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"

WRITTEN SUBMISSIONS (REDACTED) OF HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF BRITISH COLUMBIA, AS REPRESENTED BY THE MINISTER OF HEALTH

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WRITTEN SUBMISSIONS OF HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF BRITISH COLUMBIA, AS REPRESENTED BY THE MINISTER OF HEALTH ("THE MINISTRY")

INTRODUCTION

1. The matters that must be determined by the Board are whether the price of Soliris is excessive, and if so, the maximum price at which Soliris may be sold in Canada.

2. Section 86(2) of the *Patent Act* entitles a provincial minister of health to appear and make representations with respect to the matter being heard by the Board:

> (2) The Board shall give notice to the Minister of Industry or such other Minister as may be designated by the regulations and to provincial ministers of the Crown responsible for health of any hearing under section 83, and each of them is entitled to appear and make representations to the Board with respect to the matter being heard.

3. As noted by the Board in its decision dated November 24, 2015, at paragraph 35:

> In effect, subsection 86(2) recognizes that provincial ministers of health, as a primary source of funding for the purchase of patented medicines, are uniquely situated to provide information that may be relevant in the proper determination of the case.

4. Since provincial governments are a primary source of funding for the purchases of medications in Canada, information about the public funding process and the impact of drug pricing on public funders is highly relevant and important evidence for the Board to consider in determining whether the price of Soliris is excessive, and, if the Board does determine that the price is excessive, in determining the appropriate remedy.

5. Section 85 of the *Patent Act* sets out the factors that the Board is to consider in determining whether the price of a medicine is excessive. While certain factors are specified in section 85(1), section 85(2) provides that if the Board is unable to determine whether the price of a medicine is excessive after taking into account the factors set out in section 85(1), the Board may also consider, inter alia, such other factors as are, in the opinion of the Board, relevant in the circumstances.

6. The evidence provided by Eric Lun is relevant to the factors set out in sections 85(1)(a) and 85(1)(c) of the *Patent Act.* The Board may also take Mr. Lun's evidence into account pursuant to section 85(2), if required.

7. As noted by Mr. Lun during his testimony, the provinces of Ontario, Manitoba, and Newfoundland and Labrador have consented to the Ministry representing them in this matter, and support the remedy being sought by the Ministry.

SECTION 85(1)(A) OF THE *PATENT ACT*

8. Section 85(1)(a) of the *Patent Act* requires the Board to consider the price at which Soliris has been sold in Canada.

9. At list price, annual treatment costs for Soliris for an adult range between approximately $500,000 and over $700,000, depending on the indication in question.

10. In determining whether the price of Soliris is excessive, its annual treatment cost must be viewed not in isolation, but in the context of the broader effect of its cost on payors, including the opportunity costs resulting from the public funding of Soliris and the cost pressures under which public payors operate.

11. Mr. Lun testified that funding for drugs outside of hospital is provided 65 to 70% through private means, and 30 to 35% through public funding. In British Columbia, public funding is provided through the PharmaCare program.

Transcript, Volume 11, P1383

12. In the 2014/15 fiscal year, PharmaCare provided funding for 740,000 beneficiaries. The total annual expenditure of PharmaCare for 2014/15 was $1,078,990,000 and the amount paid for drugs which are considered expensive drugs for rare diseases ("EDRDs") was approximately $15,700,000.

Transcript, Volume 11, P1387-P1390
Exhibit 1, Tab 130

13. Mr. Lun indicated that the PharmaCare budget for 2016/17, 2017/18 and 2018/19 is $1,175,000,000 each year, with no growth available from year to year. He also indicated that for the last quarter of the fiscal year 2016/17, a PharmaCare budget deficit is projected.

Transcript, Volume 11, P1393
Exhibit 1, Tab 131

14. The PharmaCare budget constitutes 6.5 to 7% of the total health care budget for the Ministry.

Transcript, Volume 11, P1394

15. Although Alexion takes the position that the annual treatment cost of Soliris constitutes only a very small percentage of the annual budget of public funders,

the annual treatment cost for even one Soliris patient is very significant and must be viewed in the context of the overall budgetary constraints of the Ministry. In administering and funding the health care system, the Ministry must not only ensure that responsive and effective health care service is delivered in the province, but it must also ensure the sustainability of the health care system for future generations.

Transcript, Volume 11, P1392
Exhibit 1, Tab 131

16. In determining whether to provide funding for the purchase of any medicine, the Ministry must consider the opportunity cost -- any amount that is spent on one product is not available to spend on another. In the case of Soliris, an annual treatment cost of $500,000 for one adult patient represents $500,000 that cannot be used to treat many, many other patients; as noted by Mr. Lun, the average total paid PharmaCare cost per beneficiary in 2014/15 was $1,287. Furthermore, to the extent that the PharmaCare budget may be exceeded in any fiscal year, less funding will be available for other programs provided through the Ministry of Health, include hospital and physician services.

Transcript, Volume 11, P1388
Transcript, Volume 11, P1394

17. The annual treatment cost of Soliris represents a significant portion of the Ministry's expenditures on EDRDs. The Ministry is currently funding [redacted] EDRDs, including Soliris. The total EDRD expenditure for 2015/16 was $[redacted]; expenditures on Soliris represented $[redacted] of that amount. Furthermore,

the average cost per patient per EDRD in 2015/16 was $[redacted] – the calculation of the average includes expenditures made by the Ministry on Soliris, which has an annual treatment cost per patient considerably in excess of $[redacted].

Exhibit 1, Tab 137

18. The budgetary constraints under which the Ministry is operating cannot be expected to improve in the coming years, particularly given the increasing availability of EDRDs. While the Ministry funded [redacted] EDRDs in 2012/13 for a total expenditure of $[redacted], by 2015/16 it was funding [redacted], for a total expenditure of $[redacted] – an expenditure increase of almost 50%. A further [redacted] EDRDs are currently under review for funding. The annual treatment cost of the EDRDs currently under review for funding range from $[redacted] per adult (for [redacted]) to $[redacted] per adult (for [redacted]). Given the fact that the Ministry's PharmaCare budget is frozen for the next three fiscal years, any funding of new EDRDs that may be approved must come from the same budget amount that is currently operating under a deficit.

Exhibit 1, Tab 137
Transcript, Volume 11, P1407

19. In addition, the annual expenditures on Soliris by the Ministry are increasing from year to year. Annual growth rates in expenditure have been 17.7% (2013/14),

25.5% (2014/15) and 31.6% (2015/16), and are mainly attributable to increasing numbers of patients being covered.

Exhibit 1, Tab 137
Transcript, Volume 11, C333

20. While the provinces do have listing agreements which provide [redacted]. Mr. Lun testified that the listing agreement with Alexion relating to Soliris is [redacted].

Transcript, Volume 11, C314-315

21. Assuming that the list price of Soliris remains the same and that any renewals of the agreements include the same [redacted] provisions, [redacted]

Transcript, Volume 11, C326-C328
Exhibit 25

22. The PharmaCare expenditure information from British Columbia for Soliris relates only to expenditures for the PNH indication, as there is no coverage provided through PharmaCare (and no listing agreement with Alexion) for the aHUS indication. Mr. Lun testified that he is aware that a British Columbia hospital provides funding for Soliris for aHUS, and that the hospital pays full list price, plus a 5% markup. He is also aware of patients in British Columbia who receive private insurance coverage for Soliris for the aHUS indication.

Transcript, Volume 11, P1430, C337

23. Ontario provides funding for Soliris for aHUS for multiple patients at full list price. Ontario is also required to pay a 6% mark-up on the price of the product, which further increases the expense to the province.

Transcript, Volume 11, P1431-1432
Exhibit 29

SECTION 85(1)(C) OF THE *PATENT ACT*

24. Section 85(1)(c) of the *Patent Act* requires the Board to consider the price at which Soliris is being or has been sold in markets outside of Canada.

25. The price at which Soliris was being sold in markets outside of Canada was a very important consideration - but not the only consideration - for the pan-Canadian Pharmaceutical Alliance ("pCPA") during the negotiations between the pCPA and Alexion relating to provincial funding of Soliris.

26. Mr. Lun testified that during the negotiations in 2010 and 2011, the pCPA (with Ontario as lead negotiator) reviewed international pricing of Soliris and determined that the price of Soliris in the United States ("US") was the lowest of any of the comparator countries. [redacted]

Transcript, Volume 11, C297-303, 306-307
Exhibit 23, Tabs 4, 5 and 6

27. The fact that the price for Soliris in the US was considerably less than the list price in Canada was cause for significant concern on the part of the Ministry. The Minister of Health of the time wrote a letter to Alexion on July 6, 2011, stating as follows:

> "I wish to express my significant concerns with regards to the price that you are charging for your drug eculizumab (Soliris) in Canada. I am advised that the price that is available to American citizens mere kilometres south of us is substantially less than the price in Canada....
>
> While my staff are in negotiations with you, I must let you know that my expectations are that we are able to access a price that is comparable to what is charged in the United States (US).

Canadians deserve access to their medications at a fair price. Your inflated price is a significant barrier. Governments have a responsibility to ensure that value is achieved for the taxpayer. Agreeing to a price that is substantially greater than what you charge your US based customers would be difficult to justify, especially in these days when public dollars are scarce.

.....

I am aware of no justification for the fact that Canadians and British Columbians are being asked to pay a significantly higher price than our American neighbours.

Exhibit 23, Tab 10

Mr. Lun testified that during his ten years with the Ministry, this was the first time that a Minister had sent a letter to a company while the province was involved in drug price negotiations with that company.

Transcript, Volume 11, P1421-1423

28. The outcome of the negotiations demonstrates that even Alexion felt that the US price was a relevant consideration for the pricing of publicly-funded Soliris in Canada. The agreement that Alexion and the pCPA eventually arrived at included [redacted]

[redacted]

Exhibit 23, Tab 11
Exhibit 24
Transcript, Volume 11, C314-317

29. It was not only the US price that the pCPA was concerned with during the negotiation process. The pCPA was also aware that [redacted]

Exhibit 23, Tab 6
Transcript, Volume 11, C303-C304

ADDITIONAL FACTORS

30. The Ministry submits that in addition to all of the above, the following facts are relevant, and should be taken into consideration by the Board in its determination of whether the price of Soliris is excessive:

(a) the fact that, [redacted]

[redacted] (plus, in some cases, a mark-up) is paid for the aHUS indication by the provinces and hospitals that provide coverage for aHUS patients. While negotiations were initiated between Alexion and the pCPA for the aHUS indication, there was disagreement over the clinical coverage criteria and the discounted price and as such negotiations were stopped in February, 2016.

Transcript, Volume 11, P1430, C337

(b) the fact that private insurers provide coverage for Soliris for some Canadian patients, and those private insurers are not able to benefit from the net discount available to the provinces through their pricing agreements with Alexion.

Transcript, Volume 11, P1439

(c) the fact that public payors are subject to external pressures to provide coverage for EDRDs, and specifically in the case of Soliris, public payors were subject to lobbying by patient advocacy groups funded, at least in part, by Alexion. Furthermore, in the case of British Columbia, Alexion exerted additional pressure on the Ministry by pursuing multiple requests for information under the British Columbia *Freedom of Information and Protection of Privacy Act*. The Ministry responded to certain of the requests during the negotiation period. At the time the Ministry and

Alexion finalized the listing agreement, Alexion withdrew all remaining requests for information.

The combination of the public pressure to fund treatment with the fact that Alexion is in a monopolistic position resulted in the pCPA and the Ministry being at an inherent disadvantage in the negotiations for a discounted price for Soliris.

Transcript, Volume 11, C320-323, P1432-1435

(d) the likelihood that Alexion has entered into agreements with payors in other countries which provide for lower-than-list prices to be paid in those countries, which means that the publicly available list prices for those other countries do not accurately reflect what is actually being paid for Soliris. Specifically, Dr. Addanki testified that there may be discounts off of a public price like the wholesale acquisition cost ("WAC") in the US that would not be apparent in references to the WAC.

Transcript, Volume 11, P1333

(e) the fact that Alexion is seeking approval for three additional indications for Soliris (**Transcript, Volume 12, P1487**), and it is reasonable to expect that public payors will be subject to pressure in the future to fund Soliris treatment for any additional indications that are approved.

31. Given all of the above, the Ministry submits that the Board should find that the price at which Soliris has been, and is being, sold in Canada is excessive.

REMEDY SOUGHT BY THE MINISTRY

32. If the Board determines that the price at which Soliris has been, and is being, sold in Canada is excessive, the Ministry seeks an order by the Board establishing the maximum price at which Soliris may be sold in Canada to be equivalent to the lowest price of Soliris in the comparator countries.

33. In seeking this order, the Ministry notes its full agreement with the March 24, 2017 written submissions made in relation to remedy by Board Staff.

34. The remedy sought by the Ministry is consistent with the negotiating approach taken by the pCPA in the 2010-11 negotiations with Alexion, in that the pCPA was [redacted]

35. The provinces do not have an agreement with Alexion for the aHUS indication. While listing agreements between Alexion and the provinces for the PNH indication exist, they do not adequately address the Ministry's concerns about the cost of Soliris. In particular, the agreements include a [redacted] which [redacted] and which [redacted]

[redacted]

36. If the price of Soliris were reduced only to a level to match the median price of the comparator countries, there would be minimal benefit to the provinces.

37. It is the position of the Ministry that the lowest possible list price for Soliris would be the most beneficial to all payors, whether public or private, and would be consistent with the consumer protection mandate of the Board.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

DATED at Victoria, British Columbia, this 31st day of March, 2017.

Original signature redacted

Sharna Kraitberg, Counsel for Her Majesty the Queen
in Right of the Province of British Columbia, as represented by the
Minister of Health