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Pharma in brief - Canada

Federal Court declines to strike *quia timet* action for patent infringement

Case:	*Gilead Sciences, Inc. v Teva Canada Limited*, 2016 FC 336 (Court File No. T-1888-15), aff'g 2016 FC 16
Drug:	tenofovir disoproxil fumarate
Nature of case:	Appeal from Order dismissing motion to strike a *quia timet* action for patent infringement under the *Patent Act*, RSC 1985, c P-4 (***Patent Act***)
Successful party:	Gilead Sciences, Inc.; Gilead Sciences Canada, Inc.; and Bristol-Myers Squibb & Gilead Sciences LLC
Date of decision:	March 21, 2016

Summary

Gilead Sciences Canada, Inc. (**Gilead**) markets products containing tenofovir disoproxil fumarate (**TDF**), alone and together with other medicinal ingredients, for the treatment of HIV infection. Teva Canada Limited (**Teva**) has sought approval for generic versions of three drugs containing TDF.

Gilead sued Teva for infringement of Canadian Patent No. 2,298,059 (the **'059 Patent**). Gilead alleged past, current, and future infringement. Teva moved to strike the entire claim. Madam Prothonotary Tabib allowed the motion in part and struck Gilead's pleadings in respect of past and current infringement. However, she declined to strike amended pleadings supporting the *quia timet* claim for future infringement. Teva appealed to a judge of the Federal Court.

Barnes J dismissed Teva's appeal and allowed Gilead to maintain its *quia timet* action for infringement of the '059 Patent.

Background

As a result of successful applications under the *Patented Medicines (Notice of Compliance) Regulations*, the Minister of Health is prohibited from issuing notices of compliance (**NOCs**) to Teva for generic versions of three products containing TDF (VIREAD, TRUVADA, and ATRIPLA). Teva is seeking to impeach the patent supporting those prohibition orders (Canadian Patent No. 2,261,619).

In its impeachment action, Teva pleaded, admitted on discovery, and provided a will-say statement to the effect that it intends to come to market with products containing TDF immediately upon receipt of an NOC. Gilead obtained relief from the implied undertaking rule in order to use this information in support of its *quia timet* pleadings.

Appeal dismissed: *quia timet* action permitted

Teva argued that Prothonotary Tabib incorrectly applied the test for maintaining a *quia timet* infringement action set out in *Connaught Laboratories Limited v SmithKline Beecham Pharma Inc.*, [1998] FCJ 1851:

- The statement of claim must allege a deliberate expressed intention to engage in activity the result of which would raise a strong possibility of infringement;

- The activity to be engaged in must be alleged to be imminent and the resulting damage to the plaintiff must be alleged to be very substantial if not irreparable; and

- The facts pleaded must be cogent, precise and material; it is not sufficient that they be indefinite or speak only of intention or amount to mere speculation.

Teva argued that Prothonotary Tabib wrongly ignored the temporal aspect of the test for imminent harm and misapplied the requirement that there be a virtual inevitability of future harm, citing her own decision in *Teva Canada Limited v Novartis AG*, 2016 FC 18. In that case, Prothonotary Tabib followed an established authority on *quia timet* infringement actions and held that Novartis failed to satisfy the third prong of the test in *Connaught* because neither party has control over when, or if, the Minister of Health will issue an NOC.

Prothonotary Tabib held that Gilead's action is distinguishable from those earlier cases because Gilead could support a pleading that Teva's submissions were approvable (i.e., it is on 'patent hold') and NOCs would therefore issue immediately upon expiry of the prohibition orders.

Justice Barnes agreed that given Teva's stated intent to launch infringing products immediately upon receipt of the pending NOCs, the probability of infringement was sufficiently strong to support a *quia timet* action. The Court also held that Prothonotary Tabib properly considered the temporal requirement when concluding that since the purpose of a *quia timet* action is to stop an event before it happens, plaintiffs should not be required to wait until the event is so imminent that the action is doomed to failure. The Court held that while the temporal consideration may be relevant to the likelihood of a future event, it appears to be a "subordinate consideration" in a case where the likelihood of future harm appears high.

The Court dismissed Teva's appeal with costs and permitted Gilead's action to proceed.

Link to decisions:

Appeal: *Gilead Sciences, Inc. v Teva Canada Limited*, 2016 FC 336

Underlying decision: *Gilead Sciences, Inc. v Teva Canada Limited*, 2016 FC 31

Related decision: *Teva Canada Limited v Novartis AG*, 2016 FC 18

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

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