Federal Court  Cour fédérale

Date: 20101130

Docket: T-1357-09

Citation: 2010 FC 1209

Ottawa, Ontario, November 30, 2010

PRESENT: The Honourable Madam Justice Simpson

BETWEEN:

APOTEX INC.

Plaintiff

and

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

Defendants

REASONS FOR JUDGMENT AND JUDGMENT

[1] In this motion brought pursuant to Rule 51 of the *Federal Courts Rules*, SOR/98-106, the Defendants appeal an Order of Madam Protohonotary Martha Milczynski (the Prothonotary) dated February 22, 2010 (the Decision) wherein she refused the Defendants' motion to dismiss the action as against the Defendants Sanofi-Aventis (Sanofi France) and Sanofi-Aventis Deutschland GmbH (Sanofi Germany).

[2] The action is being specially managed by the Prothonotary.

[3] Although the cases have not been formally consolidated, this appeal was heard together with two related appeals in action T-1161-07. Separate reasons have been issued dealing with those appeals.

THE BACKGROUND

[4] This appeal concerns the regulatory scheme created by the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the Regulations). At pages 4-5 of her Decision, the Prothonotary provides the following summary of this scheme:

> Before selling a "new drug" in Canada, a manufacturer (be it an "innovator" or generic drug manufacturer), must make application for and obtain a Notice of Compliance ("NOC") from the federal Minister of Health. The issuance of a NOC constitutes marketing approval for a new drug and signifies the Minister's satisfaction that the new drug is safe and effective for human use.
>
> Under the [Regulations], an innovator drug manufacturer may submit a patent list to the Minister of Health in relation to any new drug product submissions for which the innovator has received a NOC. Such patent list may include one or more patents containing claims to the medicine contained in the drug product or its uses contained in the approved submission.
>
> Where a generic drug manufacturer seeks a NOC and has compared its drug product containing a particular medicine to the drug product of an innovator that contains the same medicine and in respect of which a NOC has already been issued, the generic must either (a) accept that the NOC will not be issued to it until the expiry of the patent(s); or (b) deliver to the innovator, a Notice of Allegation with respect to each relevant listed patent, stating that the patent has expired, that the patent is not valid or that the manufacture, use and/or marketing of the drug by the generic will not infringe any claim of the relevant patent(s).

> Upon receiving a Notice of Allegation, the innovator drug manufacturer may, within 45 days, commence a proceeding for an order prohibiting the Minister of Health from issuing a NOC to the generic until the expiration of the patent(s). Pending the disposition of the prohibition proceeding or the expiration of 24 months following commencement of the proceeding, whichever is earlier, the Minister cannot issue the NOC to the generic. This period of time is referred to as the "automatic stay" that prevents a generic from marketing its drug product, and to the extent an innovator is unsuccessful in the prohibition proceeding and the generic ultimately receives a NOC, a claim for damages may be commenced by the generic by virtue of section 8 of the [Regulations].

[5] The Defendant Sanofi-Aventis Canada Inc. (Sanofi Canada) filed the required new drug submission and patent lists, and obtained an NOC to market and sell ramipril. It is an ACE inhibitor used to treat high blood pressure. In 2003, Apotex Inc. (Apotex), applied for its own NOC for ramipril and submitted Notices of Allegation.

[6] Sanofi Canada responded to those notices by bringing five separate prohibition proceedings against Apotex. All were ultimately dismissed, and Apotex was issued its NOC on December 12, 2006.

[7] Sanofi Canada then brought an action against Apotex in Court File T-161-07 alleging infringement of one of the relevant patents. The action was dismissed by Madam Justice Judith Snider in a judgment dated June 29, 2009.

THE APOTEX CLAIM

[8] On August 14, 2009, Apotex commenced an action against Sanofi France, Sanofi Germany, Sanofi Canada, and the Schering Corporation for damages pursuant to section 8 of the Regulations. That section provides that if a "first person" applies for a prohibition order and the application is withdrawn, discontinued or dismissed, the "first person" is liable to the "second person" for any loss suffered during the period of the automatic stay. There is no dispute that Apotex is the "second person" and is entitled to bring a claim against a "first person."

[9] "First person" is defined in section 2 of the Regulations as "the person referred to in subsection 4(1)." In turn, subsection 4(1) describes the "first person" as a person who files a new drug submission, and who is entitled to submit a patent list in relation to that submission.

[10] There is no dispute that Sanofi Canada has filed a new drug submission and a patent list in relation to ramipril, and is therefore a "first person." Further there is no dispute that Sanofi France and Sanofi Germany did not file either new drug submissions or patent lists. However, Apotex submits that Sanofi France and Sanofi Germany are liable as "first persons" because of the control they exercised over Sanofi Canada. In this respect, Apotex pleads as follows in its Amended Statement of Claim dated October 15, 2009, which is the version that was before the Prothonotary (the Apotex Claim):

(a) Sanofi France, Sanofi Germany and Sanofi Canada are affiliates of one another within the Sanofi Group, of which Sanofi France is the ultimate parent (para. 7);

(b) Sanofi France oversees and directs operations of Sanofi Group subsidiaries, including research and development activities, and provides financing (para. 11);

(c) Sanofi France exerts control over the Sanofi Group (para. 12);

(d) The relevant prohibition proceedings were commenced with the agreement, authorization, assistance and cooperation of Sanofi France, Sanofi Germany, Sanofi Canada and Schering Corporation (para. 55);

(e) All Defendants are jointly and severally liable for payment of Apotex' damages (para. 73);

(f) Sanofi France, either itself or through subsidiaries including Sanofi Germany, exercised complete control over Sanofi Canada's decision-making with respect to ramipril, including (para. 74):

(i) Whether Sanofi Canada would apply for NOCs;

(ii) Whether Sanofi Canada would be permitted to include ramipril patents on its patent lists;

(iii) Whether Sanofi Canada would seek prohibition proceedings;

(iv) How Sanofi Canada would prosecute prohibition proceedings;

(v) How Sanofi Canada would market and distribute ramipril;

(vi) How Sanofi Canada would acquire or manufacture ramipril for sale;

(vii) At what price Sanofi Canada would obtain ramipril.

THE MOTIONS

[11] Motions were brought before the Prothonotary by Sanofi Canada, Sanofi Germany and Sanofi France (collectively Sanofi) on September 16, 2009 and by the Schering Corporation on October 9, 2009 seeking, *inter alia* orders striking the Apotex Claim and dismissing the action as against all defendants other than Sonofi Canada. The moving parties said that Sanofi Canada was the only "first person" since it was the only Defendant to file a new drug submission or a patent list in relation to ramipril. Because section 8 of the Regulations only creates a right of damages against a "first person," Sanofi and the Schering Corporation said that Apotex' claim failed to disclose a reasonable cause of action against Sanofi Germany, Sanofi France and the Schering Corporation.

THE DECISION

[12] The Prothonotary dismissed the action against the Schering Corporation, and that aspect of her Decision is not being challenged. However, the Prothonotary declined to strike the claim or dismiss the action against Sanofi France or Sanofi Germany, on the basis of the Federal Court of Appeal's decision in *Apotex Inc. v. Eli Lilly and Co.*, 2004 FCA 358 (*Lilly 2004*). In that case Mr. Justice John Evans wrote for the Court and indicated that a parent corporation which directs a subsidiary to file a new drug submission and a patent list might be a "first person" jointly with its subsidiary. The Court did not decide the issue but described it as a "difficult legal question" which required a trial.

[13] The Prothonotary concluded, in light of that decision, that it was not "plain and obvious" that Sanofi France and Sanofi Germany were not also first persons and that, even though the decision in *Lilly 2004* had been made in the context of a claim for disgorgement of profits (which is no longer a valid cause of action), it was broad enough to apply to the Apotex Claim.

[14] The Prothonotary also considered whether Apotex had pleaded sufficient material facts to sustain a reasonable cause of action. She held that paragraph 74 of the Apotex Claim was sufficient since it alleged that Sanofi France and Sanofi Germany had complete control and direction over Sanofi Canada and that the pleading could lead to the conclusion that Sanofi France and Sanofi Germany were "first persons," if Apotex' interpretation of "first person" were to be accepted at trial. On the other hand, the Prothonotary held that no material facts had been pleaded which could make Schering a "first person" on any possible interpretation. For these reasons, the Prothonotary struck the portions of the Apotex Claim containing allegations against Schering, and dismissed the claim against Schering, but maintained the claims against Sanofi France and Sanofi Germany.

THE ISSUES

[15] The issues on this appeal are as follows:

(a) What is the standard of review?

(b) Should the Apotex Claim be dismissed against Sanofi France and Sanofi Germany?

Issue I The Standard of Review

[16] The parties agree that the test to be applied on the review of a discretionary decision of a prothonotary is the one reformulated by the Federal Court of Appeal in *Merck & Co. Inc. v. Apotex Inc.*, 2003 FCA 488 (*Merck 2003*) at paragraph 19. There the Court said:

> To avoid the confusion which we have seen from time to time arising from the wording used by MacGuigan J.A., I think it is appropriate to slightly reformulate the test for the standard of review. I will use the occasion to reverse the sequence of the propositions as originally set out, for the practical reason that a judge should logically determine first whether the questions are vital to the final issue: it is only when they are not that the judge effectively needs to engage in the process of determining whether the orders are clearly wrong. The test would now read:
>
> Discretionary orders of prothonotaries ought not be disturbed on appeal to a judge unless:
>
> a) the questions raised in the motion are vital to the final issue of the case, or
> b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

[17] The reference in *Merck 2003* to the wording used by MacGuigan J.A. related to Mr. Justice Mark MacGuigan's decision in *R. v. Aqua-Gem Investments Ltd.*, [1993] 2. F.C. 425 (Fed. C.A.) (*Aqua-Gem*). In that case he said:

> I also agree with the Chief Justice in part as to the standard of review to be applied by a motions judge to a discretionary decision of a prothonotary. Following in particular Lord Wright in Evans v. Bartlam, [1937] A.C. 473 (H.L.) at page 484, and Lacourciere J.A. in Stoicevski v. Casement (1983), 43 O.R. (2d) 436 (Div. Ct.), discretionary orders of prothonotaries ought not to be disturbed on appeal to a judge unless:
>
> (a) they are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a

> wrong principle or upon a misapprehension of the facts, or
>
> (b) they raise questions vital to the final issue of the case.
>
> Where such discretionary orders are clearly wrong in that the prothonotary has fallen into error of law (a concept in which I include a discretion based upon a wrong principle or upon a misapprehension of the facts), or where they raise questions vital to the final issue of the case, a judge ought to exercise his own discretion de novo.

[18] The issue is whether "vitality" is to be assessed by looking at the question in the motion before the Prothonotary or by considering the Decision. In *Peter G. White Management Ltd. v. Canada*, 2007 FC 686, Mr. Justice James Hugessen concluded that, in situations (similar to the case at bar) in which the appeal is from a decision of a prothonotary dismissing a defendant's motion to strike, it is not what was sought (i.e., the question in the motion before the Prothonotary) but what was ordered by the Prothonotary (i.e., the answer) which is to be analyzed to see whether it is vital to a final issue in the case. Mr. Justice Hugessen based this conclusion on his reading of *Aqua-Gem*. Several Federal Court Judges have since adopted his interpretation. A summary of this case law on this issue is to be found in Madam Justice Anne Mactavish's decision in *Ridgeview Restaurant Limited v. The Attorney General of Canada and Steve Gibson*, 2010 FC 506 at paragraphs 20 to 24.

[19] Using Mr. Justice Hugessen's approach, the focus would be on the answer or, in other words, on the Decision made by the Prothonotary. In this case, because the Prothonotary dismissed the motion to strike, no change was made in the case – it continues to trial. In these circumstances, it cannot be said that her order was determinative of vital issues. Accordingly, review *de novo* would not be appropriate unless the Prothonotary clearly erred by exercising her discretion on a wrong principal or by misapprehending the facts and no such submission was made in this case.

[20] However, I have reviewed the Federal Court of Appeal's decisions in *Aqua-Gem* and *Merck 2003* and have observed the following:

[21] In *Aqua-Gem*, the respondent had moved to have the case dismissed for want of prosecution. The Prothonotary dismissed the motion so the action remained extant. While the question before the Prothonotary was vital in the sense that the action could be dismissed, the order was not determinative of the final issues. The judge who heard the appeal from the Prothonotary's order considered it *de novo* and the Federal Court of Appeal upheld this approach. The only possible rationale for this conclusion, in my view, is that the Court of Appeal considered the issue of vitality based on the question before the Prothonotary.

[22] Mr. Justice MacGuigan said at paragraph 95 of *Aqua-Gem* that "…discretionary orders of prothonotaries ought not to be distributed on appeal to a judge unless they raise questions vital to the final issue of the case."

[23] The word "they" appears to refer back to the word "orders" and indicates that one looks at the order made by the Prothonotary and only reviews it *de novo* if it has, in fact, had an impact on the trial that could be categorized as vital.

[24] The difficulty is that when Mr. Justice MacGuigan considered the matter, he did not actually apply the test he stated. Rather, he looked at the question before the Prothonotary. He said at paragraph 98 "Another way of putting the matter would be to say that for the test as to relevance to

the final issue of the case, the issue to be decided should be looked to before the question is answered by the prothonotary, ..."

[25] I have therefore concluded that the restatement of the *Aqua-Gem* test in *Merck 2003* gives effect to the language in Mr. Justice MacGuigan's analysis and in his conclusion in *Aqua-Gem*.

[26] *Merck 2003* was a case in which Apotex sought to make fundamental amendments to its Statement of Defence. The motions judge who reviewed the Prothonotary's decision to allow the amendment declined to treat the proposed amendments as vital and did not conduct a *de novo* review. He upheld the Prothonotary's decision to allow the Apotex amendments.

[27] The Court of Appeal held that the proposed amendments were vital and conducted its own *de novo* review. In the end, it decided not to permit the amendments. The importance of this decision for present purposed is that the restatement and the Court's subsequent analysis makes it clear that, as Sanofi submits, it is the question before the Prothonotary that is the focus of the "vitality" analysis.

[28] In 2006, the Federal Court of Appeal again dealt with the question of vitality. In *Peter G. White Management Ltd. v. The Queen*, 2006 FCA 190, the Court considered, *inter alia*, an appeal from the decision of a Federal Court motions judge on an appeal from a Prothonotary's order. Before the Prothonotary, the Crown had moved to strike the claim against the individual defendants who were a Minister of the Crown and three public servants. The Prothonotary allowed the motion. The motions judge dismissed the appeal without considering the matter *de novo*.

[29] At paragraph 33 and following, the Court of Appeal considered the standard of review and concluded that the motions judge had erred in concluding that the motion to dismiss was not vital to the final issue in the case. The Court of Appeal noted that the causes of action against the individual defendants were separate and distinct from those asserted against the Crown and found that removing the defendants put an end to the Plaintiff's causes of action against them in Federal Court.

[30] In conducting its analysis, the Court of Appeal looked at the question in the motion before the Prothonotary and concluded that it was vital. It therefore held that the motions judge ought to have determined the matter *de novo*.

[31] In view of these cases, I must next consider whether the question before the Prothonotary in this case can be said to be vital.

[32] On this issue, I have concluded that questions dealing with the presence or absence of a defendant will be vital if something essential is taken from a plaintiff if defendant is excluded. In this case, without Sanofi France and Sanofi Germany, the Plaintiff cannot argue that there could be joint liability because those defendants controlled Sanofi Canada. I therefore conclude that the removal of the defendants is a vital matter. Accordingly, the Decision not to dismiss the Apotex Claim against Sanofi France and Sanofi Germany will be reviewed *de novo*.

Issue II Should the Apotex Claim proceed against Sanofi France and Sanofi Germany?

[33] A pleading should not be struck unless it is "plain and obvious" that it discloses no reasonable cause of action: *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959 at page 980.

[34] Sanofi takes the position that, on a plain reading of subsection 4(1) of the Regulations, Sanofi Canada is the only "first person" since it was the only Defendant to file a new drug submission or a patent list in relation to ramipril. It said that, since section 8 of the Regulations only creates a right of damages against a "first person", the Apotex Claim fails to disclose a reasonable cause of action against Sanofi France and Sanofi Germany.

[35] In *Lilly 2004*, the Federal Court of Appeal considered a similar argument. A generic drug manufacturer had brought a section 8 claim against two innovator drug manufacturers: a Canadian subsidiary which had filed a new drug submission and patent list, and its American parent which had not done so. The parent sought summary judgment on the basis that it was not a "first person". As in this case, the generic's claim against the foreign parent was based on the degree of control it exercised over the Canadian subsidiary.

[36] The Court of Appeal described the issue in *Lilly 2004* at paragraph 9. It said:

> The question in dispute, therefore, is whether [the parent] can be said to have submitted the patent list to the Minister pursuant to subsection 4(1), even though the list was submitted in the name of [the subsidiary].

In my view, this is precisely the issue in the case at bar.

[37] The Court held, at paragraphs 11-13 of its decision, that common law concepts such as agency might be relevant to statutory interpretation. The Court illustrated this point saying that, if a parent company exercised a degree of control over a subsidiary such that the subsidiary could be said to be acting as its agent, the subsidiary's actions might be regarded as actions taken by both the subsidiary and the parent. Thus, the parent might be a "first person" and therefore a proper defendant.

[38] It is noteworthy that the Court added, at paragraph 14:

> Whether, for the purpose of section 8, a "first person" includes the corporation who directed the submission of the patent list in the name of its subsidiary is a sufficiently difficult legal question to require a trial.

[39] Further, at paragraph 15, the Court in *Lilly 2004* stated:

> Its resolution may depend, <u>for example</u>, on whether the "profits" recoverable under section 8 are the profits from the drug in question made by the "first person" during the period of the delay or the profits *not* made during that period by the "second person" from its version of the drug. If the intent of section 8 is to enable the "second person" to elect to recover the "first person's" profits, rather than merely its own lost profits, that might support an interpretation of "first person" which includes the corporation that controlled all relevant actions of the corporation in whose name the application for an NOC was made, the patent list was submitted and an NOC was issued. Otherwise, the second person may be unable to recover the innovator's profits and, if the statutory purpose is to enable the recovery of the profits of the directing mind of the person whose name appears on the documents listed in subsection 4(1), that statutory purpose will have been thwarted. This is because it is conceivable that intercorporate arrangements may have ensured that profits from the sale of the drug in Canada show up on the books of the parent company, not its Canadian subsidiary. [My emphasis]

[40] Sanofi's main submission, relying on paragraph 15 of *Lilly 2004*, is that the Court of Appeal decision was based on the availability of a disgorgement of profits as a remedy under section 8 of the Regulations. *Lilly* held that a cause of action for disgorgement of profits is only meaningful if the plaintiff can implead all parties who might have earned the profits. Thus, a broad interpretation of "first person" was required. However, in *Merck Frosst Canada Ltd. v. Apotex Inc.*, 2009 FCA 187, leave to appeal to the Supreme Court of Canada ref'd [2009] S.C.C.A. No. 347 (*Merck 2009*), the Federal Court of Appeal held that disgorgement of profits is not a remedy that is available under section 8. For this reason, Sanofi says that the rationale behind *Lilly 2004* has been extinguished and there is no longer any reason to give a broad or elastic interpretation to "first person."

[41] However, I am not persuaded that the *Lilly 2004* decision was premised entirely on the existence of a claim for profits. As noted above, the Court made several general statements supporting the possibility of section 8 liability on the part of a company which controlled and directed the person who actually submitted the new drug submission and patent list. For example, the Court stated that common law agency principles might apply in the section 8 context and that actions of a subsidiary might be regarded as the actions of its parent.

[42] Paragraph 15 of *Lilly 2004* simply presents disgorgement of profits as an example of a situation in which a broad definition of "first person" may be appropriate. In my view, the reference to profits was only an illustration and was not intended to be exhaustive. In other words, I think it likely that the Court in *Lilly 2004* would have reached the same conclusion about the need for a trial to decide the meaning of "first person" even if disgorgement of profits had not been available as a

remedy. Accordingly, the question of whether a "first person" includes a controlling corporation in the context of a section 8 claim for damages remains open.

[43] During the hearing, Sanofi made several arguments about how to resolve the statutory interpretation question. For example, both paragraph 4(4)(d) and subsection 6(4) of the Regulations refer to the owners of relevant patents, but subsection 4(1) does not refer to any additional parties. This suggests that the drafter of the Regulations intended to exclude the parties other than the one who filed the new drug submission and patent list from the definition of "first person" in subsection 4(1).

[44] However, it is not my role to decide the meaning of "first person". My role is to determine whether it is plain and obvious that Apotex' interpretation of "first person" must fail. In light of *Lilly 2004*, I have concluded that such a result is not plain and obvious.

[45] For all these reasons, I have reached the same conclusion as the Prothonotary. The appeal will therefore be dismissed with costs to Apotex in any event of the cause.

JUDGMENT

THIS COURT'S JUDGMENT is that the appeal is dismissed with costs payable to Apotex by Sanofi Canada in any event of the cause.

"Sandra J. Simpson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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