Federal Court of Appeal | Cour d'appel fédérale

Date: 20110131

Dockets: A-401-10
A-486-10

Citation: 2011 FCA 34

CORAM: **BLAIS C.J.**
EVANS J.A.
STRATAS J.A.

Docket: A-401-10

BETWEEN:

APOTEX INC.

Appellant

and

BRISTOL-MYERS SQUIBB COMPANY and BRISTOL-MYERS SQUIBB CANADA INC.

Respondents

Docket: A-486-10

BETWEEN:

BRISTOL-MYERS SQUIBB COMPANY and BRISTOL-MYERS SQUIBB CANADA CO.

Appellants

and

APOTEX INC.

Respondent

Heard at Toronto, Ontario, on January 26, 2011.

Judgment delivered at Ottawa, Ontario, on January 31, 2011.

REASONS FOR JUDGMENT BY: STRATAS J.A.

CONCURRED IN BY: BLAIS C.J.
EVANS J.A.

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REASONS FOR JUDGMENT

STRATAS J.A.

[1] There are two appeals before us:

(1) *The first appeal (A-401-10): an appeal by Apotex Inc. from an order of Justice Boivin of the Federal Court.* The Federal Court judge upheld an order of Prothonotary Aronovitch dated July 30, 2010. In that order, the Prothonotary granted a motion brought by Bristol-Myers Squibb Company and Bristol-Myers Squibb Canada Co. (collectively "Bristol-Myers") to strike out certain pleading amendments of Apotex. She held that Apotex was entitled to make consequential amendments to its pleadings without leave in response to certain amendments by Bristol-Myers to its pleadings. However, Apotex's amendments were more than consequential. Therefore, she invited Apotex to bring a motion amending its pleadings. Apotex did so. Its motion is the subject-matter of the second appeal.

(2) *The second appeal (A-486-10): an appeal by Bristol-Myers from an order of Justice Tremblay-Lamer of the Federal Court.* The Federal Court judge overturned an order of Prothonotary Aronovitch dated October 26, 2010. The Prothonotary refused Apotex leave to amend its pleading. The proposed amendments were exactly the

same as those considered in the first appeal. As a result of the Federal Court judge's order, Apotex is allowed to amend its pleadings.

[2] These are my reasons for judgment in both appeals; a copy will be placed in each court file. These appeals arise within a patent infringement proceeding. In this proceeding, Bristol-Myers alleges that Apotex's manufacture, use and sale of the compound nefazodone hydrochloride infringes certain claims of its patent, no. 1,198,436 (the "'436 Patent"). In its proposed amendments, Apotex alleges that the claims of the '436 Patent are invalid for lack of sound prediction and inutility.

[3] A trial of this proceeding is scheduled to start in little more than a month from now. These motions and appeals have placed a cloud over the trial.

Analysis

(1) The legal test

[4] The parties substantially agree on the legal test to be applied in assessing whether Apotex should be granted leave to amend its pleadings. A pleadings amendment should be allowed for the purpose of determining the real questions in controversy, provided that allowing the amendment would not result in an injustice to the other party that is not capable of being compensated by an

award of costs and the amendment would serve the interests of justice: *Canderel Ltd. v. Canada*, [1994] 1 F.C. 3 at page 10 (C.A.).

[5] The burden is "heavier when the amendments at issue purport to withdraw substantial admissions and would result in a radical change in the nature of the questions in controversy": *Merck & Co., Inc. v. Apotex Inc.*, 2003 FCA 488 at paragraph 32, [2004] 2 F.C.R. 459. In *Merck* at paragraph 33, this Court emphasized that a Judge or Prothonotary, faced with a motion to amend, "has the duty to consider all relevant factors."

(2) The standard of review

[6] The standard of review on an appeal from a Prothonotary's decision that raises a question vital to the final issue of the case is *de novo* review: *Canada v. Aqua-Gem Investments Ltd.*, [1993] 2 F.C. 425 at pages 462-463 (C.A.); *Merck*, *supra* at paragraph 19. The parties agree that the proposed amendment is an issue vital to the final issue of the case: if Apotex's proposed amendments are denied, it will not be able to advance a potential defence to the infringement action. Therefore, under *Aqua-Gem* and *Merck*, when the Federal Court reviewed the Prothonotary's decisions, it was obliged to do so *de novo*.

[7] In this Court, the standard of review is different. We may interfere with the Federal Court's decisions where that Court "had no grounds to interfere with the Prothonotary's decision or, in the event such grounds existed, if [the judge's] decision was arrived at on a wrong basis or was plainly

wrong": *Merck*, *supra* at paragraph 20, citing *Z.I. Pompey Industrie v. ECU-Line N.V.*, 2003 SCC 27, [2003] 1 S.C.R. 450 at paragraph 18. If we do set aside the Federal Court's decision, then we must render the judgment the Federal Court should have rendered. This means that if, as here, the Prothonotary's decision raises a question vital to the final issue of the case, in accordance with *Aqua-Gem* and *Merck*, we must review it *de novo*.

[8] Bristol-Myers submits that we should reassess this aspect of *Aqua-Gem* and *Merck* and, instead, defer to the factual findings and assessments of the Prothonotary even where they raise a question vital to the final issue of the case. Bristol-Myers submits that the Prothonotary has a superior appreciation of the proceeding because she has managed it for a decade. It notes that in the cases at bar, if a judge made the factual and mixed fact and law assessments that the Prothonotary made, we would be driven to a deferential posture by *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, a decision that postdates *Aqua-Gem*. But *Aqua-Gem* and *Merck* take us in a different direction.

[9] I am attracted to Bristol-Myers' submission. It is in accordance with the normal appellate standard of review in *Housen*, *supra*. The Court of Appeal for Ontario has now held that there is no reasoned basis to distinguish between the decision of a master and that of a judge for the purposes of the standards of review on appeal: *Zeitoun v. The Economical Insurance Group*, 2009 ONCA 415, aff'g (2009), 91 O.R. (3d) 131 (Div. Ct.). As the Divisional Court noted at paragraph 41, there is "no compelling reason for adopting differing standards of review on appeal depending solely on the

place in the judicial hierarchy occupied by the decision maker whose decision is under appeal." However, it is unnecessary to decide this point in these appeals.

(3) Distilling the four decisions to their essence

[10] The most important decisions are those in the second appeal: the decision of Prothonotary Aronovitch on October 26, 2010 to deny Apotex leave to amend its pleadings, and the decision of Justice Tremblay-Lamer (hereafter, the "Federal Court judge"), reversing the Prothonotary's decision. Those decisions concern the propriety of Apotex's proposed amendment.

[11] The decisions that are the subject of the first appeal (the Prothonotary's decision of July 30, 2010 and Justice Boivin's decision on appeal from that) arose from a motion to strike amendments made by Apotex without leave. Those amendments are the same as those the Prothonotary later considered on October 26, 2010, in the motion for leave to amend. In her decision striking the amendments, the Prothonotary did express substantive views about Apotex's amendments but she repeated those views in her later October 26, 2010 decision.

[12] Therefore, it makes sense to focus on the Prothonotary's decision of October 26, 2010 decision and Federal Court judge's decision on the appeal from it (*i.e.*, the second appeal, A-486-10).

(4) Appeal A-486-10

[13] In my view, the decision of the Federal Court judge was arrived at on a wrong basis and should be set aside. The decision of the Prothonotary dated October 26, 2010, rejecting Apotex's amendments, should be restored.

[14] The Federal Court judge unduly constrained her inquiry. She did not consider whether Apotex's amendments would serve the interests of justice, as required by *Canderel Ltd.*, *supra*, nor did she consider all of the circumstances, as required by *Merck*, *supra*. This is seen by the Federal Court judge's statement, in paragraph 21, that only "two main questions arise":

> First do the amendments at issue result in a "radical change" thus increasing the burden for Apotex to justify its proposed amendments; and second, will allowing the amendments result in an injustice to [Bristol-Myers] that is not capable of being compensated by an award of costs?

[15] Unlike the Prothonotary, the Federal Court judge did not consider certain circumstances relevant to the interests of justice. She also did not consider certain circumstances relevant to determining how "radical" the proposed amendments are. Under *Merck*, she was bound to consider all of the relevant circumstances. These circumstances are considered below and include the vague, unparticularized nature of Apotex's 2004 amendment, Apotex's pre-trial memorandum in 2007, what took place during the discoveries, and recent events in the litigation. Therefore, I would set aside the decision of the Federal Court judge.

[16] After the decision of the Federal Court judge is set aside, our task is to stand in the shoes of the Federal Court and render the decision it should have made. In accordance with *Aqua-Gem*, *supra* and *Merck*, *supra*, this means that we must conduct a *de novo* analysis of the issue without any deference to the Prothonotary's findings and conclusions in her decision of October 26, 2010.

[17] I reach the same conclusion as the Prothonotary substantially for the reasons she gave. Apotex should be denied leave to amend its pleadings.

[18] Apotex says that amendments it made to the pleading in 2004 put in play the issues of lack of sound prediction and the broad inutility of nefazodone and its salts. It alleges that the breadth of the wording of the 2004 amendments encompasses these issues. I disagree. Events just before and just after the 2004 amendments suggest otherwise.

[19] The initial pleading, as particularized, was clear. Apotex alleged that all of the compounds covered by the '436 Patent, with the exception of nefazodone and its salts, lacked utility. Discoveries confirmed that only that subject-matter was in play (see answers to questions 267-269, 293-296, 303-304, 310, 333 and 339-340).

[20] In 2003, Bristol-Myers voluntarily withdrew nefazodone hydrochloride from the market. It did so because of reports that certain patients experienced liver-related adverse side effects when they took nefazodone hydrochloride.

[21] Apotex applied for leave to amend its pleadings in 2004. In particular, in paragraph 21, it sought to add the words, "…even if one or more of the compounds of the '436 Patent have the utility promised by the '436 Patent, which is not admitted but denied…". Today, Apotex relies on the breadth of this wording. I agree with the Prothonotory who observed, in her decision of October 26, 2010, that "[n]o particulars were mentioned or given on that occasion about any other fact to support lack of utility and sound prediction." The words added in the 2004 amendments might have been seen as not satisfying the requirement in Rule 174 that material facts be pleaded. They are vague and unparticularized. However, the Prothonotary regarded these words as being aimed at only a narrow issue. In allowing Apotex to amend its pleading in 2004, she found that Apotex's amendments were based only on "recent actions" by Bristol-Myers: see the order of the Prothonotary dated July 28, 2004. The recent actions were the withdrawal of nefazodone hydrochloride from the market due to reports of liver-related side effects. In a later order relating to the scope of discoveries, the Prothonotary described the "amended pleas of inutility" introduced by the 2004 amendment as relating to "liver related side effects" and nothing else: see the order of the Prothonotary dated April 4, 2005. Finally, in her decision of October 26, 2010, the Prothonotary referred to those words as only supporting a "specific ground of inutility (liver toxicity)."

[22] If Apotex felt that the Prothonotary's interpretations in her 2004 and 2005 orders was wrong, it should have clarified the situation through a motion to amend its pleadings. It chose not to do so.

[23] Today, Apotex tells us that the decision of the Supreme Court in *Apotex Inc. v. Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 S.C.R. 153 changed the law and, therefore, necessitated the 2004 amendments to its pleadings. If that was the case, it could have addressed *Wellcome* with specific and well-particularized amendments, but did not do so. In this regard, I agree with the following comments of the Prothonotary:

> That appeal was decided in 2002. To the extent that the "new law" affected the scope of the pleading as understood by Apotex, and give rise to new pleadings on sound prediction, or utility, the time to make those amendments, withdraw admissions made, or to add particulars to sustain a pleading based on lack of utility or sound prediction was in 2003. That is even more so that pleadings were amended to add clear particulars of a specific ground of inutility (liver toxicity) in 2004. No particulars were mentioned or given on that occasion about any other fact to support lack of utility and sound prediction even though [*Wellcome*] was decided two years prior.

[24] After the pleadings amendment in 2004, discoveries ensued. The issues of lack of sound prediction and the broad inutility of nefazodone and its salts were not in play in those discoveries. In discoveries conducted on September 2, 2005, Apotex gave an undertaking that if it was going to allege other bases for inutility, it would advise (see question 975). Nearly twenty months later, Apotex did so advise.

[25] On April 30, 2007, in an answer to this undertaking, Apotex did advise of other bases for inutility: "contrary to the assertions of the '436 Patent, nefazodone does not produce 'effective antidepressant effects without causing any harmful or untoward side effects' and is not an 'improved antidepressant with minimal side effect potential' as promised." However, even though it knew of the Prothonotary's interpretations in 2004 and 2005 that the 2004 amendments were

narrower than this, and even though that answer to the undertaking suggested a broader interpretation, Apotex did nothing to clarify the situation. It did not amend its pleading at that time.

[26] Normally, this would be of small moment. The answer to the undertaking mentioned in the preceding paragraph did serve to place Bristol-Myers on notice of the potential breadth of the allegation. In those circumstances alone, a later amendment to clarify the pleading might have been met with approval.

[27] However, seven months later, there was another important development: the parties filed their pre-trial memoranda. In paragraph 27 of its pre-trial memorandum, Bristol-Myers complained that Apotex has not particularized its allegation of inutility on the basis of side effects. In paragraph 8(a) of its pre-trial memorandum, Apotex identified only one issue of inutility: inutility relating to the liver-related side effects that led to the withdrawal of the product.

[28] This exchange of pre-trial memoranda matters. Although the parties should be clear and candid at all times during the litigation about what issues are in real dispute, they certainly must come clean and be perfectly clear at the time of the pre-trial conference. In their pre-trial memoranda, there has to be full and frank discussion about all live, real issues so that "the Court [can] canvass … whether the issues to be determined at trial … have been properly considered and identified": *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd.*, 2010 FC 669 at paragraph 19 (Proth.). This prevents surprise or ambush at trial. This also prevents the Court from wasting its scarce resources by scheduling matters for trial when they are not ready. Due to the

seriousness of the representations made in the pre-trial memorandum and the importance of the objectives of a pre-trial conference, parties can later be held to what they say or do not say at the pre-trial conference: *Wenzel*, at paragraph 20. In the pre-trial memorandum and in the discussions at the pre-trial conference, there is no place for strategic non-disclosure or purposeful non-clarification. If an issue is not placed squarely on the table, all are entitled to assume that it is not on the table.

[29] The place for Apotex to identify the issues of lack of sound prediction and the broad inutility of nefazodone and its salts was in its 2007 pre-trial memorandum and at the pre-trial conference – not in a pleadings amendment sought, despite the absence of any further discoveries or new facts, roughly three years later on the eve of trial. “New facts or other compelling circumstances” might allow a party to add new issues after a pre-trial conference (*Wenzel*, at paragraph 24) – and even then there might be a significant burden to discharge – but there are no new facts or compelling circumstances here.

[30] Approximately two years after the pre-trial conference, Apotex filed expert reports that gave Bristol-Myers the impression that Apotex was now raising issues of sound prediction and inutility beyond the scope of the pleadings. Bristol-Myers objected and these motions and appeals resulted. Now in a recently-served notice to attend, Apotex shows that it now wants to conduct discoveries on the length and breadth of the entire development of nefazodone, and it seeks a further and better affidavit of documents from Bristol-Myers.

[31] In evaluating these recent developments, we must return to the pre-trial conference. First, Rule 258(4) contemplates that at the pre-trial conference a party should provide expert reports that are intended to be used at trial and that may be of assistance at the pre-trial conference. Apotex provided none addressing the assertion of broad inutility and lack of sound prediction. That happened only two years later, in 2009. Second, in order for a pre-trial conference to be held, a party must certify that "all examinations for discovery that the party intend to conduct have been completed": Rule 258(2). By the time of the pre-trial conference in this case, the parties had conducted no discoveries on the issues of lack of sound prediction and the broad inutility of nefazodone and its salts. In the words of the Prothonotary:

> There was also no discovery in respect of the sound prediction of nefazodone, ever, including following the 2004 amendments….It remains to be conducted, at this late date…
>
> Indeed, throughout the period of discovery, including the third round discovery relating to amendments regarding alleged adverse effects on the liver, the only issue that went forward relating to utility was that nefazodone does not meet the promise of the patent due to the withdrawal of the product as a result of these alleged [liver] effects. There were no particulars, amendments, discussion, or discovery relating to the lack of sound predicted utility of nefazodone or its salts, and of the inutility of nefazodone based on side effects other than liver toxicity.

[32] Now, in this Court, Apotex asks us to accept that the 2004 amendments were broad and encompassed the issues of lack of sound prediction and the broad inutility of nefazodone and its salts. If that is true, why are discoveries being started on these issues only now, well after the pre-trial conference, a conference that is to be held when discoveries have been completed? Why were these issues not clearly identified in the 2007 pre-trial conference memorandum, a memorandum which, as we have seen, is a most serious document that is relied upon by the Court and all parties?

Why did Apotex offer in these late motions what the Prothonotary describes as “amendments that have yet to be particularized” and allegations whose “facts…are not known”? I agree with the Prothonotary that “misunderstanding or ‘inadvertence’” cannot explain what has happened here.

[33] It is true that pleadings amendments should be allowed for the purpose of determining the real questions in controversy. Indeed, I note that pleadings amendments can be made at any time to achieve that purpose – even after the trial has begun, and sometimes even very late in the trial. I also acknowledge that under the *Canderel* test last minute clarification amendments, or amendments to bring the pleadings into accord with discovery or trial evidence, should often be allowed. Even in a case such as this – where a major new issue has been sprung into the proceeding at the last minute without justification, well after the pre-trial conference where all parties were obligated to come clean – I am obligated to give significant weight to the need for the real questions in controversy to be determined. I have done so. However, in my view, leave for Apotex to amend its pleadings should still be refused.

[34] For roughly an entire decade, Apotex has conducted itself in a way that suggested that the issues of lack of sound prediction and the broad inutility of nefazodone and its salts were not real questions in controversy. If they were real questions in controversy, they would have been addressed meaningfully at least at some time, if not constantly, during this decade-long litigation. Instead, those questions were no part of the discoveries or the pre-trial memoranda. Now, only at this late date – years after the exchange of pre-trial memoranda – and without any significantly new developments in the litigation, Apotex seeks a further and better affidavit of documents from

Bristol-Myers and embarks upon what the Prothonotary called a “fishing expedition” concerning “the length and breadth of the development of nefazodone.” Finally, as the Prothonotary also found, even now on the eve of trial Apotex cannot articulate these supposedly “real questions in controversy” with acceptable particularity.

[35] The countervailing considerations of injustice to Bristol-Myers and the overall interests of justice strongly support denying leave to Apotex to amend its pleadings. In this regard, I substantially agree with the reasons of the Prothonotary and adopt them as my own, along with the additional reasons I have given.

[36] In considering the overall interests of justice, I note that, except for Justice Boivin, who issued an order with rudimentary reasons set out in the preambles to his order, every judicial officer who has touched the record in this case has made strong findings concerning these countervailing considerations. The Prothonotary concluded that for Apotex “to have delayed this long…with obvious prejudice to [Bristol-Myers] is not in the interests of justice,” is “contrary to the right of the parties to the orderly progression of matters to trial” and “ought not to be countenanced.” The Federal Court judge concluded that “Apotex was aware of [Bristol-Myers’] misapprehension and purposefully, for strategic reasons, decided not to clarify the matter for [Bristol-Myers].” She added that “[t]his type of strategic manoeuvring is directly contrary to the purpose and spirit of discovery and is looked upon very unfavourably by this Court.” She made these observations even though she did not place much relevance on the pre-trial conference, a matter that is actually quite central to this matter and that, in my view, substantially undercuts Apotex’s position.

[37] Complex, high-stakes intellectual property proceedings are governed by procedural rules aimed at fairness, full and timely disclosure, and efficiency. Purposeful, strategic conduct involving non-disclosure, non-clarification or inaction, as the Prothonotary and the Federal Court judge found here, disrespects these rules and their aims. Those who disrespect the rules and their aims can hardly expect courts to smile upon them when they look for a favourable exercise of discretion under those rules.

[38] The result in this case is even clearer if we apply the admonition in *Merck*, *supra*, that the burden under the *Canderel* test is heavier when "the amendments at issue…would result in a radical change in the nature of the questions in controversy." In light of the Prothonotary's interpretation of Apotex's 2004 amendments as being restricted to liver issues and in light of the foregoing analysis, the proposed amendments would indeed result in a radical change to the nature of the questions in controversy.

[39] Therefore, in appeal A-486-10, I would allow the appeal, set aside the decision of the Federal Court judge, restore the decision dated October 26, 2010 of the Prothonotary, and award costs to Bristol-Myers here and below.

(5) Appeal A-401-10

[40] In appeal A-401-10, it follows from the foregoing analysis that there are no grounds to interfere with Justice Boivin's decision that upheld the Prothonotary's decision of July 30, 2010 that refused Apotex's proposed amendments. Therefore, in that file, I would dismiss the appeal, with costs to Bristol-Myers here and below.

"David Stratas"
J.A.

"I agree
Pierre Blais C.J."

"I agree
John M. Evans J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-401-10
AN APPEAL FROM THE ORDER OF JUSTICE BOIVIN, DATED OCTOBER 19, 2010, UPHOLDING THE ORDER OF PROTHONOTARY ARONOVITCH, DATED JULY 30, 2010-IN FEDERAL COURT FILE NO.: T-2078-00	
STYLE OF CAUSE:	Apotex Inc. v. Bristol-Myers Squibb Company and Bristol-Myers Squibb Canada Inc.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	January 26, 2011
REASONS FOR JUDGMENT BY:	Stratas J.A.
CONCURRED IN BY:	Blais C.J. EvansS J.A.
DATED:	January 31, 2011

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FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-486-10
AN APPEAL FROM THE ORDER OF JUSTICE TREMBLAY-LAMER, DATED DECEMBER 17, 2010, IN FEDERAL COURT FILE NO.: T-2078-00	
STYLE OF CAUSE:	Bristol-Myers Squibb Company and Bristol-Myers Squibb Canada Co. v. Apotex Inc.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	January 26, 2011
REASONS FOR JUDGMENT BY:	Stratas J.A.
CONCURRED IN BY:	Blais C.J. Evans J.A.
DATED:	January 31, 2011

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