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

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.

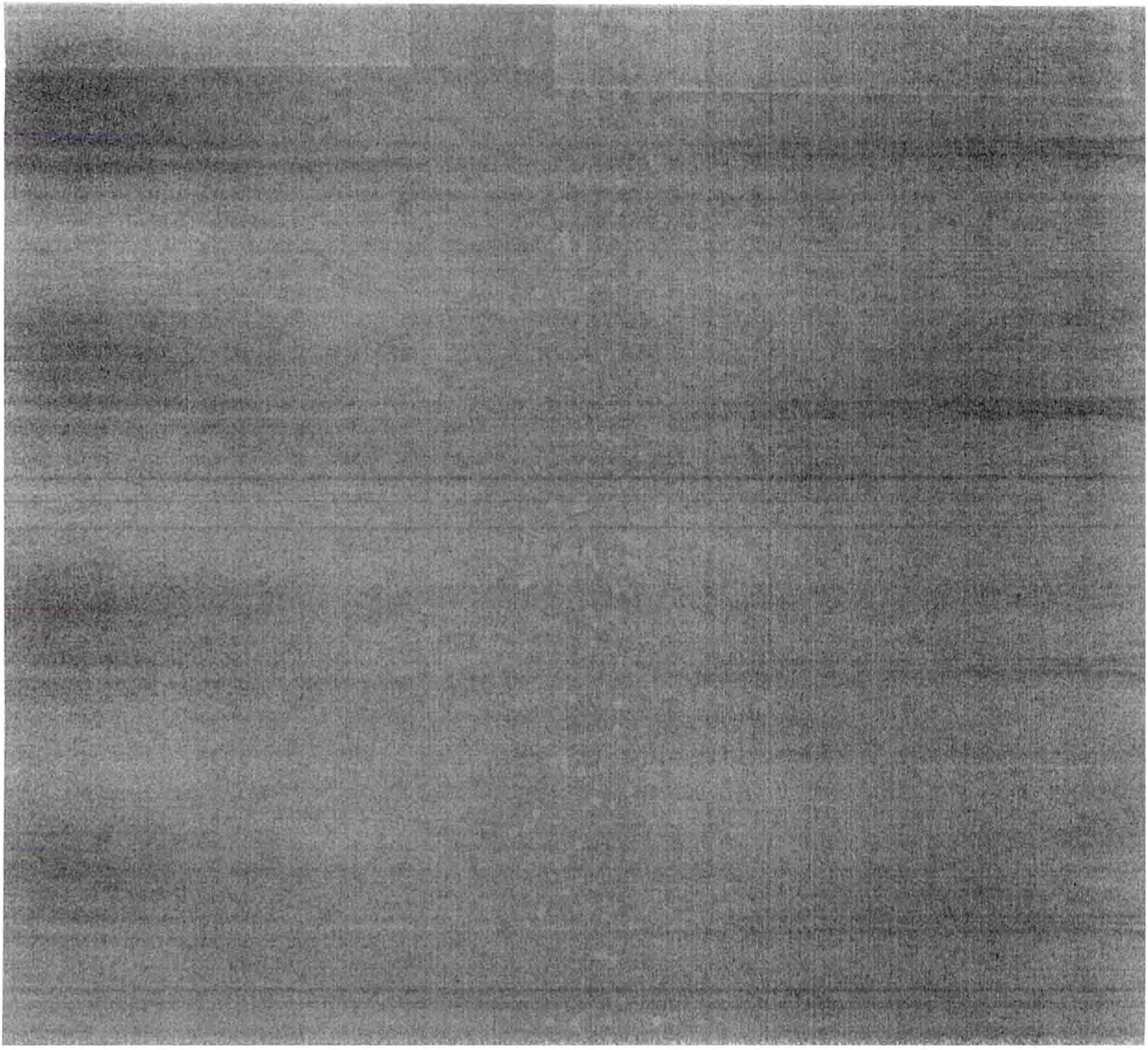
3. In its Allegations, Board Staff allege that the ex-factory price of Soliris has been "excessive" over a three-year period, beginning in 2012.

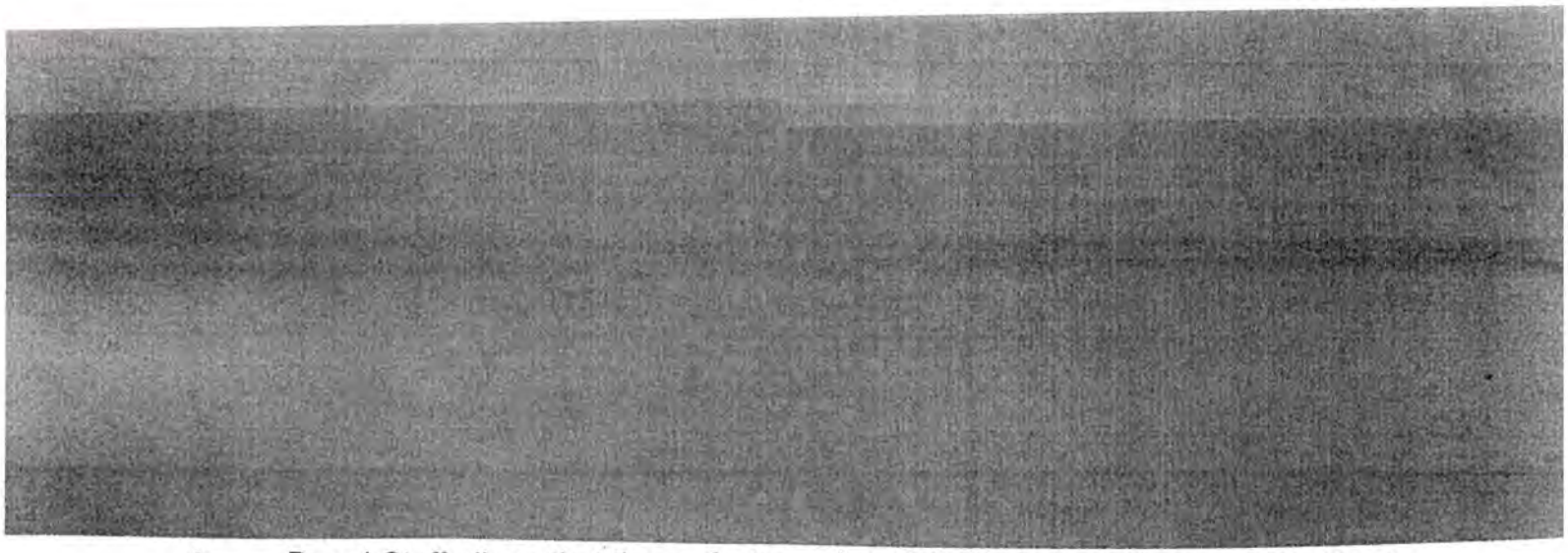
4. Board Staff have not alleged that the ex-factory price of Soliris was "excessive" when it was introduced in 2009 or before 2012.

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 <u>any</u> 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 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. Board Staff have not 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 can only assume 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 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 US), 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.

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 US price is not determinative of anything. The price of Soliris depends on comparisons with 7 reference countries of which the US 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.

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Malcolm Ruby
GOWLING LAFLEUR HENDERSON LLP
1 First Canadian Place
100 King Street West, Suite 1600
Toronto ON M5X 1G5

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GOWLING LAFLEUR HENDERSON LLP
1 First Canadian Place
100 King Street West, Suite 1600
Toronto ON M5X 1G5

Malcolm N. Ruby
Tel: 416-862-4314
Fax: 416-863-3614
malcolm.ruby@gowlings.com

Alan West
Tel: 416-862-4308
Fax: 416-863-3480
alan.west@gowlings.com

Lawyers for the Respondent

TO: **PATENTED MEDICINE PRICES REVIEW BOARD**
Legal Services Branch
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1
Tel: (613) 952-7623
Fax: (613) 952-7626

Guillaume Couillard *(Secretary of the Board)*
guillaume.couillard@pmprb-cepmb.gc.ca

Parul Shah *(Legal Counsel PMPRB)*
parul.shah@pmprb-cepmb.gc.ca

PERLEY-ROBERTSON HILL & MCDOUGAL LLP
340 Albert Street
Suite 1400
Ottawa, ON K1R 7Y6
Tel: (613) 566-2833
Fax: (613) 238-8775

David Migicovsky
dmigicovsky@perlaw.ca

Christopher Morris
cmorris@perlaw.ca

Lawyers for Board Staff

AND TO: **MEDICAL BENEFICIARY AND PHARMACEUTICAL SERVICES**
British Columbia Ministry of Health
PO Box 9652 STN PROV GOVT
Victoria BC V8W 9P4
Tel: (250) 952-1464
Fax: (250) 952-1584

Barbara Walman *(Assistant Deputy Minister)*
Barbara.Walman@gov.bc.ca

Representative for the Interveners, the Provinces and Territories - British Columbia, Yukon, Saskatchewan, Manitoba, Ontario, New Brunswick, Newfoundland, and Nova Scotia