Federal Court of Appeal | Cour d'appel fédérale

Date: 20140314

Dockets: A-460-11

Citation: 2014 FCA 65

CORAM: **SHARLOW J.A.**
DAWSON J.A.
MAINVILLE J.A.

BETWEEN:

SANOFI-AVENTIS CANADA INC. and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Appellants

and

TEVA CANADA LIMITED

Respondent

Heard at Toronto, Ontario, on October 16 and 17, 2013.

Judgment delivered at Ottawa, Ontario, on March 14, 2014.

REASONS FOR JUDGMENT BY: MAINVILLE J.A.

CONCURRED IN BY: SHARLOW J.A.
DAWSON J.A.

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REASONS FOR JUDGMENT

MAINVILLE J.A.

[1] This appeal was heard together with two other appeals in dockets A-147-12 and A-192-12 with respect to an action commenced by Teva Canada Limited ("Teva") seeking compensation from Sanofi-Aventis Canada Inc. and Sanofi-Aventis Deutschland GmbH (collectively referred to herein as "Sanofi") pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*NOC Regulations*") with respect to the drug ramipril.

[2] This Court has concurrently issued judgments and reasons for judgment with respect to the two other appeals in dockets A-147-12 and A-192-12 bearing respectively citation numbers 2014 FCA 67 and 2014 FCA 69.

[3] This appeal is from an order of Snider J. of the Federal Court ("Trial Judge") dated November 25, 2011 which dismissed Sanofi's appeal from an order of Prothonotary Aalto dated October 12, 2011 denying its motion seeking amendments to its statement of defence to include allegations respecting the two following issues.

[4] The first amendment sought to assert that in the hypothetical market which had to be established to determine the level of compensation owed under section 8 of the *NOC Regulations*, Pharmascience Inc. ("Pharmascience") would have been the first generic drug manufacturer to enter the generic ramipril market. The second amendment sought to add to the statement of defence that the HOPE indications (Heart Outcomes Prevention Evaluation *i.e.* use of ramipril in the prevention of cardiovascular events and of stroke, diabetes and congestive heart failure) for Teva's generic version of ramipril was a significant unapproved indication, and that section 8 of the *NOC Regulations* does not contemplate recovery of damages with respect to loss sales of a generic drug product for such an unapproved indication.

[5] For the reasons set out below, I would dismiss this appeal.

The decisions below

[6] At the time it submitted its motion for amendments to its defence in the Teva litigation, Sanofi was also involved in additional litigation concerning ramipril and section 8 of the *NOC Regulations* with other generic drug manufacturers, notably Laboratoire Riva Inc. and Apotex Inc. Sanofi sought similar amendments in all three proceedings, and all these motions were heard and decided together by Prothonotary Aalto.

[7] Prothonotary Aalto noted that Sanofi had sought these amendments to its pleadings (with a related motion to examine a representative of Pharmascience) some three months prior to the trials in both the Teva and Apotex proceedings. The prothonotary also noted that Sanofi had cast the two amendments in dispute as mere "clarifications" or house keeping amendments.

[8] After a careful review of the parties' submissions, Prothonotary Aalto took the view that, contrary to Sanofi's representations, both suggested amendments added new, substantial and largely speculative allegations. The prothonotary further took into account the late timing of the amendments relative to the then-looming trial dates, and concluded that Teva would be prejudiced by the real risk of having the trial adjourned as a result of the need to alter expert reports which had already been exchanged between the litigants.

[9] Reviewing the prothonotary's decision *de novo*, the Trial Judge dismissed Sanofi's appeal for essentially the same reasons as those given by the prothonotary. The Trial Judge concluded, in light of all the circumstances, that the interests of justice would not be served by allowing the amendments.

The standard of review

[10] The standard of review to be applied to a discretionary order of a prothonotary has been conclusively established by this Court in *Canada v. Aqua-Gem Investments Ltd.*, [1993] 2 F.C. 425 (F.C.A.) and in *Merck & Co. v. Apotex Inc.*, 2003 FCA 488, [2004] 2 F.C.R. 459 at paras. 17 to 20, and confirmed by the Supreme Court of Canada in *Z.I. Pompey Industrie v. ECU-Line N.V.*, 2003 SCC 27, [2003] 1 S.C.R. 450 at para. 18: such an order is not to be disturbed unless (a) the question

raised in the motion is vital to the final issue of the case, or (b) the order is clearly wrong, in the sense that the exercise of discretion by the prothonotary was based on a wrong principle of law or a misapprehension of the facts. In turn, this Court may interfere with the decision of a Federal Court judge dismissing an appeal from a discretionary order of a Prothonotary only if judge's decision is clearly wrong.

[11] In this case, the Trial Judge found it difficult to assess whether the proposed amendments were vital to the final issue of the case in light of Sanofi's inconsistent arguments concerning the nature of its amendments. As noted in the Trial Judge's order at pp. 4 and 5: "[o]n the one hand, they submit that these amendments to the pleadings are critical to their defence. On the other hand, they argue that the amendments are minor and, in the case of the HOPE amendment, merely set out a legal issue that does not even need to be pleaded." Out of an abundance of caution, the Trial Judge assumed, without deciding, that the prothonotary's decision to refuse the amendments was vital, and she thus proceeded to review the matter *de novo*.

[12] Before this Court, Sanofi (which has since changed counsel) now submits that the amendments were vital to its defence. Like the Trial Judge, I will assume, without deciding, that the amendments were vital.

Principles applicable to amendments

[13] The *Federal Courts Rules*, SOR/98-106 govern amendments to pleadings through Rules 75 to 79 as well as in Rules 200 and 201. These rules provide for a liberal approach to amendments. After extensively reviewing the jurisprudence of this Court, Décary J.A. set out the applicable

principles in *Canderel Ltd. v. Canada*, [1994] 1 F.C. 3 (C.A.) at p. 10: "while it is impossible to enumerate all the factors that a judge must take into consideration in determining whether it is just, in a given case, to authorize an amendment, the general rule is that an amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties, provided, notably, that the allowance would not result in an injustice to the other party not capable of being compensated by an award of costs and that it would serve the interests of justice."

[14] Though recognizing these well-known and long settled principles, Sanofi nevertheless submits that "pleading amendments should be permitted at any time, including on the eve of trial or even during trial, provided that allowing the amendment would not be unjust": Sanofi's memorandum at para. 21. Relying on *VISX Inc. v. Nidex Co.* (1998), 234 N.R. 94, [1998] F.C.J. No. 1766 (QL) (F.C.A.), Sanofi holds that amendments to pleadings should be granted even where there is deplorable and careless delay.

[15] In my view, Sanofi fails to take into account that there are at least two independent criteria that must be met to allow an amendment: (a) any injustice to the other party is capable of being compensated by an award of costs, and (b) the interests of justice would be served. Failure to meet one or the other of these criteria may result in the amendment being refused.

[16] The criterion based on the interests of justice notably allows a Court to consider factors related to the proper and efficient administration of justice: *Merck & Co. v. Apotex Inc.*, above at para. 35-36 and 42. As noted by Lord Griffiths in *Ketterman v. Hansel Properties Ltd.*, [1988] 1 All

E.R. 38 (H.L.) at p. 62 (cited approvingly by this Court in *Merck & Co. v. Apotex Inc.*, above at para. 30):

> Another factor that a judge must weigh in the balance is the pressure on the courts caused by the great increase in litigation and the consequent necessity that, in the interests of the whole community, legal business should be conducted efficiently. We can no longer afford to show the same indulgence towards the negligent conduct of litigation as was perhaps possible in a more leisured age. There will be cases in which justice will be better served by allowing the consequences of the negligence of the lawyers to fall on their own heads rather than by allowing an amendment at a very late stage of the proceedings.

[17] The judge deciding upon a motion to allow an amendment to the pleadings must, as a general rule, consider the timeliness of the motion, the extent to which the proposed amendment would delay the proceedings, and the manner in which the party who seeks the amendment has comported itself throughout the proceedings: *Canderel Ltd. v. Canada*, above at p. 11; *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2011 FCA 34, 414 N.R. 162 at para. 37. Monetary compensation to the other litigants through costs awards, even where possible, is thus not the only factor that must be considered and weighed. Also included in the balancing exercise is the efficiency of the judicial process itself.

Analysis

[18] The Trial Judge rightfully found that Sanofi's proposed Pharmascience amendment was brought on the "eve of the trial with no credible explanation for the lateness" and that Sanofi "has little excuse for waiting until now to raise the issue" of its proposed HOPE amendment: Trial Judge's order at pp. 6 and 7. Sanofi submitted no explanation for its tardiness to either the Trial Judge or to this Court. The inference that must be drawn from this is that there is no acceptable explanation.

[19] As I have already noted, the timing of a motion to amend is a relevant factor to be taken into account when considering whether the motion should be granted. As stated in *Canderel Ltd. v. Canada*, above at p. 11, "[a]s regards interests of justice, it may be said that the courts and the parties have a legitimate expectation in the litigation coming to an end and delays and consequent strain and anxiety imposed on all concerned by a late amendment raising a new issue may well be seen as frustrating the course of justice".

[20] In this case, not only was the timing of Sanofi's motion tardy, it also almost certainly ensured that the trial would be considerably delayed had it been allowed. In this matter, I adopt the words of Hugessen J. in *Montana Band v. Canada*, 2002 FCT 583, [2002] F.C.J. No. 774 (QL) at para. 7:

> Every amendment to pleadings will of course cause some delay but some delays are far more consequential than others. Where one is virtually on the eve of a lengthy and major trial, whose date has been known and anticipated for many months, the preparation for which has been the subject of close and intensive cooperation between counsel and the Court extending over a period of years and where the issues are many and complex and the proceedings involve numerous parties, there is simply no way in which an order for costs could possibly provide adequate compensation for the loss of the trial date. Indeed, even the attempt to assess the costs that would have been thrown away by the anticipated delay of this trial would be well-nigh impossible.

[21] This, in my view, is sufficient to dispose of the appeal.

[22] I would therefore dismiss the appeal, with costs in favour of Teva.

"Robert M. Mainville"
J.A.

“I agree.
Karen Sharlow J.A.”

“I agree.
Eleanor R. Dawson J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-460-11

(APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE SNIDER OF THE FEDERAL COURT DATED MAY 11, 2012, DOCKET NUMBER T-1161-07.)

STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC. and SANOFI-AVENTIS DEUTSCHLAND GmbH v. TEVA CANADA LIMITED
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	OCTOBER 16 AND 17, 2013
REASONS FOR JUDGMENT BY:	MAINVILLE J.A.
CONCURRED IN BY:	SHARLOW J.A. DAWSON J.A.
DATED:	MARCH 14, 2014

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