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. (the "Respondent")
and the medicine "Soliris"

Board Staff's Reply to Alexion's Written Representations

(Board Staff's Motion to Strike Paragraphs 37 and 38 of the Amended Response)

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1. The relevant facts are set out in the Written Representations of Board Staff dated July 31, 2015 (Motion to strike paragraphs 37 and 38 of Alexion's Amended Response).

2. Additionally, it must be noted that on October 5, 2015, the Panel issued its Reasons for Decision in response to Alexion's motion regarding alleged conflicts of interest. The Panel dismissed Alexion's motion in its entirety.

3. Paragraph 37(h) and (i) of Alexion's Amended Response contains allegations that Isabel Jaen Raasch and Board Staff acted contrary to ethical principles by virtue of Ms. Jaen Raasch's involvement in this litigation. Given the Panel's decision of October 5, 2015 these subparagraphs of Alexion's Amended Response must be struck.

4. Board Staff repeats and relies on its Written Representations dated July 31, 2015 in support of its position that the balance of paragraphs 37 and 38 of the Amended Response should also be struck. Board Staff also relies on its Written Representations of October 10, 2015 in Response to Alexion's motion for disclosure dated October 15, 2015.

5. The allegations contained in paragraphs 37 and 38 which are the subject matter of the within motion to strike deal with the following matters:

i) The proper role of counsel for Board Staff in an excessive price hearing (paragraphs 37(a),(b),(c),(e),(f),(g) and 38 (second sentence) of the Amended Response).

ii) The disclosure obligations of Board Staff (paragraphs 37(d),(e).

Attached as Schedule A is a copy of Alexion's Amended Response. We have colour coded the Amended Response to indicate the subject matter of the offending paragraphs in 37 and 38.

Colour Code:
Yellow – allegations relating to conflict;
Pink – allegations relating to role of counsel for Board Staff; and
Green – allegations relating to disclosure

6. Alexion's Written Representations on this motion do not provide any justification for why these allegations are of relevance to a determination by the Board as to whether the price of Soliris is excessive having regard to s. 85 of the *Patent Act*.

7. Indeed, Alexion concedes that some or all the issues raised in paragraphs 37 and 38 (second sentence) above are relevant only in the context of the various interlocutory motions before the Board regarding disclosure. Even if these matters are relevant to interlocutory motions presently before the Panel (and Board Staff strongly denies that they are relevant to the interlocutory motions) the allegations are wholly irrelevant to the hearing on its merits.

8. All of the cases relied upon by Alexion in its Written Representations of September 9, 2015 in response to this motion address the test to be applied when a party seeks to dismiss an action (or strike a defence) in its entirety and end the litigation between the parties. These cases have no application to this

motion. Board Staff does not seek to strike out the Amended Response of Alexion, nor does it seek to prevent Alexion from defending its position that the price of Soliris is not excessive. Board Staff merely seeks to have the hearing proceed in an expeditious and fair manner.

9. Board Staff submits that it is plain and obvious that paragraphs 37 and 38 (second sentence) of Alexion's Amended Response are redundant, immaterial, irrelevant, scandalous, frivolous, vexatious, and an abuse of process. They ought to be struck.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 19th day of October, 2015

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SCHEDULE A

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

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

AMENDED RESPONSE TO THE STATEMENT OF ALLEGATIONS OF BOARD STAFF

Overview

1. Respondent Alexion Pharmaceuticals Inc. ("Alexion" or "Respondent") acknowledges the allegations in paragraphs 4, 6, 7, 8, 10, 11, 12, 13, 22, 23 and 24 of the Statement of Allegations of Board Staff ("Allegations").

2. Alexion denies the remainder of the allegations.

3. In its Allegations, Board Staff allege that the ex-factory price of Soliris has been "excessive" over a three-year period, beginning in 2012.

4. Board Staff have not alleged that the ex-factory price of Soliris was "excessive" when it was introduced in 2009[1] or before 2012.

[1] While never fully understood by Alexion, Board Staff apparently took issue with the introductory price but the *de minimus* amount involved, $16,946.37 (or less than 1% of the N-NEAP), was too low to trigger Board Staff's

5. The Canadian ex-factory price of Soliris has not increased since it was introduced.

6. Moreover, with minor exceptions, the ex-factory price of Soliris has not decreased in any of the seven reference countries where Soliris has been sold internationally since the product was first introduced to the Canadian market.

7. The following graphs illustrate the actual ex-factory prices of Soliris in Canada and the seven reference countries listed in the Regulations and the 2010 *Compendium of Guidelines, Policies and Procedures* (the "Guidelines")

8. Board Staff allege that the ex-factory price of Soliris became "excessive" after its introduction, *even though the ex-factory price has not increased in Canada and has not materially changed in any of the reference countries, except the United States* ("U.S.")*where the price has increased.*

9. Despite the absence of price increases in Canada or decreases in any of the reference countries, Board Staff allege that prices in Canada became excessive in 2012 when the Canadian ex-factory price failed the "highest

international price" test in the Guidelines due entirely to changes in exchange rates.

10. Despite responding to the Panel's June 23, 2015 order requiring delivery of particulars ("Particulars Order") Board Staff have still not adequately explained ~~in the Allegations~~ how it was possible for an ex-factory price that was "non-excessive" in one year to become "excessive" in the next without a price increase in Canada or price decreases elsewhere. When asked for particulars to explain their allegation in this respect, Board Staff's counsel was unhelpful and provided no comprehensible response. ~~Alexion reserves all its rights to amend once particulars are provided or ordered, but~~ Alexion ~~can only assumes~~ still believes from the particulars delivered in response to the Particulars Order that it is only fluctuations in the international exchange rates that made the Canadian ex-factory price *appear* to have increased relative to some reference countries when *applying the international price test in the Guidelines.*

11. Board Staff have apparently concluded (and, until ordered pursuant to the Particulars Order, refused to provide material details), that if the Canadian ex-factory price somehow 'fails' (in their determination) the "highest international price" Guidelines test, the price must be "excessive" under the criteria in subsection 85(1) of the *Patent Act* (the "*Act*"). The *Act* requires the Board to take into account all price factors in s. 85(1), and to reach a reasonable determination, based on all of these factors, whether a price is "excessive". Moreover, exchange rates are not a factor listed in s.85(1) of the *Act* and it is

not evident how, without price increases in Canada and price decreases elsewhere, changes in exchange rates can result in a finding of excessive pricing under s.85(1).

12. In the Allegations, Board Staff acknowledge that the Guidelines are not binding on the Board. The Allegations, however, are clearly and solely predicated on Board Staff applying the Guidelines as if the Guidelines have prescriptive legal force.

13. The Allegations demonstrate the absurdity of applying the Guidelines in this case. Board Staff reach the arbitrary, impractical, and logically untenable position that a Canadian ex-factory price that did not change from the time the medicine was first sold in Canada and did not change in comparator countries (other than price increases in the U.S.), went from being "non-excessive" to "excessive" based on the value of foreign currency fluctuations. The result is a virtual expropriation of company revenues based on international currency fluctuations over which Alexion had no control and from which the *Act* does not purport to insulate Canadian purchasers. But even assuming the *Act* could reasonably be construed to cover international currency fluctuations, Board Staff cannot show in this case that any purchaser is actually worse off as a result of the fluctuations, which must be a necessary corollary of any determination of "excessive" pricing.

Board Staff's Errors

14. In its Allegations, Board Staff make at least five fundamental errors in reaching the conclusion that the price of Soliris has been "excessive" during the review period. They:

(a) fail to understand the meaning of "excessive" under the *Patent Act* and therefore misapply the actual test under subsection 85(1) of the *Act*, which requires the Board to take into consideration all factors under this subsection to rationally advance the purposes of the legislation;

(b) misapply the highest international price test in the Guidelines by treating it as binding, contrary to subsection 96(4) of the *Patent Act*;

(c) deviate from the economic rationale behind the Guidelines, which are intended to rationally advance the purposes of the *Act;*

(d) both in the Guidelines, and as applied in this case, Board Staff inconsistently use the word "price", sometimes to mean the nominal price (not adjusted for price level) and sometimes to mean the real price (adjusted for price level); and

(e) fail to explain and articulate how they applied international pricing from the reference countries, including the particular foreign prices and exchange rates they used for comparative purposes, and all other factors, concepts, and assumptions they relied upon when comparing the sale, purchase, or price of Soliris in Canada and the reference countries. While the particulars delivered on July 3, 2015 in response to the Particulars Order help Alexion to understand, in part, how Board Staff applied international pricing, Board staff's explanation is still incomplete.

Economic Analysis

15. Subsection 85(1) of the *Act* addresses the potential problem that a patentee's statutory monopoly during the exclusivity period might cause prices to rise to levels that will harm Canadian purchasers. The legislative intent of these provisions is not to regulate the prices of drugs *generally*. The purpose is to specifically address the potential for a patentee to abuse its patent monopoly for a patented medicine during the exclusivity period by causing prices for the medicine to be established at, or rise unacceptably to excessive levels. The provisions of the *Patent Act*, and accordingly the Board's determination whether the price of a drug is "excessive", must be interpreted in a manner consistent with that legislative purpose.

16. While the focus is obviously and necessarily on the price of the patentee's drugs in Canada, the *Act* nonetheless states that the Board must look to the "prices" of drugs in other countries: paragraph 85(1)(d). The purpose of looking at international prices is to provide an additional reference point when determining whether a "price" in Canada is or is not excessive. The word "price" is not defined in the *Act* itself.

17. Economists use the term "price" in different ways. Often the word refers to a "nominal" price as expressed in historical monetary terms. By comparison a "real" price takes into account the effect of inflation. In nominal terms, the list price of Soliris is unchanged since its introduction in 2009 whereas in real terms its price has declined by more than 8%.

18. As is well known, and uniformly recognized by economic agencies charged with making international price comparisons, conversion using nominal exchange rates does *not* capture changes or differences in real purchasing power. Exchange rates vary for many reasons other than changes in relative price levels across countries. For example, expectations regarding a central bank's monetary policy can affect an exchange rate. When *nominal* exchange rates are used to draw inferences about changes in *real* purchasing power, errors are inevitable—as the Board Staff's position in this case amply demonstrates.

19. The *Act* manifestly concerns the *real* cost to Canadian purchasers of patented medicines. At the domestic level, the *Act* permits prices of patented medicines to increase based on increases in Canada's Consumer Price Index (CPI). The CPI measures changes in Canada's domestic price level. If a medicine's nominal price increases at the same rate as the overall price level, then its "real" price remains unchanged. If the "nominal" price was not "excessive" initially, it cannot become "excessive" over time if its real price remains constant. If no CPI increases are sought, or applied, and the real price actually decreases, it tortures logic and language to assert, as Board Staff do, that a price that was not initially excessive, and that decreased over time, has become excessive.

20. It defies reason to read the *Patent Act* as meaning that an introductory price that was non-excessive, and that has declined in real terms since introduction, is nevertheless excessive for reasons outside the Board's or the

Patentee's control. Regardless of how the *Act* is read, it cannot have been intended to place revenue streams of Canada's suppliers of patented medicines, particularly those who do not increase their prices, at the mercy of the world's central bankers or other vagaries that cause international currency fluctuations.

21. The perversity of the Allegations are further illustrated by appreciating that patented drugs are what economists describe as "non-traded goods". These are products which cannot simply be purchased on the international market because of regulatory restrictions requiring the products to be purchased in Canada. Canadian purchasers cannot take advantage of changes in exchange rates to purchase products, like medicines, when the "nominal" prices of those drugs are lower in another jurisdiction.

22. When "nominal" prices decrease in another jurisdiction based on the relative strengthening of the Canadian dollar, there is no meaningful sense in which the price of a non-traded good in Canada has increased relative to the price of the same good in the foreign market. Buyers in the foreign market pay just as much, in real terms, as they did before the Canadian dollar strengthened —and so do Canadian purchasers. For traded goods, the deteriorating currency in a foreign market means that purchasers of traded goods in the foreign market are *worse* off and Canadians are *better* off. As a generalization, Canadians' money is now worth more than it was, but only for the purchase of traded goods.

23. The only sense in which Canadian prices have increased is that Canadian buyers pay more for a non-traded good than they would pay if that good were freely traded. In other words, because Canadian purchasers cannot buy medicines on the foreign market, they cannot take advantage of the (relatively) strong Canadian dollar. This constraint applies to all non-traded goods. Canadian buyers cannot, for example, "import" cheaper subway ticket prices from a foreign market. In the same sense, fees charged by doctors in Canada do not decrease when the Canadian dollar strengthens versus other currencies. It makes no sense to say, under these circumstances, that Canadian patients must "pay more" to see a doctor in Canada than they did before the dollar strengthened.

24. While the "price" of a drug in another country may be a useful factor in determining whether a price is "excessive" in Canada, Board Staff must compare prices in a way that makes economic sense and is consistent with the regulatory objectives of the *Act*. It is well known that comparing prices both internationally and over time is especially fraught with difficulty, and must be conducted with care to avoid perverse results like those Board Staff assert here. A purely mechanical and arbitrary application of the highest international price test in the Guidelines is contrary to legislative intent, defies economic sense, and leads to the absurd result that a price initially deemed "non-excessive" has become "excessive" because of currency fluctuations that make no difference whatsoever to buyers.

25. Indeed, given that Alexion has never taken any price increases to adjust for inflation, even CPI increases to which it is entitled under the Board's own Guidelines, the price of Soliris in real terms has continually *decreased* since the drug was introduced in Canada.

26. Board Staff's position effectively expropriates revenues from Alexion based on foreign currency fluctuations over which Alexion has no control. If the Canadian dollar *strengthens vis-à-vis* the comparator countries, Alexion must pay "excess revenues". If the Canadian dollar *weakens* against the same comparator currencies, however, Alexion cannot increase the price of Soliris to compensate for losses it may sustain beyond CPI rates. In effect, Board Staff wish to engage in a "heads I win, tails you lose" strategy under which it expropriates the benefit of a strengthening Canadian dollar and leaves Alexion to deal with the burden of a weak Canadian dollar by limiting increases to CPI rates. The *Act* was never intended to achieve such an arbitrary and perverse result. Indeed, the interpretation and application of the *Act* in the manner advanced by Board Staff, to enable the taking of property based on foreign exchange factors not found within the *Patent Act* and based on foreign transactions not within Alexion's control, contravenes the *Canadian Bill of Rights* in that it abrogates, abridges, infringes, and deprives Alexion of its right to a fair hearing and the enjoyment of property. Moreover, this interpretation does nothing to protect purchasers and may even deter manufacturers from selling in Canada.

27. Forcing drug manufacturers to disgorge revenues based on currency exchange rate fluctuations over which they have no control is directly contrary to the regulatory function of the Board, which is solely to determine whether the price of the drug, in Canada, is "excessive".

Other Material Facts

28. Board Staff have made several factual errors in the Allegations to colour the analysis and to provoke an incorrect result. For example, in paragraph 1, Board Staff allege that the price of Soliris is "over half a million dollars per patient". This is untrue. Soliris is dosed according to a patient's weight. Depending on the patient's weight, the cost can be as low as $80,000 per year. The same error is repeated in paragraph 9.

29. Board Staff state—repeatedly—that the price of Soliris in Canada is "higher [than] in the United States": see paras. 2, 19, 20 and 26. Even if true, this is irrelevant. Under its own Guidelines, the U.S. price is not determinative of anything. The price of Soliris depends on comparisons with 7 reference countries, of which the U.S. is but one.

30. Board Staff have alleged, in paragraphs 19 through 21, that Alexion's price is higher than Guidelines for 2014 and that "Alexion continues to sell Soliris to Canadians at the highest international price". This is also untrue and has not been established by Board Staff.

Response to Particulars Provided on July 3, 2015

31. As noted above, on June 23, 2015, a Panel of the Board granted the Particulars Order. Particulars were delivered in response to the Particulars Order on July 3, 2015.

32. For the reasons provided above, Alexion submits that none of the particulars provided by Board Staff in response to the Particulars Order in any way changes the fundamental proposition that there can be no "excessive revenues" in this case. The introductory price of Soliris in 2009 has not increased in six years, was not deemed excessive in 2010 and 2011, and the differences between Canadian and foreign prices of Soliris based on foreign exchange rate differentials are attributable to international economic and political factors beyond Alexion's control and cannot be attributed to any "abuse" of the patent for Soliris.

33. The particulars delivered consist of a cover letter dated July 3, 2015 with three Appendices – Tabs A through C. A number of tables are appended to Tab C, purportedly supporting calculations of allegedly excessive pricing amounts.

34. Table 5, behind Tab C, contains pricing information for 2014. The Table alleges $2,043,931.35 in additional "Excess Revenues" for calendar year 2014 and "Cumulative Excess Revenues" between 2012 and 2014 of $6,397,895.54.

35. Without in any way acknowledging that the particulars delivered by Board Staff on July 3, 2015 support any proper allegation of excessive pricing, the particulars and other materials delivered to date, demonstrate the following:

(a) Between 2009 and 2014, the "N-ATP" (or national average transaction price) of Soliris in Canada, $224.7333, did not **increase**. Furthermore, there was no allegation in 2010 and 2011, when the price of Soliris was identical (i.e., $224.7333) that the same price was excessive;

(b) Between 2009 and 2014, there were no material **decreases** in prices for Soliris in the seven comparator countries. In the period under review in this proceeding, 2012 through 2014, source and ex-factory prices (applying the Board's reduction formulae) were largely the same in Germany, Italy, Sweden, and the United Kingdom. During the 2012-2014 period, there were price increases in the United States of about 6.3%. Between 2013 and 2014, there were small price decreases in France (l.9%) and Switzerland (0.3%).

(c) Between 2009 and 2011, the price of Soliris in Canada was higher than in the U.S. yet there is no allegation of excessive pricing in Canada for those years on that basis. The allegation that the price of Soliris was higher in Canada than in the U.S. between 2012 and 2014 is entirely irrelevant (having no basis in the *Patent Act*, the *Patented Medicines Regulations*, the Guidelines, or the Board's jurisprudence) and is inconsistent with Board Staff's application of the HIPC test between 2009 and 2011;

(d) Between 2012 and 2014, Board Staff applied the HIPC test and calculated excess revenues based upon the difference between the highest price outside Canada (at prevailing exchange rates based on their 36-month rolling average formula) and the N-ATP. Over the last year, the currencies in the seven comparator countries listed in the Regulations have generally been increasing in value against the Canadian dollar using Board Staff's

36-month rolling average formula. Based on Board Staff's own formula and the materials provided in response to the Particulars Order, there will likely be no excess revenues in 2015 applying the HIPC test and no basis for any reduction in the current price of Soliris. The materials provided in response to the Particulars Order therefore preclude any reduction in the price of Soliris going forward;

(e) Throughout 2015, the Canadian price of Soliris, $224.733, has been lower than the price of Soliris in the United States and Switzerland based upon current exchange rates; and

(f) The Panel should refuse any request by Board Staff to freeze or limit prices based upon Consumer Price Index ("CPI") factors. To do so would be manifestly arbitrary and unfair given that Alexion has never increased the price of Soliris and has no control over international exchange rates.

36. Board Staff's application of the HIPC test contains many inconsistencies and is an unreliable basis for making any finding of excessive pricing against Alexion for the following reasons:

(a) The formulae published by Board Staff for sourcing and verifying foreign prices are based upon private *ad hoc* communications between Board Staff and "officials" in comparator countries. There is no transparency or public record of the content of those communications or how they influence foreign pricing formulas. The *Patented Medicines Regulations* require reporting of "publicly available ex-factory prices...sold to each class of customer" in foreign countries. When pricing determinations may depend upon Board Staff's formulae, Board Staff should be required to disclose publicly (as patentees must in relation to publicly available foreign ex-factory prices) all information and communications upon which their calculations depend;

(b) In 2015, the Board published its formulae for foreign price sourcing and verification. The source for verification of Swedish prices is the *Dental & Pharmaceutical Benefits Agency* (TLV), in which prices are reported in Swedish kronas. The formula published by the Board states that there is "no need" to "back out" (i.e., to reduce) prices from Sweden if TLV is used because it "corresponds to an ex-factory pharmacy price." The TLV prices mentioned for Soliris at relevant times are believed to be the same price as the Apoteket price reported by Alexion to the Board, and represent the price at which Soliris is sold to hospitals. Despite the prices being the same, Board Staff "backed out"(or reduced), the Apoteket prices reported between 2012 and 2014 producing a result of several million dollars of alleged excess revenues. In past years, the Board has similarly changed back-out formulae for other countries without there having been any change in the source price (for example, in the United Kingdom between 2012 and 2013). Alexion's liability therefore turns on arbitrary selection of foreign source pricing based on opaque formulae, inconsistent application of the formulae, and unpredictable changes in the formulae;

(c) Board Staff rejected publicly available ex-factory prices in Italy reported by Alexion. Instead, Board staff strictly applied information from only one source, an Italian publication, *l'Informatore Farmaceutico*. That publication lists only one price given to public entities. If the source reported by Alexion were used, Italy would be the highest international price for purposes of the HIPC and there would be no excessive pricing in any of the years under consideration. Indeed, even if Board Staff merely averaged the publicly available price reported by Alexion with the price paid by the public entity as recorded in *l'Informatore Farmaceutico*, it would have a substantial impact on allegations of excessive pricing.

(d) In contrast with their practice relating to Italian prices, Board Staff do apply an averaging formula to U.S. prices. The price used for the U.S. is the average of the Wholesale Acquisition Cost ("WAC") and a discounted

price given to federal government departments and agencies as listed in the Federal Supply Schedule ("FSS"). If the same averaging formula approach were used for Italian prices as are used for U.S. prices, it would have a substantial impact on allegations of excessive pricing.

(e) As with fluctuating international exchange rates, the selection and application of the foreign price verification criteria are completely outside Alexion's control and cannot even be known by a patentee until the Board publishes new criteria each year. The application of these criteria is arbitrary, inconsistent, and entirely within the Board's control. But even applying these criteria, the price of Soliris has not increased in Canada since its introduction to Canada in 2009, has not decreased in any material way in the comparator countries since 2009, and there are no allegations of excess revenue by Board Staff for the years 2010 and 2011. The vastly different outcomes for different years in the absence of any changes to Canadian and foreign prices illustrates the arbitrary, inconsistent, and even capricious nature of Board Staff's allegations of excessive pricing in this case.

37. Board Staff counsel are not conducting themselves in a manner consistent with ethical principles applicable to their prosecutorial role. In particular:

(a) The role of counsel representing Board Staff is that of a prosecutor requesting relief in the nature of a fine, or confiscation of assets, from a patentee based upon alleged abuse of a patent to generate excess revenues. The prosecutorial nature of Board Staff counsel's role is reflected in section A.3.4 of the Guidelines (referring to Board Staff's "prosecutorial functions"), the Board's Annual Report (which describes the General Counsel as the advisor to the PMPRB and the individual who "leads the prosecution team in proceedings before the Board."). Even the jurisprudence of the Board, Federal Court of Appeal, and Federal Court refer to the "prosecution" of proceedings. (See, for example, *ICN*

Pharmaceuticals Inc. v. Canada (Staff of the Patented Medicine Prices Review Board) (C.A.) [for 1997] 1 F.C. 32 (ICN) at ¶ 61; *Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)*, [2005] F.C.J. No. 1928 at ¶10; PMPRB-07-D1- *QUADRACEL and PENTACEL* (Application for leave to intervene by GlaxoSmithKline Inc.)

(b) The Code of Conduct of the Law Society of Upper Canada requires a lawyer, "when acting as a prosecutor, to act for the public in the administration of justice resolutely and honorably within the limits of the law while treating the tribunal with candour, fairness, courtesy, and respect." When engaged as a prosecutor "the lawyer's prime duty is not to seek to convict but to see that justice is done through a fair trial on the merits" and furthermore, a prosecutor "exercises a public function involving much discretion and power and must act fairly and dispassionately."

(c) In this case, counsel representing Board Staff are seeking to 'convict' at all costs, to unreasonably increase the extent and amount of the confiscation of Alexion's assets, and are unreasonably obstructing the ability of Alexion, and the Panel, to ensure a fair proceeding on the merits. They are acting in an overly adversarial fashion by deliberately withholding particulars and failing to produce and disclose evidence necessary to ensure a fair hearing on the merits.

(d) Throughout the proceeding, Alexion's counsel has sought disclosure of the documents and evidence Board Staff will rely upon in prosecuting the case. This material must be disclosed according to the Board's jurisprudence and judicial decisions relating to proceedings before the Board. The Panel, in its reasons for granting, in part, the Particulars Order, mentioned Board Staff's obligations to disclose this material. Despite all of these clear statements of Board Staff's obligations, and despite two separate requests since June 23, 2015, Board Staff counsel

continue to refuse disclosure of this crucial evidence. This adversarial and uncooperative approach by Board Staff counsel to their basic disclosure obligations interferes with, and indeed thwarts, a fair proceeding on the merits and is demonstrative of Board Staff's refusal to act fairly and dispassionately in the prosecution of the matter. Instead, Board Staff counsel are clearly adhering to an inappropriate and unfair "trial by ambush" strategy.

(e) Board Staff counsel are deliberately advancing positions before the Panel they know to be unsupported by the *Patent Act*, the *Patented Medicines Regulations*, Guidelines, or jurisprudence of the Board. These include allegations that the price of Soliris is "expensive" and that the price of Soliris in Canada is higher than in the U.S. If these were relevant considerations, they would also have held true between 2010 and 2011, yet there are no allegations of excessive pricing for those years. In effect, Board Staff counsel are advancing rhetorical, and not principled, positions that are inconsistent with their obligation to ensure a fair proceeding on the merits and deal candidly with (and not mislead) the Panel. Furthermore, Board Staff are refusing to disclose evidence to support these irrelevant positions.

(f) Conduct by Board Staff Counsel in contravention of their prosecutorial role is further demonstrated by their response to the interventions of the B.C. Attorney General and CLHIA. Board Staff counsel support these interventions knowing that the positions advanced, and the remedies requested, are unsupported by the *Patent Act*, *Patented Medicines Regulations*, Guidelines, or jurisprudence of the Board. The response of Board Staff counsel to these interventions is designed to thwart a fair hearing on the merits and is in derogation of their duty of candour to the Panel. A prosecutor acting fairly, dispassionately, and in the public interest would not support interventions seeking relief the prosecution has no basis for requesting or the tribunal has no legal authority to grant. Indeed,

Board Staff's approach is not in the public interest because of the tremendous cost, and public resources committed, to conducting a hearing before the Panel.

(g) Board Staff counsel are well aware that the only basis for advancing the prosecution lies in a comparison of the price of Soliris in Canada with the price of the medicine outside Canada. Given the absence of any price increases in Canada or materially relevant price decreases outside Canada, Board Staff are also well aware that any price differentials based on the HIPC, whether relating to exchange rates or formulation or application of the foreign price verification formulae, are entirely outside the control of Alexion and cannot be fairly characterized as "abusive." Accordingly, they seek to vilify and demonize Alexion based upon irrelevant allegations that the price of Soliris is "expensive" or higher in Canada than in the U.S. when they know that current price differentials based on the HIPC test are entirely beyond Alexion's control. This approach has the potential to mislead the Panel (and is therefore in contravention of the duty of candour) and result in an unfair hearing.

(h) Board Staff are so intent on obtaining a confiscatory order against Alexion that they have also violated basic rules of professional ethics. On July 13, 2015, Alexion learned that Isabel Raasch, a former Gowlings partner in Ottawa recently hired as PMPRB General Counsel, had become involved in the prosecution against Alexion. As a former Gowlings' partner, Gowlings' knowledge of Alexion based upon the lawyer client relationship between Gowlings and Alexion is imputed to Ms. Raasch. Alexion was entitled to assume that normal ethical principles would be observed and that an ethical screen would be implemented to ensure Ms. Raasch did not become involved in any proceeding against Alexion. Instead, Board Staff have deliberately violated that principle by permitting her to become involved in the prosecution.

(i) Board Staff's ethical lapses in relation to Ms. Raasch, their failure to properly and timely disclose evidence to ensure a fair hearing, and their advancement of irrelevant positions that will prolong a hearing brought at great expense to the public and Alexion, all serve to undermine public trust and confidence in the Board and its processes. Regulated parties and the public are not well served when prosecutorial authorities take the approach of Board Staff counsel in this proceeding.

38. Based on the material provided in response to the Particulars Order, other material filed by Board Staff and their counsel, and Board Staff's representation to the Panel that other positions in relation to 85(1) are merely argument based upon the existing record, Alexion relies on the assumption that Board Staff have stated all factors they are relying on for purposes of section 85(1) of the *Patent Act* and that the only factor turns on section 85(1)(c) and the HIPC test. Given the history of this prosecution, and in particular Board Staff's refusal to disclose documents and evidence upon which they will rely at the hearing, it would cause extreme prejudice to Alexion for Board Staff to introduce new factors, or evidence in support of new factors, under section 85(1) of the *Patent Act*.

Date: ~~March 9, 2015~~
July 17, 2015

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