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Pharma in brief - Canada

Health Canada issues notice of impact of FCA case on PM(NOC) guidance document

Health Canada recently published a notice regarding the Guidance Document: *Patented Medicines (Notice of Compliance) Regulation*s.

Health Canada did not make any actual changes within the guidance document, but simply provided notice that the Federal Court of Appeal's decision in *Teva Canada Limited v Pfizer Canada Inc*, 2016 FCA 248 will affect the application of section 5 of the *Regulations* with respect to administrative drug submissions.

As we reported, the *Teva* decision involved two generic drug submissions that cross-referenced the submission of another generic company that had received a Notice of Compliance (**NOC**). The Minister of Health issued NOCs for the two generic products without requiring notice to the innovator company in the form of a Notice of Allegation (**NOA**).

In both cases, the innovator companies brought an application for judicial review and the minister's decisions were set aside. The minister and the respective generic manufacturers appealed. The issue in both appeals is 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 Federal Court of Appeal allowed the appeals, holding that in the circumstances the generic companies were not required to serve NOAs. The FCA found that it is relevant to consider whether the generic company took advantage of the early working exception, and also considered the interpretation of the word "submission," which requires consideration of each individual submission. 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.

The FCA found that on the facts of these cases, the generic companies did not need to serve NOAs on the innovator companies.

Links:

Notice and Guidance Document.

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

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