NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Generic companies seek leave to appeal to the Supreme Court of Canada on whether generics are "patentees" and subject to the jurisdiction of the PMPRB

Case: *Canada (Attorney General) v. Sandoz Canada Inc.*
Canada (Attorney General) v. Ratiopharm Inc. (now Teva Canada Limited)
Nature of case: *Appeal of judicial review of decision of PMPRB*
Successful party: *Patented Medicine Prices Review Board*
Date of decision: *November 6, 2015*

Summary

On January 5, 2016 Sandoz and Ratiopharm filed for leave to appeal with the Supreme Court of Canada in connection the Federal Court of Appeal decisions that held generic manufacturers that sell patented medicines in Canada can be "patentees" under the price reporting requirements under the *Patent Act* (the "Act") and be subject to the jurisdiction of the Patented Medicine Prices Review Board ("PMPRB" or "Board").

Background

Ratiopharm Inc. ("Ratiopharm", now part of Teva Canada Limited) sold a number of generic medicines in Canada pursuant to various supply and licensing agreements, including ratio-salbutamol HFA ("Ratio-HFA"), the generic equivalent of a patented medicine manufactured and sold in Canada by GlaxoSmithKline Inc. Sandoz Canada Inc. ("Sandoz"), a wholly owned subsidiary of Novartis Canada Inc., sold generic versions of medicines in Canada covered by patents owned by Novartis (or one of its subsidiaries) through various purchase orders. In each case, the generic manufacturers were not granted or transferred any patent rights associated with the marketed medicines.

In each of the cases for Sandoz and Ratiopharm, the PMPRB concluded that generic companies that sell patented products in Canada pursuant to a license or supply agreement fall within the definition of a "patentee" under section 79(1) of the Act, despite not owning any patents or holding a monopoly over the medicines at issue. The PMPRB concluded that a person need not own a patent pertaining to a medicine in order be a "patentee" because the statutory definition of the term includes persons "entitled to the benefit of the patent for that invention" and does not specifically require ownership of the patent.

Upon judicial review of the PMPRB's decision, the Federal Court found that neither Sandoz nor Ratiopharm was a "patentee" within the meaning of the Act. The Federal Court found that the Board would be exceeding its jurisdiction over the companies if it required price reporting for persons who did not own the patents pertaining to those medicines sold. In both cases, the Federal Court held that neither Sandoz nor Ratiopharm held the exclusive benefits and rights that inure to patent holders, and as a result were not "patentees" within the meaning of the Act. The Federal Court also

held that the provisions of the Act relating to the PMPRB and price regulation of patented medicines were constitutionally valid and fell within federal jurisdiction.

Issues

The main issue on appeal was whether the PMPRB properly concluded that Ratiopharm and Sandoz were "patentees" under section 79(1) of the Act.

The second issue, applicable only to Sandoz, was whether the Board erred in finding that Sandoz was a "patentee" on the basis that it sold the medicines in question pursuant to an implied license.

The Federal Court of Appeal also addressed the constitutional challenge brought by Ratiopharm and Sandoz of whether the price regulation provisions are constitutionally valid when applied to non-patent holders.

"Patentees"

The Court of Appeal held that the Board's interpretation of "patentee" under section 79(1) of the Act was entitled to deference. The Court of Appeal affirmed the Board's finding that the legislative purpose of its enabling provisions was consumer protection against excessively priced patented medicines and not merely to prevent *patent holders* from pricing their medicines excessively. The Federal Court of Appeal held that the Federal Court failed to appreciate that the mischief of excessive pricing could be caused by parties other than patent holders.

In addition, the Court of Appeal held that the distinction between "generic" and "innovator" drug companies is not relevant to the Board's jurisdiction, as those terms are not present in the text of the legislation and are irrelevant to the question of whether the party is a "patentee" under section 79(1) of the Act.

PMPRB's finding of Sandoz's Implied License

The Court of Appeal addressed the issue of whether Sandoz had an implied license with respect to the patents at issue. The Court was persuaded by the fact that but for the consent of Novartis the Sandoz medicines would not have been issued a NOC by Health Canada. The Court of Appeal upheld the Board's holding that Sandoz was a person entitled to exercise rights in relation to a patent arising out of an implied license to sell the medicine, even though it did not have any express legal rights under the patent, such as the right to exclude others from practicing the invention.

Constitutional Challenge

The Federal Court of Appeal upheld the Board's conclusion that the price reporting provisions of the Act are constitutionally valid with respect to patent holders. The Court of Appeal also held that the provisions are constitutionally valid when applied to persons who exercise the right to sell patented medicines without owning patent rights, as follows:

> "there is no basis for the argument that the connection with the patent ceases to be sufficient to meet the constitutional imperative when the person targeted holds a license to sell a patent without holding the patent. As was explained in *ICN*, the harm which the Act seeks to prevent arises by reason of the exercise of the patent pertaining to the medicine being sold, with the result that nothing turns on the fact that the person exercising the selling rights does not hold the patent itself."[1]

[1] Para 121; citing *ICN Pharmaceuticals Inc. v. Canada (Staff of the Patented Medicine Prices Review Board), [1997]* 1 FC 32 at para 76.

Conclusion

The Federal Court of Appeal allowed the appeal and held that both Ratiopharm and Sandoz were "patentees" under section 79(1) of the Act and fell within the jurisdiction of the PMPRB price reporting requirements. This decision 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.

Other issues including whether the respective patents in each case pertain to the medicine and the $65.8 million pricing adjustment for excess revenues against Ratiopharm for the sale of Ratio-HFA, were referred back to the Federal Court for determination.

Sandoz and Ratiopharm have filed for leave to appeal with the Supreme Court of Canada.

Link to decision:

Canada (Attorney General) v. Sandoz Canada Inc. and Canada (Attorney General) v. Ratiopharm Inc. (now Teva Canada Limited), 2015 FCA 249

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