Federal Court Appeal Confirms that Obviousness Analysis is Flexible, Contextual, Expansive and Fact-Driven

January 25, 2019

Teva Canada Limited v Pfizer Canada Inc, 2019 FCA 15 and Apotex Inc v Pfizer Canada Inc, 2019 FCA 16

These two decisions were companion appeals, heard separately, from two separate PM(NOC) applications, brought by Pfizer in relation to its 668 Patent concerning a drug called O-desmethyl-venlafaxine (ODC). More specifically the appeal related to a particular crystal form of a particular salt of ODV, known as Form I ODV succinate. The Brown J. of the Federal Court found in both cases that the allegations of invalidity were not justified, and granted prohibition orders.

Teva and Apotex each appealed the Federal Court's finding that the allegation of invalidity due to obviousness was not justified. It was argued in both cases that Brown J. had erred by implicitly considering the properties of Form I ODV succinate as part of the inventive concept, which had been found to be the drug itself. Additionally, Teva and Apotex both argued that the Federal Court had erred by not following the Federal Court of Appeal's decisions in Bristol-Myers Squibb Canada Co v Teva Canada Ltd, 2017 FCA 76 [Atazanavir] and Ratiopharm Inc v Pfizer Ltd, 2010 FCA 204 [Amlodipine].

However, the Federal Court of Appeal rejected these arguments and dismissed the appeal. It was held that Brown J. had not improperly considered the properties of the drug as part of the inventive concept, as it was clear from the reasons that the finding of non-obviousness had been based on the inability of the skilled person to predict that Form I ODV succinate itself could be made or that it even existed. Additionally, the Sanofi obviousness analysis is not to be undertaken in a rigid way, but instead must be a flexible, contextual, expansive and fact-driven inquiry. Therefore it was in fact open to the Federal Court to take the properties of the invention into consideration to provide relevant context.

Similarly, the Federal Court of Appeal also held that there was no error in the lower court's treatment of the Atazanavir and Amlodipine cases. The Court of Appeal stated that while these and other past obviousness cases can be helpful illustrations of how to conduct the analysis, each case is to be decided on the basis of the specific evidence before the judge. Brown J. had considered those cases and found that they did not

establish any "hard and fast" rules on whether conducting salt screens or any other type of experimentation is obvious or not. The Court of Appeal confirmed that where there are broad factual similarities but also otherwise significant differences between cases, past decisions should not be used to force a given conclusion on obviousness.

There were some issues specific to each appeal. In Teva's case, it was argued that Brown J. had erred in relying on evidence concerning attempts by the inventors to develop another salt, ODV fumarate, as this information was not in the public domain. Additionally, it was argued that evidence of skepticism that the issues encountered with that salt could be overcome was hearsay and should not have been considered. The Court of Appeal rejected both arguments, finding that the attempts to develop ODV fumarate were properly considered as part of the amount of effort to obtain the invention, in accordance with Sanofi that expressly permits consideration of the inventors' course of conduct. Furthermore, even if the alleged hearsay evidence were excluded, it was only one factor and would not have changed the results of the obviousness analysis.

Similarly, in the Apotex appeal, the Court also rejected arguments that Brown J. should have restricted his consideration of the inventors' course of conduct to those experiments that directly led to the initial preparation of Form I ODV succinate. It was open to the Federal Court to consider whether time, money, and effort was expended in other attempts to achieve the result of the invention, and further work that was done to characterize the new crystal form after it was first prepared and identified.

Lastly, the Court of Appeal also found that Brown J. had not erred by refusing to accept evidence put forward by Apotex on the issue of obviousness as the basis for allegations of anticipation. Anticipation had been raised by Apotex in its NOA, Pfizer did not respond because Apotex filed no evidence regarding anticipation. Apotex then argued in its memorandum that the 668 Patent was anticipated, based on the affidavit evidence it had put forward regarding obviousness. Brown J. rejected this evidence, on the basis that the experts had not been instructed on obviousness, the evidence had been tendered in respect of obviousness, not anticipation, and that the parties should not be able to rely on imbedded evidence to attack the patent after the evidence is complete.

The Court of Appeal rejected the argument that the Federal Court had erred on the issue of anticipation. It was held that Brown J. had in fact considered the only possibly anticipatory prior art reference and found that it did not disclose the invention. Therefore, even if the evidence had been accepted, it would not have led to a finding of anticipation.

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