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ARTICLE

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Patent Decision

FCA allows appeal regarding lack of utility finding in light of Supreme Court's recent decision in Esomeprazole
Bristol-Myers Squibb Canada Co. v. Apotex Inc., 2017 FCA 190

This was an appeal of the Federal Court's ("FC") decision dismissing Bristol-Myers Squibb's ("BMS") prohibition application in respect of its two patents listed against dasatinib (see 2017 FC 296, our summary here). Specifically, the FC held that Apotex's allegations regarding the invalidity of the 932 Patent were justified as BMS failed to establish that all of the promised utilities for claim 27 were demonstrated or soundly predicted as of the relevant date. In respect of the 898 Patent, the FC held that Apotex's allegations regarding invalidity were justified since BMS had failed to establish that the two claims in issue were not obvious and not invalid due to double patenting.

Following the argument of the appeal to the Federal Court of Appeal ("FCA"), the Supreme Court of Canada issued its decision in AstraZeneca Canada Inc v Apotex Inc, 2017 SCC 36 ("Esomeprazole"), "which fundamentally recasts the principles applicable to assessing whether patents meet the utility requirement in section 2 of the Patent Act". The parties were allowed to make post-hearing submissions as to the impact of the Supreme Court's decision on the present appeal.

The FCA held that the FC's determination regarding the lack of utility of claim 27 of the 932 Patent could not stand, and granted the appeal in respect of the 932 Patent. Following the Supreme Court's guidance, the FCA set out the two steps of the test for utility to claim 27 of the 932 Patent: 1) determine the subject-matter of the claim; and 2) determine whether this subject-matter was shown to be useful either by demonstration or sound prediction as of the filing date.

The FCA found that, contrary to what Apotex claimed, the relevant subject-matter of the claim in issue is merely the compound, dasatinib. The FCA also concluded that BMS had demonstrated as of the relevant date that dasatinib had at least a scintilla of utility. As of the filing date, BMS had demonstrated that dasatinib acted to inhibit Src-family protein tyrosine kinases ("PTKs"). Such demonstration is referred to in the specification of the Patent itself, and confirmed in the evidence of the inventors filed. The FCA also noted that the "discovery of a substance that acted to inhibit certain PTKs represented an important advance and certainly meets the minimal utility requirements that are now applicable following the decision of the Supreme Court in Esomeprazole".

The FCA also dismissed Apotex's claim that the 932 Patent fails to comply with the requirements of subsection 27(3) of the Patent Act. This issue was not challenged on appeal. The FCA found that Apotex could not try to raise this issue in its supplemental written submissions, where it was granted leave to only make submissions as to the impact of Esomeprazole on the present issues in dispute.

The appeal in respect of the 898 Patent was dismissed. The FCA upheld the FC's finding that claims 1 and 3 of the 898 Patent were obvious. The FCA found it unnecessary to examine the ground of appeal relating to double patenting.

Federal Courts Update

The Federal Court issued two Notices: 1) Guideline for Actions under the Amended PMNOC Regulations; and 2) Scheduling Practice for the Hearing of Applications.

IP Updates

CIPO issued a Practice Notice for Objection Proceedings under Section 11.13 of the Trade-marks Act.

The Canada Border Services Agency ("CBSA") issued a Customs Notice to indicate that the CBSA accepts information on shipments of counterfeit or pirated goods that are dangerous destined to Canada.

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