Federal Court  Cour fédérale

Date: 20110812

Dockets: T-2021-10

Citation: 2016 FC 18

Ottawa, Ontario, August 12, 2011

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

TEVA CANADA LIMITED

Plaintiff (Defendant by Counterclaim)

and

NOVARTIS AG

Defendant (Plaintiff by Counterclaim)

ORDER

UPON the motion of the Plaintiff, Teva Canada Limited ("Teva") for an order striking certain portions of the Defendant's Amended Statement of Defence and Counterclaim without leave to amend.

UPON CONSIDERING the parties' respective motion records and hearing the representations of counsel.

The various impugned paragraphs raise several distinct issues. Some paragraphs relate to more than one issue. Instead of examining the paragraphs individually or attempt to group the paragraphs according to the issues raised, I have found it more efficient to deal with each issue in turn.

Past or present infringement of the '203 Patent

The Counterclaim, in respect of the claim of past or present infringement of the '203 Patent, contains broad and un-particularized allegations that Teva "has, without the consent of the Plaintiffs, purchased, made and had made for it in Canada, constructed and had constructed for it in Canada; imported and had imported for it into Canada, used in Canada […] imatinib, imatinib mesylate and imatinib products." Such broad allegations, when not supported by other allegations of material facts, are improper and abusive as they are only intended to enable the plaintiffs to get to discovery to bootstrap their claim, as found in a long line of jurisprudence (see for example *Caterpillar Tractor Co. v. Babcock Allatt Ltd.* (1982), 67 C. P. R. (2d) 135, affirmed (1983), 72 C.P.R. (2d) 286 and *Astrazeneca Canada Inc. et al. v. Novopharm Limited* 2009 FC 1209 affirmed at 2010 FCA 2012;) The question here is whether the Defendant by Counterclaim, Novartis AG ("Novartis"), has otherwise pleaded sufficient material facts which, if proven, could support a cause of action.

The additional facts alleged in the Counterclaim are as follows: that Teva has personally, and through ratiopharm, filed ANDSs with Health Canada for its proposed imatinib products, that Teva has changed its Form Vs with Health Canada from a statement that it would await patent expiry to an allegation of invalidity or non-infringement of the '203 Patent, that a related company,

Teva Pharmaceutical Industries Ltd. has filed patent applications in Canada relating to imatinib, that Teva Pharmaceutical Industries Ltd. has filed a drug master file with the US FDA for imatinib products manufactured in Mexico and Italy, that Teva has indicated "that it has an imatinib product available and that it can come to market with it", and that a trial date is being considered in this matter in September 2012 or later, but prior to the expiration of the patent in April 2003. From these facts, Novartis concludes that Teva has or is importing into Canada infringing imatinib product in commercial quantities for stockpiling purposes in contemplation of its entry onto the market either so soon as it has successfully impeached the '203 Patent or immediately after its expiry. No additional facts were provided by Novartis in response to a request for particulars made by Teva.

Apart from the allegation that Teva has indicated that it had an imatinib product "available" to it and that it can come to market with it, with which I will deal below, the specific facts alleged in the Counterclaim are not materially different from those in *Astrazeneca, supra* and in *Eli Lilly Canada Inc. et al. v. Nu-Pharm Inc.* 2011 FC 255. In both cases, the only particular facts pleaded tended to show that the defendants, through filing applications for an NOC, obtaining an NOC or securing an early date for the determination of a prohibition proceeding, and taking various concrete steps to secure early entrance into the market in order to benefit from a "springboard" effect, were positioning themselves to enter the market imminently. In both cases, the plaintiffs had pleaded, on the basis of those facts, that the defendant was currently importing or stockpiling an infringing product. In both cases, Judges of this Court found that insufficient material facts had been pleaded to support a cause of action in past or current infringement. I cannot see that the additional allegations, in Novartis' pleading, that a related company has filed patent applications in Canada relating to the product or has filed a drug master file in the US naming specific suppliers in other

countries (notably, not Canada) makes a substantial difference to this type of allegations. Even if taken as true, these facts could not, of themselves, reasonably lead to a finding that Teva has in the past or is currently committing any infringing acts in Canada. As for Teva's statement, made by one of its representatives in the context of a cross-examination on affidavit, to the effect that Teva has product "available", it is also insufficient. Availability is not synonymous with actual possession; taken in context, the word "available" connotes more readily that the product can be obtained than that it is in actual possession. This is to be contrasted with the facts that were alleged in the case of *Allergan, Inc. et al. v. Apotex Inc. et al.*, unreported, Federal Court file T-1267-10, November 9, 2010, affirmed at 2011 FCA 134, where it was specifically alleged that Apotex had indicated in its filing with the US FDA that it had made and used the product in Canada and that Apotex had been issued a tentative approval to manufacture the product in Canada.

Novartis also argues that it has specifically pleaded that Teva has engaged in infringing activities, including those related to process development, improvements and optimization for commercial manufacture, scale up, production, production batch manufacture, retention of samples, etc. in the course of the preparation of its ANDS, and that these activities are infringing unless Teva alleges in defence and proves at trial that these activities related "solely" to exempt uses. As potential defenses are not to be considered on a motion to strike, Novartis argues that these allegations of infringement ought not to be struck. That specific argument was raised and dismissed by Madam Justice Snider in *Eli Lilly Canada Inc. v. Nu-Pharm, supra,* and I am bound, by the rules of *stare decisis,* to follow her determination.

Finally, Novartis argues that it has pleaded that the very act of the preparation of the ANDS constitutes an act of infringement, which the Federal Court of Appeal characterized in *Astrazeneca, supra*, as new point that had yet to be judicially considered. The Federal Court of Appeal in that case warned that this novel act of infringement would have to be specifically pleaded before it could be addressed. Here, while it is true that Novartis has alleged that Teva has filed an ANDS, it has not specifically pleaded that this constitutes, in and of itself, an act of infringement. Further, it seems to me that Justice Snider also dealt with that argument in *Eli Lilly Canada Inc. v. Nu-Pharm*, and rejected it.

I am therefore satisfied that those parts of the Counterclaim which claim for and plead past or present infringement of the '203 Patent ought to be struck.

<u>*Quia timet* injunction in respect of the '203 Patent</u>

Teva does not seek, in the principal action, a declaration that its product does not infringe the '203 Patent. Accordingly, the decision in *Apotex Inc. v. H Lundbeck A/S* 2010 FC 807 is not applicable here. Novartis does not contest that in the circumstances, therefore, the criteria for a valid *quia timet* proceeding, as set out in *Connaught Laboratories Ltd. v. SmithKline Beecham Pharma Inc.*, must be met.

I am satisfied that the Counterclaim alleges that Novartis would suffer very substantial and perhaps irreparable damage if the apprehended infringement were to take place. That criteria is clearly met.

I now turn to the requirement that the statement of claim allege a deliberate expressed intention to engage in an activity the result of which would raise a strong possibility of infringement.

With respect to all composition claims of the '203 Patent, the facts pleaded could not possibly lead to the conclusion that Teva intends to or would enter the market without having first secured an NOC. It is plain and obvious that in order to secure an NOC, Teva must first succeed in this impeachment action in respect of the composition claims. I note here that Novartis conceded at the hearing that it was not a possible outcome for Novartis to be unsuccessful in the companion prohibition proceeding against Teva if Teva's impeachment action were to fail. Thus, it is plain and obvious that Teva only intends to come to market if the composition claims of the '203 Patent are declared invalid, in which event there would not be any possibility of infringement of those claims. As also mentioned above, insufficient material facts have been alleged to support a finding that Teva is carrying out any infringing activities pending its receipt of an NOC. There is likewise no material facts alleged that would allow a finding that it would do so in the future.

The matter is different with respect to claim 44 of the '203 Patent. That claim is a process claim, and even though Teva is also seeking a declaration of invalidity with respect to that claim, it is not disputed that the companion prohibition proceeding does not include an allegation with respect to claim 44, and that Teva may receive an NOC even if the validity of that process claim is upheld. Accordingly, it is perfectly conceivable that Teva could, if it obtained and an NOC prior to the expiration of the '203 Patent, begin selling imatinib products infringing claim 44 of the '203 Patent. Does the Counterclaim allege a deliberate expressed intention to do so?

Contrary to Teva's argument, I am satisfied that it does so through cogent, precise and material facts. First, Teva itself admits, at paragraphs 16 to 18 of its Statement of Claim, that it is an interested party within the meaning of section 60 (1) of the *Patent Act* because it intends to market imatinib tablets in Canada and that in order to sell those tablets prior to the expiry of the '203 Patent it must either successfully impeach the relevant claims of that patent or succeed in an application under the *PM (NOC) Regulations*, both of which it is endeavouring to do. A clearer expression of intent would be difficult to conceive. If there were any doubts, the allegations in the Counterclaim to the effect that Teva had initially filed its ANDS expressing its intention to await patent expiry and recently changed its position to allege invalidity, that this action was instituted while the patent only had a few years left to run before expiration and that the trial in this matter is contemplated to be held even though the patent will have six months or less to run, and that Teva's representative has declared that Teva has a product available and can come to market with it, all corroborate that expressed intention. Although Teva argued that the exact timing of Teva coming to market remained subject to a corporate decision being taken, the allegations of an expressed intent, of an ability to begin possibly infringing activities, combined with the recent conduct of Teva, convey a sense of purpose and urgency speaking to much more than a mere possibility. In the circumstances, the allegations of the Counterclaim are more than sufficient to meet that criterion. Indeed, it seems that these allegations of expressed intent were precisely those that were found missing in *Connaught Laboratories*.

It is on the last criteria on of the *Connaught Laboratories* test that Novartis' allegations fail. Novartis does not allege that Teva's application for an NOC has been approved and/or is on "patent hold" awaiting simply the resolution of the prohibition proceedings or the expiration of the patent.

Teva therefore argues that the alleged imminence of the infringement is speculative, as it is contingent upon it obtaining an NOC from Health Canada.

That specific argument was found to be determining in *Pfizer Research and Development Co. N.V./S. A.. v. Lilly ICOS LLC*, (2003) 20 7C. P. R. (4th) 86:

> "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."

This decision was further cited and applied in *Astrazeneca Canada Inc. v. Novopharm Limited, supra*. I am bound to follow these precedents.

Infringement of the '470 Patent

The '470 Patent is a use patent. There is no allegation in the Counterclaim to the effect that Teva has sold or marketed or is currently selling or marketing its product in Canada, thereby infringing the '470 Patent. To the extent the Counterclaim could be read as alleging past or present infringement of that patent, it would be based on the same argument as discussed above, that the mere filing of in an ANDS constitutes infringement. The same determination therefore applies to this argument.

As regards future infringement, again, the fact that an NOC which would enable the sale of Teva's imatinib products – whether for an infringing or non-infringing use – has yet to be issued is fatal to the *quia timet* proceeding in respect of the '470 Patent. I need therefore not say more about these allegations.

Miscellaneous "Surplus" allegations

With the exception of paragraph 53 of the Amended Statement of Defence, which is plainly and obviously a specific response to a paragraph of the original Statement of Claim of Teva which has since been withdrawn, I have not been convinced that it is plain and obvious that the allegations cannot, under any circumstances, be relevant or support a reasonably arguable defence. Moreover, the impugned paragraphs, if not material, are no more than "surplus statements". As Teva has neither presented evidence nor a cogent argument that it would be prejudiced by these statements remaining in the Statement of Defence, the decision in *Apotex Inc. v. Glaxo Group Limited et al.*, 2001 FCT 1351 is applicable, and I decline to strike out these allegations.

IT IS ORDERED THAT:

1. The Plaintiff's motion is granted in part.

2. Paragraph 53, subparagraphs 114 (b) to (g), and paragraphs 116 to 142 of the Amended Statement of Defence and Counterclaim of the Defendant are hereby struck.

3. The Plaintiff shall serve and file, no later than 15 days from the date of this Order, and amended Reply and Defence to Counterclaim.

4. Costs of this motion are awarded in favour of the Plaintiff.

"Mireille Tabib"

Prothonotary