

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

December 09, 2020

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.¹ 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,² 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."³ 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".⁴

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

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

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

³ Ibid. at para 12.

⁴ Ibid. at para 14.

By

Beverley Moore

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BLG Offices

Calgary

Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3

T 403.232.9500
F 403.266.1395

Ottawa

World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9

T 613.237.5160
F 613.230.8842

Vancouver

1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2

T 604.687.5744
F 604.687.1415

Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749

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