Federal Court  Cour fédérale

Date: 20141219

Docket: T-1332-12

Citation: 2014 FC 1249

Ottawa, Ontario, December 19, 2014

PRESENT: The Honourable Madam Justice Gleason

BETWEEN:

ACTELION PHARMACEUTICALS CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA AND PHARMASCIENCE INC., MYLAN PHARMACEUTICALS ULC, COBALT PHARMACEUTICALS COMPANY AND SANDOZ CANADA INC.

Respondents

JUDGMENT AND REASONS

[1] In this application for judicial review the applicant, Actelion Pharmaceuticals Canada Inc. [Actelion], seeks declaratory relief and an order setting aside the decisions of the respondent, the Minister of Health [the Minister], awarding early Notices of Compliance [NOCs] to the respondents, Cobalt Pharmaceuticals Company [Cobalt] and Sadoz Canada Inc. [Sandoz],

for drugs that are the pharmaceutical and bioequivalent of a drug that Actelion produces and held patent rights for under a patent listed on the Patent Register established under sections 3 – 4 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the PMNOC Regulations].

[2] More specifically, Actelion sells bosentan, a hypertension drug, in Canada under the brand name TRACLEER. It is the owner of Patent No. 2,071,193 [the 193 Patent], which pertains to TRACLEER. The 193 Patent expired on June 12, 2012, but prior to its expiry was listed on the Patent Register.

[3] On January 5, 2011, the respondent, Mylan Pharmaceuticals ULC [Mylan], sent Actelion a Notice of Allegation [an NOA] with respect to the 193 Patent. In response, Actelion initiated a prohibition application on February 18, 2011, pursuant to section 6 of the PMNOC Regulations, but subsequently settled the case. On August 31, 2011, Mylan sent a letter to the Office of Patented Medicines and Liaison [OPML] at Health Canada withdrawing its NOA, and on September 2, 2011, Actelion discontinued its prohibition application. A few days later, it wrote to the OPML indicating that it was permitting Mylan to make, construct, use or sell bosentan in Canada as of May 29, 2012. On May 29, 2012, Health Canada issued an NOC to Mylan for its bosentan product.

[4] On March 22, 2012, the respondent, Pharmascience Inc. [Pharmascience], also sent Actelion an NOA with respect to the 193 Patent. In response, Actelion began a second prohibition application on May 4, 2012, but soon thereafter reached a settlement with

Pharmascience. On May 28, 2012, Pharmascience sent a letter to the OPML withdrawing its NOA and on the same day Actelion wrote to the OPML indicating that it was permitting Pharmascience to make, construct, use or sell bosentan in Canada as of May 29, 2012. On May 30, 2012, Actelion discontinued its prohibition application in respect of Pharmascience, and on May 29, 2012, Health Canada issued an NOC to Pharmascience for its bosentan product.

[5] On an unspecified date, Sandoz reached a licensing agreement with Pharmascience under which Sandoz was permitted to market Pharmascience's bosentan product under Sandoz's label. On April 25, 2012, Sandoz filed an administrative drug submission seeking approval from the Minister to market bosentan under the brand name SANDOZ-BOSENTAN, cross-referencing the Pharmascience submission.

[6] Cobalt also reached a licensing agreement with Pharmascience under which Cobalt was similarly permitted to market Pharmascience's bosentan product under Cobalt's label. On May 4, 2012, Cobalt likewise filed an administrative drug submission seeking approval from the Minister to market bosentan under the brand name CO-BOSENTAN, cross-referencing the Pharmascience submission.

[7] On June 4, 2012, the Minister issued NOCs to Sandoz and Cobalt for their bosentan products. In so doing, the Minister applied recent amendments to its Guidance Document, Patented Medicines (Notice of Compliance) Regulations [the Guidance Document]. These amendments purport to allow the Minister of Health to issue early NOCs to companies who market a generic version of a drug listed on the Patent Register, without being required to serve a

Notice of Allegation [NOA] on the patent-holder under section 5 of the PMNOC Regulations, if the company has been licensed to sell the drug by another company that has previously complied with section 5 of the PMNOC Regulations.

[8] In the present application for judicial review, Actelion seeks declarations that the Minister lacked the authority to issue the NOCs to Cobalt and Sandoz and also seeks orders setting them aside.

[9] For the reasons given in *Pfizer Canada Inc. v The Attorney General of Canada and Teva Canada Limited*, T-1703-13, 2014 FC 1243, [*Pfizer*], issued concurrently with this judgment, I find that the amendments to the Guidance Document contravene the PMNOC Regulations and that the Minister was not entitled to issue the NOCs to Cobalt and Sandoz. I do not find it necessary to address Actelion's natural justice arguments. It follows that Actelion is entitled to the declaratory relief it seeks in respect of the interpretation of the PMNOC Regulations.

[10] However, it appears that the request for an order quashing the NOCs may well be moot as the 193 Patent expired on June 12, 2014. The parties did not fully argue the potential mootness of this remedy before me and I therefore direct that if Actelion wishes to pursue its request for an order quashing the decisions of the Minister to issue NOCs to Cobalt and Sandoz, it must file submissions within 30 days setting out its arguments as to why this remedy is not moot. If such submissions are filed, the respondents may file responding submissions within 30 days of receipt of Actelion's submissions, and, if it desires, Actelion may file reply submissions within 15 days of receipt of the responding submissions.

[11] Costs should follow the event and should be based on the mid-point of Column III of Tariff B to the *Federal Courts Rules*, SOR/98-106. As in *Pfizer*, I remit the issue of the quantification of costs to the parties and trust that they will be able to settle on the amount(s) payable. In the event they are unable to do so, their respective positions on costs should be set out in the supplemental submissions on mootness or, if no such submissions are made, in submissions dealing solely with costs, which shall be filed within 45 days of the date of this Judgment.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. This application for judicial review is granted, and this Court declares that the OPML failed to comply with the PMNOC Regulations by failing to require Cobalt and Sandoz to address the 193 Patent before issuing them NOCs for their bosentan products;
2. If Actelion wishes to pursue its request for an order quashing the decisions of the Minister to issue NOCs to Cobalt and Sandoz, it shall file submissions within 30 days setting out its arguments as to why this remedy is not moot. If such submissions are filed, the respondents may file responding submissions within 30 days of receipt of Actelion's submissions, and, if it desires, Actelion may file reply submissions within 15 days of receipt of the responding submissions; and
3. Actelion is entitled to costs at the mid-point of Column III of Tariff B, to be settled by the parties or determined by the Court in accordance with the procedure outlined in paragraph 11 of these Reasons.

"Mary J.L. Gleason"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1332-12
STYLE OF CAUSE:	ACTELION PHARMACEUTICALS CANADA INC. v ATTORNEY GENERAL OF CANADA AND THE MINISTER OF HEALTH, AND, PHARMASCIENCE INC., MYLAN PHARMACEUTICALS ULC, COBALT PHARMACEUTICALS COMPANY AND SANDOZ CANADA INC.
PLACE OF HEARING:	OTTAWA, ONTARIO
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DATED:	DECEMBER 19, 2014

APPEARANCES:

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