Court File No.: A-102-18

FEDERAL COURT OF APPEAL

BETWEEN:

RADU HOCIUNG

Appellant

and

MINISTER OF PUBLIC SAFETY AND EMERGENCY PREPAREDNESS

Respondent

INDEX

Federal Court of Appeal  Cour d'appel fédérale

Date: 20160610

Dockets: A-499-14
A-33-15

Citation: 2016 FCA 176

CORAM: **DAWSON J.A.**
STRATAS J.A.
DE MONTIGNY J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

GILEAD SCIENCES INC.

Respondent

Heard at Toronto, Ontario, on October 29, 2015.

Judgment delivered at Ottawa, Ontario, on June 10, 2016.

REASONS FOR JUDGMENT BY: STRATAS J.A.

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

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REASONS FOR JUDGMENT

STRATAS J.A.

[1] In the Federal Court, Teva Canada Limited brought two consecutive motions for leave to amend its statement of claim. By orders dated November 3, 2014 and January 19, 2015, the Federal Court (both *per* Barnes J.) dismissed the motions. Teva now appeals both.

[2] These are the reasons for judgment on both appeals. A copy of these reasons shall be placed in each appeal file.

[3] In my view, the Federal Court committed no reviewable error in making the orders. Therefore, I would dismiss the appeals with costs.

A. The impeachment action

[4] In the summer of 2012, Teva issued a statement of claim in the Federal Court impeaching claims 1 to 32 of Canadian patent number 2,261,619 and claims 1 to 14 of Canadian patent number 2,298,059.

[5] In that statement of claim, Teva alleges that the claims in the '619 Patent are invalid for obviousness, anticipation, lack of utility and insufficient disclosure. It alleges that the claims in the '059 Patent are invalid for obviousness, double patenting, overbreadth, lack of utility and ambiguity. The allegations against the '059 Patent have been discontinued.

[6] The '619 and '059 Patents have been the subject of proceedings under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. In those proceedings, Teva's notice of allegation alleged that the inventors of the '619 Patent had not soundly predicted utility. In its statement of claim, Teva decided not to advance this ground.

[7] The respondent, Gilead Sciences Inc., has defended against the claim, denying all grounds of invalidity. Discoveries have followed and are complete. Teva has had the opportunity to examine Gilead's discovery representative on two separate occasions, five of the six inventors of the '619 Patent, and the three inventors of the '059 Patent.

B. Teva's first motion for leave to amend the statement of claim

[8] Roughly two years after the statement of claim was issued, Teva moved for leave to amend its statement of claim. Some amendments were of a minor, housekeeping nature; others were much more contentious. The contentious amendments alleged that the '619 Patent was fraudulently obtained by misleading the Patent Office and, thus, the '619 Patent is invalid and void for material misrepresentation contrary to subsection 53(1) of the *Patent Act*, R.S.C. 1985, c. P-4.

C. The Prothonotary's ruling on the motion

[9] The first motion came before the Prothonotary. She granted the minor, housekeeping amendments.

[10] As for the contentious amendments, she dismissed the motion on the ground that the proposed amendments lacked particularity. However she allowed Teva to renew its motion on further and better particulars.

D. The motion in the Federal Court

[11] Teva renewed its motion, this time adding particulars such as the names of the inventors whose evidence it relies upon and offering more details on the misrepresentation. Its motion came before the Federal Court (*per* Barnes J., who is the designated trial judge).

[12] Before the Federal Court, Teva submitted that the allegations it wanted to add to its claim were based on evidence obtained during discovery.

[13] According to Teva, the '619 Patent claims a vast number of prodrugs of phosphonate nucleotide analogues. By the filing date of the patent, Gilead had made only a small number of these compounds. Teva said that on discovery, the inventors and the representative of Gilead admitted that they had not made and did not believe they could make any predictions of utility across the broad class of compounds claimed in the '619 Patent.

[14] In light of this, Teva took the view that Gilead has committed a material misrepresentation by filing the '619 Patent without a factual foundation to prove or to soundly predict utility. So Teva sought to amend its statement of claim to add this allegation, along with the material facts supporting it.

[15] By order dated November 3, 2014, the Federal Court dismissed Teva's motion. Its reasons for doing so shall be analyzed in more detail below. But, in short, the Federal Court

found that the amendments improperly added allegations tantamount to fraud without sufficient evidence. Further, the allegations had no reasonable prospect of success.

E. The second motion in the Federal Court

[16] Within two weeks of the Federal Court's order on the first motion, Teva brought a second motion seeking leave to amend its pleadings. Teva relied on certain discovery evidence to assert that only a very small number of the compounds claimed in the '619 Patent had been made and that the inventors did not and could not predict the efficacy of those compounds. Teva noted that the '619 Patent nevertheless claims these compounds.

[17] From this, Teva sought to plead that the '619 Patent is invalid because what is disclosed in the specification is not the invention "as contemplated by the inventor," as required by subsection 27(3) of the *Patent Act*.

[18] The second motion came before the Federal Court (again *per* Barnes J., who is the designated trial judge). By order dated January 19, 2015, the Federal Court dismissed the motion.

[19] Again, the Federal Court's reasons for dismissing the motion will be considered further below. But for present purposes, the Federal Court found that the proposed amendments were not supported by the discovery evidence. The amendments lacked a reasonable prospect of success.

And, in the Federal Court's view, Teva's second motion should have been brought with its first motion; it was essentially the same motion brought on the same basis.

F. The standard of review on appeal to this Court

[20] In their memoranda of fact and law, the parties disagreed concerning the standard of review that this Court should apply in these appeals. However, by the time of the hearing in this Court, this Court had released new jurisprudence on the standard of review.

[21] In its memorandum, Teva suggested that the issues associated with its pleadings amendment are vital to the final issues in the case and so this Court should perform a *de novo* review. But that is the standard of review applied in a Rule 51 appeal from a Prothonotary. Here, Teva's motions were decided on their merits by a judge of the Federal Court acting on the merits at first instance, not as a Rule 51 appeal court.

[22] In its memorandum, Gilead submitted that the Federal Court's decision is one of discretion. Therefore, it can be set aside only if there was an error of law, a misapprehension of the facts or a wrongful exercise of discretion in that no weight or no sufficient weight was given to relevant considerations, or consideration was given to irrelevant factors.

[23] But, in recent jurisprudence, this Court has altered that formulation of the standard of review of orders such as the ones in this appeal in an effort to homogenize the law on standard of review concerning all appeals of orders. See *Imperial Manufacturing Group Inc. v. Decor Grates*

Incorporated, 2015 FCA 100, [2016] 1 F.C.R. 246 rev'g *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588 at p. 594, 58 C.P.R. (3d) 209 at p. 213 (C.A.); see also, more recently, *Turmel v. Canada*, 2016 FCA 9. In accordance with those recent authorities, the standard of review for the orders before us is the usual appellate standard set out in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235.

[24] Therefore, according to that recent jurisprudence, to succeed in this appeal Teva must persuade us that the Federal Court erred on a pure question of law or on a legal principle that can be extracted from a question of mixed fact and law. Absent that sort of legal error, Teva can succeed only if it demonstrates palpable and overriding error. A palpable and overriding error is one that is both obvious and determinative in the sense that it undermines the outcome reached below. See generally *Canada v. South Yukon Forest Corporation*, 2012 FCA 165, 431 N.R. 286 at paragraph 46.

[25] However, as will be seen, regardless of how one enunciates the standard of review, the standard of review is deferential. And as will be explained below, under that deferential standard Teva has failed to persuade us that we should interfere with the Federal Court's orders.

G. Analysis of the order made on the first motion: the November 3, 2014 order

[26] Motions for leave to amend are governed by Rule 75 of the *Federal Courts Rules*, SOR/98-106. Amendments should be allowed "for the purpose of determining the real questions in controversy between the parties" as long as they "would serve the interests of justice" and they

will not work "an injustice to the other party" that is "not capable of being compensated by an award of costs": *Canderel Ltd. v. Canada*, [1994] 1 F.C. 3 at p. 10, [1993] F.C.J. No. 777 (C.A.).

[27] In this Court, Teva stresses that pleadings amendments prompted by evidence obtained at discovery, such as the amendments it proposes here, are beneficial in that they can refocus and particularize points in controversy, thereby facilitating the trial of an action: *Dené Tha' First Nation v. Canada (Attorney General)*, 2008 FC 679, 168 A.C.W.S. (3d) 510 (Proth.); *Hoechst Marion Roussel Deutchland Gmbh v. Adir et Cie* (2000), 190 F.T.R. 233, 97 A.C.W.S. (3d) 891 (T.D.). It adds that Gilead has shown no prejudice it would suffer if the amendments are granted.

[28] But all that is potentially beside the point: it makes no sense for a court to allow an amendment that is doomed to fail. Here, Teva's proposed amendments advance new grounds supporting the relief sought. But if the grounds do not have some reasonable prospect of success, allowing them into the litigation does nothing other than to complicate and protract it needlessly and pointlessly.

[29] Unsurprisingly, the absence of a reasonable prospect of success is a well-established reason for a court to dismiss a motion for leave to amend: *Bauer Hockey Corp. v. Sport Maska Inc. (Reebok-CCM Hockey)*, 2014 FCA 158, 122 C.P.R. (4th) 97; *Visx Inc. v. Nidek Co.* (1996), 209 N.R. 342, 72 C.P.R. (3d) 19 at p. 24; and see also *R. v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42, [2011] 3 S.C.R. 45 at paras. 17-20 on the meaning of "reasonable prospect of success" in the context of motions to strike claims, a meaning that *Bauer* suggests (at para. 16) equally applies on the issue whether the Court should grant a proposed pleadings amendment.

[30] The standard of "reasonable prospect of success" is more than just assessing whether there is just a mathematical chance of success. In deciding whether an amendment has a reasonable prospect of success, its chances of success must be examined in the context of the law and the litigation process, and a realistic view must be taken: *Imperial Tobacco*, above at para. 25.

[31] In the jurisprudence, the requirement that the amendment have a reasonable prospect of success has become a threshold issue: see, *e.g.*, *Remo Imports Ltd. v. Jaguar Cars Ltd.*, 2005 FC 870, 41 C.P.R. (4th) 111 at para. 49. Normally, only if that threshold is crossed will the Court go further and investigate other matters, such as the prejudice the opposing party may suffer as a result of the amendment.

[32] In its analysis in support of the dismissal of the first motion, the Federal Court proceeded in that way, considering whether the proposed amendments had a reasonable prospect of success. The Federal Court found that it did not need to consider any other matters: at the outset, it found that Teva's proposed amendments had no reasonable prospect of success:

> In my view the amendments proposed by Teva have, on the evidence presented, no reasonable prospect of success. Even with a generous interpretation of the evidence put forward by Teva, there is no possibility that relief under section 53 of the *Patent Act* would be available.

(Para. 7 of the Federal Court's November 3, 2014 order.)

[33] On appeal to us, Teva submits that this finding is vitiated by legal error. Teva submits that the Federal Court improperly made it easier for courts to find that a ground has no

"reasonable prospect of success." Put another way, Teva says that the Federal Court has departed from the liberal approach that it must follow when considering whether to grant leave to amend pleadings.

[34] In this regard, Teva focuses upon the Federal Court's statement (at para. 6 of its order) that "[t]he landscape for permitting pleadings amendments has shifted somewhat since the Supreme Court of Canada decision in *Hryniak v. Mauldin*, 2014 SCC 7, [[2014] 1 S.C.R. 87]." The Federal Court added (also at para. 6) that "[a]lthough the guiding principle of a reasonable prospect of success remains in place, it is tempered by the competing concerns about access to justice, proportionality and judicial efficiency," concepts the Supreme Court emphasized in *Hryniak*.

[35] I reject Teva's submission. In referring to *Hryniak*, the Federal Court did not change the meaning of "reasonable prospect of success" and thereby commit legal error.

[36] Faced with a submission that a first-instance court applied improper principle, an appellate court must review in a holistic and fair way the reasons offered by the first-instance court against the record before it. Often first-instance courts do not describe the principles that bear upon their decisions in a perfectly precise or encyclopedic way. Yet, in many such cases, a holistic and fair review of their reasons against the record confirms they brought to bear all correct principles in their decision.

[37] That is the case here. Construing the reasons in a holistic and fair way, the Federal Court did not alter the "reasonable prospect of success" ground. Rather, it asked itself whether the proposed amendments had a reasonable prospect of success, added no gloss to that question, and found on the facts and the law that the amendments could not possibly succeed.

[38] In this regard, the Federal Court found (at para. 7) that "[e]ven with a generous interpretation of the evidence put forward by Teva, there is no possibility that relief under section 53 of the Patent Act would be available." The evidence proffered by Teva in support of its proposed pleadings amendment is concerned with the issue of obviousness at a time before the claimed invention was obtained and had nothing to do with what Gilead knew or believed when it filed its application or whether the efficacy of the untested compounds could be predicted from those that were tested and found to be useful. The Federal Court also found that Teva had taken too much from the scientists' statements, misinterpreting their import (at paras. 7 and 8). In its view, the scientists' statements, properly interpreted, were nothing more than expressions of scientific uncertainty during the inventive process and did not support Teva's proposed amendments. Finally, the Federal Court noted (at para. 5) that the proposed amendments raise very serious allegations of fraud that require strong supporting evidence.

[39] The Federal Court's analysis in this regard shows an understanding and application of proper legal principles. Further, its analysis of the facts before it and its application of the legal principles to those facts is not vitiated by palpable and overriding error.

[40] As for the Federal Court's reference to *Hryniak*, viewed in its proper context it was nothing more than an attempt to reinforce the idea that—for reasons of access to justice, proportionality and judicial efficiency—amendments that do not have a reasonable prospect of success should not be permitted to go forward. That is a truism: proposed amendments that cannot succeed should be cast aside.

H. Analysis of the order made on the second motion: the January 19, 2015 order

[41] The Federal Court found Teva's second motion to be based on "essentially the same factual matters" as the first motion. Indeed, in advancing its second motion, Teva relied on the same discovery evidence that it said prompted the first motion.

[42] The Federal Court dismissed Teva's motion for basically the same reasons it dismissed the first. It found again that Teva had read too much into the discovery evidence. In this regard, the Federal Court reiterated what it said in para. 7 in its reasons for the November 3, 2014 order: the evidence could not be reasonably construed in the manner Teva was construing it and so the proposed amendment could not succeed in law.

[43] The Federal Court also observed (at para. 5 of its January 19, 2015 order) that Teva's second motion in effect encouraged it to sit on appeal of its disposition of the first motion. In so many words, it found that the second motion was an instance of improper relitigation of the first motion.

[44] The Federal Court added a further reason for rejecting the proposed amendments as having no reasonable prospect of success. In its view, Teva had improperly conflated the concepts of inutility (under s. 2 of the *Patent Act*) and insufficiency (under ss. 27(3) of the *Patent Act*), a methodology inconsistent with this Court's holding in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, [2009] 1 F.C.R. 253. Whether or not Gilead could predict or did predict the utility of all of the claimed compounds says nothing about whether the person of skill had sufficient information to work the invention.

[45] I see no legal error in any of the Federal Court's analysis, nor any palpable and overriding error. I have the following additional specific comments.

[46] Teva submits that the Federal Court applied too high a standard in assessing whether its proposed amendment had any reasonable prospect of success. It suggests that the Federal Court improperly required Teva not just to show that the grounds advanced by the amendments were tenable, but to go further and to prove its case to a high level of persuasion. Teva stresses that this Court has adopted a liberal approach to pleading amendments and the Federal Court went against that approach: see, *e.g.*, *Anderson Consulting v. Canada*, [1998] 1 F.C. 605, 220 N.R. 35; *Merck & Co., Inc. v. Apotex Inc.*, 2003 FCA 488, [2004] 2 F.C.R. 459 at para. 31.

[47] Construing the Federal Court's reasons in a holistic and fair way, I do not agree that the Federal Court imposed too high a burden upon Teva or otherwise applied a test wrong in law. Rather, this is a case where on the facts the Federal Court found that Teva's proposed amendments did not have even a remote chance of success.

[48] Teva also submits that the Federal Court was wrong to characterize its second motion as essentially a rerun of the first or an appeal of the first.

[49] This submission I also reject. The Federal Court's characterization was based on its appreciation of the facts before it and it did not commit palpable and overriding error in adopting that characterization. Indeed, I agree with the Federal Court's characterization of the motions before it.

I. Other submissions by Gilead

[50] Gilead advances other submissions in support of the dismissal of the motions, such as the lack of particularity in the amendments sought in the first motion, the prejudice it would suffer as a result of the amendments being sought late, and the fact that long ago, during the proceedings under the *PMNOC Regulations*, Teva was aware of the issues it now seeks to add to the statement of claim at this late date.

[51] It is unnecessary to deal with these submissions except to note that these would provide additional bases for upholding the orders the Federal Court made.

J. Proposed disposition

[52] I would dismiss the appeals with costs.

"David Stratas"

J.A.

"I agree.
Eleanor R. Dawson J.A."

"I agree.
Yves de Montigny J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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DATED:	JUNE 10, 2016

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