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Pharma in brief – Canada

FCA considers impact of successful infringement judgement on prior order for s. 8 damages

Case:	*AstraZeneca Canada inc. v. Apotex Inc.*, 2016 FCA 194 (Court File No. A-311-15, A-187-12), aff'g 2015 FC 799
Drug:	LOSEC® (omeprazole)
Nature of case:	Appeal from motion to vary decision under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (***Regulations***)
Successful party:	Apotex
Date of decision:	July 7, 2016

Summary

This decision is an appeal from a judgement of the Federal Court declining to vary its decision awarding damages to Apotex under section 8 of the Regulations. AstraZeneca brought the motion to vary the section 8 decision following its success in an infringement action relating to the same product. The Federal Court of Appeal dismissed AstraZeneca's appeal

Background

On May 11, 2012, Justice Hughes held that Apotex was entitled to compensation under section 8 of the *Regulations* as a result of a prohibition proceeding relating to omeprazole and Canadian Patent No. 2,133,762, which was dismissed on March 2, 2004 (see our summary of the decision here). Damages will be quantified in a subsequent reference.

In the section 8 proceeding, AstraZeneca argued that Apotex was not entitled to damages because any sales of Apotex's omeprazole product made during the relevant period would infringe another AstraZeneca patent, Canadian Patent No. 1,292,693 (**693 Patent**). The 693 Patent was the subject of a pending infringement action between the same parties. AstraZeneca also argued that such infringement was a relevant consideration to reduce or eliminate the damages owed to Apotex in the section 8 proceeding.

Justice Hughes rejected both arguments. He held it was for the Court hearing the pending infringement action to craft an appropriate remedy in light of any compensation awarded in the section 8 proceeding, if the Court concluded that the patent is valid and infringed. Refusing to compensate the generic in the section 8 proceeding based on an infringement action would not be appropriate. Justice Hughes' decision was affirmed by the Federal Court of Appeal on March 3, 2011.

On March 16, 2015, Justice Barnes of the Federal Court held that the 693 Patent was valid and infringed by Apotex (see our summary of the decision here).

Following his decision, AstraZeneca moved to vary Justice Hughes' judgement in the section 8 proceeding to allow the reference judge to have regard to Justice Barnes' decision both in determining Apotex's entitlement to damages and

under section 8(5) of the Regulations. AstraZeneca argued that Justice Barnes' finding was a matter that arose or was discovered after the decision was rendered and justified its reconsideration.

On June 26, 2015, Justice Hughes dismissed AstraZeneca's motion.

Relevance of parallel infringement action in a section 8 proceeding

Justice Dawson, writing for the Federal Court of Appeal, noted that the Court of Appeal has previously agreed with Justice Hughes' conclusion that it is for the judge hearing the infringement action to ensure a party is not under- or overcompensated. She also agreed that Justice Barnes' finding that the 693 Patent was valid and infringed is not a matter that "arose or was discovered" after the judgement in the section 8 proceeding issued that would warrant a variation of the judgement. Justice Hughes had expressly considered this scenario, and the fact that the infringement action is no longer "pending" and that AstraZeneca's patent was found to be valid and infringed by Apotex does not affect his reasoning.

Justice Dawson reiterated that to minimize the consequences of inconsistent findings in infringement and section 8 proceedings, it remains for the judge hearing the infringement action "to ensure that overall, taking both proceedings together, a party is compensated for its provable loss, if any, on proper principles, no more and no less."

Original decision maker is the best placed to hear a motion to vary his judgement

Justice Hughes also dismissed AstraZeneca's motion to vary on the basis that it was for the Federal Court of Appeal, and not the Federal Court, to hear the motion since it affirmed his original decision in the section 8 proceeding. Justice Dawson disagreed with this conclusion and held that, when a decision is upheld by the Court of Appeal, the original decision maker is the person best placed to decide whether a newly discovered matter would have affected the original judgement.

Links:

AstraZeneca Canada Inc. v. Apotex Inc., Justice Hughes' decision – 2015 FC 799. Court of Appeal decision - 2016 FCA 194.
Section 8 action - *Apotex Inc. v. AstraZeneca Canada Inc.*, 2012 FC 559, aff'd 2013 FCA 77
Prohibition proceeding - *AstraZeneca AB v. Apotex Inc.*, 2004 FC 313

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