

Pharma in brief - Canada

Federal Court of Appeal raises new questions about the test for obviousness-type double-patenting in tadalafil case

Case:	<i>Apotex Inc. v Eli Lilly Canada Inc.</i> , 2016 FCA 267 (A-330-15), aff'g 2015 FC 875 (T-1598-13)
Drug:	CIALIS [®] (tadalafil)
Nature of case:	Appeal from application for prohibition order granted pursuant to section 6 of the <i>Patented Medicines (Notice of Compliance) Regulations</i> , SOR/93-133 (the Regulations)
Successful party:	Eli Lilly Canada Inc. and ICOS Corporation (collectively Lilly)
Date of decision:	November 4, 2016

Summary

Lilly markets CIALIS[®] (tadalafil) in Canada for the treatment of erectile dysfunction (**ED**). Both Mylan Pharmaceuticals ULC and Apotex Inc. sought approval for generic versions of tadalafil and were opposed by Lilly. In each case, the Federal Court allowed Lilly's application and granted prohibition orders. As we [reported](#), earlier this year, the Court of Appeal dismissed an appeal from the decision in the Mylan case (the **Mylan Appeal**).

In this case, Apotex asked the Court of Appeal (**FCA**) to overturn the lower court's findings on obviousness-type double-patenting, overruling its own decision in the *Mylan Appeal*, as well as insufficiency. The FCA dismissed Apotex's appeal on both counts.

Background

The double-patenting issue in the tadalafil cases concerns two of Lilly's patents. The earlier patent, Canadian Patent No. 2,181,377 (**377 Patent**), claims tadalafil and the use of tadalafil in the treatment of various disorders, but not treatment of ED specifically. The later patent, Canadian Patent No. 2,226,784 (**784 Patent**), claims the use of tadalafil for the treatment of ED. Mylan and Apotex both alleged that the later patent was invalid for obviousness-type double-patenting over the earlier one.

The parties in each case framed the double-patenting issue as turning on the relevant date for comparing the two patents. The issue was significant because it determined whether the court was permitted to consider art published after the priority date of Lilly's first patent, which Mylan and Apotex said substantiated their allegations.

- **The Mylan case.** In the Mylan case, Justice de Montigny decided that the relevant date was one of the two priority dates and based his analysis upon the earlier 377 Patent priority date. The FCA found no reviewable error with this approach and declined to definitely choose between the two priority dates. The FCA did, however, reject Mylan's assertion of a later date: the publication date of the second 784 Patent.
- **The Apotex case.** Apotex argued that the relevant date was the publication date of the later 784 Patent, as Mylan did on its appeal. Justice Gleason agreed with de Montigny J that the choice was between the two priority dates and rejected Apotex's publication-date argument. Gleason J. also declined to specify a single relevant date between the two patent

priority dates because Apotex's allegation was not justified on either date. Gleason J. did, however, comment that there was a sound argument for using the priority date of the later patent.

Obviousness-type double-patenting

In the present appeal, Apotex persisted in its argument that obviousness-type double-patenting is assessed as of the publication date of the later patent, based on the Supreme Court's decision in *Whirlpool Corp v Camco Inc*, 2000 SCC 67 (**Whirlpool**). Apotex also argued that the *Mylan Appeal* must be overruled as "manifestly wrong," and that the FCA was in any event required to follow *Whirlpool* as a matter of *stare decisis*.

The FCA found no basis to interfere with the prior decisions on this issue and dismissed Apotex's appeal. The FCA held that the Supreme Court did not decide the relevant date for conducting the obviousness-type double-patenting analysis in *Whirlpool*. The FCA also declined to specify a relevant date for assessing double-patenting, instead holding that: "[t]his remains an open question."

The FCA's judgment also raised new questions about the relevant date. In *obiter*, Pelletier JA commented:

The fact that this issue has not arisen in this form in the past may be an indication that there may be other ways to approach it. Perhaps, the Court, having construed the claims of each of the patents with the assistance of the persons skilled in the art, simply compares the claims and decides whether the later claims are patentably distinct from the earlier claims on the basis of the insights which it has gained in the course of the construction of the patents. [...] This is not to argue that this approach is any more correct than the comparison date approach but rather that, going forward, parties should not feel that they are locked into the framework chosen by the parties in these cases.

In light of these comments, we expect future cases to grapple with the relevant date for obviousness-type double-patenting.

Insufficiency is a question of mixed fact and law

Apotex also argued that in the court below, Gleason J erred in law when she found that the disclosure of the later patent was sufficient. The FCA held that application of the legal test for sufficiency of disclosure to the facts of the case is a question of mixed fact and law, reviewable on the standard of palpable and overriding error. The FCA refused to revisit Gleason J's preference for the evidence of Lilly's experts on this issue and dismissed the appeal.

Links:

This decision: *Apotex Inc v Eli Lilly Canada Inc*, [2016 FCA 267](#), aff'g [2015 FC 875](#)

The Mylan decisions: *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, [2016 FCA 119](#) (reported [here](#)), aff'g [2015 FC 17](#)

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.