F ederal Court		Cour fédérale

Date: 20091124

Docket: T-1563-09

Citation: 2009 FC 1209

Toronto, Ontario, November 24, 2009

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

ASTRAZENECA CANADA INC.,
IPR PHARMACEUTICALS, INC.,
ASTRAZENECA UK LIMITED and
SHIONOGI SEIYAKU KABUSHIKI KAISHA

Plaintiffs

and

NOVOPHARM LIMITED

Defendant

REASONS FOR ORDER AND ORDER

[1] The Defendant, Novopharm, has brought a motion to strike out the Statement of Claim and dismiss this action. For the reasons that follow, I am allowing the motion with costs to Novopharm.

[2] This action is brought by the Plaintiffs AstraZeneca et. al. by a Statement of Claim filed September 18, 2009, in which it is alleged that the Plaintiffs comprise the owner of Canadian Patent 2,072,945 (the '945 Patent) and those having rights under that patent. It is alleged, as summarized in paragraph 35 of the Statement of Claim, that the Defendant Novopharm has and will continue to infringe certain claims of the '945 Patent. Relief by way of a declaration of infringement, an injunction, delivery up, damages or profits, costs, interest and other relief is claimed.

[3] The portion of the Statement of Claim dealing with the allegations of infringement is set out at paragraphs 24 to 35 of the Statement of Claim as follows:

> *24. Novopharm has made or had made for it and imported or had imported for it, rosuvastatin, rosuvastatin calcium and pharmaceutical compositions containing rosuvastatin calcium together with a pharmaceutically acceptable carrier. The pharmaceutical compositions are useful as HMG-CoA reductase inhibitors and for treating hypercholesterolemia, hyperlipoproteinemia and atherosclerosis.*
>
> *25. Novopharm filed an Abbreviated New Drug Submission ("ANDS") on August 29, 2008 with Health Canada for a Notice of Compliance ("NOC") for rosuvastatin calcium tablets and had compared its tablets to AstraZeneca Canada's CRESTOR tablets.*
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> *26. NOVO-ROSUVASTATIN is Novopharm's brand name for its rosuvastatin calcium tablets.*
>
> *27. Novopharm has made or had made for it and imported or had imported for it, rosuvastatin, rosuvastatin calcium and NOVO-ROSUVASTATIN for commercial use.*
>
> *28. NOVO-ROSUVASTATIN will be sold by Novopharm and used as an HMG-CoA reductase inhibitor and for treating hypercholesterolemia, hyperlipoproteinemia and atherosclerosis.*
>
> *29. In September 2008, Novopharm served AstraZeneca Canada with a Notice of Allegation ("NOA") pursuant to section 5(1) of the Patented Medicines (Notice of Compliance) Regulations*

> *("Regulations") regarding the active pharmaceutical substance rosuvastatin calcium and the '945 patent.*
>
> *30. On October 23, 2008, in response to the Novopharm NOA, AstraZeneca Canada commenced an application under the Regulations seeking an order prohibiting the Minister of Health from issuing an NOC to Novopharm until the expiry of the '945 patent (Court File No. T-1636-08).*
>
> *31. Novopharm requested a December 2009 or earliest subsequent hearing date in order to advance the issuance of an NOC for and its sale of NOVO-ROSUVASTATIN tablets. A hearing on the merits is anticipated in March 2010 and a decision is expected shortly thereafter.*
>
> *32. Novopharm will market and sell its NOVO-ROSUVASTATIN tablets in Canada immediately upon the issuance of an NOC.*
>
> *33. Novopharm has a policy of seeking to be an early entrant in the generic market in Canada for patented pharmaceutical products, including CRESTOR.*
>
> *34. The aforementioned activities of Novopharm have been and will be without the consents of any of the Plaintiffs.*
>
> *35. By reason of the above activities, Novopharm has and will continue to infringe claims 1-3, 5-6, 9, and 15-16 of the '945 patent.*

[4] Novopharm requested particulars of these pleadings. AstraZeneca refused. No defence has been filed. Instead Novopharm has moved to strike.

[5] The Defendant Novopharm moves to strike the Statement of Claim on various grounds:

1. It is an abuse of process;

2. It is a fishing expedition;

3. It fails to plead material facts;

4. It fails to satisfy the criteria for pleading a *quia timet* action:

- deliberate expressed intention to engage in activity the result of which would raise a strong possibility of infringement;

- the activity must be imminent;

- the resulting damage must be very substantial; and

- the facts pleaded must be cogent, precise and material.

[6] The Plaintiffs AstraZeneca argue that the pleadings are sufficient. Further, they argue, there is a new climate emerging wherein a more pragmatic and efficient approach is to be taken by the Court and litigants in situations such as these where there are parallel NOC proceedings underway at the same time as an action for infringement of the same patent is taken.

[7] I fully agree with counsel for AstraZeneca that the NOC procedure requires revision. In many ways such proceedings have become too complex, they lack the features of an ordinary action such as discovery, live witnesses and the result fails to become binding as *res judicata*. Several efforts have been made to suggest changes for improvement. These efforts should be ongoing with the encouragement of the Court. That encouragement, however, cannot extend to reversing established jurisprudence or making rulings that are, in effect, legislative changes.

[8] The allegations made in the Statement of Claim as to infringement essentially are:

- Novopharm has made or had made for it or imported a medicine “for commercial use”;

- Novopharm, has filed an Abbreviated New Drug Submission (ANDS) with Health Canada and seeks a Notice of Compliance (NOC) which will permit it to sell the medicine in Canada.

- AstraZeneca has commenced proceedings in this Court to prohibit Novopharm from receiving an NOC, which will be heard in March 2010; and

- If Novopharm succeeds in the NOC proceedings it will market the medicine in Canada thus infringing the patent.

[9] AstraZeneca argues that this action should be heard within two years and invites Novopharm to consent to an interlocutory injunction subject to the usual undertakings from AstraZeneca. Novopharm replies that it should not be twice vexed in dealing with both this action and the NOC proceeding, nor should it be bullied into accepting an injunction even subject to undertaking.

STRIKING OUT PLEADINGS

A. *Failing to Plead a Cause of Action*

[10] Rule 221(1)(a) of this Court permits a Statement of Claim to be struck out where it fails to disclose a reasonable cause of action. In this regard, no evidence outside the pleading may be considered and, usually, that which is pleaded is to be accepted as true and provable in evidence at the appropriate time. However, pleadings that are based on assumptions and speculation and those that are incapable of proof cannot be taken as true.

[11] In this regard, the Supreme Court of Canada, Wilson J. for the Court, wrote at paragraphs 30 and 31 of *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959:

> *While this Court has had a somewhat limited opportunity to consider how the rules regarding the striking out of a statement of claim are to be applied, it has nonetheless consistently upheld the "plain and obvious" test. Justice Estey, speaking for the Court in Attorney General of Canada v. Inuit Tapirisat of Canada, [1980] 2 S.C.R. 735, stated at p. 740:*
>
> > *As I have said, all the facts pleaded in the statement of claim must be deemed to have been proven. On a motion such as this a court should, of course, dismiss the action or strike out any claim made by the plaintiff only in plain and obvious cases and where the court is satisfied that "the case is beyond doubt": Ross v. Scottish Union and National Insurance Co.*
>
> *I had occasion to affirm this proposition in Operation Dismantle Inc. v. The Queen, [1985] 1 S.C.R. 441. At pages 486-87 I provided the following summary of the law in this area (with which the rest of the Court concurred):*
>
> > *The law then would appear to be clear. The facts pleaded are to be taken as proved. When so taken, the*

> *question is do they disclose a reasonable cause of action, i.e. a cause of action "with some chance of success" (Drummond-Jackson v. British Medical Association, [1970] 1 All E.R. 1094) or, as Le Dain J. put it in Dowson v. Government of Canada (1981), 37 N.R. 127 (F.C.A.), at p. 138, is it "plain and obvious that the action cannot succeed?"*

And at p. 477 I observed:

> *It would seem then that as a general principle the Courts will be hesitant to strike out a statement of claim as disclosing no reasonable cause of action. The fact that reaching a conclusion on this preliminary issue requires lengthy argument will not be determinative of the matter nor will the novelty of the cause of action militate against the plaintiffs. [Emphasis added.]*

[12] However, in *Operation Dismantle v. The Queen*, [1985] 1 S.C.R. 441, Dickson J. for the majority, wrote at page 455 of the reported decision:

> *(c)* *The Rule that Facts in a Statement of Claim Must be Taken as Proven*
>
> *We are not, in my opinion, required by the principle enunciated in Inuit Tapirisat, supra, to take as true the appellants' allegations concerning the possible consequences of the testing of the cruise missile. The rule that the material facts in a statement of claim must be taken as true for the purpose of determining whether it discloses a reasonable cause of action does not require that allegations based on assumptions and speculations be taken as true. The very nature of such an allegation is that it cannot be proven to be true by the adduction of evidence. It would, therefore, be improper to accept that such an allegation is true. No violence is done to the rule where allegations, incapable of proof, are not taken as proven.*

[13] There is no doubt that a competent solicitor can draft a Statement of Claim that has the appearance of setting out a cause of action. For instance, in a patent infringement action, there is no great difficulty in crafting a pleading such as the one at issue that says, in effect, the Plaintiffs own

and have rights in respect of a patent directed to a medicine, the Defendants possess such a medicine that they want to make use of and sell commercially if and when the NOC hurdles have been overcome.

[14] The flaw in such a pleading is first that it assumes that the NOC hurdles will be overcome, a surprising assumption coming from parties who, in the NOC proceedings, are attempting to prevent that very thing. The second is that the Defendant, if it overcomes the NOC hurdles, will immediately enter the Canadian marketplace with an infringing product. This is an assumption as to the state of mind and intentions of the Defendant.

[15] The Plaintiffs provide, in effect, two answers to such criticisms of their pleadings. First, they say that any question as to what the Defendant has done or intends to do can be explored on discovery whereupon a satisfactory case can thereafter be made out. Second, they say that the pleading is a *quia timet* pleading and a Plaintiff is entitled to anticipate what a Defendant will do and commence an action accordingly. Both these arguments can be addressed by considering whether the action, as pleaded, is an abuse of process.

B. *Abuse of Process – Fishing Expedition*

[16] Rule 221(1)(f) of this Court permits a Statement of Claim or other pleading to be struck out if it is an abuse of process.

[17] There are many decisions of this Court that state that an action cannot be brought on speculation in the hope that sufficient facts may be gleaned on discovery that will support the allegations made in the pleadings. Often this is referred to as a fishing expedition. I cite only one of them, which is exemplary of the others. Rothstein J (as he then was a Judge of this Court) wrote in *Merck & Co. Inc. v. Apotex Inc.* (1997), 72 C.P.R. (3d) 515 at page 516:

> *According to the submissions of counsel for the Plaintiffs, paragraphs 18, 19 and 20 of the Plaintiffs' pleading refer to the threat by Apotex of infringement approximately one year from now. The basis is that the Plaintiffs have written to Apotex asking if it will infringe in the future. Apotex has not responded. This is the basis of the threat which the Plaintiffs plead. The Plaintiffs have provided some further particulars by way of a letter but the letter adds nothing to what is already known.*
>
> *I think these paragraphs must be struck out for two reasons. First, the pleadings are only intended to enable the plaintiffs to get to discovery to bootstrap their claim; while discovery is for the purpose of obtaining admissions from the other party and ascertaining the position of the other party, it is not a fishing expedition simpliciter, which is what it would be used for here. Second, the threat, even if it could be substantiated, is approximately one year away according to Plaintiffs' counsel. At best, these paragraphs are premature. Paragraphs 18, 19 and 20 are struck out.*

[18] The pleadings in the Statement of Claim in the present action that the Defendant has acquired the medicine “for commercial use” and intends to sell it lacks any material facts to support the plea. Bald allegations such as these must be supported by material facts. It is not an answer to say that, given discovery, these facts can be ascertained. That is an abuse.

QUIA TIMIT

[19] An action taken on the basis of anticipation has been called a *quia timit* (because one fears) action. A thorough review of the jurisprudence in respect of such an action was undertaken by Gibson J. of this Court in *Connaught Laboratories Ltd. v. SmithKline Beecham Pharma Ltd.* (1998), 86 C.P.R. (3d) 36. Counsel for the parties in the present matter do not disagree with the summary of law which he presented at paragraph 20 of his Reasons:

> *From the foregoing authorities, I derive the following criteria for allegations that must be evident on the face of a statement of claim initiating a quia timet proceedings alleging patent infringement: the statement of claim must allege a deliberate expressed intention to engage in activity the result of which would raise a strong possibility of infringement; the activity to be engaged in must be alleged to be imminent and the resulting damage to the plaintiff must be alleged to be very substantial if not irreparable; and, finally, the facts pleaded must be cogent, precise and material. It is not sufficient that they be indefinite or speak only of intention or amount to mere speculation.*

[20] It is important to note the factual circumstances in *Connaught.* The Defendant had received, about two years previously, a Notice of Compliance to sell a drug in Canada and that related companies had been selling outside Canada for some period of time. Nonetheless, Gibson J. held that it was insufficient to speak only of intention or to plead something that amounted to mere speculation.

[21] In *Pfizer Research and Development Co. N.V./S.A. v. Lily ICOS LLC,* (2003) 27 C.P.R. (4th) 86, Heneghan J of this Court was presented with a situation where a drug company was seeking an NOC to sell a drug in Canada that was allegedly the subject of a patent owned by the Plaintiff. It was alleged by the Plaintiff that the company would act immediately upon receipt of the necessary

regulatory approval to import, make, distribute, promote and sell an allegedly infringing drug. The Defendant drug company moved to strike the action on the basis that it was speculative and premature. Heneghan J. agreed. She struck the action and wrote at paragraphs 24 and 25 of her Reasons:

> *In my opinion, the Plaintiffs have failed to plead sufficient facts in their Amended Statement of Claim to satisfy the necessary criteria for launching a quia timet action. The Defendants have brought an action relative to the validity of the Patent, court file number T-341-02. In that Statement of Claim, their intentions are expressly set out, as seeking regulatory approval for tadalafil in order to offer it for sale in Canada as an oral therapeutic agent for the treatment of male erectile dysfunction. However, the Plaintiffs have not satisfied me that action by the Defendants upon this deliberate, expressed intention is imminent.*
>
> *I make no finding as to whether this deliberate, expressed intention of the Defendants raises a strong possibility of infringement. The Plaintiffs have not demonstrated the temporal aspect of the criteria for commencing a quia timet action. Neither party has control over when, or if, the government will issue regulatory approval for its product. In my opinion, the Plaintiffs have not pleaded facts to support its allegation that the Defendants' allegedly infringing activities are imminent. This motion for an order striking out the Amended Statement of Claim in its entirety is granted as the Plaintiffs have failed to properly plead a quia timet action; it is plain and obvious that the pleading discloses no reasonable cause of action.*

[22] More recently, Prothonotary Aalto of this Court in *GlaxoSmithKline Biologicals S.A. v. Novartis Vaccines and Diagnostics, Inc.*, 2007 FC 833 was faced with an action brought by GlaxoSmithKline (GSK) to impeach a Novartis patent. GSK alleged in the Statement of Claim that it wished to sell in Canada a vaccine containing the same elements as described in the patent. Novartis defended the action and counterclaimed on the basis that GSK intended to sell its vaccine and will infringe. That defence and counterclaim was struck out as being speculative. Prothonotary Aalto wrote at paragraphs 14 to 16 of his Reasons:

> *As noted by Justice Reed in* Faulding (Canada) Inc. *v.* Pharmacia S.p.A. *(1998), 82 C.P.R. (3d) 435 at p. 439:*
>
> > *Claims for infringement that are premised on indefinite acts in the future are in the realm of speculation. As such they are premature and should be struck out. [citations omitted] Similarly, pleas founded on the "intention of a party to do certain acts are improper and will be struck [citations omitted]*
>
> *Novartis argues that the pleadings are sufficient to support a* quia timet *case of patent infringement and that the pleading complies with the test for a* quia timet *proceeding for patent infringement. They argue that there is no basis for GSK bringing this action now to declare the 507 Patent invalid as it expires in less than three years. They argue that the only possible conclusion is that GSK plans to sell the GSK Adjuvant imminently and well before the 507 Patent expires. This is an entirely speculative argument. There are no material facts pleaded of how imminent such activity of GSK is nor any other material fact other than mere possibility of infringing acts. None of the authorities cited by the Novartis assist their cause. Material facts may come to the attention of Novartis which may support a* quia timet *action for patent infringement. There are none presently pleaded.*
>
> *Further, the Counterclaim and paragraph 7 should not be used as a weapon to permit Novartis to get to discovery and "bootstrap their claim" and use the discovery process improperly as a fishing expedition (see Justice Rothstein's comments in* Merck & Co. *v.* Apotex Inc. *(1997), 72 C.P.R. (3d) 515 at p. 516).*

[23] There is no material difference between the pleadings in the three cases referred to above and the pleadings in the present Statement of Claim. There has been a bit of “wordsmithing” done to the present Statement of Claim, however, put into a realistic perspective, all that is said is that <u>if</u> Novopharm prevails in the NOC proceeding after trial or appeal it will <u>most probably</u> get an NOC

and then most likely commence to sell the patented drug in Canada. This pleading is not materially different from those that were struck out before by this Court.

[24] Therefore, the Statement of Claim will be struck out and the action dismissed but without prejudice to the Plaintiffs to file a new action should new, non-speculative, circumstances arise.

[25] I invited counsel to make submissions as to costs and their quantum. Both agreed that the prevailing party should get costs. Novopharm's counsel suggested $10,000.00. AstraZeneca's counsel suggested $4,000.00 to $5,000.00. Costs will be awarded to the prevailing party, Novopharm, fixed at the sum of $5,000.00, inclusive of all fees, disbursements and GST.

ORDER

For the Reasons given:

THIS COURT ORDERS that:

1. The Statement of Claim filed September 18,2009 herein is struck out;

2. This action is dismissed without prejudice to the Plaintiffs to file a new action when new, non-speculative circumstances arise; and

3. The Defendant is entitled to recover costs from the Plaintiffs fixed in the sum of $5,000.00, inclusive of all fees, disbursements and GST.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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