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Pharma in brief - Canada

Canada's patent utility standard and "promise" doctrine to go before Supreme Court of Canada

Case: AstraZeneca Canada Inc. v. Apotex Inc. (SCC file no. 36654)

Drug: NEXIUM® (esomeprazole)

Nature of case: Leave to Appeal of a judgment on invalidity of Canadian Patent No. 2,139,653 ('653 Patent)

Successful party: AstraZeneca Canada Inc.

Date of decision: March 10, 2016

Summary

On March 10, 2016, the Supreme Court of Canada (SCC) granted AstraZeneca Canada Inc. (AstraZeneca) leave to appeal an order of the Federal Court of Appeal (FCA) affirming the Trial Judge's finding that the '653 Patent is invalid for lack of utility (FCA Decision).

The FCA Decision contains an extensive discussion on the applicable standard for patent utility in Canada, including the "promise" doctrine. This is an opportunity for the SCC to provide guidance on an issue that has been the subject of much debate over recent years.

The prior '653 patent proceedings

Apotex Inc. (**Apotex**) sought to impeach the '653 Patent on the basis of lack of utility, anticipation and obviousness. Justice Rennie held that the promised utility of the '653 Patent (compounds provide improved pharmacokinetic and metabolic properties with an improved therapeutic profile) was not demonstrated nor soundly predicted at the Canadian filing date. Apotex's allegations of obviousness and anticipation were dismissed.

AstraZeneca appealed Justice Rennie's decision on the following grounds: (a) he failed to consider the patent's promised utility on a claim by claim basis; (b) he failed to construe the utility of the claims in a manner consistent with the inventive concept and; (c) he failed to apply a purposive construction to the promise of utility. The Federal Court of Appeal determined that the trial judge properly construed the "promise" of the patent by considering the patent as a whole through the eyes of the skilled reader, and properly considered the difference between "goals" and "promises". The appeal was dismissed.

Link to decisions:

The Supreme Court of Canada Case Summary may be found at: http://www.scc-csc.ca/case-dossier/info/sum-som-eng.aspx?cas=36654

Our summary of the Federal Court of Appeal decision may be found at:

http://www.nortonrosefulbright.com/knowledge/publications/130963/pharma-in-brief-federal-court-of-appeal-finds-that-promised-utility-need-not-be-coterminous-with-the-inven

The Federal Court decision may be found at:

http://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/72284/index.do

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For more information, please contact your IP/Life sciences and healthcare practice professional at Norton Rose Fulbright Canada LLP. For a complete list of our IP team, <u>click here</u>. For a complete list of our Life sciences and healthcare team, <u>click here</u>.

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