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Pharma in brief - Canada

Federal Court of Appeal revisits obviousness: guidance provided on "inventive concept" and "obvious to try" test

Case:	*Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2017 FCA 76 (A-191-16), aff'g (for different reasons) 2016 FC 580 (Court File No. T-1364-14)
Drug:	REYATAZ® (atazanavir bisulfate)
Nature of case:	Appeal from application for prohibition order granted pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party:	Teva Canada Limited (**Teva**)
Date of decision:	April 11, 2017

Summary

The Federal Court of Appeal has provided guidance on the meaning of "inventive concept." In dismissing an appeal from the Federal Court's finding that claims for the bisulfate salt of atazanavir were obvious, the Court of Appeal also provided guidance on the application of the leading *Plavix* decisions regarding this issue.

Background

Bristol-Myers Squibb Canada Co. markets atazanavir bisulfate in Canada under the name REYATAZ® for treating HIV. As we reported, following a successful prohibition application under the *Regulations* brought by Bristol-Myers Squibb Canada Co., Bristol-Myers Squibb Holdings Ireland, and Novartis AG (collectively, **BMS**), the minister of health was prohibited from issuing a notice of compliance for Teva's proposed generic atazanavir product until the expiry of the compound patent that was at issue in the case.

This appeal concerns a second patent: Canadian Patent No. 2,317,736 (the **Salt Patent**). BMS's application for the Salt Patent was dismissed on the basis of Teva's obviousness allegation. BMS argued that the court below, having concluded that each of the elements of the inventive concept could not be predicted, was bound to apply the "obvious to try" test in its favour and reject Teva's allegation. The Court of Appeal did not agree with the application judge's reasons, but upheld the result and dismissed the appeal.

Theory: what is the test for obviousness after *Plavix 1* and *Plavix 2*?

BMS framed the issue on appeal as a question of law regarding the proper application of the "obvious to try" test, which was introduced into Canadian law by the Supreme Court in *Apotex Inc v Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 (***Plavix 1***). The Court of Appeal undertook a detailed review of the legal standard for obviousness both before and after *Plavix 1*, including its own findings in *Sanofi-Aventis v Apotex Inc*, 2013 FCA 186 (***Plavix 2***). Writing for the Court of Appeal, Pelletier J.A. cautioned against "a categorical approach to obviousness" as being inappropriate: *Plavix 1* clearly indicates there is "no single or mandatory approach" to assessing obviousness. Justice Pelletier stated the governing authority remains *Plavix 1*; as a result, "One should be wary of seeing things in *Plavix 2* that have no foundation in *Plavix 1*." The court emphasized that while *Plavix 1* provided a new structure for the obviousness analysis

and recognized the usefulness of the "obvious to try" questions in some circumstances, the test should not be applied in a "rigid," "acontextual" fashion. The obvious to try questions will not be appropriate in every case.

The Court of Appeal also addressed whether the "inventive concept," also introduced by the Supreme Court in *Plavix 1*, was intended to change the definition of obviousness. Noting the obviousness analysis is directed to the difference between the prior art and a "second point," the Court of Appeal asked: did the Supreme Court redefine the second point as it was understood to be prior to *Plavix 1*? Justice Pelletier was unwilling to find that the Supreme Court changed substantive law by implication to make inventiveness more or less likely. Instead, the Court of Appeal concluded that "'inventive concept' is not materially different from 'the solution taught by the patent,'" which has often been treated as synonymous with "what is claimed" or simply "the invention."

Application: wrong inventive concept, right result

The Court of Appeal held that the court below erred, but not in its application of the obvious to try factors as argued by BMS. Rather, the court erred in law in its identification of the inventive concept.

Justice Mactavish had held that the inventive concept was Type-I atazanavir bisulfate having three advantageous properties: improved bioavailability over atazanavir free base, crystallinity, and stability. It was uncontradicted that improved bioavailability was predictable but crystallinity and stability were not. Applying the "solution taught" definition of the inventive concept, the Court of Appeal disagreed that crystallinity and stability were part of the inventive concept. It concluded that the inventive concept was atazanavir bisulfate, a salt of atazanavir that is pharmaceutically acceptable because it has equal or better bioavailability than the atazanavir free base.

The Court of Appeal concluded there was no difference between the state of the art and the correctly defined inventive concept. There was thus no predicate for the question of whether the difference was obvious, ending the analysis.

The Court of Appeal also concluded that if there were a difference between the state of the art and the inventive concept, it could have been bridged without inventiveness because the skilled person would have expected to obtain a salt with improved bioavailability over the free base of atazanavir by conducting a salt screen. As a result, there was no need to consider the obvious to try factors. Further, the Court of Appeal held that if it were necessary to consider the obvious to try factors, the facts regarding the nature, extent, and amount of effort required to achieve the invention would have been dispositive. The remainder of the factors supported the same conclusion.

As a result, the appeal was dismissed.

Links:

This decision: *Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2017 FCA 76

Underlying Federal Court decision: *Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2016 FC 580 (Pharma in Brief here)

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