Federal Court  Cour fédérale

Date: 20110527

Docket: T-1773-07

Citation: 2011 FC 626

Ottawa, Ontario, May 27, 2011

PRESENT: The Honourable Mr. Justice Lemieux

BETWEEN:

ELI LILLY CANADA INC. and ELI LILLY AND COMPANY

Plaintiffs

and

HOSPIRA HEALTHCARE CORPORATION

Defendant

REASONS FOR JUDGMENT AND JUDGMENT

I. Introduction and Background

[1] This proceeding is an appeal by the defendant Hospira Healthcare Corporation (Hospira) from the January 28, 2011 decision of Prothonotary Tabib who, pursuant to Rule 75 of the Federal Courts Rules (SOR/98-106) (the Rules), allowed the plaintiffs (Lilly) to amend their Statement of claim in a patent infringement action filed in this Court on October 4, 2007.

[2] In its action Lilly claims Hospira has infringed its Canadian Patent 2,098,881 (the '881 Patent) by importing for sale in Canada and selling here gemcitabine hydrochloride in finished dosage form (the imported product) and specifically that the active pharmaceutical ingredient (API) in the imported product which is manufactured in China by Hansen Pharmaceutical Co. Ltd. (Hansen) uses a process which infringes the '881 Patent.

[3] It is not disputed by the parties that the overall process of synthesizing the API gemcitabine involves a number of steps and that the patented process is an intermediate step known as a glycosylation reaction induced by a SN2 reaction (the patented process).

[4] Hospira's defence is that the gemcitabine in its imported product is derived from a glycosylation reaction obtained through a SN1 reaction which does not infringe the '881 Patent because that patent only covers the SN2 reaction. Hospira adds that when it applied to the Minister of Health in Canada (the Minister) to obtain a Notice of Compliance (NOC) enabling it to import and sell the imported product in Canada, it disclosed to the Minister its glycosylation reaction was induced by a SN1 reaction.

[5] In it original Statement of Claim Lilly asserted at paragraph 20s and 25 the following:

> 20. The processes claimed in the '881 Patent are the only processes that can produce commercial quantities of gemcitabine in an efficient and cost-effective manner. The Plaintiffs are unaware of any commercial scale that can produce regulatory quality gemcitabine that will not infringe Claims 1-6, 8-13 of the '881 Patent.
>
> 25. The only processes that are commercially viable are those processes claimed in the '881 Patent. Consequently, the process used by Hospira and its suppliers to manufacture bulk gemcitabine fall under claims of the '881 Patent and is set out in Appendix A.

[6] Hospira filed its Statement of Defence and Counterclaim on January 24, 2008. Its response to Lilly's paragraph 20 is as follows:

> 19. Hospira denies all of the allegations set forth in paragraph 20 of the Amended Statement of Claim. One or more processes, other than as purportedly described by the '881 patent, are known and may be used for the commercial production of gemitabine [sic], such as those referenced at page 1, lines 6 – 26 of the '881 patent. A person skilled in the art would be able to usefully and efficiently synthesize gemcitabine for commercial production using a process that does not infringe any claim of the '881 patent, by making use of information in the public domain that predates the filing of the '881 patent, namely the teachings of the prior art exemplified by the patents and publications listed in Schedule 1 hereto, when read in the light of common general knowledge in the art.

[7] In terms of Lilly's former paragraph 25, Hospira simply denied the allegation.

[8] In the decision under review, Prothonotary Tabib allowed Lilly to make two amendments to its Statement of Claim. First, she allowed Lilly to make a modification to the language found in paragraph 20 which had not previously been amended. Second, she allowed Lilly to add a new cause of action, namely, infringement by Hospira of three Canadian patents owned or licensed by Lilly: Canadian patent 2,324,128 (the '128 Patent), Canadian patent 1,331,194 (the '194 Patent) and Canadian patent 1,330,989 (the '989 Patent). Specifically, the new claims say that the processes used by Hansen to manufacture gemcitabine for Hospira infringe those Patents.

[9] The new language in paragraph 20 is now simply:

> 20. The processes claimed in the '881 Patent produce commercial quantities of gemcitabine in the most efficient and cost effective manner.

[10] For the sake of completeness I should add that paragraph 25 of Lilly's original Statement of Claim had been deleted by Lilly when it made its first amendment to the Statement of Claim.

[11] In terms of the new claims permitted to be added to the Lilly Statement of Claim, Prothonotary Tabib wrote:

> The '128 Patent is actually a process patent covering the SN1 reaction; the '194 Patent relates to a process upstream of the glycosylation reaction (which can be either an SN1 or SN2 pathway), and the '989 is for a process downstream of the glycosylation reaction, which can again use either an SN1 or an SN2 pathway, but would more commonly apply to an SN1 pathway. [Emphasis added]

II. Further Context

[12] To properly understand the amendments sought by Lilly further context is necessary; it relates to the December 8, 2008 motion made by Lilly for an order that Hospira file a further and better affidavit of documents including; (1) the open part of its Drug Master File (DMF); (2) the relevant and unredacted parts of its Abbreviated New Drug Submission (ANDS) filed with the Minister of Health which lead to its obtaining the NOC; and (3) the Master Production Batch Records which would disclose the exact nature of the reaction Hansen used at the glycosylation step on the way to synthesize the gemcitabine in the imported product.

[13] Lilly's motion was heard by Prothonotary Tabib on June 19, 2009; she granted Lilly's request. She noted:

> 1. Hospira alleged that the process Hansen used to obtain the glycosylation reaction is a previously known and disclosed process known as the SN1 reaction.

> 2. Both parties agreed if Hospira's gemcitabine was and is indeed manufactured via the SN1 reaction there could be no infringement of the '881 Patent because it claims only glycosylation through the SN2 reaction. [Emphasis added]

[14] She noted a further concession by Lilly relating to the disclosure by Hospira of portions of its ANDS filed with the Minister. Lilly conceded that reaction corresponded to the SN1 reaction and that "if it is indeed the process followed by Hansen, there is no infringement."

[15] Both parties agreed that the Batch Production Records sought by Lilly "would constitute direct evidence of the process actually used by Hansen in manufacturing the bulk gemcitabine, and assuming that they are accurate, would constitute direct evidence of whether the process used by Hansen is the SN1 reaction or the SN2 reaction, and therefore, whether or not there is infringement." [Emphasis added]

[16] Her order was appealed to the Federal Court. I heard the appeal and dismissed it (See *Eli Lilly Canada Inc. v Hospira Healthcare Corporation* 2009 FC 1316) and this decision was sustained on further appeal to the Federal Court of Appeal (See *Hospira Healthcare Corporation v Eli Lilly Canada Inc.* 2010 FCA 282 dated October 26, 2010).

[17] It should be mentioned that Hospira applied to the Federal Court for a stay of Prothonotary Tabib's June 19, 2009 order; that stay application was dismissed by the Court on July 30, 2009 so that compliance with her order remained Hospira's obligation pending the determination of the appeals.

[18] Not being satisfied with the level of compliance with the disclosure order made by Prothonotary Tabib, particularly with the production of the Batch Production Records from Hansen, Lilly in September 2009 sought the aid of the U.S. District Court to compel Hansen's exclusive North American sales and regulatory agent, Chemwerth Inc., to produce and depose respecting Hansen's certificates of analysis, relevant Batch Records for the imported product sold in Canada and the portion of Hansen's regulatory submission to the FDA in the United States.

[19] Lilly was successful on its U.S. motion with a subpoena issuing compelling production and deposition. Chemwerth and Hospira apparently resisted compliance; Lilly sought an order of compliance. Chemwerth resisted, by filing the declaration of Chemwerth's Executive Vice-President, Mr. Song Lin, that Hansen had more than one process for making gemcitabine:

> 5. I understand that Lilly through its subpoena has also requested from Chemwerth confidential information regarding Hansen's method for making gemcitabine to be soled to customers other than Hospira and distributed in the U.S. market. This information is directed to a process that is not used to manufacture gemcitabine provided to Hospira and is described in batch records provided to the FDA and DMF No. 18810…. [Emphasis in original]

[20] Lilly's application to the U.S. District Court for compliance was successful; an order of compliance was issued on June 15, 2010 and an appeal from that order was dismissed on July 27, 2010. Mr. Song Lin was deposed after Chemwerth produced the subpoenaed documents.

[21] It was after Mr. Lin's deposition that Canadian counsel to Lilly wrote Prothonotary Tabib on August 31, 2010 to advise that Lilly would seek leave to amend its Statement of Claim.

[22] In terms of the stage of the procedures in the Lilly action, the parties are still at the pre-discovery stage.

III. The Prothonotary's Decision

[23] The essence of the Prothonotary's decision is found in the following paragraph of her reasons:

> As Hospira has not pleaded that the proposed amendments do not disclose an arguable case, and that it has not succeeded in showing that they represent an impermissible withdrawal of an admission, a radical departure from previous pleadings or an abuse of process, leave to amend ought to be granted unless it causes Hospira prejudice that cannot be compensated by costs. I can see no such prejudice. As to cost consequences of the amendments, I cannot conceive of any costs thrown away as a result of the amendment or that would result from the amendment and would have been avoided had the amendments been made earlier, except for the cost to Hospira of preparing an amended statement of defence. Apart from the proceedings surrounding the U.S. discovery of Chemwerth, no discoveries have taken place in this action yet. Further, as mentioned above, I do not believe that Hospira would have been less adamant or vigorous in defending Lilly's efforts to obtain discovery of Hansen's records and processes, nor that it would have been more successful in these efforts if the pleadings had originally stood as now proposed. [Emphasis added]

[24] On the issue of the withdrawal of an admission Prothonotary Tabib was of the view not all facts alleged in pleadings constitute admission, the withdrawal of which must be closely scrutinized. She wrote "an admission is generally understood to be the acknowledgment of facts relevant to an adversary's case or which adversely affects the admitting party's case." She concluded the allegation initially made that the SN2 process was the only viable process was clearly made to advance its case, could not have advanced or helped Hospira's case or harmed Lilly's case as it was when it was made. Moreover, Hospira denied the allegation and asserted the contrary that the SN1

process could and had been used on a commercial scale by Hansen. The dilution of the allegation at paragraph 20, in her view, did not in any way vary or change Hospira's defence.

[25] On the issue of the adding of a new cause of action, the Prothonotary wrote that in the circumstances, Lilly's amendment to plead that, if Hansen is not using the SN2 process, then it is using an SN1 process covered by other patents "was certainly the addition of a new and alternative cause of action but it is not a radical departure from the earlier pleading".

[26] Hospira submitted to the Prothonotary that it was an abuse of process for Lilly to have obtained, on the basis of an affirmation that the SN2 reaction was the only commercially viable one, discovery of the details of Hansen's process which it could not otherwise have obtained and then to use those details to ambush Hospira and Hansen that the process infringes other patents than the '881 Patent. Prothonotary Tabib did not agree. She wrote:

> Lilly did not offer evidence on this motion to explain its apparent about-face on the issue of the commercial viability of the SN1 process. Nevertheless, the Court will not presume or infer bad faith in the absence of compelling reasons to do so. It is true that Lilly's initial pleadings were categorical: No other commercially viable process existed. I have no reason to doubt that that pleading reflected, at that time, Lilly's belief, even if it may have since evolved. Indeed, Lilly tendered the evidence of its in-house expert, Dr. Kjell, to substantiate and explain that view. Dr. Kjell's evidence was appropriately nuanced: He expressed his scepticism and the reasons for it. Dr. Kjell was cross-examined and held firm on his opinion. The Court accepted Dr. Kjell's evidence, but not as proof that there could only be one commercially viable process, but as making it "reasonably likely" that an SN2 process was being used. In any event, the Court's principal conclusion was based on the *prima facie* relevance of the batch production records and on its finding that, in the circumstances (and without even considering Dr. Kjell's evidence), Hospira had not established a presumption that its ANDS was conclusive evidence of the likely content of the batch records.

> Likewise, it does not appear that the U.S. Courts relied on Lilly's allegation of a single commercially viable process as the necessary and single foundation for its decision to authorize Chemwerth's discovery. [Emphasis added]

[27] Prothonotary Tabib considered whether, had Lilly initially framed its action as an alternative plea of infringement between the '881 Patent and the '128 Patents, an order would likely have issued declaring Hansen's Batch Production Records to be relevant and opening the door to discovery in the United States. She was satisfied the outcome would not have been different because there was persuasive evidence before the Court to the effect the SN2 reaction is fundamentally more efficient and desirable than the SN1 reaction and the issue of which process was actually used was still on the table and even though both an SN1 and a SN2 reaction might be infringing, the '128 Patents had expired and no injunction could be pronounced, the remedies would vary considerably depending which patent infringed. She added:

> Finally, there is no suggestion that Hospira was taken by surprise or misled into taking any position prejudicial to its interests by Lilly's initial pleadings and subsequent amendments. The three new patents sought to be asserted by Lilly are of public knowledge, and Hospira itself acknowledged that the SN1 process allegedly used by Hansen was based on the work of Dr. Chou, one of the inventors of the newly asserted patents.

IV. Legal Principles on Leave to Amend

[28] Three decisions of the Federal Court of Appeal have settled those principles:

a. *Canderel Ltd. v Canada (C.A.)* [1994] 1 FC 3 (*Canderel*);
b. *Merck & Co., Inc. v Apotex Inc.*, 2003 FCA 488 (*Merck*); and
c. The very recent decision in *Apotex Inc. v Bristol-Myers Squibb Company*, 2011 FCA 34 (*Apotex*)

[29] The legal principles expressed in those three cases may be summarized as follows:

i. "A pleadings amendment should be allowed [at any stage of an action] 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." (*Apotex* at para 4).

ii. "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* at para 32)

iii. The decision maker "has the duty to consider all relevant factors".

iv. Relevant factors appropriate to gauge whether an amendment will serve the interests of justice or will not cause an injustice to the other party will vary according to the specific circumstances of each particular case. At paragraph 33 in *Merck* Justice Décary wrote:

> The nature, timing and circumstances vary from one amendment to the other and from one type of amendment to the other, and one must be careful not to generalize judicial pronouncements made in a given context. The prothonotary or judge seized with the motion to amend has the duty to consider all relevant factors. There is, for example, as noted by Lord Griffiths in *Ketteman*, at page 62, "a clear difference between allowing amendments to clarify the issues in dispute and those that permit a distinct defence to be raised for the first time". There is also a clear difference between allowing amendments at trial and allowing amendments before trial (see *Glisic v. Canada*, [1988] 1 F.C. 731 (C.A.), at page 740; *Ketteman*, *supra*). There is also a clear difference, I suggest, between allowing amendments that amount to the withdrawal of an admission and amendments that do not, and a clear difference between allowing amendments that amount to withdrawal of a substantial admission the result of which is to

> alter the cause of action and one that relates to a mere admission of fact. [Emphasis added]

v. In *Canderel*, the amendment was refused. It was proposed by the Crown to the trial judge on the fifth day of trial and would raise a completely new issue which should have been well before and was completely contrary to the position previously advanced in its pleadings and in discovery.

vi. In *Apotex* the proposed amendment sought was after discovery had been conducted, expert reports prepared, pre-trial memoranda exchanged and a pre-trial conference conducted. Those amendments would introduce new elements to what issues were in dispute and would radically alter the nature of the questions in controversy. Leave to amend was denied by Justice Stratas.

vii. In *Merck* the same result – leave to amend was denied by Justice Décary. At paragraph 27 and 28:

> The proposed amendments, in my view, represent a dramatic departure from the position until now advanced by Apotex in its pleadings. Its defence of non-infringement was essentially based on the fact that it had acquired lisinopril made prior to the issuance, on October 16, 1990, of the 350 patent and on the fact that it had acquired lisinopril made under a compulsory licence issued to its supplier, Delmar. Apotex' pleadings in these and other proceedings has always assumed that were it not for those facts, there would be infringement of the 350 patent. The construction of the patent and the chemical composition of lisinopril has never been an issue.
>
> The proposed amendments, clearly, would add a totally new defence to the statement of defence, a new defence that would go to the heart of the claim of the 350 patent and require expert evidence that could not have been contemplated by the appellants at the discovery stage in view of the admissions already made in the pleadings and in the proceedings. They are, in my view, vital to the final issue of the case. A *de novo* review of the decision of the Prothonotary was therefore warranted and the Applications Judge erred in finding that it

> was not. I must, therefore, exercise *de novo* the discretion the Applications Judge failed to exercise.

V. The Standard of Review

[30] In *Merck*, Justice Décary expressed the standard of review in these terms at paragraphs 19 and 25:

> 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."
>
> When is an amendment a routine one as opposed to a vital one? It would be imprudent to attempt any kind of formal categorization. It is much preferable to determine the point on a case-by-case basis (see *Trevor Nicholas Construction Co. v. Canada (Minister for Public Works)*, 2003 FCT 255; [2003] F.C.J. No. 357 (T.D.) (QL), *per* O'Keefe J. at paragraph 7, affd, 2003 FCA 428; [2003] F.C.J. No. 1706 (C.A.) (QL)). I note that amendments that would advance additional claims or causes of action have consistently been found, in the Federal Court of Canada, to be vital for the purposes of the *Aqua-Gem* test (see *Scannar Industries Inc. (Receiver of) v. Canada*, [1994] 1 C.T.C. 215 (F.C.T.D.), Denault J., affd [1994] 2 C.T.C. 185 (F.C.A.); *Trevor Nicholas Construction Co.*, *supra*; *Louis Bull Band v. Canada*, 2003 FCT 732; [2003] F.C.J. No. 961 (T.D.) (QL) (Snider J.)). [Emphasis added]

[31] In my view, I am required to review the Prothonotary's decision *de novo*. Clearly, the addition of new claims of infringement related to the three additional patents, in addition to the '881 Patent, are vital to the final issue of the case i.e. to its final resolution. If the amendment is not

allowed, Lilly will not be able to advance a claim that the actual process used by Hansen for Hospira, in relation to its sales in Canada, whether it be the SN2 reaction or the SN1 reaction violates the appropriate Lilly patents.

[32] In terms of the amendment to paragraph 20 of Lilly's Statement of Claim, I view it as being ancillary or consequential to the new claims sought to be advanced by Lilly in respect of the SN1 reaction.

VI. Conclusion

[33] Reviewing the matter *do novo*, this appeal must be dismissed for two reasons. First, I am in full agreement with the Prothonotary's reasons. The amendment to paragraph 20 of the Statement of Claim does not withdraw an admission because that paragraph is simply an assertion of fact which Hospira has denied. Adding the new cause of action claiming the imported product infringed three Lilly patents is not a radical departure from the pleadings because the issue of how the glycosylation process for the imported product, be it the SN1 or the SN2 reaction, was always on the table. Clearly, the amendments do not constitute an abuse of process and Hospira has failed to show any prejudice which cannot be compensated by costs.

[34] Hospira's counsel stressed that Lilly's evidence was put on the record through a law clerk employed by Lilly's legal counsel. The purpose of the affidavit, in my view, was not to provide evidence on the merits of the appeal but to put before the Court the documentary record and nothing more.

[35] My second reason is that the amendment falls squarely within the legal principles which have interpreted Rule 75 of the Rules. Discovery has yet to be conducted. The additional cause of action is an alternative plea that clarifies the issues in dispute. The purpose of the amendments is to determine the real questions in controversy; they do not result in an injustice to Hospira and finally, they serve the interest of justice because they will enable the parties to put forward a complete case which will enable the Court to properly adjudicate the issue of infringement.

JUDGMENT

THIS COURT'S JUDGMENT is that this appeal is dismissed with costs.

"François Lemieux"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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