



Cialis Canadian Patent Knocks Out Double Patenting Challenge

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Eli Lilly's Canadian patent on treatment of erectile dysfunction with Cialis continues to defy all challengers. A recent appeal case originated from a Notice of Compliance proceeding brought by the generic drug manufacturer, *Apotex*¹, marked the fourth time that the Federal Courts² have rebuffed allegations of invalidity. This patent (no. 2,226,784) claims an improvement invention which is the **use** of tadalafil in the treatment of erectile dysfunction. The latest cases considered whether this use patent contains "patentably distinct" claims relative to an earlier Eli Lilly Canadian patent covering the tadalafil **compound** (no. 2,181,377). The basis of the challenge was that if the use patent claims were not novel and inventive over the compound patent claims, then the use claims would be *invalid* under Canada's strict double patenting laws.

Against longshot odds, Apotex argued at its Federal Court of Appeal hearing that a different panel of judges of the same court was wrong in its decision released two weeks earlier. The earlier decision was a very similar Cialis double patenting case lost by Mylan³. Apotex argued that the *Mylan* case decision erred because the Appeal Court did not follow the Supreme Court's decision in *Whirlpool Corp v Camco Inc*⁴ in regards to the relevant date in comparing the claims of two patents for obviousness-type double patenting, with regards to priority date versus patent publication date⁵.

The Court found that *Whirlpool* had not decided on the relevant comparison date for obviousness-type double patenting analysis. Apotex wanted a later comparison date used for the double patenting analysis, which was the *publication date of the use patent*, not its priority dates. Basically, a later comparison date is more likely to help the generic company kill the patent. As time passes, there is usually more knowledge in the public domain - science marches along and there are more publications with the passage of time. More knowledge means the generic company has more ammunition to try to argue that the patent is obvious and invalid.

As expected, the FCA decided against Apotex and in favour of its own panel's earlier decision. However, the court's decision did little else to clarify the landscape for future cases. The other dates the Court could choose for the comparison were priority application dates for the compound and the use patent. The Court did not pick a date since there was no change in the common general knowledge between the two priority dates. Therefore, choosing either date would result in the finding that there was no double patenting. The Court also said that there could be other approaches taken to double patenting where the choice of date takes a back seat. For instance, the Court has in the past simply compared the claims and decided whether the later claims were patentably distinct from the earlier claims.

It appears that the Appeal Court was not only reticent to settle the issue of the correct relevant date for an obviousness-type double patenting analysis, but also further muddied the waters. The persistent challenger Apotex has since filed leave to appeal to the Supreme Court of Canada⁷. This is an opportunity for the Supreme Court to provide useful guidance on the relevant date as well as the preferred approach in analysing double patenting issues.

While we cannot predict whether the Supreme Court will hear the case, a refusal would mean that *Apotex* and *Mylan*, despite the

lack of clarity on the issue of the correct relevant date, will be the authorities for the time being. Lower courts would have to weigh the relevant date issue, as well as considering divergent analytical approaches that do not depend on a critical date. Importantly for Eli Lilly, a refusal for the Supreme Court to hear this case would mean that its Canadian patent on treatment of erectile dysfunction with Cialis has, once again, risen to the challenge, and remains undefeated.

Update: On April 27, 2017, the Supreme Court of Canada dismissed the application for leave to appeal with costs to the respondents, Eli Lilly Canada Inc. and Icos Corporation.

¹ *Apotex Inc v Eli Lilly Canada Inc*, 2016 FCA 267 [hereinafter “*Apotex*”].

² Twice at the Federal Court, and twice at the Federal Court of Appeal.

³ *Mylan Pharmaceutical ULC v Eli Lilly Canada Inc*, 2016 FCA 119 [hereinafter “*Mylan*”].

⁴ (2000), SCC 67.

⁵ In the *Mylan* proceeding, there were three possible candidates for the relevant date for obviousness-type double patenting. They are 1) priority date of the compound patent (January 21, 1994 -- preferred by Eli Lilly) 2) priority date of the use patent (July 14, 1995); and 3) the publication date of the use patent (February 6, 1997 -- preferred by Mylan). The Court held that the publication date of the use patent was not appropriate because s.28.3 of the *Patent Act* restricted the prior art to be considered when assessing classical obviousness to prior art published before the claim date (*i.e.* priority date in this instance). The Court found that there is no reason to allow a challenger alleging obviousness-type double patenting to point to prior art after the claim date, but not allowing the same to a challenger alleging classical obviousness.

⁶ See: *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] SCR 49; and *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61.

⁷ *Apotex Inc v Eli Lilly Canada Inc, et al*, Supreme Court of Canada Docket 37368.