

Federal Court



Cour fédérale

**Date: 20170106**

**Docket: T-1160-16**

**Citation: 2017 FC 21**

**BETWEEN:**

**ALEXION PHARMACEUTICALS INC.**

**Applicant**

**and**

**THE ATTORNEY GENERAL OF CANADA**

**Respondent**

**REASONS FOR AN ORDER dated December 28, 2016**

**SIMPSON J.**

[1] Alexion Pharmaceuticals Inc. [Alexion] has filed a Notice of Motion pursuant to Federal Court Rule 51 in which it appeals two Orders made by Prothonotary Aylen dated September 1, 2016.

[2] The first Order struck, as premature, Alexion's Application for Judicial Review of a decision of the Patented Medicine Prices Review Board [the Board] allowing certain amendments to the Board's Notice of Allegation. The appeal from this Order will be described as the "First Appeal".

[3] In the second Order, the Prothonotary dismissed as moot Alexion's motion for an order on consent protecting certain information as confidential. The appeal from this Order will be described as the "Second Appeal".

I. The First Appeal

[4] Alexion is a Delaware company headquartered in New Haven, Connecticut. It has marketed Soliris (eculizumab) in Canada through a Canadian affiliate since 2009. Soliris is used to treat rare and devastating blood and genetic disorders.

[5] On January 15, 2015, the Board's Staff delivered a Statement of Allegations stating that from 2012 to 2014, Soliris had been sold at an excessive price [the Allegations]. The Allegations included a request for the following relief:

- i) An Order requiring Alexion to "reduce the price of Soliris within 30 days from the date of the Board's Order to a price that does not exceed the international median among the comparator countries";
- ii) An Order requiring Alexion to "offset the cumulative excess revenues it has received during the period of 1 January 2012 to 30 June 2014 by making a payment to Her Majesty in Right of Canada, within 30 days of the date of the Board's Order, in the amount of [REDACTED]"; and
- iii) "Any other remedies Board Staff may seek and the Board may permit".

[6] The international price referred to in paragraph i) above is known as the median international price comparison or MIPC and the test based on that price is called the MPIC Test.

[7] A Notice of Hearing was issued on January 20, 2015 indicating that the Board would hold a public hearing to determine whether excessive prices had been charged. In December 2015, the parties agreed to an 11 day hearing which was scheduled to start on June 27, 2016.

[8] However, on May 20, 2016, the Board's Staff brought a motion for leave to amend the Allegations to add alternative remedies [the Amendments] including a request that Alexion be ordered to reduce the price of Soliris to a price not exceeding the international lowest price among all comparator countries [the LIPC Test]. The MPIC and LIPC Tests will be referred to collectively as the [Price Tests].

[9] The Amendments make it possible for the Board to ignore the MIPC Test in favour of the LIPC Test and find increased cumulative excess revenues.

[10] The Amendments also make it possible for the Board to award remedies retroactively to 2009. I have so concluded because the Amendments show at paragraph 31(d) that the period from January 1, 2012 to June 30, 2014, which had been claimed as the period for which excess revenues were to be offset, has been deleted. Accordingly, in my view, the Amendments leave it open to the Board to make an order covering a period prior to 2012. There is therefore potential for a remedy from 2009. This view is reinforced by the fact that paragraph 31 of the Amendments show pricing calculations which are redacted but which date back to 2009.

[11] In its decision dated June 10, 2016, the Board allowed the Amendments on the basis that the prejudice suffered by Alexion could be remedied by adjourning the hearing. The hearing has

now been extended and rescheduled. It is projected to last 19 days and is to commence in mid-January 2017.

[12] Alexion's Application for Judicial Review was filed on July 13, 2016 [the Application]. It seeks to quash the Board's decision to allow the Amendments, and asks for declarations that i) the Board has no jurisdiction to retroactively confiscate revenues from excessive prices and ii) the Board must consult with industry under section 96(5) of the *Patent Act*, RSC, 1985, c P-4, [the Act] before making changes to the applicable Price Tests. Section 96(5) of the Act says that the Board 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" before making any guidelines [the Consultations].

[13] On July 29, 2016, the Respondent moved to strike Alexion's Application before Prothonotary Ayles on the basis that it is premature because, absent exceptional circumstances, interlocutory rulings by administrative tribunals should not be challenged until the tribunal has made its final decision. The Respondent relied on *C.B. Powell Ltd v Canada (Border Services Agency)*, 2010 FCA 61 at paragraphs 30 – 33.

[14] The Prothonotary exercised her discretion and concluded that the facts did not disclose exceptional circumstances. She noted that if excessive pricing were established at the hearing, Alexion could make all its arguments to the Board against the alternative remedies described in

the Amendments. Further, she observed that the arguments about the remedies could also be advanced, if necessary, on an application for judicial review of the Board's decision.

[15] On this appeal Alexion made submissions similar to those made before the Prothonotary.

They include the following:

- a) Alexion should not be required to face a hearing where Price Tests which have not been the subject of Consultations are in use;
- b) Remedies should not be retroactive and the payments sought on this basis are crippling and are not justified by the Act or its Regulations;
- c) The extension of the hearing by 8 days is a drastic change.
- d) The Amendments are contrary to the Rule of Law.

[16] I have found no palpable or overriding error in the Prothonotary's decision on the motion to strike. She has not applied wrong principles or misapprehended any evidence. I share her view that the arguments Alexion wishes to advance about the retroactivity of the alternative remedies sought and the applicability of the Price Tests can be made before the Board and, if necessary, on a subsequent application for judicial review of the Board's decision. I agree with the Prothonotary that Alexion's submissions do not raise fundamental questions about the Rule of Law.

[17] While it appears that there is potential for a drastic impact on Alexion if excessive pricing is found and if remedies are granted in line with the Amendments, that impact is not certain and

not immediate. In my view, the Amendments and the increase in the length of the hearing before the Board do not constitute exceptional circumstances.

[18] For these Reasons, the First Appeal was dismissed.

## II. The Second Appeal

[19] The Prothonotary also dealt with Alexion's motion on consent for an order that certain material be treated as confidential [the Motion and the Confidential Material]. She understood that the confidentiality order was sought to protect certain information during the Application and she therefore dismissed the Motion as moot because she had struck the Application.

[20] Alexion submits that the Confidential Material was intended for the Prothonotary's use on the Motion to Strike and that ignoring it constituted an error in law.

[21] I have considered Alexion's letter to the Federal Court dated October 21, 2016 and other materials in the Court file which were before the Prothonotary. I have found that the Prothonotary would reasonably have understood that the Confidential Material was put forward only for future use at the hearing of the Application. Nothing in the material suggests that the Confidential Material was relevant on the Motion to Strike.

[22] I have therefore concluded that the Prothonotary did not err in law. Her decision was correct and she did not misapprehend the facts when she dismissed the Motion for mootness.

[23] For these Reasons, the Second Appeal was dismissed. However, Alexion remains entitled to bring a fresh Motion for protection of the Confidential Material.

"Sandra J. Simpson"

---

Judge

Ottawa, Ontario  
January 6, 2017

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-1160-16

**STYLE OF CAUSE:** ALEXION PHARMACEUTICALS INC. v THE  
ATTORNEY GENERAL OF CANADA

**PLACE OF HEARING:** TORONTO, ONTARIO

**DATE OF HEARING:** NOVEMBER 9, 2016

**REASONS FOR ORDER:** SIMPSON J.

**DATED:** JANUARY 6, 2017

**APPEARANCES:**

Malcolm Ruby  
David T. Woodfield

FOR THE APPLICANT

Joseph Cheng  
Christine Mohr

FOR THE RESPONDENT

**SOLICITORS OF RECORD:**

Gowling WLG (Canada) LLP  
Barristers and Solicitors  
Toronto, Ontario

FOR THE APPLICANT

William F. Pentney, Q.C.  
Deputy Attorney General of  
Canada  
Ottawa, Ontario

FOR THE RESPONDENT