

## Pharma in brief - Canada

### Federal Court of Appeal dismisses appeal of prohibition application for mootness

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<b>Case:</b>	<i>Amgen Canada Inc. v Apotex Inc.</i> , 2016 FCA 196 (Court File No. A-501-15)
<b>Drug:</b>	NEUPOGEN® (filgrastim)
<b>Nature of case:</b>	Motion for dismissal of an appeal from an application for prohibition pursuant to section 6 of the <i>Patented Medicines (Notice of Compliance) Regulations</i> , SOR/93-133 (the <b>Regulations</b> )
<b>Successful party:</b>	Apotex Inc.
<b>Date of decision:</b>	July 15, 2016

#### Summary

Amgen Canada Inc. and Amgen Inc. (collectively, **Amgen**) market and sell filgrastim in Canada under the name NEUPOGEN® for use in the treatment of neutropenia. In November 2015, the Federal Court dismissed Amgen's application for an order prohibiting the Minister of Health from issuing a Notice of Compliance (**NOC**) to Apotex Inc. for its subsequent-entry biologic (or biosimilar) of filgrastim for two dosage strengths (reported [here](#)). Apotex received an NOC for one of the dosage strengths in December 2015.

Amgen sought an expedited appeal of the dismissal, and Apotex moved to have the appeal dismissed for mootness.

Apotex argued that the Minister had already issued an NOC to Apotex, and therefore a prohibition order would serve no purpose. Amgen opposed the motion by pointing to Apotex filing a claim for damages pursuant to section 8 of the *Regulations*. Apotex's claim was triggered by the dismissal of Amgen's application. Amgen argued that a reversal of the decision would extinguish Apotex's right to bring this claim, and therefore, as Apotex's section 8 action was live and not a mere possibility, the appeal would have a real and practical effect on the parties' rights.

The Federal Court of Appeal dismissed Amgen's appeal. The court confirmed that an appeal is moot when an NOC has already issued, and held that it should not exercise its discretion to hear the moot appeal. Although the court agreed with Amgen that a live section 8 claim impacts the parties rights "in a real and practical way," this was not adequate to distinguish previous cases. The court confirmed that when a patentee can assert its patent, including in the context of section 8, the pending appeal loses any practical utility and hearing the appeal would serve only to waste scarce judicial resources.

Amgen has sought leave to appeal to the Supreme Court.

#### Links:

*Amgen Canada Inc v Apotex Inc*, [2016 FCA 196](#)

Prohibition proceeding: *Amgen Canada Inc v Canada (Minister of Health)*, [2015 FC 1261](#)

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