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Patent Decisions

Court of Appeal Dismisses Appeal for Different Reasons and Provides Review of the Obvious to Try Test
Bristol-Myers Squibb Canada Co. v. Teva Canada Limited, 2017 FCA 76
Drug: atazanavir

The Court of Appeal dismissed Bristol-Myers Squibb's appeal from the Trial Judge's decision refusing its application for a writ of prohibition on the basis that Teva's allegation of invalidity for obviousness was justified. The underlying proceeding related to two patents and an order of prohibition was granted in respect of the '840 Patent, but not the '736 Patent (see 2016 FC 580,our summary here). This appeal concerned only the '736 Patent, which covered a salt of atazanavir.

The Trial Judge had found that the allegation of obviousness was justified since it was more or less self-evident to a person skilled in the art that improving the solubility of atazanavir ought to improve its bioavailability. On appeal, Bristol-Myers Squibb argued that the Trial Judge had failed to properly apply the "obvious to try" test as set out by the Supreme Court in*Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61("*Plavix*").

The Court of Appeal came to the same conclusion as the Trial Judge but for different reasons. After a thorough review of *Plavix* as it related to obviousness, the Court of Appeal found that Bristol-Myers Squibb's categorical approach to obviousness was inappropriate. Bristol-Myers Squibb had submitted that obviousness cannot be shown unless all the elements of the inventive concept can be predicted with a high degree of certainty. The Court of Appeal disagreed, noting that not every case requires recourse to the "obvious to try" test and not every recourse to the "obvious to try" test must follow in the furrow of the preceding application of that test.

With respect to the Trial Judge's findings, the Court found that she had erred in the identification of the inventive concept, which focused on the properties of atazanavir bisulfate. The Court of Appeal found that the inventive concept in this case was atazanavir bisulfate, a salt of atazanavir which is pharmaceutically acceptable because it has equal or better bioavailability than the atazanavir free base. Having correctly

identified the inventive concept, the Court of Appeal concluded that there was no difference between the prior art and the inventive concept or the solution taught by the patent. Therefore, Teva's allegation of obviousness was justified according to step 3 of the obviousness framework, and it was not necessary to apply the "obvious to try" test. The Court of Appeal noted that Teva's allegation that the '736 Patent was obvious would have still been justified under the "obvious to try" test.

Court of Appeal Grants Appeal as it Relates to Duty to Mitigate
Apotex Inc. v. Canada, 2017 FCA 73

In this decision, the Court of Appeal was considering an appeal by Apotex of various findings of the Court relating to its action seeking damages from Her Majesty the Queen, as representative of the Minister of Health (see 2014 FC 1087). Apotex asserted, among other allegations, that the Health Protection Branch committed misfeasance in a public office and acted negligently, as well as breach of a settlement agreement. The Court found that Health Canada was liable on the basis of the tort of misfeasance in a public office and negligence. The Court lowered Apotex's damages on the basis that Apotex failed to mitigate its damages. The allegation of breach of the agreement was dismissed. Apotex appealed on several grounds and Health Canada cross-appealed.

The Court of Appeal reversed only in respect of the Court's finding that Apotex's damages should be reduced for failure to mitigate.

The Court of Appeal provided a lengthy summary of the Court's decision. With respect to the duty to mitigate, the Court of Appeal noted that Apotex made a number of arguments in this regard. However, the Court of Appeal considered only whether the Court erred by "requiring Apotex to accede to the use of a Canadian reference product in order to mitigate its loss." The Court of Appeal indicated that it was necessary for the Court to consider whether Apotex acted reasonably in its course of action, and not determine that there is only one reasonable course of action, which was not followed by Apotex. Upon reviewing Apotex's actual course of conduct, the Court of Appeal found that Apotex took a number of steps, including repeated interactions with Health Canada, to address the issue. Further, the Court of Appeal noted that the Court failed to recognize that Apotex's position related to its strategic and economic interests beyond a single drug submission.

The Court of Appeal varied the judgment to remove the finding that Apotex failed to mitigate its loss. As the case was bifurcated, the damages portion was to proceed on this basis. The Court of Appeal found that each party should bear its own costs.

Par

Chantal Saunders, Beverley Moore, Adrian J. Howard

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Bureaux BLG

Calgary

Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3

T 403.232.9500
F 403.266.1395

Ottawa

World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9

T 613.237.5160
F 613.230.8842

Vancouver

1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2

T 604.687.5744
F 604.687.1415

Montréal

1000, rue De La Gauchetière Ouest
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749