

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"**

**NOTICE OF MOTION
AND WRITTEN REPRESENTATIONS**

(Motion in Writing for Particulars of Relief
sought by Board Staff under Section 83 of the *Patent Act*)

RESPONDENT, ALEXION Pharmaceuticals Inc. ("Alexion"), makes this motion in writing at the direction of the Hearing Panel ("Panel") given in the case conference held before the Panel on Wednesday, 21 December 2016.

THE MOTION IS FOR:

1. An Order that Board Staff deliver to Alexion and the Panel forthwith the following particulars of the Allegations in the Amended Statement of Allegations ("Amended Allegations"):

(a) under section 83(1)(a) of the *Patent Act*, the specific reduction (or reductions) in price for Soliris that Board Staff requests the Panel to order in relation to future sales of Soliris in Canada;

(b) under section 83(1)(c) of the *Patent Act*, the specific amount (or amounts) Board Staff are asking the Panel to order Alexion to forfeit to Her Majesty in right of Canada based upon past sales of Soliris in Canada, including the particular years for which the forfeiture is sought;

(c) the specific test, or tests, relied on by Board Staff for any request for a reduction in the price of Soliris in relation to future sales of Soliris in Canada or for forfeiture to Her Majesty in right of Canada based upon past sales of Soliris in Canada in particular years;

(d) the sources, and specific identification, of the international prices used by Board Staff for purposes of comparing the Canadian price of Soliris with the price of Soliris sold in other countries under any test used for requesting a reduction in the price of Soliris in relation to future sales of Soliris in Canada or for forfeiture to Her Majesty in right of Canada based upon any past sales of Soliris in Canada in particular years;

(e) the actual international exchange rates used by Board Staff to convert any international price used by Board Staff for purposes of comparing the Canadian price of Soliris with the price of Soliris sold in other countries under any test used for requesting a reduction in the price of Soliris in relation to future sales of Soliris in Canada or for forfeiture to Her Majesty in right of Canada based upon any past sales of Soliris in Canada in particular years; and

(f) the calculations used by Board Staff under any test relied upon by Board Staff to request a reduction in the price of future sales of Soliris in Canada or for forfeiture to Her Majesty in right of Canada based upon any past sales of Soliris in Canada in particular years.

THE GROUNDS AND WRITTEN REPRESENTATIONS FOR THE MOTION ARE:

2. Alexion is the subject of a confiscation and forfeiture prosecution before the Panel in relation to sales of Soliris in Canada.

3. Soliris was approved by the Board as a “breakthrough” medicine and introduced on the Canadian market in 2009 at a price of \$224.73/ML. In 2010 and 2011, the Board, in annual compliance reports, stated that the price of Soliris was compliant with Guidelines published by the Board.

4. In the seven years that Soliris has been on the Canadian market, the price of Soliris has never increased. Not even CPI increases have been requested. In real terms, the price of Soliris has fallen by about 10%. There have been no material reductions in the prices of Soliris in the seven comparator countries used by the Board to monitor the price of Soliris in Canada under the Highest International Price Comparison (“HIPC”) test.

5. Between 2012 and 2014 the Canadian dollar increased in value against the Euro and other European currencies. The variations in foreign exchange rates created the illusion that the Canadian price of Soliris was the highest among Canada and the seven comparator countries under the HIPC test using the Board’s foreign exchange

rate methodology. The Board's Guidelines acknowledge that "Exchange rate variations" create "Unusual Circumstances" under the HIPC test that are "a result of events beyond the control of the patentee."

6. Even though the price of Soliris has never increased, has fallen in real terms, and foreign exchange rates are beyond Alexion's control, the Board commenced an investigation into the price of Soliris and followed with a prosecution before this Panel. In an original Statement of Allegations delivered in January 2015, Board Staff sought an order that Alexion forfeit to Her Majesty in right of Canada about \$5.6 million for past sales of Soliris between 2012 and 2014 and that the future price of Soliris in Canada be reduced to approximately \$215.95 as of 30 June 2014.

7. On 23 June 2015, in response to a Motion for Particulars, the Panel ordered Board Staff ("particulars order") to provide "details of and concerning all sources used by Board Staff in calculating international prices, and any calculations used, made, or considered by Board Staff in determining all international prices and foreign currency exchange rates upon which allegations of excessive pricing under the [HIPC test] are based."

8. On 3 July 2015, in response to the particulars order, Board Staff delivered a new demand requesting forfeiture to Her Majesty in right of Canada of about \$6.4 million and a reduction in price going forward to \$218.01 as of 31 December 2014 applying the HIPC test.

9. Based upon the 3 July 2015 demand, Alexion prepared fact and expert evidence in anticipation of a hearing to commence in June 2016.

10. In late May 2016, about one month before the scheduled hearing date, Board Staff moved to amend the Statement of Allegations to plead alternative forms of confiscatory liability involving retroactive application of newly-invented liability tests—a newly-applied Median International Price Comparison (“MIPC”) test and a newly-invented Lowest International Price Comparison (“LIPC”) test— both of which lie entirely outside the Guidelines. Under the newly-applied MIPC test, Board Staff sought retroactive forfeiture to Her Majesty of past revenues of \$18,109,287.56 for past sales of Soliris back to 2009 and a reduction in the price of Soliris to \$213.52 going forward. Under the newly-invented LIPC test, Board Staff sought retroactive forfeiture to Her Majesty in right of Canada of \$67,017,803.63 for past sales of Soliris back to 2009 and a reduction in the price of Soliris to \$174.80 going forward.

11. The May 2016 motion by Board Staff also requested retroactive relief against Alexion based on application of the newly-invented tests using IMS MIDAS data, a non-public price source not found within the Guidelines, *Patented Medicines Regulations*, or previously used by the Board for international pricing. Under the newly-modified, and retroactively applied, MIPC test based on IMS data, Board Staff sought forfeiture to Her Majesty in right of Canada of \$35,565,068.74 for past sales of Soliris dating back to 2009 and a reduction in the price of Soliris to \$197.73 going forward. Under the newly-invented, and retroactively applied, LIPC test based on IMS data, Board Staff sought forfeiture of \$91,908,321.21 to Her Majesty based on sales back to 2009 and a reduction in the price of Soliris to \$152.95 going forward.

12. Alexion objected to the retroactive application of newly-invented tests falling outside the Guidelines. The Panel nonetheless granted the amendments and the length of the hearing was significantly increased to accommodate the scope of the new relief sought by Board Staff. Alexion continues to object, in the strongest terms, to the fundamentally unfair, and unprincipled, nature of the amendments, which are affront to the rule of law and, in the words of Ruth Sullivan, Canada's leading commentator on statutory interpretation, "a direct assault on the principle of adequate notice."¹

13. On 15 December 2016, about a month before the rescheduled hearing was to begin, Board Staff delivered a letter informing Alexion that they had yet again changed the basis for calculating their forfeiture demands for past sales of Soliris and price reductions of Soliris going forward.

14. The 15 December 2016 letter and attachments indicate that Board Staff now seek forfeiture to Her Majesty under the HIPC test of \$4,378,817.01 based on past sales by Alexion (between 2012 and 2015) and a price of \$225.11 for Soliris going forward. The letter further states that Board Staff now seek retroactive forfeiture to Her Majesty under the newly-applied MIPC test of \$21,214,366.94 based on past sales by Alexion (between 2009 and 2016) and a reduction in the price for Soliris to \$209.03 going forward. Finally, the letter indicates that Board Staff now seek retroactive forfeiture to Her Majesty under the newly-invented LIPC test of \$78,125,303.63 for past sales of Soliris (between 2009 and 2016) and a reduction in the price for Soliris to \$174.73 going forward. No information was provided in the 15 December 2016 letter that updates or reconciles forfeiture demands or price reductions based upon IMS

¹ Sullivan on the Construction of Statutes (LexisNexis Canada Inc. 2014), at 25.7 and 25.8.

MIDAS data with the new foreign price information the Panel is now being asked to apply.

15. The different prices, tests, sources, calculations, forfeiture demands based on past sales, and requests for price reductions going forward, are contained in four separate, complex, and conflicting schedules and appendices received between January 2015 and December 2016. Some of the documents contain extensive footnotes with unexplained acronyms and unsupported calculations. Furthermore, the 15 December 2016 letter from Board Staff counsel contains an unexplained reference to German pricing. The presentation of pricing information in the four documents is opaque, confusing, disorganized, and conflicting and therefore presents a significant challenge for Alexion to untangle and compare the respective documents and information contained within the documents. Alexion, their counsel, and their experts, and the Panel should not be forced to spend substantial time and resources reviewing, organizing, and interpreting the different information in the various documents. The confusing and disorganized state of the materials could lead to incorrect conclusions.

16. To avoid confusion, Board Staff should be required to provide Alexion and the Panel with one document that constitutes, in effect, Board Staff's "prayer for relief", including relief in the alternative, in which Board Staff clearly and succinctly state: the alternative tests they propose; the foreign price sources they have used; the different currency exchange rates they have applied at different times; and the calculations they have used under each test for all forfeiture demands based on past sales and the requested price reductions going forward.

17. Any party subject to substantial asset forfeiture liability should have clear and precise notice of all amounts a prosecuting authority seeks to forfeit. Where forfeiture is based upon different price sources and varying foreign exchange rates, the sources and rates should be clearly identified and the calculations underlying the forfeiture/confiscation demands should be precise, consistent, and clearly stated. Clarity and precision are particularly important where a prosecuting authority changes forfeiture demands over time and, as in this case, seeks retroactive confiscation/forfeiture of assets based upon previously unpublished rules and tests not found within published regulatory guidelines.

18. Alexion and the Panel require, in one succinct document, particulars relating to each test Board Staff urges the panel to apply, the identification of all foreign prices relied on for each test, identification and explanation of all currency exchange rates applied for each test, and clarification of all calculations underlying each forfeiture demand and proposed reduction in price going forward under each test. The particulars are essential to address Board Staff's shifting case theory and the moving target of retroactive forfeiture and confiscation Alexion must contend with.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of the motion:

19. Letter from Board Staff counsel to Alexion counsel dated 15 December 2016;
20. Letter from Board Staff counsel to Alexion dated 20 December 2016; and
21. Letter from Alexion counsel to the Board dated 21 December 2016.

Dated: 23 December 2016

Original signed by

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