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Pharma in brief - Canada

Federal Court of Appeal opines that one standard of review should apply to all civil appeals

Case:	*Bayer Inc. v. Fresenius Kabi Canada Ltd.*, 2016 FCA 13 (Court File No. A-312-15), aff'g 2015 FC 797, aff'g 2015 FC 388
Drug:	AVELOX® I.V. (moxifloxacin hydrochloride)
Nature of case:	Appeal from an Order of the Federal Court affirming Prothonotary's decision to strike portions of an application pursuant to section 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party:	Fresenius Kabi Canada Ltd.
Date of decision:	January 19, 2016

Summary

The Federal Court of Appeal has suggested that the palpable and overriding error standard of review (as set out by the Supreme Court in *Housen v. Nikolaisen*, 2002 SCC 33) should apply to all civil appeals, including those from orders of prothonotaries. However, in this case it ultimately applied the "wrong basis or clearly wrong" standard of review, and upheld a Prothonotary's decision to strike an application brought under section 6 of the *Regulations* on the grounds that the applicant's evidence could not support a conclusion of direct or induced infringement.

Background

Bayer Inc. and Bayer Intellectual Property GmbH (**Bayer**) market moxifloxacin hydrochloride intravenous solution for injection in Canada under the name AVELOX® I.V., an antibiotic. Fresenius Kabi Canada Ltd. (formerly Pharmaceutical Partners of Canada Inc., collectively, **Fresenius**) has sought approval for a generic version of moxifloxacin hydrochloride product for injection.

Bayer brought an application under section 6 of the *Regulations*, including an allegation that Fresenius was infringing or inducing infringement of Canadian Patent No. 2,378,424 (the **424 Patent**). Fresenius brought a motion to strike portions of Bayer's application pursuant to paragraph 6(5)(b) of the *Regulations*, on the grounds that Bayer's evidence could not support a conclusion of direct infringement or induced infringement of the 424 Patent by Fresenius.

The 424 Patent is entitled "Moxifloxacin Formulation Containing Common Salt", and includes a formulation for intravenous administration. All 49 claims of the 424 Patent require moxifloxacin with sodium chloride within specified concentrations.

On the motion before the Prothonotary, Bayer conceded there was no evidence of direct infringement but argued that Fresenius would induce health practitioners to infringe the 424 Patent by representations made in its Product Monograph.

Fresenius' motion was granted. The Prothonotary held that it was plain and obvious that Bayer had no reasonable chance of success in demonstrating that Fresenius was or would be inducing infringement of the 424 Patent, as it had not established that Fresenius would influence any direct infringer to the point that, without the influence, direct infringement would not take place.

The Federal Court arrived at the same result for substantially the same reasons as the Prothonotary. Bayer appealed the decision.

The standard of review

Both parties submitted that the standard of review to be applied was "palpable and overriding error". The Court of Appeal agreed that this would be the standard, except that this case was an appeal from an appeal of a Prothonotary's decision. In such cases, the Court of Appeal can only interfere with the underlying decision where the Federal Court had no grounds to interfere with the Prothonotary's decision or, in the event such grounds existed, if the decision of the Federal Court was arrived at on a wrong basis or was plainly wrong.

The Court of Appeal commented that the palpable and overriding error standard should be the single general standard for all civil appeals. However, given that it had not received full argument on this point, the Court applied the standard associated with these types of appeals, noting that it would have also dismissed the appeal if the standard had been palpable and overriding error.

Bayer's appeal dismissed

The Court of Appeal held that as the Federal Court set out the applicable principles of the law on inducement (which were not disputed by either party) the decision "was not arrived at on a wrong basis". Further, in applying those principles, the Federal Court was "not plainly wrong" in finding as a fact that: (1) the product monograph does not instruct or direct that Fresenius' product be co-administered with 0.9% sodium chloride and (2) a general reference to sodium chloride in the product monograph was obligatory and fell short of inducement.

Bayer argued that the Federal Court Judge had applied too low a test for striking out portions of its application under paragraph 6(5)(b) of the *Regulations*. The Court of Appeal held that the Federal Court Judge was entitled to assess the evidence, and found no basis on which to interfere with those findings.

Links:

Bayer Inc. et al. v. Fresenius Kabi Canada Ltd. et al., 2016 FCA 13 aff'g 2015 FC 797 aff'g 2015 FC 388

Pharma in brief - No induced infringement: Patent struck from application under s. 6(5)(b) of the PM(NOC) Regulations

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