

Federal Court



Cour fédérale

**Date: 20160321**

**Docket: T-1888-15**

**Citation: 2016 FC 336**

**Ottawa, Ontario, March 21, 2016**

**PRESENT: The Honourable Mr. Justice Barnes**

**BETWEEN:**

**GILEAD SCIENCES, INC.,  
GILEAD SCIENCES CANADA, INC., AND  
BRISTOL-MYERS SQUIBB &  
GILEAD SCIENCES LLC**

**Plaintiffs**

**and**

**TEVA CANADA LIMITED**

**Defendant**

**ORDER AND REASONS**

[1] The Defendant, Teva Canada Limited, has moved under Federal Courts Rule 51 appealing the order of Prothonotary Mireille Tabib by which she declined to strike out the Plaintiffs' (collectively "Gilead") Statement of Claim in its entirety. Although Prothonotary Tabib struck some of Gilead's pleadings, she allowed the action to continue on the

basis of amended allegations of a likely future (*quia timet*) infringement. Teva contends that this aspect of the decision was made in error and that the action should be dismissed in its entirety.

[2] Teva does not dispute that Prothonotary Tabib identified the correct legal test for maintaining a *quia timet* proceeding as described in the following passage from *Connaught Laboratories Limited v Smithkline Beecham Pharma Inc*, 158 FTR 194, [1998] FCJ No 1851:

20 From the foregoing authorities, I derive the following criteria for allegations that must be evident on the face of a statement of claim initiating a *quia timet* proceedings alleging patent infringement: 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, finally, 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.

[3] It is in the application of the above test to the facts that Teva asserts that an error was made.

[4] I agree with Teva that for an issue of this type, the applicable standard of review on appeal under Rule 51 is whether a palpable and overriding error was made. A “palpable” error is one that is obvious and “overriding” error is one going to the core of the outcome of the case: see *Bayer Inc v Fresenius Kabi Canada Ltd*, 2016 FCA 13, [2016] FCJ No 43 and *Imperial Manufacturing Group Inc v Décor Grates Inc*, 2015 FCA 100, [2015] FCJ No 503.

[5] The errors Teva asserts are 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. Teva argues that inasmuch as Teva’s medicinal product is on patent hold and a Notice of Compliance [NOC] could not be issued before the Gilead blocking patent (the 619 Patent) is either declared invalid or expires, the test of imminence was not made out. These arguments are more fully set out in the following passages from Teva’s Written Representations:

22. Prothonotary Tabib has held that approvability satisfies the imminence criterion in the test for a *quia timet* action for infringement, notwithstanding that on the facts as pleaded, the alleged infringement may not occur at all and certainly could not occur for at least 18 months.

However, without the proposed amendments, Gilead’s statement of claim suffers from the same fatal defect as Novartis’ did: Absent allegations to the effect that Teva’s application for an NOC is approvable and that an NOC will issue as soon as the 619 Patent expires or is declared invalid, the statement of claim lacks sufficient material facts to show that the infringement is imminent; the infringement remains speculative, contingent upon whether and when Health Canada might approve the submissions for an NOC. ... I am satisfied that the discovery evidence, and the amendments proposed, are sufficiently cogent, precise and material to satisfy the criterion of imminence...

Order of Prothonotary Tabib dated January 8, 2016  
at ¶27-28, TMR, Tab 2.

23. ***This is an error of law.*** This approach strips away the temporal aspect to the test for imminence and is directly contrary to the established jurisprudence teaching that imminence indicates a “virtual inevitability” that the event will occur or that there is a high probability that the harm “will in fact” occur. Furthermore, the Prothonotary’s finding that being on patent hold means an NOC will issue contradicts the jurisprudence from both the Federal Court and the Federal Court of Appeal stating that there is no legal significance to being on patent hold and that this does not mean an NOC will issue.

[6] There is no doubt on the evidence that Teva has declared a clear intention to come to market with its competing version of Gilead's tenofovir disoproxil product as soon as it can obtain a NOC. This could occur if the Court invalidates the 619 Patent following the impeachment trial now scheduled to commence in late November, or, failing invalidation, when the Patent expires on July 25, 2017.

[7] Teva says, nonetheless, that there is no guarantee that a NOC will issue and, even if it does, a potential infringement a year or more away is not an "imminent infringement".

[8] The Prothonotary drew an inference that Teva's ANDS had been approved by the Minister and was on patent hold. In the absence of contrary evidence from Teva, that inference is unassailable. I accept Teva's point that the issuance of a NOC is not inevitable but, at the same time, the likelihood of that event is not a matter of speculation. The question to be answered is whether the issuance of a NOC to Teva in these circumstances was sufficiently likely that Teva would then be positioned to act on its stated intention to immediately enter the market.

[9] Prothonotary Tabib referred to "a strong possibility of infringement" which is consistent with the language found in *Connaught Laboratories Limited*, above, and in several other authorities. In *Zoocheck Canada Inc v Canada*, 2008 FC 540, [2008] FCJ No. 714, Justice Russel Zinn adopted "a high probability that the apprehended harm will in fact occur" as the test for imminence in the grant of a *quia timet* injunction. In *Canadian Civil Liberties Assn . Toronto Police Service*, 2010 ONSC 3525, [2010] OJ No 2715, Justice D. M. Brown surveyed several authorities on point and noted the following language: "a high degree of probability that the

harm will in fact occur”, “proof of imminent danger”, “proof that the apprehended damage, will, if it comes, be very substantial” and “a very real likelihood” of harm. In a situation where the Teva product has been contingently approved by the Minister and where Teva has unequivocally stated that, on receipt of a NOC, it will enter the market, the conclusion that a strong possibility of infringement was present cannot be characterized as an error, let alone a palpable and overriding error.

[10] I also do not agree with Teva that Prothonotary Tabib wrongly conflated the temporal aspect of imminence with the likelihood of a NOC issuing followed by an infringement. Clearly she recognized the temporal requirement in the following passage:

[31] Finally, I am satisfied that the probability that infringement will occur in July 2017 is sufficiently imminent to justify a *quia timet* action. The purpose of a *quia timet* action is to stop an event before it happens. Given that streamlined infringement actions may now be heard and determined in two years, it is neither premature nor pointless to institute such an action 22 months before the occurrence of the event to be avoided. To ask that a plaintiff wait until the event is so imminent that there is not enough time to reasonably bring the proceeding to conclusion would be to doom such actions to failure to achieve their goal or to impose unreasonably tight schedules on the parties and the Court.

[11] At the same time the requirement of imminence in the temporal sense may be relevant in the determination of the likelihood of a future event. A potential event that is more distant in time may be an event that is less likely to occur. Furthermore temporal imminence appears to be a subordinate consideration in a case where the likelihood of future harm appears high: see *Canadian Civil Liberties Assn v Toronto Police Service*, above, at para 88.

[12] As things presently stand, the action should be permitted to proceed as it is framed. Of course, if circumstances change, the Court can always reconsider the viability of the proceeding.

[13] Costs in the amount of \$4,500.00 are payable to Gilead.

**ORDER**

**THIS COURT ORDERS** that this motion is dismissed with costs payable to Gilead in the amount of \$4,500.00.

"R.L. Barnes"

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Judge

**FEDERAL COURT**  
**SOLICITORS OF RECORD**

**DOCKET:** T-1888-15

**STYLE OF CAUSE:** GILEAD SCIENCES, INC., GILEAD SCIENCES  
CANADA, INC., AND BRISTOL-MYERS SQUIBB &  
GILEAD SCIENCES LLC v TEVA CANADA LIMITED

**PLACE OF HEARING:** OTTAWA, ONTARIO

**DATE OF HEARING:** FEBRUARY 11, 2016

**ORDER AND REASONS:** BARNES J.

**DATED:** MARCH 21, 2016

**APPEARANCES:**

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