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Pharma in brief - Canada

Supreme Court dismisses leave to appeal regarding test for obviousness-type double patenting in tadalafil s.6 case

Case: Apotex Inc v Eli Lilly Canada Inc, et al (SCC Docket 37368)

Drug: CIALIS[®] (tadalafil)

Nature of case: Application for leave to appeal decision upholding prohibition order granted pursuant to section 6 of the

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 (the Regulations)

Successful party: Eli Lilly Canada Inc. and ICOS Corporation (collectively Eli Lilly)

Date of decision: April 27, 2017

Summary

On April 27 the Supreme Court dismissed Apotex Inc.'s (Apotex) application for leave to appeal the Federal Court of Appeal (**FCA**) decision upholding the order prohibiting the minister of health from granting a notice of compliance to Apotex for its generic version of tadalafil under section 6 of the *Regulations*.

As we <u>reported</u>, the FCA dismissed Apotex's appeal of the lower court's decision on obviousness-type double patenting and insufficiency, and rejected Apotex's argument that obviousness-type double patenting is assessed as of the publication date of the later patent. The FCA declined to specify the relevant date for this analysis, holding that "[t]his remains an open question."

Eli Lilly was also successful in overcoming a double patenting attack in another s. 6 proceeding relating to the same patent against Mylan. Mylan also appealed and in that case the FCA declined to choose between the priority dates of the two patents, but did reject Mylan's assertion of the publication date of the second patent as the appropriate date.

Links to decisions:

SCC Decision: *Apotex Inc v Eli Lilly Canada Inc*, Supreme Court of Canada – Judgments in Leave Applications (37368)

FCA Decision: Apotex Inc v Eli Lilly Canada Inc, 2016 FCA 267

Trial Decision: Eli Lilly Canada Inc v Apotex Inc, 2015 FC 875

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