

# Federal Court of Appeal clarifies standard for granting leave in NOC cases

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When the Patented Medicines (Notice of Compliance) Regulations (the NOC Regulations) were amended in 2017, the procedure governing their proceedings was amended to, among other things, provide that an appeal from any interlocutory order would be heard by the Federal Court of Appeal (FCA) only with leave.<sup>1</sup> **This introduced two changes: (i) removing an appeal to a Federal Court judge from a decision of a Prothonotary, and (ii) introducing a requirement to obtain leave.** The FCA has since heard many motions for leave, but has not issued reasons with respect to those motions. In a recent decision, the FCA issued reasons outlining the criteria under which leave to appeal would be granted,<sup>2</sup> bringing clarity to the matter.

## The appellate standard of review

The Court stated that the normal standard for granting leave is a ‘fairly arguable case’, but that this evaluation must take place in the context of the appellate standard of review. Thus, if the review standard is correctness, the appellant must show that the decision below was arguably wrong. Further, if the review standard is palpable and overriding error, the appellant must show it can overcome that deferential standard. The deference the FCA gives to case management orders adds to this burden. The FCA **held that “good counsel, in pursuing the interests of their clients, tend to characterize something as an error of law or of extricable principle when, in fact, it is nothing of the sort.”<sup>3</sup> Thus, the FCA must scrutinize the alleged error to determine the relevant standard.** In addition, the Court held that the appellant must show that the decision under appeal will have a direct impact on the overall success or failure of the case. The Court held that the nature of amendments to the NOC Regulations suggest that leave **should be granted only in matters of “prime significance and materiality”<sup>4</sup>.**

This guidance from the FCA will be of great use to the IP bar in NOC proceedings.

<sup>1</sup> Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, S.O.R./2017-166, s. 6.11.

<sup>2</sup> [Apotex Inc. v. Allergan Inc. et al, 2020 FCA 208](#).

<sup>3</sup> Ibid. at para 12.

<sup>4</sup> Ibid. at para 14.

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