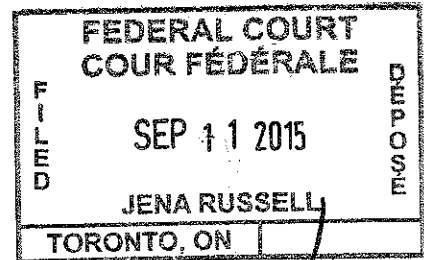


Court File No. T-1537-15

FEDERAL COURT



BETWEEN:

ALEXION PHARMACEUTICALS INC.

Applicant

- and -

**PATENTED MEDICINE PRICES REVIEW BOARD and
ATTORNEY GENERAL OF CANADA**

Respondents

APPLICATION UNDER section 18.1 and 18.2 of the *Federal Courts Act*, R.S.C. 1985, c. F-7 (the "*Federal Courts Act*"), and Part V of the *Federal Court Rules*, 1998, SOR/98-106, as amended

**NOTICE OF APPLICATION UNDER SECTIONS 18(1)(a) and
18(1)(b) OF *THE FEDERAL COURTS ACT***

TO THE RESPONDENTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Applicant. The relief claimed against you is set out in the following pages.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of the hearing will be as requested

by the Applicant. The Applicant requests that this Application be heard at the Federal Court, 180 Queen St. West, Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the Application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in FORM 305 prescribed by the Federal Courts Rules and serve it on the Applicant's solicitor, WITHIN 10 DAYS after being served with this Notice of Application.

Copies of the Federal Court Rules, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (613-992-4238) or any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

September 11, 2015

Issued by: _____

(Registry Officer)

Address of
local office:

180 Queen Street West, Suite 200
Toronto, ON M5V 3L6

To: The Administrator of this Honourable Court
Federal Court
180 Queen Street West, Suite 200
Toronto, ON M5V 3L6

And To: Patented Medicine Prices Review Board
The Secretary of the Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

And To: Attorney General Of Canada
Attention: Director, Ontario Regional Office
Department of Justice (Toronto)
130 King Street West, Suite 3400
Box 36, Exchange Tower
Toronto, ON M5X 1K6

APPLICATION

NATURE OF APPLICATION

This is an Application under sections 18(1)(a) and 18(1)(b) of the *Federal Courts Act*. The Applicant, Alexion Pharmaceuticals Inc. (“Alexion”), seeks a declaratory judgment against the Attorney General of Canada and a writ of prohibition against the Patented Medicine Prices Review Board (the “Board”).

ALEXION MAKES APPLICATION FOR ORDERS:

1. Declaring that sections 83 through 86 of the *Patent Act R.S.C. 1985, c. P-4*, as amended (the “*Patent Act*”), and the words “in any proceeding under s. 83” in section 87(1) (the “impugned provisions”) are *ultra vires* the Parliament of Canada in that the price regulation scheme created by the impugned provisions exceeds the powers granted to Parliament under s. 91(22), or other federal power, of the *Constitution Act, 1867* and improperly intrudes into provincial jurisdiction over property and civil rights in the province under s. 92(13) of the *Constitution Act, 1867*;
2. That the Board be prohibited from proceeding with a hearing under s. 83 of the *Patent Act*, or making any order concerning the price at which Alexion is selling or has sold the medicine Soliris in any market in Canada.
3. Granting Alexion its costs of this Application; and
4. Such further or other relief as the Applicant requests and the Honourable Court deems just to grant.

THE GROUNDS FOR THE APPLICATION ARE:

1. Alexion is a Delaware company located in Cheshire, Connecticut. It markets in Canada a patented medicine known as Soliris.
2. On January 20, 2015, the Board issued a Notice of Hearing notifying Alexion that the Board would “determine whether, under section 83 and 85 of the *Patent Act*...[Alexion] is selling or has sold...Soliris in any market in Canada at a price that, in the Board’s opinion, is or was excessive and if so, what order, if any, should be made.”
3. The Notice of Hearing further states:

B. POWER OF BOARD WITH RESPECT TO EXCESSIVE PRICES

2. In the event that the Board finds that the Respondent (Alexion) is selling Soliris in any market in Canada at a price that, in the Board’s opinion, is excessive, the Board may, by order, direct the Respondent to cause the maximum price at which the Respondent sells Soliris in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

3. In addition, in the event that the Board finds that the Respondent has, while a patentee, sold Soliris in any market in Canada at a price that, in the Board’s opinion was excessive, the Board may, by order, direct the Respondent to do any one or more of the following things as will, in the Board’s opinion, offset the amount of the excess revenue determined by it to have been derived by the Respondent from the sale of Soliris:

(a) reduce the price at which the Respondent sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

(b) reduce the price at which the Respondent sells one other medicine to which a patented invention of the Respondent pertains in any market in Canada, to such extent and for such period as is specified in the order;

(c) pay to Her Majesty in right of Canada an amount specified in the order.

4. Any other remedies Board Staff may seek and the Board may permit.

4. The price of Soliris in Canada has neither increased since it was first introduced on the Canadian market in 2009, nor decreased in the countries where the product is sold outside Canada. In 2010 and 2011, the Board explicitly acknowledged that the introductory price of Soliris was not excessive based on international pricing of the product.
5. The Board's allegations of excessive pricing between 2012 and 2014 are not based on price increases in Canada or price decreases outside Canada but, rather, on exchange rate fluctuations in the value of Canadian currency due to factors that the Board acknowledges are outside Alexion's control. The Board is thus seeking to use its alleged price control powers to confiscate a significant portion of Alexion's revenues based upon international market forces over which Alexion has no control.
6. In public documents, the Board describes its mandate as "protect[ing] consumers" and its "mission" as "contribut[ing] to Canadian health care by ensuring that prices of patented medicines are not excessive."
7. The Board's stated objectives of protecting consumers and promoting health care cannot be grounded in the federal power to control patents of invention and discovery under s. 91(22) of the *Constitution Act, 1867* or other federal power under that Act.

8. The federal price regulation scheme created by the impugned provisions intrudes on provincial jurisdiction over property and civil rights under s. 91(13) of the *Constitution Act, 1867*. The scheme is invalid and, given the extent of the intrusion into provincial jurisdiction, cannot be sufficiently integrated within the *Patent Act*.
9. Price controls by the federal government are permitted only in national emergencies that do not exist in relation to the price of Soliris or other patented medicines.
10. Such further and other grounds as counsel may argue and this Honourable Court hear.

THE APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

1. The Applicant's Legislative History Brief;
2. Affidavits of Jonathan D. Putnam and Lionel Bently to be filed; and
3. Such further and other material as counsel may adduce and this Honourable Court admit.

Date: September 11 , 2015



GOWLING LAFLEUR HENDERSON LLP

Barristers & Solicitors
1 First Canadian Place,
100 King Street West, Suite 1600
Toronto ON M5X 1G5

Tel: 416-862-7525

Fax: 416-862-7661

per **Malcolm Ruby (#25970G)**

Tel: 416-862-4314

Fax: 416-862-7661

malcolm.ruby@gowlings.com

David T. Woodfield (#41229R)

Tel: 416-862-4313

Fax: 416-862-7661

david.woodfield@gowlings.com

Lawyers for the Applicant

ALERXION PHARMACEUTICALS INC.

Applicant

- and -

PATENTED MEDICINE PRICES REVIEW BOARD et al

Respondents

DUPLICATE
DUPLICATA
SEP 11 2015
TORONTO

FEDERAL COURT
PROCEEDING COMMENCED
AT TORONTO

NOTICE OF APPLICATION

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

Tel: 416-862-7525
Fax: 416-862-7661

Malcolm Ruby (#25970G)
Tel: 416-862-4314
Fax: 416-862-7661
malcolm.ruby@gowlings.com

David T. Woodfield (#41229R)
Tel: 416-862-4313
Fax: 416-862-7661
david.woodfield@gowlings.com

Lawyers for the Applicant