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Pharma in brief - Canada

Update on recent PMPRB litigation

Cases: *Canada (Attorney General) v Sandoz Canada Inc. and Canada (Attorney General) v Ratiopharm Inc. (now Teva Canada Limited)* (SCC: 36798)

Alexion Pharmaceuticals Inc. v Attorney General of Canada (Court File No. T-1537-15)

Alexion Pharmaceuticals Inc. v Attorney General of Canada (Court File No. T-1160-16)

Overview

The role and powers of the Patented Medicine Prices Review Board (the "PMPRB" or the "Board") are at issue in a number of recent proceedings. In particular, the Board's jurisdiction over generic products and the constitutionality of the excessive pricing provisions of the *Patent Act* have been raised. The PMPRB's excessive pricing guidelines have also been a topic of debate.

We provide an overview and update of these proceedings below.

Canada (Attorney General) v Sandoz Canada Inc. and Canada (Attorney General) v Ratiopharm Inc. (now Teva Canada Limited) ("*Sandoz*")

As we reported in January, Sandoz and Ratiopharm filed leave to appeal to the Supreme Court of Canada in respect of the Federal Court of Appeal's decision (2015 FCA 249) that generics can be "patentees" under the excessive price provisions of the *Patent Act* (ss. 83 to 86 and 87(1)). On September 8, 2016, the application for leave to appeal to the SCC was discontinued.

The FCA had also sent two of the issues back to the Federal Court for redetermination: namely (1) whether the patents pertained to the medicines in issue; and (2) whether Ratiopharm had sold ratio-HFA at excessive prices. In addition to the SCC discontinuance, the generic companies also discontinued these Federal Court judicial review applications.

As a result of the discontinuance, the PMPRB has jurisdiction to control the prices charged for patented medicines sold by both patent holders and non-patent holders who exercise selling rights under a license. This may be of importance to manufacturers engaged in various distribution models in Canada, for example those engaged in various licensing arrangements, obtaining authorization from a manufacturer to cross-reference Health Canada submissions or the implementation of an internal pseudo-generic division.

Alexion Pharmaceuticals Inc. v Attorney General of Canada

Federal Court Dockets: T-1537-15/16-A-29

In September 2015, Alexion brought a judicial review application challenging the constitutionality of the pricing provisions of the *Patent Act*. Alexion's application stemmed from the PMPRB's proceeding against Alexion in respect of its drug SOLIRIS® (eculizumab).

As we reported, the Federal Court struck Alexion's application in June 2016, in part on the grounds that *Sandoz* had "fully and finally determined that these sections [i.e. the excessive price provisions] are in fact *intra vires* and constitutional."

However, the court also noted that, "[w]hile *Sandoz* is focused on whether or not a generic manufacturer is captured by the definition of 'patentee' in the *Patent* Act and thereby is subject to the jurisdiction of the Board, should the Supreme Court of Canada grant leave to appeal, the issue of the constitutionality of the price control regime and the jurisdiction of the Board as contained in the Impugned Provisions would be open for consideration by the Supreme Court. However, that is for the Supreme Court to decide."

Alexion has appealed this decision**.**

Alexion also filed for leave to intervene in Sandoz's SCC leave application, in part because it related to Alexion's constitutional challenge of the price control provisions.

Given that the Supreme Court did not decide these issues in the *Sandoz* case, the proceeding to watch will be Alexion's appeal of the court's decision to strike its application.

Federal Court Docket: T-1160-16

In June 2016, Alexion also sought review of the panel's decision allowing the Board staff to file an Amended Statement of Allegations that claimed a new basis for excess revenue based on the lowest international price comparison test (the "LIPC Test"). Alexion argued that "the amendments directly violate the most basic notions of the rule of law and due process" by permitting the potential retroactive application of the LIPC Test, which was not articulated in the PMPRB guidelines when SOLIRIS® first came on the Canadian market.

This proceeding is particularly relevant since the PMPRB is currently seeking feedback on the excessive pricing factors in its guidelines.

The Attorney General of Canada brought a motion to strike the application on the grounds that the panel's decision was an interlocutory decision, which, absent exceptional circumstances, should not be reviewed. On September 1, 2016, Prothonotary Aylen granted the AG's motion and struck Alexion's application. The court held that the amendments were only pleading alternative remedies, and were not a retroactive application of regulatory requirements.

Alexion has also appealed this decision.

Links to decisions:

Sandoz FCA Decision: *Attorney General of Canada v Sandoz Canada Inc*, 2015 FCA 249

Alexion Motion to Dismiss in T-1537-15: *Alexion Pharmaceuticals Inc v Attorney General of Canada*, 2016 FC 716

Alexion Motion to Dismiss in T-1160-16: *Alexion Pharmaceuticals Inc v Attorney General of Canada*, 2016 FC 998

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

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