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Clarity on the Test for Inducing Infringement in Canadian Patent Law

Indirect infringement or “inducement” often arises in pharmaceutical patent infringement cases where a defendant generic manufacturer may not ultimately “use” the drug in question (*i.e.*, directly infringe). Since 2011, the Federal Court of Appeal’s (“FCA”) *Corlac Inc v Weatherford Canada Inc* decision has frequently been cited as the leading authority for the tripartate test for inducement. In 2020, the Federal Court suggested that *Corlac* had changed the law of inducement—particularly at the second step determining influence—thereby requiring “a higher threshold for establishing inducement than was applied in the earlier cases”. In the recent decision of *Teva Canada Limited v Janssen Inc* (“*Paliperidone* ”), the FCA has rejected that interpretation of *Corlac*. The FCA held that *Corlac* incorporates the same principles of inducing infringement as had been established in cases dating back to 1906. In doing so, it overturned the lower Court’s inducement determination based on a supposed higher standard and found that the defendant was liable for inducement when the *Corlac* test was properly applied.

While the *Paliperidone* decision also deals with issues of obviousness and direct infringement, we focus on the issue of inducement below.

Background and the Federal Court Decision

The action underlying the *Paliperidone* decision concerns a proceeding under Canada’s *Patented Medicines Notice of Compliance* (*PM(NOC)*) *Regulations* for patent infringement of Janssen’s Canadian Patent No. 2,655,335 (the “335 Patent”). The 335 Patent relates to dosing regimens of injectable paliperidone palmitate formulations for the treatment of schizophrenia and related disorders. The claims relate to prefilled syringes, use of a dosage form, and Swiss-type claims relating to the use of paliperidone in the manufacture of a medicament.

On the issue of inducement, Janssen argued that Teva would induce infringement of the 335 Patent from the sale of its own generic paliperidone palmitate product in Canada. In considering the issue, the Federal Court applied the tripartite

test for inducement from *Corlac*, requiring the patentee to establish that:

> 1. the act(s) of infringement must have been completed by the direct infringer;
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> 2. the completion of the act(s) of infringement were influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place; and
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> 3. the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement.

The Federal Court found that Janssen had established the first of the *Corlac* factors, but not the second (the third factor was not considered). The Federal Court found that the decision in *Corlac* sets out a more stringent test than had previously been required such that a defendant now will not be found to induce infringement unless the patentee establishes that, "but for" the defendant's acts, the infringement did not (or in the context of *PM(NOC)* actions, would not) occur. Applying that standard to the second factor, the Federal Court found that Janssen had not established that Teva's Product Monograph ("PM") would influence physicians to prescribe the claimed dose to the point that, absent the information in the PM, direct infringement would not occur. It found that the selection of doses would ultimately be made by physicians based on various factors *beyond* Teva's PM, and therefore failed to satisfy the "but for" requirement.

FCA Says *Corlac* Did Not Elevate the Inducement Standard

The Federal Court's finding of a "higher degree of causality" was reversed on appeal. The FCA in *Paliperidone* found it was an error in law for the lower Court to find that *Corlac* changed the law by incorporating a higher threshold at the second step for finding inducement. After an extensive review of the case law going back to 1906, the FCA stated "it is clear that *Corlac* did not change the law regarding the requisite element for inducing infringement" – the decision in *Corlac* incorporates the same principles for inducing infringement as were previously embraced. This error led the Federal Court to incorrectly apply "an unduly onerous requirement" and to incorrectly focus only on the skill and judgment of prescribing physicians while excluding Teva's role in inducing infringement.

FCA Insights on Inducement and Product Monographs

The FCA in *Paliperidone* noted that in the case of a generic drug, "inclusion as one of the recommended uses within the PM

for the drug of the alleged infringing use, among others, has been found to be sufficient to constitute the requisite encouragement to satisfy the second prong of the test for inducement". According to the FCA: "It matters not that physicians use their own skill and judgment in dispensing the drug, nor that they must make an active choice to perform the infringing use, as physicians invariably exercise similar skill and judgment whenever a drug is prescribed to a patient". The FCA concluded that the infringing use was one of several taught in Teva's PM and product label, and therefore, "[t]his finding inevitably leads to the conclusion that Teva would induce infringement of the use claims".

The FCA also proceeded to apply the third *Corlac* factor (not considered by the Federal Court), namely whether the influence was (or would be in the context of *PM(NOC)* actions) knowingly exercised by the inducer such that the inducer knows that the influence will result in the completion of the act of infringement. The Court concluded that the third element "is easily met as Teva must be presumed to have been aware of the contents of its PM and what it recommended".

Takeaways

The *Paliperidone* decision provides a detailed recitation of the law of inducement, confirmation that the inducement test has remained consistent throughout its history in Canadian law, and that the standard was not elevated by *Corlac*. Additionally, in the context of pharmaceutical patent actions including those under the *PM(NOC) Regulations*, particular insight relating to product monographs and induced infringement is provided.