## Federal Court of Appeal



### Cour d'appel fédérale

Date: 20191104

**Docket: A-301-18** 

**Citation: 2019 FCA 273** 

CORAM: STRATAS J.A.

WEBB J.A.

DE MONTIGNY J.A.

#### **BETWEEN:**

# MILLENNIUM PHARMACEUTICALS INC., JANSSEN INC., CILAG GMBH INTERNATIONAL, CILAG AG and JANSSEN PHARMACEUTICA NV

**Appellants** 

and

#### TEVA CANADA LIMITED and THE UNITED STATES OF AMERICA represented by THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Respondents** 

Heard at Ottawa, Ontario, on September 9 and 10, 2019.

Judgment delivered at Ottawa, Ontario, on November 4, 2019.

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: WEBB J.A.
DE MONTIGNY J.A.

## Federal Court of Appeal



### Cour d'appel fédérale

Date: 20191104

**Docket: A-301-18** 

**Citation: 2019 FCA 273** 

CORAM: STRATAS J.A.

WEBB J.A.

DE MONTIGNY J.A.

#### **BETWEEN:**

# MILLENNIUM PHARMACEUTICALS INC., JANSSEN INC., CILAG GMBH INTERNATIONAL, CILAG AG and JANSSEN PHARMACEUTICA NV

**Appellants** 

and

#### TEVA CANADA LIMITED and THE UNITED STATES OF AMERICA represented by THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Respondents** 

#### **REASONS FOR JUDGMENT**

#### STRATAS J.A.

[1] The appellants appeal from the judgment dated July 18, 2018 of the Federal Court (*per* Locke J.): 2018 FC 754. In its judgment, the Federal Court granted the respondent compensation for losses suffered during the time its version of a cancer-treating drug with the active ingredient

bortezomib was kept off the market. The Federal Court found two of the appellants' patents invalid for obviousness.

- [2] On appeal, the appellants attack the finding of obviousness. They submit that the Federal Court did not follow the principles set out by the Supreme Court in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265.
- [3] I reject the appellants' submission. A fair reading of the Federal Court's reasons from beginning to end in light of the record before it shows that it properly applied the proper legal test for obviousness.
- [4] In applying the legal test for obviousness to the evidence before it, the Federal Court concluded as follows (at para. 203):

Having now considered each of the characteristic components of bortezomib individually, I must now consider whether it was inventive to have selected all of them in combination. In my view, it was not. I have already concluded that the selection of each of the components individually was not inventive, and there is nothing in the combination of these components that prompts me to conclude that the selection of all of them together was any less obvious. There are a finite number of possible practical combinations to try, and any of them would have been expected to offer some potency. The testing involved would have been routine and there was nothing inventive in the decision to conduct such testing.

[5] This is a conclusion of mixed fact and law that does not contain an error in legal principle. The appellants can succeed in their appeal only if they can establish palpable and overriding error: *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235.

Palpable and overriding error is a difficult standard to meet. In one case, this Court explained the standard as one where "[t]he entire tree [must] fall"; "it is not enough to pull at leaves and branches and leave the tree standing": *South Yukon Forest Corp. v. Canada*, 2012 FCA 165, 4 B.L.R. (5th) 31 at para. 46, approved in *Benheim v. St. Germain*, 2016 SCC 48, [2016] 2 S.C.R. 352 at para. 38. In another case, this Court explained the standard as follows:

"Palpable" means an error that is obvious. Many things can qualify as "palpable." Examples include obvious illogic in the reasons (such as factual findings that cannot sit together), findings made without any admissible evidence or evidence received in accordance with the doctrine of judicial notice, findings based on improper inferences or logical error, and the failure to make findings due to a complete or near-complete disregard of evidence.

...

"Overriding" means an error that affects the outcome of the case. It may be that a particular fact should not have been found because there is no evidence to support it. If this palpably wrong fact is excluded but the outcome stands without it, the error is not "overriding." The judgment of the first-instance court remains in place.

There may also be situations where a palpable error by itself is not overriding but when seen together with other palpable errors, the outcome of the case can no longer be left to stand. So to speak, the tree is felled not by one decisive chop but by several telling ones.

(Mahjoub v. Canada (Citizenship and Immigration), 2017 FCA 157, [2018] 2 F.C.R. 344 at paras. 62, 64-65)

[7] The appellants have not met this standard. They have picked at the leaves and branches, but the tree remains standing.

- [8] The appellants try to demonstrate palpable and overriding error by parsing individual paragraphs of the Federal Court's reasons closely and alleging defects. To some extent, they followed the same approach when trying to show that the wrong legal test for obviousness was followed. We often see appellants trying this approach. A few words about it are apposite.
- [9] Some defects in reasons—gaps, imprecise wording or phrases that may seem wrong when read literally and in isolation—can suggest the presence of palpable and overriding error. But seldom do appellate courts draw that conclusion. Instead, more often than not, appellate courts view these things as byproducts, artefacts and imperfections of the first-instance court's distillation and synthesizing of reams of complicated data into brief, comprehensible reasons. Appellate courts do not automatically construe these things as misunderstandings of the legal principles or instances of faulty application of the law to the facts: *South Yukon* at para. 49; *Mahjoub* at para. 69.
- [10] To this end, *South Yukon* instructs appellate courts (at para. 51) "to distinguish true palpable and overriding error on the one hand" from "the legitimate by-product of distillation and synthesis or innocent inadequacies of expression on the other." An inquiry into palpable and overriding error overlooks matters of form and gets at the substance of what the first-instance court did.
- [11] To do this, an appellate court must go beyond the literal words of the first-instance court's reasons, construing and understanding them "as a whole" in their wider context, "including the evidentiary record before the court, the submissions made, the issues that were

live before the court, and the fact that judges are presumed to know the law on basic points": *Canada v. Long Plain First Nation*, 2015 FCA 177, 388 D.L.R. (4th) 209 at para. 143; *R. v. R.E.M.*, 2008 SCC 51, [2008] 3 S.C.R. 3 at paras. 35, 55. The appellate court must also keep front of mind the rebuttable presumption that the first-instance court reviewed and considered all of the evidence: *Housen* at para. 46. Reasons sometimes fail to mention a particular matter or body of evidence, address an issue in a cursory way, or express something awkwardly or infelicitously. But the wider context often reveals what the first-instance court considered and decided, and why.

- [12] Admittedly, the line between true palpable and overriding error on the one hand and mere inadequacies of expression on the other can be subtle and indistinct. The best appellate advocates know this and deploy their best tools of persuasion to push an appellate court to one side of the line or the other.
- [13] Returning to the case at hand, the appellants have not persuaded me of any palpable and overriding error in the Federal Court's decision. A few examples will suffice; the remainder offered by the appellants fall well short of the "palpable and overriding" threshold.
- The appellants submit that the Federal Court improperly employed hindsight in its analysis when it broke down bortezomib into component parts for the purpose of analysis. A fair reading of the Federal Court's reasons from beginning to end alongside the record before it shows that it was aware of the improper use of hindsight and did not fall into this trap when applying the test from *Sanofi*: see, *e.g.*, paras. 81, 86, 180. The Federal Court had ample evidence

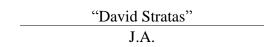
upon which to find, without employing hindsight, that the selection of components of bortezomib lack inventive ingenuity.

- The appellants also submit that the Federal Court engaged in improper "cherry-picking" when it ignored prior art that taught away from the claimed invention. A fair reading of the Federal Court's reasons from beginning to end and in context shows that the Federal Court made factual findings about the prior art based on the expert evidence that was before it and evaluated the claimed inventions against that prior art as required by *Sanofi*. I see no error in legal principle or palpable and overriding error.
- [16] The appellants cite evidence upon which the Federal Court could have found in their favour. But that alone does not establish palpable and overriding error. Preferring one line of evidence over another is the exclusive prerogative of the first-instance court. This is especially true in cases such as this where the first-instance court raised serious concerns about the impartiality of certain expert witnesses (at paras. 119-133). Absent true palpable and overriding error, the appellate court must leave in place the first-instance court's evaluation of the evidence.
- [17] Overall, the respondent submits that the appellant is trying to transform adverse findings of fact and mixed fact and law into errors of legal principle to avoid the difficult standard of palpable and overriding error. I agree. The appellants have raised no error of law. On the issues of fact and mixed fact and law they have raised, they have not identified any palpable and overriding error as the concept is understood in law.

[18] Therefore, I would dismiss the appeal with costs.

[19] The style of cause is irregular and I would amend it. Under the *Federal Courts Rules*, S.O.R. 98/106, parties in appeals are appellants, respondents or interveners. The appellants named the United States of America separately as "a party added pursuant to s. 55(3) of the *Patent Act*". It should be named as a respondent. The style of cause on this document reflects the

amendment I propose.



"I agree Wyman W. Webb J.A."

"I agree

Yves de Montigny J.A."

#### FEDERAL COURT OF APPEAL

#### NAMES OF COUNSEL AND SOLICITORS OF RECORD

**DOCKET:** A-301-18

APPEAL FROM A JUDGMENT OF THE HONOURABLE MR. JUSTICE LOCKE DATED JULY 18, 2018, DOCKET NO. T-944-15

STYLE OF CAUSE: MILLENNIUM

PHARMACEUTICALS INC. *ET AL.* v. TEVA CANADA LIMITED

ET AL.

PLACE OF HEARING: OTTAWA, ONTARIO

**DATE OF HEARING:** SEPTEMBER 9 AND 10, 2019

**REASONS FOR JUDGMENT BY:** STRATAS J.A.

**CONCURRED IN BY:** WEBB, DE MONTIGNY JJ.A

**DATED:** NOVEMBER 4, 2019

**APPEARANCES**:

James Mills FOR THE APPELLANTS,

Chantal Saunders MILLENNIUM

PHARMACEUTICALS INC.,

David Aitken FOR THE RESPONDENT, TEVA

Bryan Norrie CANADA LIMITED

**SOLICITORS OF RECORD:** 

Borden Ladner Gervais LLP FOR THE APPELLANTS,

Ottawa, Ontario MILLENNIUM

PHARMACEUTICALS INC.,

Blake, Cassels & Graydon LLP

Toronto, Ontario

FOR THE APPELLANTS, JANSSEN INC., CILAG GMBH, CILAG AG AND JANSSEN PHARMACEUTICA NV

Aitken Klee LLP Ottawa, Ontario

FOR THE RESPONDENT, TEVA CANADA LIMITED

Gowling (WLG) Canada LLP Ottawa, Ontario

FOR THE RESPONDENT, THE UNITED STATES OF AMERICA REPRESENTED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES