

## Pharma in brief - Canada

### Federal Court of Appeal upholds validity, infringement of omeprazole formulation patent; finds provincial limitations periods may apply to infringing acts for “Old Act” Patents

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<b>Case:</b>	<i>AstraZeneca Canada Inc v Apotex Inc</i> , 2017 FCA 9 (Court File No. A-201-15)
<b>Drug:</b>	LOSEC <sup>®</sup> (omeprazole)
<b>Nature of case:</b>	Appeal from validity and infringement action under the <i>Patent Act</i> , RSC 1985, c P-4 ( <b>Patent Act</b> )
<b>Successful party:</b>	AstraZeneca Canada Inc., Aktiebolaget Hässle, AstraZeneca AB (collectively, <b>AstraZeneca</b> ) on validity and infringement issues; Apotex Inc. on limitations period issues.
<b>Date of decision:</b>	January 12, 2017

#### Summary

On January 12, 2017, the Federal Court of Appeal upheld findings of the Federal Court (reported [here](#)) declaring the asserted claims of Canadian Patent No. 1,292,693 (**693 Patent**) to be valid and infringed by Apotex's manufacture, sale, and promotion of Apo-Omeprazole capsules, a generic version of AstraZeneca's LOSEC<sup>®</sup>. The Federal Court of Appeal upheld the Federal Court's construction of the 693 Patent, as well as its findings on infringement and validity. However, Apotex's appeal in respect of the appropriate limitation period for infringing activities was allowed. The Federal Court of Appeal found that, in respect of patents filed before October 1, 1989 (**Old Act Patents**), provincial limitations may apply where the cause of action for any specific act of infringement arises entirely within a particular province.

The Court of Appeal dismissed AstraZeneca's cross-appeal seeking punitive damages.

The underlying action was bifurcated and the damages reference is scheduled to commence on January 30, 2017. On January 16, 2017, AstraZeneca filed a motion for reconsideration, seeking to amend the order to permit only consideration of the Ontario limitations period, rather than provincial limitations periods more broadly. AstraZeneca argues that only infringing activity in Ontario was in issue before the court and that Apotex has not pled or argued any other provincial limitation period as a defence.

#### Limitation period for infringement of Old Act Patents

Apotex's appeal of the Federal Court's finding that a six-year limitation period applied in respect of all of Apotex's acts of infringement was allowed.

The 693 Patent was subject to the provisions of the *Patent Act* as it read in 1987 (the date of filing of the 693 Patent). That version of the *Patent Act* did not contain a specific provision dealing with the limitation period applicable to infringement actions, as the provision providing for the six-year limitation period was not added until 1993. Thus, the limitations periods in the *Federal Courts Act*, RSC 1985, c F-7 applied.

The Federal Court of Appeal's analysis turned on the interpretation of the *Federal Courts Act*, which provides for the application of provincial limitation periods for any "cause of action arising in that province" and a six-year limitation period for a "cause of action arising otherwise than in a province."

The Federal Court of Appeal found that each act of infringement is a distinct cause of action and that a cause of action arises in a province if all of the elements of the cause of action occur in that province. In that situation, section 39(1) of the *Federal Courts Act* provides that the limitation period prescribed by the province in which the cause of action arose applies.

The Federal Court of Appeal rejected AstraZeneca's arguments that the six-year limitation should apply where a single transaction could comprise multiple acts of infringement (for example, by sale and by inducement). The court held that although onerous, the limitation period for each individual act of infringement must be determined and noted that such intensive inquiries would only apply in respect of Old Act Patents given the introduction of a six-year limitation period in the *Patent Act* in 1993.

## Infringement and validity

**Claims Construction and Infringement.** Validity and infringement largely turned on the construction of claim 1. After providing a detailed analysis of the disclosure, the Federal Court of Appeal agreed with the Federal Court's construction of claim 1, finding that it was in line with the purpose of the invention and the inventive concept agreed upon by the parties. On this construction, the Federal Court of Appeal upheld the Federal Court's finding that Apotex's Apo-Omeprazole capsules infringed the 693 Patent.

**Validity.** The Federal Court of Appeal found that claim 1 of the 693 Patent was not ambiguous nor overbroad. It also found that the disclosure was sufficient, noting that the patent need only describe one method or process for making the claimed product, and that routine testing to determine whether a new method provided the claimed product was permissible. Finally, the Court found that the inventors had properly disclosed a sound factual basis to predict the utility of preparations having the essential elements of claim 1.

## Cross-appeal on punitive damages

AstraZeneca cross-appealed on the issue of punitive damages, alleging Apotex had been deceptive in the context of a settlement obtained in earlier NOC proceedings involving the same patent. The Court of Appeal reiterated that punitive damages are only awarded in exceptional patent infringement cases, and it was not prepared to disturb the Federal Court's findings of facts on the issue.

## Link:

[2017 FCA 9](#)

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