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Pharma in brief - Canada

Innovator seeks leave to appeal to SCC on whether Minister can issue NOC without notice to first person for cross-referenced generic drug submission

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Case:	*Janssen Inc, et al, v Hospira Healthcare Corporation, et al* (SCC Docket: 37342)
Drug:	REMICADE® (infliximab)
Nature of case:	Appeal of judicial review of a decision of the Minister of Health to not require notice under section 5 of the *Patented Medicines (Notice of Compliance) Regulations* (***Regulations***)
Appellants:	Janssen Inc.
Respondents:	Hospira Healthcare Corporation
Date:	December 9, 2016

Janssen filed an application for leave to appeal with the Supreme Court of Canada (**SCC**) on December 9, 2016, with respect to the Federal Court of Appeal (**FCA**) decision addressing a generic manufacturer's ability to obtain a notice of compliance (**NOC**) by way of cross-referenced drug submission.

As we reported, the FCA recently held that the Minister of Health's (**Minister**) decision to issue an NOC to a generic manufacturer for a cross-referenced submission without providing notice to the innovator company was reasonable.

The Minister had issued NOCs for two generic products without the generics serving a notice of allegation. The innovator companies brought applications for judicial review, and the Minister's decisions were set aside by the Federal Court. The Minister and the respective generic manufacturers appealed. In both appeals, the issue was whether the Minister was permitted to issue NOCs to the generic companies without requiring them to address relevant patents on the patent register pursuant to section 5 of the *Regulations*.

The FCA allowed the appeals, finding that it is relevant to consider whether the generic company took advantage of the early working exception. The FCA held that the focus should be on the drug product itself and whether the changes reflected in the submission give rise to a new or different basis for asserting that a particular product is infringing. In both cases, the generic companies sought approval for products that were identical to a previously approved generic product and any potential infringement could be addressed in infringement proceedings.

Following the release of the FCA's decision, Health Canada provided notice that the decision will affect the application of section 5 of the *Regulations* with respect to administrative drug submissions (reported here).

Links:

- **SCC Docket:** 37342
- **Federal Court of Appeal Decision:** *Teva Canada Limited et al v Pfizer Canada Inc et al,* 2016 FCA 248
- **Federal Court Decision:** *Pfizer Canada Inc v Canada (Health),* 2014 FC 1243

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

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