

Pharma in brief - Canada

Federal Court strikes application to declare the price control provisions of the *Patent Act* unconstitutional

Case:	<i>Alexion Pharmaceuticals Inc. v Attorney General of Canada</i> , 2016 FC 716 (Court File No. T-1537-15)
Drug:	SOLIRIS® (eculizumab)
Nature of case:	Application for declaratory relief that ss. 80-86 and part of 87(1) of the <i>Patent Act</i> , RSC 1985, c P-4 (Patent Act) are unconstitutional and <i>ultra vires</i> the Parliament of Canada and prohibition order preventing the PMPRB from proceeding with a hearing under s. 83.
Successful party:	Attorney General of Canada
Date of decision:	June 23, 2016

Summary

In January 2015, the Patented Medicine Prices Review Board (**PMPRB** or **Board**) commenced a proceeding against Alexion Pharmaceuticals Inc. alleging it had sold its drug SOLIRIS® (eculizumab) at an excessive price. As a result of the ongoing PMPRB proceeding, Alexion brought an application seeking declaratory relief that sections 80 through 86, and the words “*in any proceeding under section 83*” of section 87(1) of the *Patent Act* (**Impugned Provisions**) are unconstitutional and *ultra vires* the federal powers granted to Parliament. Alexion also sought an order prohibiting the PMPRB from continuing the proceeding against Alexion.

The Attorney General of Canada (**AG**) brought a motion to strike the application on the grounds that the constitutionality of the Impugned Provisions has been fully determined in prior case law, and therefore the application is bereft of any chance of success.

The Court granted the AG’s motion and struck Alexion’s application with costs.

The Impugned Provisions are Constitutional

Alexion argued that the prior line of case law had not dealt with the constitutionality of the Impugned Provisions directly, and the evidence submitted by Alexion provides a complete record for a full analysis of the pith and substance of the provisions. For this reason, Alexion argued that the application is not bereft of any chance of success.

The AG’s position was that the constitutionality of the Impugned Provisions had been determined in prior jurisprudence and the application should be struck. The Court reviewed the line of case law relied upon by the AG and concluded that the provisions of the *Patent Act* dealing with pricing of patented medicines fell within the federal jurisdiction and were constitutional.

The Court noted that the most recent decision on this matter, *Attorney General (Canada) v. Sandoz Canada Inc.*, 2015 FCA 249 (**Sandoz**), is the subject of an application for leave to appeal to the Supreme Court of Canada, the outcome of which is currently pending (reported [here](#)). The central issue in the *Sandoz* decision was whether the lower court properly held that Sandoz, a generic manufacturer, fell outside the jurisdiction of the PMPRB and was not a “patentee”

under the *Patent Act*. The Court in *Sandoz* also commented on the constitutionality of the Impugned Provisions and held that the lower court correctly held that “the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents...”

Alexion’s Application is Struck

Neither party sought a stay of the proceeding pending the outcome of *Sandoz’s* leave to appeal to the Supreme Court of Canada. The Court held that the doctrine of *stare decisis* applied in this situation and the decision of the Federal Court of Appeal in *Sandoz* was sufficient to dispose of the motion. As a result, the Court granted the motion of the AG and struck the application brought by Alexion.

Link to Decision

[*Alexion Pharmaceuticals Inc. v Attorney General of Canada, 2016 FC 716.*](#)

Karen Sie
Kristin Wall
Sara Zborovski

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

For a complete list of our IP team, [click here](#). For a complete list of our Life sciences and healthcare team, [click here](#).

Norton Rose Fulbright Canada LLP, Norton Rose Fulbright LLP, Norton Rose Fulbright Australia, Norton Rose Fulbright South Africa Inc and Norton Rose Fulbright US LLP are separate legal entities and all of them are members of Norton Rose Fulbright Verein, a Swiss verein. Norton Rose Fulbright Verein helps coordinate the activities of the members but does not itself provide legal services to clients.

References to “Norton Rose Fulbright”, “the law firm”, and “legal practice” are to one or more of the Norton Rose Fulbright members or to one of their respective affiliates (together “Norton Rose Fulbright entity/entities”). No individual who is a member, partner, shareholder, director, employee or consultant of, in or to any Norton Rose Fulbright entity (whether or not such individual is described as a “partner”) accepts or assumes responsibility, or has any liability, to any person in respect of this communication. Any reference to a partner or director is to a member, employee or consultant with equivalent standing and qualifications of the relevant Norton Rose Fulbright entity.

The purpose of this communication is to provide general information of a legal nature. It does not contain a full analysis of the law nor does it constitute an opinion of any Norton Rose Fulbright entity on the points of law discussed. You must take specific legal advice on any particular matter which concerns you. If you require any advice or further information, please speak to your usual contact at Norton Rose Fulbright.