Federal Court  Cour fédérale

Date: 20110303

Docket: T-1548-10

Citation: 2011 FC 255

Ottawa, Ontario, March 3, 2011

PRESENT: The Honourable Madam Justice Snider

BETWEEN:

ELI LILLY CANADA INC.,
ELI LLILY AND COMPANY,
ELI LILLY AND COMPANY LIMITED
AND ELI LILLY SA

Plaintiffs

and

NU-PHARM INC.

Defendant

REASONS FOR ORDER AND ORDER

I. Background

[1] The Plaintiffs, Eli Lilly Canada Inc., Eli Lilly and Company, Eli Lilly and Company Limited and Eli Lilly S.A. (collectively referred to as Eli Lilly or the Plaintiffs), hold patent rights to Canadian Letters Patent No. 2,041,113 (the '113 Patent). The '113 Patent claims the compound olanzapine, a medication useful in the treatment of various disorders of the central nervous system.

Olanzapine is sold by Eli Lilly using the trade name ZYPREXA. By Statement of Claim issued September 27, 2010, the Plaintiffs commenced an action for patent infringement against Nu-Pharm Inc. (Nu-Pharm or the Defendant).

[2] In response to the Plaintiffs' action, Nu-Pharm brought a motion to strike the Statement of Claim. In an Order dated November 16, 2010, Prothonotary Milczynski struck out the Plaintiffs' claim and awarded costs of $3000 to Nu-Pharm. The Plaintiffs now seek an Order setting aside the November 16, 2010 Order.

II. Standard of Review

[3] The parties are agreed that the decision of the Prothonotary to strike the Statement of Claim raises a question vital to the final issue of the case. Where a Prothonotary's decision raises a question vital to the final issue of the case, the standard of review is *de novo* (*Canada v Aqua-Gem Investments Ltd.*, [1993] 2 FC 425, [1993] 1 CTC 186 at pages 462-463 (FCA); *Merck & Co., Inc. v Apotex Inc.*, 2003 FCA 488, 315 NR 175 at paragraph 19). This means that I must conduct an analysis of the issues without any deference to the Prothonotary's findings in her decision of November 16, 2010.

[4] The overarching question before me is whether the Plaintiffs' claim should be struck. In my view, for the reasons below, I agree with Prothonotary Milczynski and would strike the Statement of Claim.

III. Relevant Principles

[5] Before examining the merits of the appeal, it is useful to review the principles related to the striking of a claim.

[6] The purpose of pleadings is to define the question in controversy between the litigants and to give the defendant fair notice of the case to be met (*Weatherall v Canada (AG),* [1989] 1 FC 18, 86 NR 168 at paragraph 14).

[7] Rule 174 of the *Federal Courts Rules*, SOR/98-106 [the *Rules*] states that, “Every pleading shall contain a concise statement of the material facts on which the party relies, but shall not include evidence by which those facts are to be proved.” The Federal Court of Appeal in *Merchant Law Group v Canada (Revenue Agency)*, 2010 FCA 184, 321 DLR (4th) 301 at paragraph 34 stated:

> [I]f the requirement of pleading material facts did not exist in Rule 174 or if courts did not enforce it according to its terms, parties would be able to make the broadest, most sweeping allegations without evidence and embark upon a fishing expedition. As this Court has said, "an action at law is not a fishing expedition and a plaintiff who starts proceedings simply in the hope that something will turn up abuses the court's process": Painblanc v. Kastner (1994), 58 C.P.R. (3d) 502, 176 N.R. 68 (Fed. C.A.) at paragraph 4.
>
> [Emphasis added.]

[8] Rule 221(1)(c) of the *Rules* permits the Court to strike out a pleading that is “scandalous, frivolous or vexatious” or “is otherwise an abuse of the process of the Court”. A wealth of jurisprudence provides some guideposts for this analysis.

[9] An action must do more than present mere allegations. Stated differently, an action is not a fishing expedition. As noted by Justice Addy, in *Caterpillar Tractor Co. v Babcock Allatt Ltd.*, [1983] 1 FC 487, 67 CPR (2d) 135 at paragraphs 13, aff'd (1983), 72 CPR (2d) 286, [1983] FCJ No 528 (QL) (FCA):

> It is not an answer to an application to strike out, for the party to say that, if he had unrestricted discovery of his opponent, he might then be in a position to sustain the allegations.

[10] In the context of an action for patent infringement, the Defendant argues that, the Plaintiff must give details of the activities that allegedly contribute to the alleged infringement. I agree. If the "material facts" of the infringement are not present, the Statement of Claim should be struck out.

[11] However, the threshold for striking out a statement of claim is high. As discussed by Justice Layden-Stevenson (as she was then), in *Pharmaceutical Partners of Canada Inc. v Faulding (Canada) Inc*. (2002), 21 CPR (4th) 166, [2002] FCJ No 1305 (QL) (FCTD) at paragraph 13, a statement of claim should not be struck out:

> [S]o long as a cause of action, however tenuous, can be gleaned from a perusal of the statement of claim. The onus, on the party moving to strike, is heavy and it must be shown that it beyond doubt that the case cannot possibly succeed at trial.

[12] The Supreme Court of Canada in *Hunt v. T & N pl*c, [1990] 2 SCR 959, 74 DLR (4th) 321 articulated the test to be applied before a pleading is struck. At paragraph 33, Madam Justice Wilson stated:

> As in England, if there is a chance that the plaintiff might succeed, then the plaintiff should not be "driven from the judgment seat". Neither the length and complexity of the issues, the novelty of the

> cause of action, nor the potential for the defendant to present a strong defence should present the plaintiff from proceeding with his or her case.

[13] In general terms, it appears to me that a statement of claim for an infringement of a patent right should clearly show:

- the facts by virtue of which the law recognizes a defined right as belonging to the plaintiff, and

- the facts that constitute an encroachment by the defendant on that defined right of the plaintiff

IV. Application of the Principles

[14] In the case at bar, I accept that the Statement of Claim shows the facts by virtue of which the law recognizes a defined right as belonging to the Plaintiffs. However, the question in this case is whether the Statement of Claim sets out the facts that constitute an encroachment by the defendant on that defined right of the plaintiff. I will review the Statement of Claim and the material facts pleaded.

[15] In summary form, the Plaintiffs submit that their Statement of Claim clearly pleads that Nu-Pharm's actions in submitting an abbreviated new drug submission (ANDS) pursuant to the applicable provisions of the *Food and Drug Regulations*, CRC 1978, c 870 [the *Food and Drug Regulations*], and the publication of a Notice of Compliance (NOC) and Drug Identification

Number (DIN) constitute infringement of the '113 Patent and thus the pleadings are sufficient to permit the action to proceed. They also rely on the results of their cross-examination of Mr. Richard Benyak, President of Nu-Pharm, to argue that the actions of Nu-Pharm (or an unidentified third party) do or will extend beyond the bounds of obtaining an NOC.

[16] In their Statement of Claim, the Plaintiffs include the following claims:

> 19. The defendant has, without consent of the Plaintiffs, purchased, made, or had made for it either in Canada or abroad, constructed or had constructed for it either in Canada or abroad, imported or had imported for it into Canada, sold or exported from Canada for sale abroad, used in Canada and intends to make, construct, use and sell to other to be used, the compound olanzapine. More particularly, Nu-Pharm has done and intends to do each of the following in relation to the compound olanzapine:
>
> (a) Manufacture the compound;
>
> (b) Have the compound manufactured for it;
>
> (c) Purchase and import the compound into Canada;
>
> (d) Formulate tablets containing the compound;
>
> (e) Have formulated tablets containing the compound;
>
> (f) Sell and distribute and arrange for the distribution of tablets containing the compound in Canada; and
>
> (g) Export from Canada tablets containing the compound.
>
> 21. In particular, the defendant has developed a generic version of olanzapine, and has filed an abbreviated new drug submission ("ANDS") with the Minister of Health to enable it to sell its version of olanzapine. Nu-Pharm intends to sell its version under the brand name Nu-olanzapine and in its ANDS has compared its olanzapine products with at least Lilly Canada's ZYPREXA and ZYPREXA ZYDIS olanzapine. In this regard, Nu-Pharm has imported, manufactured, or had manufactured for it bulk olanzapine; has formulated or had formulated for it this bulk

> material into finished dosage form; has packaged the finished dosage form to be ready to sell, has stockpiled bulk and/or finished dosage form of olanzapine to sell, and has offered for sale and sold olanzapine in finished dosage form.

[17] In her decision, Prothonotary Milczynski provided the following reasons for striking the Statement of Claim:

> The Plaintiffs state that they are not aware of the "full extent" of Nu-Pharm's allegedly infringing activities. However, as the Statement of Claim clearly indicates, the Plaintiffs are unaware to any extent of the Defendant's alleged infringing activities. The allegations are bare assertions without foundation or material facts. The Plaintiffs conceded at the hearing of this motion that the fact of obtaining a Notice of Compliance under the Patented Medicines (Notice of Compliance) Regulations is not pleaded to, in and of itself, constitute an infringement of the 113 Patent. As the evidence filed on this motion through the affidavit of Richard Benyak shows, since receiving the NOC, Nu-Pharm has not manufactured olanzapine or had olanzapine manufactured for it, purchased or imported olanzapine or had olanzapine imported for [it], formulated olanzapine or had olanzapine formulated for it, packaged, stockpiled, or exported olanzapine, offered it for sale or distributed or arranged for its distribution.

[18] Pivotal in the reasoning of Prothonotary Milczynski was the case of *AstraZeneca Canada Inc. v Novopharm Ltd.*, 2009 FC 1209, 80 CPR (4th) 397 [*AstraZeneca FC*], aff'd 2010 FCA 112, 83 CPR (4th) 241 [*AstraZeneca FCA*]. In her reasons, Prothonotary Milczynski stated:

> As the Court noted in *AstraZeneca Canada Inc.* v. *Novopharm Ltd.* (2009), 80 CPR (4th) 397 , aff'd (2010), 83 CPR (4th) 241, where a plaintiff can present no rational argument based on evidence or the law in support of the claim, the action is an abuse. An action is not a fishing expedition. The Plaintiffs are not entitled to use bald pleas to force production, discovery and attempt to "bootstrap" their case. As submitted by Nu-Pharm, an action cannot be brought on assumptions and speculation in the hopes that something will turn up.

[19] The facts of *AstraZeneca FC* bear similarity to those before me. In that case, the Statement of Claim alleged that the defendant was currently infringing the plaintiffs' patent by making or having made for it commercial quantities of the infringing product (current infringement), and would infringe the patent upon successfully resisting the plaintiffs' pending prohibition application and obtaining an NOC for its novo-rosuvastatin tablets (*quia timet* or future infringement). The motions judge, Justice Roger Hughes, concluded that the claim of current infringement was an abuse of process as it was based on bald allegations made without any evidentiary foundation. With respect to the future infringement, Justice Hughes found that the allegations were speculative in nature and lacked the degree of certainty required to support a *quia timet* action.

[20] The Court of Appeal upheld the decision of Justice Hughes. Before the Court of Appeal, the plaintiffs argued that the Notice of Allegation (NOA) served by the defendant constituted, in and of itself, an act of infringement and that this fact alone is sufficient to ground an action for infringement. In response to this argument, the Court of Appeal (*AstraZeneca FCA*, above, at paragraphs 8-9) stated as follows:

> The appellants' final contention — i.e., that the NOA is in itself an act of infringement and that as this point has yet to be judicially considered, the claim cannot be said to be bereft of any chance of success — is not addressed by the Federal Court Judge. The respondent maintains that this is because the argument was not put to the Federal Court Judge and urges us not to deal with this argument on that ground.The fact that the argument was not addressed by the Federal Court Judge does suggest that it was not made or insisted upon by the appellants. In any event, <u>what the appellants seek to raise is a novel act of infringement which would have to be specifically pleaded</u> before it can be addressed. No such allegation is made in the Statement of Claim.
>
> [Emphasis added.]

[21] Following the remarks of the Court of Appeal, it appears that a specific pleading that the ANDS, the NOC and DIN constitute acts of infringement may be a sufficient basis for allowing the action to proceed. Before me, the Plaintiffs submit that they have specifically pleaded this "act of infringement" in paragraph 21 of their Statement of Claim. I do not agree.

[22] I accept that there are notable factual differences between the case before me and that before the Courts in *AstraZeneca FC*, above:

- In *AstraZeneca FC*, the plaintiffs had been requested and had refused to provide particulars. In this case, no such request has been made.

- In *AstraZeneca* FC, no NOC had been issued. In this case, an NOC has been issued, indicating that a number of activities must have taken place, as required under the applicable provisions of the Food and Drug Regulations.

[23] Nevertheless, the statements of principle in both *AstraZeneca FC* and *AstraZeneca FCA* are, in my view, equally applicable to this appeal. In particular, while the Statement of Claim before me is lengthier and more detailed than that examined by Justice Hughes and the Court of Appeal in *AstraZeneca*, it suffers from the same problems.

[24] The Plaintiffs argue, before me, that the Statement of Claim clearly discloses that the alleged "act of infringement" is the preparation of the ANDS and the acquisition of an NOC. The first point to make is that, in my view, and in spite of the capable written and oral submissions by

the Plaintiffs, the Statement of Claim is not as clear as the Plaintiffs would have me believe. Before the Prothonotary, the Plaintiffs conceded the fact that obtaining an NOC was not pleaded. The Plaintiffs now argue the opposite. While this is a *de novo* appeal, it seems to me that the Plaintiffs ought not to be able to resile from admissions made to the Prothonotary. At the very least, the change of position demonstrates the problem with the Statement of Claim as drafted. If the pleadings are not clear to two lawyers working for the same client and the same law firm, how can they be said to be satisfactory to defend against a motion to strike?

[25] In any event, even if I accept the arguments that paragraphs 19-21 of the Statement of Claim plead that the preparation of the ANDS and the obtaining of the NOC are acts of infringement, I am not persuaded of the merits of continuing the action.

[26] Section 55.2(1) of the *Patent Act*, RSC 1985, c P-4 [the *Patent Act*] provides a specific exemption from infringement for the making, constructing, using or selling of a patented invention solely for the purposes reasonably related to the development and submission of information required for regulatory purposes. The Statement of Claim does not address whether the allegations are directed to activity covered by s. 55.2(1) or to other activity and, if so, what that other activity is.

[27] The Plaintiffs argue that Mr. Benyak has acknowledged, in cross-examination on his affidavit, that the Defendant obtained its NOC with the goal of selling into government markets and selling its products on tender and on contract. Thus, the Plaintiffs argue, the activities

engaged in by Nu-Pharm were not “solely” for purposes covered by the s. 55.2(1) exemption. I do not agree.

[28] In the Statement of Claim before me, there is absolutely nothing pleaded that is not part of the regulatory requirements for the preparation and filing of an ANDS. Without something pleaded beyond the regulatory requirements, s. 52.2(1) of the *Patent Act* applies. Moreover, we have the clear, sworn statements of Mr. Benyak that Nu-Pharm has not done (or caused to be done) anything other than meet the requirements of the applicable regulatory scheme. The attempts of the Plaintiffs to characterize the actions of Nu-Pharm (or an unidentified third party) as something beyond meeting regulatory requirements are speculative, at best.

[29] Nor do I believe that, on the facts of this case, it is necessary for Nu-Pharm to put forward s. 55.2(1) as a defence in a properly-filed Statement of Defence. The Plaintiffs raise the decision of this Court in *Laboratoires Servier v Apotex Inc.*, 2008 FC 825, 67 CPR (4th) 241 at paragraphs 163-168 [*Servier*], aff’d 2009 FCA 222, 75 CPR (4th) 443 as authority for the proposition that a careful examination of facts related to the question of experimental use must be made; this, the Plaintiffs assert, requires the Defendant to file a Statement of Defence specifically pleading the facts related to the exemption. The situation in *Servier* was much different. In that case, the acts of infringement were clearly and explicitly pleaded. The Court only turned to the possible exemptions after it had already concluded that there had been infringement of a valid patent. The exercise referred to in the cited passage only took place once the claim of infringement had been proven. There is no such case before me. The requirement for

"meticulous evidence" (*Servier*, above, at para. 164) does not arise where the Statement of Claim does not on its face disclose an act of infringement.

[30] In the face of the pleadings before me and s. 55.2(1) of the *Patent Act*, the Statement of Claim discloses no reasonable cause of action.

[31] Aside from the alleged claim that Nu-Pharm's actions in obtaining its NOC and DIN for nu-olanzapine constitute infringement, the pleadings disclose nothing beyond an assertion that Nu-Pharm is positioning itself, through an unnamed third party, to enter the market for olanzapine and, that by doing so, Nu-Pharm will infringe the patent. Quite simply, the Plaintiffs claim that Nu-Pharm's business arrangements may yield the basis for an allegation of infringement once the '113 Patent has expired. In other words, contrary to the submissions of the Plaintiffs, the Statement of Claim is, at least in part, very much a *quia timet* proceeding to which the findings of Justice Hughes and the Court of Appeal in *AstraZeneca FCA* are applicable. The Plaintiffs' allegations that Nu-Pharm has done something that actually infringes the '113 Patent, or that may permit it to "springboard" to an act of infringement once the patent has expired, are bare assertions without foundation or material facts.

V. Conclusion

[32] In sum, having considered the matter *de novo*, I agree with the conclusion of Prothonotary Milcynzski; the Statement of Claim should be struck. Should the Plaintiffs find

further and better support for their speculations, they are free to bring a new action for infringement with pleadings that meet the acceptable standards.

[33] Costs awarded in the hearing of this motion before Prothonotary Milczynski are affirmed. Costs of this motion are fixed at $2500.

ORDER

THIS COURT ORDERS that:

1. the motion in appeal of the decision of Prothonotary Milczynski is dismissed; and

2. costs in the amount of $2500 are awarded to the Defendant.

"Judith A. Snider"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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