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Pharma in brief - Canada

Federal Court of Appeal upholds prohibition order: relevant date for assessing obvious-type double-patenting is considered

Case:	*Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc.*, 2016 FCA 119 (Court File No. A-47-15), aff'g 2015 FC 17
Drug:	CIALIS® (tadalafil)
Nature of case:	Appeal from application for prohibition granted pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party:	Eli Lilly Canada Inc.
Date of decision:	April 20, 2016

Summary

Eli Lilly Canada Inc. (**Lilly**) markets tadalafil in Canada under the name CIALIS® for the treatment of erectile dysfunction (**ED**). Mylan Pharmaceuticals ULC (**Mylan**) sought approval for a generic version of tadalafil.

The Federal Court prohibited the Minister from issuing a Notice of Compliance (**NOC**) to Mylan in respect of tadalafil, finding that Mylan had not justified its allegations of obviousness-type double-patenting or lack of sound prediction. The Court of Appeal upheld the decision.

Obviousness-type double-patenting

Canadian Patent No. 2,226,784 (**784 Patent**) is listed on the patent register in respect of CIALIS®. It claims tadalafil and 3-methyl tadalafil for use in the treatment of ED. The 784 Patent has a priority date of July 14, 1995, a Canadian filing date of July 11, 1996, and a publication date of February 6, 1997.

Lilly owns another patent—Canadian Patent No. 2,181,377 (**377 Patent**)—which claims tadalafil and the use of tadalafil in the treatment of various disorders, but not treatment of ED specifically. It had a priority date of January 21, 1994 and a Canadian filing date of January 19, 1995, both of which precede the priority date of the 784 Patent in issue.

The Court of Appeal focused on two issues in respect of obviousness-type double-patenting: claims construction and the correct date for the analysis.

The Court of Appeal found that the Federal Court erred in referring to the specification when construing the claims of the 377 Patent, holding that the rules of construction preclude reference to the specification when the claims are clear. As the 377 Patent unambiguously claimed tadalafil without any reference to its use as a PDE V inhibitor, no reference to the specification was required. The Court of Appeal ultimately found that the error had no effect, as it imposed a higher burden on Lilly.

As to the correct date for conducting the obviousness-type double-patenting assessment, the Court of Appeal identified three possible dates: (1) the priority date of the earlier 377 Patent (Lilly's preferred date); (2) the priority date of the 784 Patent; or (3) the publication date of the 784 Patent (Mylan's preferred date).

The Court of Appeal rejected Mylan's preferred date finding that it would be inappropriate to use any date after the claim date of the impugned patent (in this case, the 784 Patent). The Court of Appeal reasoned that section 28.3 of the *Patent Act* limited the prior art to be considered in a classical obviousness analysis to prior art published before the claim date. There was no principled basis to permit prior art after the claim date to be considered in the context of an obviousness-type double-patenting analysis, but not classical obviousness.

As between the two remaining dates, the Court of Appeal did not determine which date was appropriate. It found that there was no change in the common general knowledge between the two priority dates. Therefore, at either date, the claims of the 784 Patent would not have been obvious.

Notably, in a separate proceeding, Apotex similarly unsuccessfully alleged—among other things—that the 784 Patent was invalid for obviousness-type double-patenting. Apotex alleged that the Canadian filing date of the 784 Patent was the relevant date for the inquiry. Neither the Federal Court nor the Court of Appeal in the Mylan case considered this date in their analyses. In the Apotex decision, Justice Gleason held that the correct date was one of the priority dates of the two patents. However, she did not determine which was the correct date, as she came to the same result for both. The Apotex decision is currently under appeal and will be heard on May 5, 2016.

Sound prediction

Mylan also argued that the oral administration of 3-methyl tadalafil for treatment of ED was not soundly predicted because there was no disclosure of the oral bioavailability of 3-methyl tadalafil in the patent.

The Federal Court did not consider whether the utility of 3-methyl tadalafil had been soundly predicted, as 3-methyl tadalafil was encompassed by a *Markush* claim that encompassed tadalafil, for which the utility was soundly predicted. The Federal Court reasoned that it was unnecessary to consider whether each compound would work. The Court of Appeal found that the Federal Court judge erred and that a *Markush* claim requires that each compound in the claimed class have utility. However, the error was of no consequence because there was evidence before the Judge that the utility of 3-methyl tadalafil had been soundly predicted.

Link to decisions:

Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc., et al., 2016 FCA 119

Federal Court decision: *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC*, 2015 FC 17

Apotex decision: *Eli Lilly Canada Inc. v. Apotex Inc*, 2015 FC 875

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