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# Pharma in brief - Canada

## Federal Court of Appeal denies leave to amend statement of claim and harmonizes the standard of review for all appeals

**Case:** *Teva Canada Limited v Gilead Sciences Inc.*, 2016 FCA 176
**Nature of case:** Appeal from Orders refusing leave to amend statement of claim
**Successful party:** Gilead Sciences Inc.
**Date of decision:** June 10, 2016

### Summary

The Federal Court of Appeal has dismissed two appeals arising out of two consecutive motions brought by Teva Canada Limited for leave to amend its statement of claim. In doing so, the Federal Court of Appeal found that the standard of review to apply to all civil appeals is the standard of palpable and overriding error articulated by the Supreme Court in *Housen v Nikolaisen*, 2002 SCC 33.

### Background

In 2012, Teva issued a statement of claim to impeach two patents owned by Gilead Sciences Inc.: Canadian Patent No. 2,261,619 (the 619 Patent) and Canadian Patent No. 2,298,059 (the 059 Patent). The allegations against the 059 Patent have been dropped, and were not at issue on this appeal.

Roughly two years later, Teva sought leave to amend its statement of claim based on information it obtained during examinations for discovery. Teva's proposed amendment alleged that the 619 Patent was fraudulently obtained by misleading the Patent Office and was invalid under subsection 53(1) of the *Patent Act*.

The Prothonotary dismissed the motion, finding that the proposed amendments lacked particularity, but allowed Teva to bring a second motion for further and better particulars.

The second time around, Teva used answers given during discovery to argue that Gilead had not made the class of compounds claimed in the 619 Patent and did not believe it could predict utility across the class. Teva argued that Gilead had made a material misrepresentation to the Patent Office by filing the 619 Patent without a factual basis to prove or soundly predict utility.

On November 3, 2014, the Federal Court dismissed the motion, finding that the proposed amendment was not supported by the evidence and had no reasonable prospect of success.

Within two weeks of the Federal Court's order, relying on the same discovery evidence used in the first motion, Teva brought a second motion for leave to amend its statement of claim. Teva alleged that the 619 Patent was invalid because the specification did not disclose the invention "as contemplated by the inventor", contrary to subsection 27(3) of the *Patent Act*.

On January 19, 2015, the same Federal Court judge dismissed Teva's second motion for substantially the same reasons as the first motion. He also ruled that if he allowed the amendments, he would effectively be sitting on appeal from his earlier order. Teva appealed both decisions to the Federal Court of Appeal.

## Standard of review

Relying on its own recent jurisprudence, the Federal Court of Appeal found that the standard of review for appeals from all orders is the standard articulated by the Supreme Court in *Housen* v *Nikolaisen*, 2002 SCC 33: on questions of law or where a legal principle can be extracted from a question of mixed fact and law, the standard is correctness. Otherwise, the standard of review is one of palpable and overriding error.

The Federal Court of Appeal is trying to homogenize the standard of review for all appeals of orders. Previously, the Federal Court of Appeal would only interfere with discretionary orders of the Federal Court in interlocutory matters where the Federal Court proceeded on a wrong principle, gave insufficient weight to relevant factors, misapprehended the facts or where an obvious injustice would result.

## Teva's appeal dismissed

The Federal Court of Appeal found that the Federal Court did not alter the test for pleading amendments by finding that, for reasons of access to justice, proportionality and efficiency, amendments that do not have a reasonable prospect of success should not be allowed.

The Federal Court of Appeal agreed with the Federal Court that section 53 of the *Patent Act* raises serious allegations of fraud that require strong supporting evidence, and even with a generous interpretation of the evidence, there was no possibility of relief under section 53 of the *Patent Act.* Rather, Teva had taken too much from the scientists' statements, which were nothing more than expressions of scientific uncertainty during the inventive process.

Furthermore, Teva had improperly conflated the concepts of inutility and insufficiency under sections 2 and 27(3) of the *Patent Act* respectively. Whether Gilead could predict the utility of the compounds claimed in the 619 Patent does not equate with whether a skilled person had sufficient information to work the invention.

The Federal Court of Appeal further agreed with the Federal Court that Teva's second motion was an improper relitigation of its first motion that raised essentially the same factual matters. Teva's second motion in effect encouraged the Federal Court judge to sit on appeal of his disposition of the first motion. Both appeals were dismissed with costs. Norton Rose Fulbright Canada LLP successfully represented Gilead in this matter.

## Link to the decision:

**Federal Court of Appeal Decision:** *Teva Canada Limited v Gilead Sciences Inc.*, 2016 FCA 176

**Federal Court Decisions (unreported):** Order dated November 3, 2014, Order dated January 19, 2015

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