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Federal Court of Appeal provides much-needed clarity on the "obvious to try" test and meaning of "inventive concept"

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In this Update

- Federal Court of Appeal in *Bristol-Myers Squibb Canada Co. v Teva Canada Limited*, 2017 FCA 76 upheld Justice Mactavish's decision reported at 2016 FC 580 in a case regarding a patent for the HIV and AIDS drug atazanavir
- Court held that "inventive concept" is typically synonymous with "the solution taught by the patent"
- Court provided greater flexibility in assessing obviousness by refusing to limit the obviousness analysis to the "obvious to try" test
- background and future implications on pharmaceutical patent litigation

The Federal Court of Appeal (the Court) has now provided much-needed clarity and guidance on two critical points in Canadian patent law: the meaning of "inventive concept" and the use of the "obvious to try" test in the obviousness analysis.

The Federal Court of Appeal in *Bristol-Myers Squibb Canada Co. v Teva Canada Limited*, 2017 FCA 76, upheld Justice Mactavish's decision in which she found Teva's allegation that Canadian Patent No. 2,317,736 (the 736 Patent) was invalid for obviousness was justified.

The Court held that the "inventive concept" is typically "the solution taught by the patent" which is often synonymous with "what is claimed in the patent" or "the invention." The Court has now provided much-needed clarity on how to identify the "inventive concept" of a patent. The "inventive concept" is often an issue of contention between the parties and focus of legal argument, because depending upon how it is defined, a finding of obviousness can be more or less likely. By linking the "inventive concept" to the claims and the solution taught by the patent, the Court has made it easier to identify the "inventive concept" and determine whether a patent is obvious.

The Court has also provided greater flexibility in assessing obviousness by taking an expansive view of the obviousness inquiry and refusing to limit the obviousness analysis to the "obvious to try" test. The Court found that the "obvious to try" test is only one way of addressing the issue of obviousness. There is no hard and fast rule for assessing obviousness. Other tests can be used including the analysis used in *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289. The Court rejected the notion that obviousness cannot be shown unless all the elements of the "inventive concept" can be predicted with a high degree

of certainty.

Background and the decision

Atazanavir is a drug used to treat HIV (human immunodeficiency virus) and AIDS (acquired immunodeficiency syndrome). It was known that the use of atazanavir free base in treating HIV and AIDS was limited by its poor bioavailability. The 736 Patent related to the Type-I atazanavir bisulfate salt.

Justice Mactavish had found that the inventive concept of the 736 Patent was the anhydrous crystalline solid form of Type-I atazanavir bisulfate salts which has stability and improved bioavailability over the free base. Justice Mactavish found that the improved bioavailability was obvious. The other elements of the "inventive concept" were found to be inherent characteristics of Type-I atazanavir bisulfate salt and not an invention.

Although the Federal Court of Appeal agreed with Justice Mactavish's conclusion that the 736 Patent was obvious, the Court found she had erred in identifying the "inventive concept" by focussing on the properties of the salt. The Court held that the "inventive concept" is the solution taught by the patent, which in this case is atazanavir bisulfate, a salt of atazanavir which is pharmaceutically acceptable because it has equal or better bioavailability than the atazanavir base.

The Court concluded that the 736 Patent was obvious because there was no difference between the prior art and the "inventive concept." The Court stated that if any difference did exist between the prior art and "inventive concept," the difference could be bridged using only the common general knowledge of the person skilled in the art.

The Court noted that it was not necessary to apply the "obvious to try" test, but if it were necessary to apply the test, the "inventive concept" would have been "obvious to try". The Court found that the extent, nature and amount of effort to get Type-I atazanavir bisulfate demonstrated that its discovery was obvious.

In the high-stakes and contentious world of pharmaceutical patent litigation, the guidance provided by the Federal Court of Appeal will no doubt impact many cases currently pending and to come. It is currently unknown whether leave to appeal the decision to the Supreme Court of Canada will be sought.