicines in Canada are not excessive..."[Emphasis in original.]

176. The use of guidelines to achieve fairness and consistency is heavily emphasized in administrative law. While guidelines are not "binding", departing without substantial and compelling reasons from established guidelines was described by the Supreme Court of Canada in *Baker* as indicative of an unreasonable exercise of statutory powers:[375]

> 72 Third, the guidelines issued by the Minister to immigration officers recognize and reflect the values and approach discussed above and articulated in the Convention...The guidelines are a useful indicator of what constitutes a reasonable interpretation of the power conferred by the section, and the fact that this decision was contrary to their directives is of great help in assessing whether the decision was an unreasonable exercise of the H & C power. [Underlining added.]

177. Observing guidelines has been considered as an important mechanism for ensuring consistency and fairness and of upholding the rule of law. The Federal Court of Appeal described this important role of guidelines in *Thamotharem* as follows:[376]

> 60 The use of guidelines, and other "soft law" techniques, to achieve an acceptable level of consistency in administrative decisions is particularly important for tribunals exercising discretion, whether on procedural, evidential or substantive issues, in the performance of adjudicative functions. This is especially true for large tribunals, such as the Board, which sit in panels; in the case of the RPD, as already noted, a panel typically comprises a single member.
>
> 61 It is fundamental to the idea of justice that adjudicators, whether in administrative tribunals or courts, strive to ensure that similar cases receive the same treatment. This point was made eloquently by Gonthier J. when writing for the majority in IWA v. Consolidated-Bathurst Packaging Ltd., [1990] 1 S.C.R. 282, at page 327 (Consolidated-Bathurst):
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> > It is obvious that coherence in administrative decision making must be fostered. The outcome of disputes should not depend on the identity of the persons sitting on the panel for this result would be [TRANSLATION]"difficult to reconcile with the notion of equality before the law, which is one of the main corollaries of the rule of law, and perhaps also the most intelligible one". [Citation omitted.] [Emphasis added]

Interpretation of Paragraph 85(1)(a)

178. The interpretation and function of s. 85(1)(a) is relatively straightforward. Subsection 85(1)(a) establishes the relevant price, or prices, at which a medicine has "been sold in the relevant market." In this case Canada is the "relevant market." Since Soliris was introduced on the Canadian market in

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[375] *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] S.C.J. No. 39, para. 72.
[376] *Thamotharem v. Canada (Minister of Citizenship and Immigration)*, [2007] F.C.J. No. 734, paras. 60 and 61 (F.C.A.).

2009, the "package price" for a 300mg vial of Soliris has been $6,742 and the unit price, $224,7333 per 10mg/mL.

179. A price arrived at under s. 85(1)(a) is used as the basis for applying the factors, and comparisons, mandated in s. 85(1)(b),(c), and (d).

180. Using s. 85(1)(a) as the starting point for the interpretive process has been addressed frequently in decisions of the Board and the Federal Court. For example, in *Leo Pharma*, the Federal Court described the purpose of s. 85(1)(a) as follows:[377]

> 47 A plain reading of the Act leads to the logical conclusion that it is on the basis of [the] information provided by a patentee under paragraph 80(1)(b) of the Act that the Board will be able to determine the first factor listed under paragraph 85(1)(a) of the Act, namely the price at which the medicine has been sold in the relevant market. [Emphasis added.]

181. Two basic considerations concerning interpretation of the s. 85(1)(a) can be readily discerned. First, s. 80(1)(b) of the *Act* (together with the *Regulations*) and s. 85(1)(a) must be read together because the information filed by the patentee, as required by the *Act* and *Regulations*, establishes the "price at which the medicine has been sold in the relevant market". Second, determination of the relevant price under s. 85(1)(a) is used as the basis for the comparisons necessary under the other factors in s. 85(1) of the *Act*. None of the *Act*, *Regulations*, *Guidelines*, or jurisprudence give s. 85(1)(a) independent substantive content as a basis for comparisons, for example, with Canadian *per capita* GDP or median family income; and there is no requirement for a patentee to collect and report such "information" under the *Act*, the *Regulations*, *Guidelines*, or from any other source other than those stipulated in s. 80(1)(b).

182. This function of s. 85(1)(a) is well established in decisions of the Board. For example, in *Dovobet*, (the Board decision judicially reviewed in *Leo Pharma*) the Board described the process as follows:[378]

> To simplify the terminology in subsection 85(1), it can be said that it requires the Board to determine whether or not the price of a medicine in Canada is excessive (taking into account changes in the Consumer Price Index) by comparing the price of the medicine in Canada [85(1)(a)] to:
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> 1) the price of comparable medicines in Canada [85(1)(b)];
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> 2) the price of the medicine in other countries [85(1)(c)]; and

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[377] *Leo Pharma Inc. v. Canada (Attorney General)*, 2007 FC 306, para. 47. (F.C.).
[378] April 19, 2006, PMPRB-04-D2-DOVOBET, p. 7.

3) the price of comparable medicines in other countries [85(1)(c)].

The factors set out in subsection 85(1) are exhaustive of the factors that the Board may consider and the Board must give due consideration to each of them when reviewing the price of a medicine for the purposes of a potential order under section 83 of the Act.

183. The Board commented in *Adderall XR* that these principles were "...cited with agreement by the Federal Court ...":[379]

In the Leo Pharma decision, articulating principles cited with agreement by the Federal Court on judicial review of that decision, the Board said:

"To simplify the terminology in subsection 85(1), it can be said that it requires the Board to determine whether or not the price of a medicine in Canada is excessive (taking into account changes in the Consumer Price Index) by comparing the price of the medicine in Canada [85(1)(a)] to:

1) the price of comparable medicines in Canada [85(1)(b)];

2) the price of the medicine in other countries [85(1)(c)]; and

3) the price of comparable medicines in other countries [85(1)(c)]." [Emphasis added]

184. in *Penlac,* the Board stated:[380]

6. Subsection 85(1) will be considered more completely later in these Reasons, but it can be seen that paragraph 85(1)(b) of the Act obliges the Board to consider the prices of other medicines "in the same therapeutic class" as the medicine under review. Paragraph 85(1)(c) requires the Board to consider the prices of the medicine in "countries other than Canada" (often referred to as the international pricing of the medicine). Both of these provisions, and the interaction between them, gave rise to debate between the parties. Paragraphs 85(1)(a) (establishing the price at which Penlac was sold in Canada) and 85(1)(d) (changes in the Consumer Price Index or "CPI") were potentially relevant but not contentious. [Emphasis added.]

185. The purpose of s. 85(1)(a) is therefore to establish the relevant price of a medicine as the basis for comparison under the other factors in s. 85(1). The "contextual" interpretation of paragraph 85(1)(a), that Board Staff advance[381] is incorrect and outside the logical system of the *Act* and *Regulations* as determined by the Federal Court and in previous decisions of the Board. The proposed interpretive approach also finds no support in the *Guidelines.*

186. No case before this Board, or before the Federal Court, has ever interpreted s. 85(1)(a) as permitting, let alone requiring, an independent substantive "contextual" analysis. In a case where a

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[379] April 10, 2008 Decision: PMPRB-06-D3-ADDERALL XR, para. 14.
[380] January 31, 2011 Decision: PMPRB-07-D2-PENLAC, para.6.
[381] See paras. 83 through 87 of the Written Submissions of Board Staff.

medicine is sold in Canada at a consistent price across markets, s. 85(1)(a) is the starting point. Based on information that must be reported under s. 80 (1) of the *Act* and *Regulations,* s. 85(1)(a) establishes the price of the medicine in the relevant market for purposes of applying the other factors, including the comparisons, contained in s. 85(1).

Interpretation of s. 85(1)(c)

187. Subsection 85(1)(c) is the statutory factor under which the price of a medicine sold in a relevant Canadian market is compared with the price of the medicine sold in other countries.

188. As with s. 85(1)(a), the pricing information to be used for the comparison in s. 85(1)(c) originates from information reported under s. 80(1)(b) of the *Act* and s. 4 of the *Regulations*, which require a patentee to supply publicly available ex-factory prices at which the medicine was sold to each class of customer in the 7 comparator countries listed is Schedule A to the *Regulations.* No individual country among the 7 is accorded any prominence in weight or special status in the *Act*, *Regulations*, or *Guidelines.*

189. The s. 85(1)(c) factor, which in this case involves a comparison of the price of Soliris in Canada with the prices of Soliris in the 7 comparator countries, must be interpreted based on the same logic stated by the Federal Court in *Leo Pharma.*

190. The tests the Board employs in the *Guidelines* to interpret the requirements where the product is a "breakthrough" medicine are not controversial. The introductory price of a "breakthrough" medicine is established based on the median international price from among the 7 countries listed in the *Regulations*. In this case, the former *Guidelines* apply to the introductory price of Soliris, which was established in 2009. In subsequent years, the maximum allowable price of a "breakthrough" medicine under the current *Guidelines* is capped by the highest international price, based on the HIPC test found in Schedule 6 of the current *Guidelines.*

191. The pertinent language from Schedule 6 applicable to this proceeding is the following:

> **1. Highest International Price Comparison (HIPC) Test**
>
> 1.1 Subject to Schedule 6, section 1.2, both at introduction and in future years, the Average Transaction Price of a patented drug product at the national level...will be presumed to be excessive if it exceeds the highest price of the same strength and dosage form of the same patented drug product for each country listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States).

2. Exchange Rates

2.2 To calculate the HIPC test for an existing patented drug product, the exchange rates used are the simple average of the thirty-six monthly average noon spot exchange rates for each country (taken to eight decimal places), as published by the Bank of Canada for the thirty-six months ending with the last month of the pricing period under review. For example, if the pricing period under review is July to December 2009, the exchange rates used are for the months of January 2006 through December 2009.

3. Existing Drug Products with Unusual Circumstances

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:

- Exchange rate variations;
- A foreign regulator forcing price reductions; or
- The highest priced drug product is removed from the market.

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.

192. Section C.12.1 of the *Guidelines* also mentions the HIPC test:

C.12.1 The price of an existing patented drug product will be presumed to be excessive if the National Average Transaction Price exceeds the National Non-Excessive Average Price as determined by the lower of:

The change in the CPI as per the CPI-Adjustment Methodology (see Schedule 9); or

The result of the Highest International Price Comparison test (see Schedule 6).

193. In this case, there is no factual dispute that the sole 'trigger' for the investigation of Soliris involved the "unusual circumstances" described in Schedule 6. Specifically, "exchange rate variations" that were "beyond the control" of Alexion created a price for Soliris that "appears excessive" for the years between 2012 and 2015. Section 1.1 of Schedule 6 states that, in the circumstances, the price of Soliris "will be presumed to be excessive."

194. Significantly, neither the *Act* nor the *Regulations* make any mention of foreign exchange rates in relation to international comparisons. Use of foreign exchange rates, and the HIPC test, is entirely the creation of Board Staff in the *Guidelines*.

195. All fact and expert witnesses agreed in this case that Soliris was a "non-traded" good, meaning that Canadians could not, and did not, use Canadian dollars to purchase Soliris outside Canada. There was similar agreement that: (a) the nominal Canadian price of Soliris had not increased between introduction in 2009 and the hearing; (b) the nominal price of Soliris in the 7 comparator countries had not decreased in the currency of those countries between 2009 and the hearing. The only change in the 7 comparator countries was a price increase in the United States.

Interpretation of Subsection 85(1)(d)

196. Subsection 85(1)(d) requires the Board to take into consideration changes in the CPI. The *Act* and *Regulations* do not specify how the Board is to take CPI into consideration. Under the *Guidelines*, the price of an existing patented drug product will be presumed to be excessive if the price increases by more than the Board's CPI-Adjustment Methodology found in Schedule 9. No inflation-adjusted price under the CPI-Adjustment Methodology can exceed the highest international price under the HIPC.[382]

197. In this case, the predominant consideration under s. 85(1)(d) is that the price of Soliris in Canada has never increased and, in fact, has *decreased* by more than 10% based on changes in the CPI. The decrease in price based on the CPI is not contested by *Board Staff* or either intervener and was conceded by Prof. Schwindt.[383] Mr. Soriano valued Soliris in 2016 inflation-adjusted Canadian dollars, at $199.05 per unit of 10 mg/10 mL.[384]

Liability Under *Guidelines* Not Proven

a) Burden of Proof Not Met

198. In evidence presented to the Panel, Board Staff failed to prove an essential element of their case that was identified by Mr. Soriano in his April 2016 report. Mr. Lemay had no knowledge of either the foreign price source selection process or of how back-out formulae are devised to determine ex-factory prices upon which price comparisons are made and excessive revenues calculated. He indicated that the sources and formulae were determined by staff employed in the "Policy Branch" of the

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[382] This is subject to allowances made for increasing at a greater rate under the "DIP methodology" found in Schedule 10, and under a provision in Schedule 9 specific to price reductions taken to "offset" excessive revenues.
[383] See para.150 above.
[384] Transcript, P2309.

Board, none of whom testified.[385] The most Mr. Lemay could do was point to documents posted on the Board's website that revealed a source or back-out formula. He did not, however, provide any explanation or rationale as to: why the source, or back-out formula, was used; why a source and/or formula was used in one year but not in another year; or why a different source/formula was used from one year to the next or, for that matter, why a back-out formula was applied in a particular year. [386] Mr. Lemay admitted that Board Staff's Disclosure Letter contained materially inaccurate statements on disclosure of foreign sources and pricing information.

199. Quite apart from the sources and back-out formulae, Board Staff have delivered inconsistent and conflicting information on pricing and alleged excess revenues.[387]

b) No Proof of Sources and Back-Out Formulae

200. As communicated in detail above in the "Facts" section of these written submissions[388], Mr. Soriano raised significant concerns in his report and testimony about Board Staff's foreign price sources and back-out formulae. Mr. Soriano said the "veracity of the inputs to those formulas remain a question to me." Despite being a highly experienced accountant and business valuator, Mr. Soriano was unable to "understand the adjustments that had been made in those mechanical calculations" under the back-out formulae.[389] He confirmed that "he did not have the information to assess [the back-out] formulas" even though the "back-outs...account for almost $2 million of excess revenues" that had been sought from Alexion by the PMPRB.[390] He also expressed serious concerns regarding the "opaqueness..in terms of what [Board Staff are] actually doing with these back-outs."[391]

201. Mr. Soriano also noted significant concerns with the various price sources because different sources for various countries were used for different years. Furthermore, as noted in para. 144 above, back-out formulae were sometimes applied to a particular source, and sometimes no back-out formula was applied to the same source.

202. Mr. Soriano raised these issues in his report delivered in mid-April 2016. Board Staff presumably had witnesses available from the Board's Policy Branch who could explain how foreign source and back-out formulae were derived but chose to avoid transparency by putting Mr. Lemay forward as the Board's sole fact witnesses. Board Staff must have known that Mr. Lemay had no ability to explain how

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[385] Transcript, C123; P310, P594-P595; P597; P599; P616.
[386] See paras. 99-102; 143-144 above.
[387] See paras. 99-103, and 143-144 above
[388] See paras. 92-95 above.
[389] Transcript, P2292-P2293.
[390] Transcript, P. 2295.
[391] Transcript, P. 2297.

foreign sources were selected or back-out formulae derived. Mr. Lemay could only point to documents on the website or say that the process was determined by the Policy Branch.[392] No one from the Policy Branch testified and at no point did Board Staff adduce any evidence to show how the formulae that figured so prominently in their calculation of excess revenue was derived. Moreover, Alexion was deprived of any opportunity to cross-examine a witness from the Policy Branch or even the Board Staff member who prepared the charts containing the foreign prices based upon the sources and formulae selected and applied by the Board.

203. It is apparent from Board Staff's disclosures that back-out formulae were only applied during the relevant period to price sources of two countries, Germany and Sweden. As the countries with the highest prices, understanding the selection of the sources and the back-out formulae in Germany and Sweden is essential to a determination of liability and calculation of excess revenues, if any. Mr. Soriano was unequivocal in his report, examination in chief, and cross-examination that this information was never disclosed despite the information being critical to a proper understanding of how Board Staff calculated the prices in those two countries.

204. Mr. Soriano identified in his report and testimony that Board Staff applied a formula to reduce the Swedish price in 2013 and 2014 but did not apply the same formula in 2015. He noted that if the reduction of the Swedish price based on this formula in 2013 and 2014 was "reversed" to be consistent with what Board Staff did in 2015 then the excess revenues would be reduced by approximately $2 million.[393] Board Staff's 15 December letter apparently accepted this reduction and contained a new, and lower, number for excess revenues (see Tab 113 of the Joint Book of Documents).

205. Selection of foreign sources, application of back-out formulae to foreign source prices, and verification procedures for foreign source prices are not the subject of any provision in the *Act* or *Guidelines*. These are administrative actions taken by Board Staff outside the *Guidelines*. Accurate and precise evidence proving these amounts is essential to establishing financial liability against a patentee, particularly when liability involves forfeiture of monies payable to Her Majesty.

206. The complete absence of any evidence on these critical issues, which were well known to Board Staff from Mr. Soriano's report before the hearing, is a fatal flaw in Board Staff's case and demonstrates that an essential element to find liability was unproven. Accordingly, there is no factual basis in the record for even making even a presumption of an excessive price.

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[392] Transcript, P. C121
[393] Transcript, P2296-P2297 and Soriano Report p. 9-10, para. 23(b).

207. Indeed, Board Staff's conduct in this proceeding in relation to revealing foreign sources, back-out formulas, and prices based upon foreign sources and back-out formulas, has not been transparent or consistent. Based upon the evidence summarized above in paragraph 93, it is apparent that Board Staff did not respond fully and accurately to the Disclosure Letter delivered in response to the Panel's Order for Particulars, specifically in relation to the back-out formula for Sweden. Moreover, on 15 December 2016 Board Staff counsel delivered correspondence attaching "updated tables which Board Staff will be relying upon at the hearing." The 15 December 2016 letter again revealed different use of a back-out formula for Sweden. Board Staff have subsequently attempted to withdraw, or improperly claim privilege in relation to the letter, even in the face of a clear Panel ruling on the issue. Accordingly, not only is there no evidence to prove the foreign sources and back-out information but Board Staff, and their counsel, have not been fair or transparent in relation to the issue.

c) Inconsistent and Inaccurate Disclosure by Board Staff

208. It became apparent from the cross-examination of Mr. Lemay[394] that Board Staff, in their Disclosure Letter delivered in response to the Panel's order regarding particulars, had made several statements that were inaccurate, untrue, and incomplete. Specifically, the Disclosure Letter inaccurately represented that: (1) ex-factory foreign prices reported by Alexion had "matched" prices verified by Board Staff when Board Staff's verification process showed that *higher* international prices for Soliris had been identified by Board Staff; (2) "discrepancies" in prices were attributable to inaccurate reporting by Alexion of higher foreign prices when, in fact, most discrepancies were based on higher prices found by Board Staff; and (3) higher foreign prices found by Board Staff from some sources were not disclosed.

209. These problems are recited in detail in paragraph 93 above but bear repeating:

> (a) **No Match**—The Table on page 6 of the Disclosure Letter states that the 2013 price reported by Alexion for Sweden "matched Board Staff's prices." This statement was false. The 2013 Swedish price found by Board Staff was $217.2790, $3.37 higher than the Swedish price of $213.9103 reported by Alexion.[395] Similarly, page 6 of the Disclosure Letter stated that Board Staff's prices and Alexion's reported prices for the United States "matched...with minor discrepancies due, in part, to rounding from to the fourth decimal place." This statement was also false: the 2014 price found by Board Staff for the United States was $1.66 higher than the price reported by Alexion (significantly higher than a rounding to the fourth decimal place.)[396]

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[394] See paras. 92-95 above.
[395] Transcript, P636-P638; Exhibit 4A.
[396] Transcript, P639-P640; Exhibit 4A.

(b) **Minor Discrepancies Favour Alexion**—The "minor" discrepancies for France for 2012 and 2014, and German for 2014, favoured Alexion.[397]

(c) **Discrepancies in Alexion's Favour Not Disclosed**—The Disclosure Letter did not disclose a 2013 Italian price found by Board Staff that was $9.27 higher than the price found by Alexion.[398] Nor did the Disclosure Letter disclose that Board Staff's 2013 price for France was about $2.20 higher than the price reported by Alexion.[399]

210. Board Staff's evidence on prices and alleged excess revenues is conflicting and inconsistent. Various summaries prepared by Board Staff show alleged excessive revenues in the range of $4.3 million to $6.4 million for the period between 2012 and 2015. Mr. Lemay could not explain why there were differences in the totals.

211. The excess revenues alleged by Board Staff have constantly shifted. For example, in February 2013 Alexion received a Compliance Status Notice showing alleged excess revenues of $1,666,392.09 for 2012.[400] In February 2014, Alexion received a Compliance Status Notice showing excess revenues of $1,666,392.09 for 2012, $572,697.22 for 2013, and a cumulative excess revenue figure of $2,239,089.31.[401] Two months later, in April 2014, Alexion received correspondence indicating that total excess revenues for 2012 and 2013 had increased to $4,097,670.81.[402] Since delivery of the Statement of Allegations in January 2015, Alexion has received no fewer than 5 tables showing alleged excess of revenue based on the *Guidelines* of $5,617,480.42,[403] $6,397,895.54[404], $4,743,572.88 (twice),[405] and $4,378,817.01.[406]

212. The HIPC figures in communications received from Board Staff have also constantly changed. At various times the 2012 HIPC for Germany was either $212.6455 or $214.2568. The 2013 Swedish price has been stated by Board Staff to be $213.9103, $215.6225, and $217.2790. The 2014 Swedish price has been $218.0922, $220.3276, $221.5267, and $222.0913. All of these figures could have a material impact on any alleged excessive revenues. The reasons for these differences was not properly explained by Mr. Lemay or in any other evidence.

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[397] Transcript, P620, P623 (France); P628 (Germany); Exhibit 4A.
[398] Transcript, P629-P631; Exhibit 4A.
[399] Transcript, P620P-622; Exhibit 4A.
[400] Joint Book, Volume 1, Tab 32.
[401] Joint Book, Volume 1, Tab 41.
[402] Joint Book, Volume 9, Tab 117.
[403] Exhibit 5.
[404] Joint Book, Volume 8, Tab 112, Table 5.
[405] Joint Book, Volume 7, Tab 98 (1); Joint Book, Volume 8, Table 1.
[406] Joint Book, Volume 8, Tab 113, Table 3.

213. Furthermore, despite repeated requests and the representation that final information in 2016 would be presented to Alexion and the Panel in March 2017, Board Staff have failed to produce any information or tables calculating the N-NEAP and CPI adjusted figures to the end of 2016.

214. The evidence of alleged excess revenues is unreliable hearsay.[407] Alexion was deprived of the opportunity to cross-examine the person, or persons, who actually prepared the various documents, including the tables containing conflicting data. Even though the Panel may not be bound by strict rules of evidence, there is still a requirement that evidence be consistent and reliable and not offend principles of natural justice, including the right to cross-examine an appropriate witness. See: *B(J) v. Catholic Children's Aid Society of Metropolitan Toronto.*[408]

215. While the Panel can admit evidence that may not be admissible in a court,[409] it is still necessary for Board Staff to establish an adequate factual underpinning,[410] and an important finding, particularly if it involves a penalty, cannot be based solely on hearsay evidence.[411] In one reported decision, a criminal court refused to rely on hearsay in a forfeiture proceeding.[412] See: *Canada (Attorney General) v. Luther*, 2001 NSPC 31 at paras 21-22.

216. Board Staff's evidence quantifying excessive revenues is inconsistent and based on unreliable hearsay. In the circumstances, Board Staff have failed to prove a second essential element of their case; proper quantification of alleged excess revenues.

d) Presumption Rebutted

217. The *Leo Pharma* decision concluded that the "presumption in the Guidelines that the price of a medicine sold in Canada will be considered excessive if it is higher than in any of the comparator countries...is merely a presumption which a patentee can challenge before the Board." [Emphasis added.][413] Earlier versions of the *Guidelines* explicitly recognized the rebuttable nature of

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[407] "While hearsay may well be admissible in this type of hearing, see Statutory Powers Procedure Act, RSO 1990, c S.22, s 15, there must be some basis for finding that the evidence is sufficiently reliable ... This testimony from the respondent was so entirely lacking in detail that it provided no basis upon which the Board could make a reasonable decision." See: *Anten v. Bhalerao*, 2013 ONCA 499 at para. 32.
[408] [1987] O.J. No. 2614.
[409] *Pfizer Canada Inc. v. Teva Canada Ltd.* 2016 FCA 161.
[410] Robert Macaulay & James Sprague, Practice and Procedure Before Administrative Tribunals (Toronto: Carswell, 1991) (loose-leaf 2016 supplement release-10), at 17.1(c).
[411] *Bond v New Brunswick (Board of Management)*, [1992] N.B.J. No. 567, 129 N.B.R. (2d) 149; *B(J) v. Catholic Children's Aid Society of Metropolitan Toronto*; [1987] OJ No 2614 at para. 13.
[412] Canada (Attorney General) v. Luther, 2001 NSPC 31 at paras. 21-22.
[413] Leo Pharma, para. 40.

presumptions.[414] The Act and *Guidelines* do not use mandatory or conclusive language to the effect that a price "will" or "shall" be excessive."

218. In *Teva Neuroscience G.P.-S.E.N.C.*, Justice Hughes observed that focussing on one "presumption" to the exclusion of other factors was a reviewable error: [415]

> 48. I am therefore troubled by the Board's Guidelines, in particular section 9.1 earlier referred to, which provides that if price increases exceed the cumulative CPI increase in the relevant period, there is a presumption that the price is "excessive". Such a presumption effectively ignores the other factors a), b) and c) of section 85(1). [Emphasis added.]

219. In a subsequent judicial review in *Teva Neuroscience G.P.-S.E.N.C.*, the Federal Court agreed with an observation by a panel that it may "fly in the face of common sense" to apply a presumption in a given context. No case has ever suggested that the *Guidelines* create or contemplate a regime of absolute liability based on presumptions: the *Guidelines* raise only rebuttable presumptions.

220. In this case, the evidence establishes that the presumption of an excessive price is rebutted for at least the following reasons:

> (a) The price of Soliris has not increased since the product was first introduced on the Canadian market in June 2009;
>
> (b) The price of Soliris was deemed to be within Guidelines, and not excessive, in 2010 and 2011; The prices of Soliris in the 7 comparator countries have not decreased since 2009 meaning that Canadian purchasers were not deprived during the relevant period of any price advantages afforded to payers in the 7 comparator countries;
>
> (c) Measured by the CPI, the price of Soliris has fallen in real terms by about 10% since 2009, (5.5% between 2012 and 2015) [416] and the current inflation-adjusted unit price of Soliris is now less than $200;[417]
>
> (d) The prices of Soliris in the 7 comparator countries have not decreased since 2009 meaning that Canadian purchasers were not deprived during the relevant period of any price advantages afforded to payers in the 7 comparator countries;
>
> (e) Soliris is a non-traded good, meaning that Soliris was not, and could not be, purchased outside Canada in Canadian dollars in the 7 comparator countries while the Canadian dollar was appreciating in value against the currencies of those countries;
>
> (f) Mr. Soriano's calculations showed that if inflation rates in the 7 comparator countries were taken into account, or PPP exchange rates applied, the Canadian price would not be excessive;

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[414] 1988 *Guidelines*.
[415] *Teva Neuroscience G.P.-S.E.N.C. v. Canada (Attorney General)*, [2009] F.C.J. No. 1597 (FC).
[416] Soriano Report, at pg. 5, Table 3.
[417] Transcript, P2308-P2309.

(g) The existence of the [redacted] with public insurers since 2011 means that approximately [redacted];

(h) Most private insurers who reimburse payment of Soliris apply co-pay arrangements of up to 20% meaning that even private insurers reimburse at a substantially discounted price;[418]

(i) No individual Canadian pays for Soliris, meaning that no "consumer protection" issue has been raised in this case;

(j) The absence of any price increase, the decrease in price based on price inflation, and deemed compliance in 2010 and 2011 lead to the conclusion that there is no patent abuse in this case; and

(k) The only trigger for the investigation leading to the hearing involved foreign exchange variations entirely outside Alexion's control.

There was substantial agreement among all fact and expert witnesses on these fundamental points.

221. The Supreme Court of Canada stated in *Celgene* that the Board's consumer protection mandate is predicated on preventing "abuse" of a patentee's monopoly power to the detriment of Canadian consumers.[419] The absence of any 'detriment' from price increases, and the benefits of price decreases based on CPI, further rebut any inference, or even suggestion, of consumer harm in Canada in this case. There is, in fact, no evidence of consumer harm. Nor is there any evidence that Alexion abused its patent for Soliris; the presumption of excessive pricing was triggered entirely by foreign exchange variations beyond Alexion's control. Dr. Putnam's expert evidence that patent abuse and consumer protection were not engaged on the facts of this case was not challenged by Board Staff or their experts.[420]

222. Alexion therefore submits that any presumption of "excessive revenues" was fully rebutted by the factual and expert evidence adduced before the Panel. Imposing any order for repayment of revenues, or a price reduction in the face of their evidence, would be fundamentally unfair and akin to imposition of absolute liability for events that were entirely beyond Alexion's control. The determination of whether the presumption is rebutted takes place within the *Guidelines* based upon the evidence before the Panel.

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[418] Transcript, P1467-P1468.
[419] *Celgene Corp. v. Canada (Attorney General)*, [2011] S.C.J. No. 1 at paras. 28 and 29 (S.C.C.).
[420] Exhibit 34, paras. 66-81.

Alternative Tests to Confiscate Alexion's Assets are Contrary to Basic Principles of Statutory Interpretation and the *Canadian Bill of Rights*

223. The alternative price tests advocated by Board Staff and the Ministry include the so-called lowest international price" (or LIPC) test[421] and selection of the U.S. or U.K. prices as representing the lowest price.[422] These tests are newly-invented and fall outside the *Act*, *Regulations*, *Guidelines*, or jurisprudence of the Board. To apply the tests retroactively would be inconsistent, unfair, and contrary to the rule of law and concepts of justice. Use of the alternative price tests for the first time against Alexion violates the most fundamental notions of fair notice and due process of law.

224. In the 30-year history of the Board, no decision of a panel, or of the Federal Court, has ever departed from the *Guidelines*, or concluded that the *Guidelines* "do not result in an appropriate implementation of section 85 of the Act" to the *detriment* of a patentee. All previous decisions departing from the *Guidelines*, whether made by Board panels or the Federal Court, have been to the benefit of a patentee on the basis that the *Guidelines* were either inconsistent with the *Act* or worked unfairly against a patentee on the facts of a particular case.

225. To illustrate, in three decisions, either the Federal Court or a Board Panel have accepted variations from the *Guidelines* to the benefit of a patentee. In the *Copaxone* decisions, the Federal Court twice stated that the CPI adjustment methodology in the *Guidelines* cannot be used as an absolute limitation on the price of a medicine. In the *Adderall XR* decision, a panel of the Board concluded that the "...Guidelines did not constitute an appropriate implementation of the terms of the Act", and adopted a non-excessive price that was greater than the price established by the *Guidelines*. In the "*Quadracel and Pentacel*" decisions, the panel accepted a variation of the CPI methodology in the *Guidelines* to the benefit of the patentee to take into account certain discounts given to a public purchaser.

226. There is a cogent reason for this approach. A finding of excessive pricing under Section 85(1) of the *Act* allows the Board to order payment of a patentee's allegedly "excessive" revenues to Her Majesty the Queen in Right of Canada under s. 83(2)(c) of the *Act*. In this respect, the *Act* is confiscatory and involves deprivation or forfeiture to the Crown of revenues lawfully earned by a patentee.

227. Legislation that purports to confiscate or deprive a person, natural or legal, of property must be strictly construed. If there is any doubt or ambiguity about interpretation, it must be resolved in favour of

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[421] See Section VIII of Board Staff's Submissions: "The Price of Soliris is Excessive and should be Capped at the Lowest International Price".
[422] See Section VIII(G) "The Price Cap for Soliris should be based on the U.S. and U. K. Prices".

the party against whom confiscation or deprivation is sought. This principle is firmly established in jurisprudence of the Supreme Court of Canada and the *Canadian Bill of Rights*.

228. In his authoritative book, *The Interpretation of Legislation in Canada*, Pierre-André Côté elaborates on the nature of laws that encroach on property rights. Quoting *Maxwell on the Interpretation of Statutes*, Côté states:[423]

> Laws which encroach on the rights and freedoms of the citizen are interpreted strictly by the courts. As Maxwell wrote (at page 251):
>
> Statutes which encroach on the rights of the subject, whether as regards his person or property, are subject to a strict construction in the same way as penal Acts. It is a recognized rule that they should be interpreted, if possible, so as to respect such rights, and if there is any ambiguity the construction which is in favour of the freedom of the individual should be adopted.

229. As Côté explains, "strict interpretation" is often used interchangeably to mean "not extending to situations not formally provided," and "restrictive (in the narrow sense)."[424] Regarding enjoyment of property rights, Côté states:[425]

> ...encroachments on the enjoyment of property should be interpreted rigorously and restrictively.
>
> Rigorous interpretation: conditions imposed by statute that limit the enjoyment of property must be followed strictly. Restrictive interpretation: if a genuine problem in interpreting a statute that limits the enjoyment of property arises, the judge is justified in choosing the construction that limits the effect of the law and favours the enjoyment of property.
>
> The principle is particularly relevant to expropriation legislation. The courts require that the legislature express themselves extremely clearly where there is an intention to expropriate or confiscate without compensation.

230. In *Dell Holdings Ltd*, the Supreme Court of Canada stated;[426]

> To take all or part of a person's property constitutes a severe loss and a very significant interference with a citizen's private property rights. It follows that the power of an expropriating authority should be strictly construed in favour of those whose rights have been affected. This principle has been stressed by eminent writers and emphasized in decisions of this Court.

231. While *Dell Holdings Ltd* involved expropriation, the Supreme Court has made similar statements in cases involving other forms of confiscation or property deprivation. For example, in *Manitoba Fisheries Ltd. v. R,* a deprivation involved accumulated goodwill in a business. The Court stated:

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[423] Pierre-André Côté, *The Interpretation of Legislation in Canada* (4th ed.), (Toronto: Thomson Reuters, 2011) at 494.
[424] *Ibid.*, at 495.
[425] *Ibid.*, at 511-512.
[426] *Dell Holdings Ltd. v. Toronto Area Transit Operating Authority*, [1997] 1 SCR 32 at paras. 20-21.

> There is no express language in the Act providing for the payment of compensation by the federal Crown, but the appellant relies upon the long established rule which is succinctly stated by Lord Atkinson in *A.G. v. De Keyser's Royal Hotel Ltd.*, where he said:
>
> > The recognized rule for the construction of statutes is that, unless the words of the statute clearly so demand, a statute is not to be construed so as to take away the property of a subject without compensation.

See also, *British Columbia v. Tener,* (deprivation of mineral exploration rights by province.)[427]

232. In *Authorson (Litigation Guardian Of) v. Canada (Attorney General)*,[428] the Supreme Court of Canada confirmed that statutory language must be "unambiguously phrased" to circumvent the protections of the Canadian *Bill of Rights*, one of which is "enjoyment of property rights."

233. Long-standing principles of statutory construction, and the *Canadian Bill of Rights*, preclude interpretation of the *Act* to retroactively apply new tests (including the "revised" MIPC or so-called LIPC) invented and advocated by Board Staff after the commencement of this case. The proposed new tests increase confiscation exposure "to situations not formally provided" for in the *Act* or *Guidelines*. Moreover, the new tests completely violate principles of fair notice because no patentee could be aware of even the possibility of financial exposure based on retroactive application of previously unpublished tests. Neither Parliament in the *Act*, nor the Board itself in the *Guidelines*, has said anything about application of new tests: the absence of any mention at all is the very antithesis of the type of "express language", "clear demand", or "due process of law" required by the common law and the *Canadian Bill of Rights* before a new liability test affecting Alexion's property rights can be created or applied. Furthermore, application of the tests contravenes the principles of "Fairness, transparency, openness and predictability" mentioned in the Preamble to the *Guidelines*.

234. It is also important to note that in the long investigative process in this case that took place over two years and involved good faith negotiations. Board Staff never once mentioned application of these new tests. It is a violation of principles of good faith and *bona fides* to advance liability theories that were never mentioned in the investigative process and lie outside the *Guidelines* Board Staff have instructed patentees to follow. The *Guidelines* and common law principles of natural justice and fairness create and impose duties of good faith and fair dealing on public officials like Board Staff. The duties are at least equal to, if not greater than, the duties the Supreme Court of Canada has imposed on private contracting parties: see *Bhasin v. Hrynew* [2014] 3 S.C.R. 494.

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[427] [1985] 1 S.C.R. 533.
[428] [2003] S.C.C. 29 at para. 55.

235. Finally, as CLHIA explicitly acknowledges in its submission, application of the tests would result in a "penalty" to Alexion that the Panel has no jurisdiction to impose in the circumstances.[429]

Applying Alternative Tests to Expropriate Assets is Contrary to International Law

236. Alexion is a foreign investor in Canada. International norms and Canada's international treaty obligations prohibit expropriation of assets of an investor without notice and fair compensation. These international obligations also prohibit arbitrary, discriminatory, and unjust treatment of an investment as well as treatment that violates basic notions of due process, transparency, and the rule of law. All Canadian law, including laws applied by the Panel, must be interpreted in conformity with Canada's customary and treaty-based international law obligations. The application of alternative tests proposed by Board Staff, the Ministry, or CLHIA, if adopted by the Panel, would be directly contrary to Canada's international obligations and for this reason cannot be applied as a reasonable interpretation of s. 85.

237. The domestic law of Canada is presumed to conform to international law. The presumption of conformity is based on the rule of judicial policy that, as a matter of law, courts will strive to avoid constructions of domestic law under which the state would be in violation of its international obligations, unless the wording of the law clearly compels that result. The presumption applies equally to customary international law and international treaty obligations and serves to inform the development of the common law, the interpretation of legislation, and the exercise of discretion by decision-makers.[430]

238. Customary international law is automatically incorporated into Canadian law pursuant to the common law doctrine of adoption. This automatic incorporation of customary international law rules is justified on the basis that international custom, as the law of nations, is also the law of Canada unless, in a valid exercise of its sovereignty, Canada expressly declares that Canadian law should operate notwithstanding international law. The presumption of conformity applies equally to international treaty obligations. Parliament is presumed to act in compliance with Canada's obligations as a signatory of international treaties and as a member of the international community. In deciding between possible interpretations, courts and tribunals will avoid a construction that places Canada in breach of its international obligations.[431]

Canada's International Law Obligations Prohibit Unlawful Expropriation of Foreign Owned Assets

239. The customary minimum standard of treatment of foreign investors includes rules against expropriation of property. It is well established that foreign assets may only be lawfully expropriated if

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[429] Sanofi Pasteur - 2011 FC 859, para 44.
[430] *R. v. Hape*, [2007] 2 S.C.R. 292, 2007 SCC 26, para. 53.
[431] *Ibid*, paras. 39, 53-54.

done for a public purpose, in accordance with due process of law, in a non-discriminatory manner, and on payment of prompt, adequate and effective compensation.[432] Customary international law recognizes the concept of "indirect" expropriation, or the confiscation of assets through regulatory measures: "a taking of property includes not only an outright taking of property but also any such unreasonable interference with the use, enjoyment, or disposal of property as to justify an inference that the owner thereof will not be able to use, enjoy or dispose of the property within a reasonable period of time after the inception of such interference."[433] Where assets are confiscated indirectly through regulatory measures, illegality will be the rule, since there will have been no compensation paid to the foreign investor.[434]

240. Canada is bound to adhere to a number of multilateral and bilateral investment treaties that prohibit unlawful expropriation of property owned by foreign investors in Canada. For example, NAFTA Article 1110(1) specifically prohibits the Government of Canada from taking measures to confiscate assets[435] of U.S. investors operating within Canada.

241. Like customary international law, NAFTA recognizes that expropriation "includes not only open, deliberate and acknowledged takings of property, such as outright seizure or formal or obligatory transfer of title in favour of the host State, but also covert or incidental interference with the use of property which has the effect of depriving the owner, in whole or in significant part, of the use of reasonably-to-be-expected economic benefit of property even if not necessarily to the obvious benefit of the home State".[436] The jurisprudence acknowledges that there are many ways in which governmental authorities may significantly reduce the economic benefits of a business, and that the imposition of an unreasonable regulatory regime is one such measure.[437]

242. Non-discriminatory regulatory measures that are adopted for a public purpose and enacted in accordance with due process generally will not be considered expropriatory.[438] The same cannot be said for a measure that is discriminatory and not in accordance with due process, lacks proportionality

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[432] R. Dolzer and C. Schreuer, *Principles of International Investment Law*, Oxford University Press 2008, pages 90-91.
[433] Ibid, p. 94, FN 20, citing LB Sohn and RR Baxter, 'Responsibility of States for Injuries to the Economic Interests of Aliens' (1961) 55 AJIL 545, 553 (Article 10(3)(a)); cited in Dolzer/Schreuer, p.94, FN 20].
[434] Ibid, p. 91.
[435] NAFTA Article 1139 defines investment to include "real estate or other property, tangible or intangible, acquired in the expectation or used for the purposes of economic benefit or other business purposes"; A patent is intangible property acquired or used for the purpose of economic benefit.
[436] *Metalclad v. Mexico*, Award, 30 August 2000, para. 108, available at: http://www.italaw.com/sites/default/files/case-documents/ita0510.pdf.
[437] *Feldman v. Mexico*, Award, 16 December 2002, para 103, available at: http://www.italaw.com/sites/default/files/case-documents/ita0319.pdf.
[438] *Methanex v. USA*, Award, 3 August 2005, Part IV, Chapter D, p. 4, para. 4, available at: http://www.italaw.com/sites/default/files/case-documents/ita0529.pdf.

between the means employed and the aim sought to be realized, lacks *bona fides*, and is wholly contrary to the investor's reasonable "investment backed" expectations.[439]

243. The alternative tests proposed by Board Staff, the provinces, and CHLIA meet all indicia of an unlawful confiscatory action. The tests, and sources used to apply the tests, including the IMS MIDAS data have not been applied before against a patentee, are not mentioned in the *Act* or *Guidelines,* are being selectively and retroactively applied against Alexion, and are sought to be applied in complete disregard of due process and basic principles of fairness, transparency, openness, and predictability. If adopted by the Board, the result would be wholly disproportionate to any reasonable and *bona fide* regulatory objective, and completely contrary to Alexion's reasonable expectations.

Applying the Alternative Tests Would Contravene Canada's Obligation to Accord a Minimum Standard of Treatment to Foreign Investors

244. Once Canada has admitted a foreign investment, it is required to accord a minimum standard of treatment to that investment, under both customary law and treaty obligations.[440] While the minimum standard of treatment encompasses protection against unlawful expropriation, the standard also more broadly prohibits any conduct that is arbitrary, unfair, unjust, or discriminatory.

245. The NAFTA obligation to accord a minimum standard of treatment found in Article 1105 of the Treaty reflects the customary standard. In *Waste Management v. Mexico*, the Tribunal defined the standard, in part, as follows: "the minimum standard of treatment of fair and equitable treatment is infringed by conduct attributable to the State and harmful to the claimant if the conduct is arbitrary, grossly unfair, unjust or idiosyncratic, is discriminatory ... or involves a lack of due process leading to an outcome which offends judicial propriety—as might be the case with a manifest failure of natural justice in judicial proceedings or a complete lack of transparency and candour in an administrative process. In applying this standard it is relevant that the treatment is in breach of representations made by the host State which were reasonably relied on by the claimant."[441]

246. The requirement of transparency and the protection of legitimate expectations based on the legal framework as it stood at the time the investment is made are part of fair and equitable treatment standard. In *Metalclad v. Mexico*, a breach of fair and equitable treatment was found, among other

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[439] *Fireman's Fund Insurance Company v. United Mexican States*, Award, 17 July 2006, pages 81-84, available at: http://www.italaw.com/sites/default/files/case-documents/ita0331.pdf.
[440] R. Dolzer and C. Schreuer, supra, p.7, FN 230.
[441] *Waste Management v Mexico*, Final Award, 30 April 2004, para. 98, available at: http://www.italaw.com/sites/default/files/case-documents/ita0900.pdf.

reasons, because: "Mexico failed to ensure a transparent and predictable framework for Metalclad's business planning and investment".[442]

247. Board Staff's proposal, supported by the Ministry, to apply new and unprecedented alternative tests in the proceeding contravenes basic notions of fairness and falls far below the required standard. Fair procedure is considered an elementary requirement of the rule of law and a vital element of the fair and equitable treatment component of the minimum standard of treatment.[443] Imposition of liability based on the proposed new tests would not be "procedurally fair" would violate basic notions of transparency and candour in the administrative process. The proposed application of new alternative tests not found in the *Act*, *Regulations*, *Guidelines* or jurisprudence is manifestly unpredictable and contrary to Alexion's legitimate expectation that its investment would be permitted to operate within a stable business environment supported by basic rule of law principles.

Legitimate Expectations of Notice

248. The *Act* and *Guidelines* give rise to the legitimate expectation that any substantive change to the tests used to establish "excessive revenues" be enacted through the statutory procedure, and that patentees like Alexion would be given "notice" of any such changes *in advance* of accruing potential liabilities for alleged "excessive" revenues.

249. The Supreme Court has set out the considerations that are relevant to the common law duty of procedural fairness.[444] The Federal Court has held that the duty of fairness applies to the Board's decisions.[445]

250. The Supreme Court has also held that:[446]

> Where a government official makes representations within the scope of his or her authority to an individual about an administrative process that the government will follow, and the representations said to give rise to the legitimate expectations are clear, unambiguous and unqualified, the government may be held to its word, provided the representations are procedural in nature and do not conflict with the decision maker's statutory duty. Proof of reliance is not a requisite. It will be a breach of the duty of fairness for the decision maker to fail in a substantial way to live up to its undertaking.

251. Should the panel adopt Board Staff's alternative tests, Alexion will be deprived of procedural fairness and the statutory right to advance notice of the tests that will be used to evaluate its price. It is

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[442] *Metalclad v. Mexico*, Award, 30 August 2000, supra, para. 99.
[443] R. Dolzer and C.Schreuer, supra, p.142.
[444] *Baker v. Canada (Minister of Citizenship and Immigration)*, [1992] 2 S.C.R. 817 at paras. 23-27.
[445] *Sanofi-Aventis Canada Inc. v. Canada (Attorney General)*, 2009 FC 965 at para. 41.
[446] *Canada (Attorney General) v. Mavi*, [2011] 2 S.C.R. 504 at para. 68/

an obvious unfairness to apply such tests retroactively and without notice; it is doubly so, when the decision maker has repeatedly and publicly stated that the *Guidelines* determine compliance, and that they will only be amended after notice and comment.

252. The alternative positions advanced by Board Staff violate "*the most fundamental tenet of the rule of law*...that those who are governed by law must have knowledge of [the law] before acting."[447] The alternative arguments urge retroactive application of newly-invented rules and tests not found in: the *Act*; the *Regulations*; *Guidelines* or the Board's own jurisprudence. Retroactive application of new rules is "a direct assault on the principle of adequate notice."[448]

253. The alternative positions also run contrary to established administrative practices before the Board and undermine the legal and regulatory foundation on which Alexion and all other pharmaceutical manufacturers set the prices of their patented medicines in Canada. The arguments directly violate the most basic notions of the rule of law and due process, and are particularly dubious given the Board's publicly-stated commitment to ensure "predictability", "fairness", "openness", and "transparency."

254. In *Apotex Inc. v. Merck & Co ("Apotex")*,[449] the Federal Court of Appeal held the retroactive application of regulatory requirements under the *Act* is the type of action that offends the rule of law:

> The concern of courts about unauthorized regulations that cause retrospective or retroactive effects or interfere with vested rights is founded upon aspects of the rule of law. "Citizens choose how to act in the belief that the state will impose the legal consequences determined by the legal text discoverable at that time and not on other texts which were not in existence at the time of the relevant action"...It is unfair to change the rules later and catch those who planned their affairs under the former law. [Emphasis added.]

255. Alexion submits that raising new grounds for confiscatory liability and urging departure from the *Guidelines* for the first time in a hearing against an individual company is a colourable attempt to evade the notice and comment provisions in the *Act*. Adoption of the new tests would be a breach of the duty of procedural fairness.

256. There could be serious negative consequences for a determination of liability against Alexion attributable to foreign exchange variations beyond the company's control based on application of newly-invented rules, like the LIPC or modified MIPC. Certainty and predictability in the regulatory environment would be seriously compromised. *Guidelines* compliance would be threatened because there would be no assurance that the *Guidelines* defined the limits of liability, for future pricing or

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[447] Sullivan on the Construction of Statutes (LexisNexis Canada Inc. 2014), Motion Record, Tab 13, at 25.7.
[448] *Ibid*, at 25.8.
[449] *Apotex Inc. v. Merck & Co*, 2011 FCA 329

confiscatory liability. Manufacturers would be deterred from entering, or remaining in, the Canadian market and selling or developing innovative new therapies, including medicines for rare or ultra-rare diseases.

Calculation of Excess Revenues

257. Alexion asserts that Board Staff have failed to establish a crucial element of their case because there is no evidence explaining the source selection and back-out formulae upon which their case depends. The evidence they rely on to quantify allegedly excess revenues is based upon unreliable hearsay. Furthermore, any presumption of excessive revenues has been fully rebutted. Without in any way conceding that any alleged excess revenues should be payable, and under reserve all of its rights, Alexion makes the following submissions on one aspect of the excess revenues claimed by Board Staff.

258. Evidence before the Panel shows that if any one of a number of offsets is taken into account, the quantum of excess revenues is completely offset. For example, the [redacted] more than offsets the alleged excess revenues of $2.23 million alleged within the year-end 2013 compliance statement received by Alexion on 25 February 2014,[451] the $4.097 million demanded in Ms. Tognet's 29 April 2014 letter,[452] or the $4.3 million claimed in the 15 December 2016 letter. Board Staff's reliance on the *Pfizer* decision in this case is misplaced. The *Pfizer* decision did not alter, or overrule, the finding of the Federal Court in *Leo Pharma* that distribution of "free goods" voluntarily reported to the Board could be taken into account; in that case the free goods were distributed to physicians and patients rather than to the drug wholesaler and did not involve the "factory gate" price of the product in that case.

259. Even if the [redacted] were paid by Alexion directly to Innomar amounting to [redacted] The total was comprised of [redacted] and a [redacted] These payments were directly to Alexion's customer and [redacted] The Innomar [redacted] exceeded the $972,586.52 in total excess revenues calculated by Board Staff for 2014 ($813,128.34) and 2015 ($159,458.18).[456] Furthermore, Mr. Haslam testified that if Alexion had taken infusion costs into account in its Form 2 filings, the price of Soliris would have decreased further and offset excessive revenues.

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[450] Joint Book, Tab 39, pg. 3; Transcript,C469-C472.
[451] Joint Book, Tab 41.
[452] Joint Book, Volume 9, Tab 117.
[453] Exhibits 46 and 47.
[454] Exhibit 47.
[455] Exhibit 46.
[456] Joint Book, Tab 113, Table 3.

260. Mr. Soriano's report shows that alleged excess revenues accruing between 2012 and 2015 would also be eliminated if the Panel took into account the CPI adjusted price for Soliris. Specifically, Table 3, on page 5 of the Soriano report shows that between 2012 and 2015 purchasers saved [redacted] million because no inflationary increases were taken for Soliris and the real cost of Soliris declined by %5.5. This is yet another potential offset proven through Mr. Soriano's undisputed evidence. An analogous offset was approved by the Federal Court and ultimately the Board in the *Quadracel and Pentacel* decisions.

Subsection 85(2)

261. Alexion submits that the information and evidence presented during the hearing on the "factors referred to in subsection 85(1)" leaves the Panel "able" to make a determination that the price of Soliris has not been sold at an excessive price in Canada. Accordingly, there is no requirement to consider subsection 85(2), which states:

> 85(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:
>
> (a) the costs of making and marketing the medicine; and
>
> (b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

262. There are only two types of "factor" stated in subsection 85(2): (1) the "costs of making and marketing the medicine"; and (2) "such other factors ... as are, in the opinion of the Board, relevant in the circumstances".

263. In the *Pfizer* decision, the Federal Court quoted from the legislative history of the *Act* when evaluating the Board's constitutional jurisdiction:[457]

> 59 In this regard, Harvie Andre, the then Minister of Consumer and Corporate Affairs, stated in committee proceedings that:
>
> > We do not constitutionally have the ability in Canada of setting prices at the federal level. But again, it is worth repeating that it is not right to say there are not strong price control mechanisms in Canada; there are. They are at the provincial level. Through the fact that they purchase 60% of the drugs, have formularies in some provinces, and can have laws that direct that pharmacists must provide the lowest cost equivalent, and through the bulk purchasing and so on, the net result is that we do have in fact a price control system in Canada.

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[457] *Pfizer Canada Inc. v. Canada (Attorney General)*, 2009 FC 719 at paras. 59-60(FC).

> 60 Minister Andre went on to observe that "it is not intended that the Board would be a profit-control mechanism. The Board is intended ... as a watchdog on the general prices of pharmaceuticals within Canada".

264. The factors in subsection 85(2) must be understood in the context of the overall purpose of *Act*. Subsection 85(2) is not a "profit control mechanism".

Cost of Making and Marketing a Medicine

265. The *Virazole* decision contains some analysis of subsection 85(2)(a):[458]

> There would have to be compelling reasons for the Board to determine the MNE on the basis of a patentee's costs of making and marketing a medicine and it seems likely that the instances in which that analysis will be appropriate will be rare. However, it is not inconceivable that, where the criteria in subsection 85(2) were properly being considered by the Board, a patentee could present evidence which would satisfy the Board that the MNE for a medicine could be established by reference to the costs of making and marketing the medicine.
>
> Nonetheless, even where the Board is instructed by the Act that it may consider such evidence, it is not axiomatic that in each case the costs of making and marketing the medicine will establish a floor for the MNE of the medicine. While each case would have to be considered on its merits, it seems probable that the Board would, pursuant to clause 85(2)(b), examine the broader context in which the situation arose before coming to a conclusion on the point. Also, it will always be for the Board itself, after consideration of the relevant evidence, to make its own determination on the identification, characterization and relevance of each element of costs alleged by a patentee to comprise part of the costs of making and marketing the medicine.
>
> Finally, it should be noted that, given the potentially complex and contentious nature of the financial and accounting evidence on this issue, the Board expects <u>that the determination of a MNE by reference to the costs of making and marketing the medicine would only be possible where the Board received clear and reliable evidence on the point</u>. [Emphasis added.]

266. The *Virazole* panel envisaged, based on the text of s. 85(2)(a), that the provision would: (a) be invoked by a patentee; (b) deal with "a floor" price for the medicine; (c) involve a detailed analysis of different categories of costs; and (d) require "clear and reliable evidence."

267. The subsection 85(2)(a) factor was further considered in the *Copaxone* decision, where the panel noted:[459]

> 48. The Panel is cognizant that this is the first time that the Board is required to address excessive pricing issues based on paragraph 85(2)(a) factors and that the Guidelines provide no guidance on this issue. Paragraph 85(2)(a) refers to "the costs of making and marketing the medicine". Obviously costs are regularly incurred by patentees in the

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[458] Decision: PMPRB-95-D5/VIRAZOLE, at p. 11.
[459] February 25, 2008 Decision: PMPRB-06-D2-COPAXONE, at para. 48.

> making and marketing of medicines. Thus, it is only in exceptional circumstances that the Board is prepared to consider costs of this nature under this provision. It must normally be something which demonstrates that the costs incurred in making or marketing the medicine are so exceptional or provide such an obvious benefit to users that the Board is entitled to rely on this provision.

268. The *Copaxone* panel also contemplated that only the patentee would invoke the section, pointed out that the *Guidelines* provided no guidance on the issue, and stated that it would only be in "exceptional circumstances" that a patentee would be successful in persuading the Board to consider this kind of evidence.

269. Alexion has never raised s. 85(2)(a) and there is no "clear and reliable evidence on the point" before the Panel. Indeed, there is no evidence at all. In the circumstances, "the costs of making and marketing the medicine" are simply not a factor of any kind in this case. Board Staff's attempts to create a "reverse onus" under this section have no basis in the jurisprudence, principles of statutory interpretation, the *Guidelines*, or logic.

Other Factors Relevant in the Circumstances

270. Paragraph 85(2)(b) contemplates application of "other factors" enacted by regulation or "as are, in the opinion of the Board, relevant in the circumstances". No regulation has been enacted.

271. The *Virazole* decision contemplated that 85(2)(b) might be used to "examine the broader context in which" an issue was raised under 85(2)(a). The *Copaxone* case correctly noted that the *Guidelines* contained "no guidance" concerning how issues of excessive pricing should be addressed under s. 85(2).

272. It is submitted that no "other factors" could be applicable in this case, particularly if they worked to the detriment of a patentee, unless there was publication, for example in the *Guidelines* of a "Board policy on the pricing of drugs used to treat orphan diseases." This is the minimum level of notice that would be required. Application of a new factor never previously published could not be relied upon to support confiscation or forfeiture of a patentee's assets. It would be completely contrary to the requirements of strict construction, procedural fairness, natural justice, and the Canadian *Bill of Rights* to use an open-ended statutory discretion to create, for the first time against a patentee in a pending case, new "factors" supporting interference with a patentee's property rights.

273. Finally, any such factors, assuming they were articulated at all, would have to be clearly stated in the particular case and then proven on the basis of "... clear and reliable evidence", as the *Virazole* panel noted.

274. No articulation of any "other relevant factors" has ever occurred in this case. In the absence of a factor having been articulated, there can be no evidence at all, let alone any "clear and reliable" evidence to support such a factor. Any "other relevant factors" relied on by Board Staff under 85(2)(b) in this case are a complete mystery. While paragraph 272 purports to list "factors", the factors are nothing more than bald rhetorical allegations, such as "Soliris is one of the most expensive medicines in the world"[460] and "[t]here has been no evidence led to establish the reason for the extreme cost of Soliris ...".[461] None of these assertions so much as suggest what the "other factors" are, let alone how they should be applied with any fairness or precision.

275. Alexion submits that Board Staff has failed to properly state any basis why, if the Panel "is unable" to make the determination that the price of Soliris is "excessive" under subsection 85(1), the Panel should make a determination under subsection 85(2).

CONCLUSION

276. The *Act* and *Guidelines* do not, and were never intended to, impose a regime of absolute liability.

277. The *Act* creates a process, now well established in the case law, that a drug price is first established under s. 85(1)(a) based on information reported under s. 80(1) and the *Regulations*. When no alternative medicines in the same therapeutic class are applicable (as in this case), the Canadian price of the drug is compared with: prices of the same drug in the 7 comparator countries under s. 85(1)(c); and, as required under s. 85(1)(d), changes in the overall price level in the Canadian economy reflected in the CPI.

278. Each of the two comparative factors must be considered and weighed fairly. Applying the two applicable factors in this case can only lead to the conclusion that Soliris is not excessively priced because: the Canadian price has never increased; prices in the other countries have never decreased; and the Canadian price has indisputably fallen given changes in the overall price level as reflected in the CPI. The only thing that changed in this case was the value of the Canadian dollar in relation to European currencies. Foreign exchange rates are not a statutory factor and were irrelevant to any purchasing decision made in this case because Soliris is a non-traded good that cannot be purchased outside Canada with Canadian currency, no matter what the value of the Canadian dollar relative to European currencies at any given point in time.

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[460] Board Staff, *Written Submissions*, para. 272(a).
[461] Board Staff, *Written Submissions*, para. 272(b).

279. Board Staff failed to prove that the Canadian price was the highest among the comparator countries. Their calculations depended on foreign price sources and back-out formulae (created in a process that occurs outside the *Act* and *Guidelines*) that were not established through an appropriate witness at the hearing, even though the issue was flagged by a highly qualified expert in a report delivered several months before the hearing commenced. But quite apart from the failure to prove the highest international price, there are a myriad of reasons that rebut any presumption of excessive price, chief among them the absence of any evidence of consumer harm or patent abuse.

280. Board Staff's attempts to devise new liability rules outside the *Act* and *Guidelines* and apply the rules retroactively are fundamentally unfair, violate long-standing canons of construction, and offend the very *Guidelines* the Board has encouraged Alexion and the rest of the pharmaceutical industry to follow.

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Original signature redacted

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SCHEDULE "A"
LIST OF AUTHORITIES

TAB

1. *Pfizer Canada Inc. v. Canada (Attorney General)*, [2009] F.C.J. No. 82 (FC).
2. *ICN Pharmaceuticals Inc. v. Canada*, [1996] F.C.J. No. 112 (FC)
3. *Teva Neuroscience G.P.-S.E.N.C. v. Canada (Attorney General)*, [2009] FC 1155 (FC).
4. April 19, 2006, PMPRB-04-D2-DOVOBET
5. April 10, 2008 Decision: PMPRB-06-D3-ADDERALL XR
6. June 14, 2012 Decision: PMPRB-07-D6-QUADRACEL and PENTACEL
7. *CIBA-Geigy Canada Ltd. v. Canada (Patented Medicine Prices Review Board)*, [1994] 3 FCR 425.
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