

FCA Confirms Test for Inducing Patent Infringement

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In *Teva Canada Limited v. Janssen Inc.*, 2023 FCA 68, the Federal Court of Appeal confirmed that its previous decision in *Corlac Inc. v. Weatherford Canada Inc.*, 2011 FCA 228 did not change the test for patent infringement by inducement. To establish induced infringement, the patentee must prove that the alleged inducer influenced the direct infringer to the point that, without such encouragement, infringement would not have occurred. The Federal Court of Appeal canvassed a range of cases and circumstances where induced infringement had been established and overturned the trial judge's formulation of the test for induced infringement as requiring "but for" for causation.

Background

Paliperidone palmitate is a drug used to treat schizophrenia and related disorders. It is marketed in Canada by Janssen Inc. as INVEGA SUSTENNA. Janssen's Canadian Patent 2,655,335 (the 335 Patent) contains 63 claims related to dosing regimens for long-acting injectable formulations.

Teva filed an Abbreviated New Drug Submission (ANDS) to market generic prefilled syringes of paliperidone palmitate in Canada. Janssen alleged infringement of the 335 Patent. The asserted claims were categorized into three sets:

- claims 1 to 16 related to prefilled syringes adapted for administration according to the claimed dosing regimens;
- claims 17 to 32 related to a use of a dosage form according to the claimed dosing regimens; and
- claims 33 to 48 related to use of paliperidone as paliperidone palmitate in the manufacture/preparation of a medicament adapted for administration according to the claimed dosing regimen.

The Trial Decision

At trial, only obviousness and infringement were in dispute; the trial judge held that the asserted claims were valid and not obvious. The trial judge also held that Teva would directly infringe claims 1 to 16 and 33 to 48 of the 335 Patent if it marketed its paliperidone product. However, the trial judge held that claims 17 to 32 would not be directly infringed.

Cassels

The trial judge considered the three-part test for inducing patent infringement and concluded that Teva would not induce infringement of any of the asserted claims. To establish induced infringement, the patentee must establish that:

- the act(s) of infringement were completed by the direct infringer;
- 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
- the influence must knowingly be exercised by the inducer, i.e., the inducer knows that this influence will result in the completion of the act(s) of infringement.

The trial judge found that Teva's product monograph did not influence physicians to the point that they would be compelled to use the patented dosing regime. Although it was a factor, ultimately the trial judge found that the selection of a maintenance dose would be made by physicians based on various factors beyond what was set out in Teva's product monograph.

The trial judge granted a permanent injunction prohibiting Teva from marketing its paliperidone product in Canada.

Teva appealed the Federal Court's conclusions on obviousness and direct infringement, and Janssen cross-appealed the finding on induced infringement.

Appeal Allowed on Inducing Infringement

The Federal Court of Appeal agreed that the patent was not obvious and would be directly infringed. The Federal Court of Appeal also found that Teva would induce infringement.

Janssen argued that the trial judge erred in law by:

- applying an unduly onerous requirement at the second prong of the analysis for inducement (i.e., that without the inducer's influence, infringement would not have taken place); and
- focusing only on the skill and judgement of prescribing physicians and excluding Teva's role in inducing infringement of the use claims.

The Court found that the trial judge imposed a higher degree of causality than actually required in the second prong of the test for inducing infringement. The test, as formulated, expressly requires that the alleged inducer influenced the direct infringer to the point that, without such encouragement, infringement would not have occurred. The Court of Appeal found that by characterizing this as a "but for" test, the trial judge applied an unduly onerous causation requirement and incorrectly focussed on the skill and judgment of the prescribing physicians rather than Teva's role in promoting the infringing product through the product

monograph.

Considering past cases and applying the proper test, the Court found that trial judge's finding that the "capable, approved, and intended use" for Teva's product incorporated all the dosing and administration elements of the product claims, including the use of the continuous maintenance doses claimed in the 335 Patent, should have resulted in the Court finding that Teva would induce infringement of the use claims.

This is an important decision because it reviews the history of inducing infringement under Canadian law and confirms that patent infringement by inducement can arise in a variety of circumstances, including cases where the inducement occurs through "subtle" references. Notwithstanding the express language used to describe the test, the Court of Appeal concluded that *Corlac* did not change the test for inducing patent infringement.

This publication is a general summary of the law. It does not replace legal advice tailored to your specific circumstances.