

Pharma in brief - Canada

Supreme Court of Canada denies Apotex leave to appeal Lovastatin infringement damages

Case:	<i>Apotex Inc., et al. v. Merck & Co. Inc., et al.</i> (SCC docket no. 36655)
Drug:	MEVACOR [®] (<i>lovastatin</i>)
Nature of case:	Leave to appeal from damages decision following a declaration that Canadian Patent No. 1,161,380 (380 Patent) was valid and infringed
Successful party:	Merck & Co. Inc. and Merck Canada Inc.
Date of decision:	14 April 2016

Summary

On April 14, 2016, the Supreme Court of Canada (**SCC**) dismissed Apotex Inc. and Apotex Fermentation Inc.'s (**Apotex**) application for leave to appeal a Federal Court of Appeal (**FCA**) decision upholding a damage award for infringement of a patent relating to lovastatin. The FCA held that a non-infringing alternative (**NIA**) defence is legally relevant when assessing damages, but that Apotex failed to establish on the evidence that it could and would have pursued the NIA in the "but for" world.

Background

As we previously [reported](#), in the liability phase, the Trial Judge found that Apotex infringed the 380 Patent for a method for making lovastatin using a microorganism of the genus *Aspergillus terreus* (AFI-1). The trial decision was confirmed by the FCA. In the damages phase, the Federal Court (**FC**) found that Merck was entitled to a total damages award of \$119,054,327, plus pre-judgement and post-judgement interest, and rejected Apotex's arguments that the existence of an NIA is a relevant factor in the assessment of damages.

Apotex appealed the decision on multiple grounds, including that the FC erred by rejecting the legal relevance of non-infringing lovastatin when computing damages, and that the damages for which it is liable should be reduced because it had a NIA available. The FCA held that the availability of an NIA is relevant in law when assessing the patentee's lost sales. However, while Apotex established that it had a real and viable NIA, the FCA found that the evidence did not support Apotex's contention that it could and would have pursued its NIA in the "but for" world. The FCA dismissed Apotex's appeal with costs.

As a result of the SCC's dismissal of Apotex's appeal, the FCA decision has been affirmed: an NIA defence is available as a matter of law in the assessment of damages subject to being established on the facts of each case.

Link to decisions:

SCC docket 36655 may be found [here](#).

[Apotex Inc et al v Merck & Co et al, 2015 FCA 171](#)

[Merck & Co., Inc. v. Apotex Inc., 2013 FC 751](#)

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For more information, please contact your IP/Life sciences and healthcare practice professional at Norton Rose Fulbright Canada LLP.

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