

CITATION: Actavis Pharma Company v. Alcon Canada Inc. et al., 2016 ONSC 7151
COURT FILE NO.: CV-15-542062
DATE: 2016-11-18

SUPERIOR COURT OF JUSTICE - ONTARIO

RE: Actavis Pharma Company

AND:

Alcon Canada Inc., Alcon Research, Ltd., and Kyowa Hakko Kirin Co., Ltd

BEFORE: The Honourable Madam Justice Jasmine Akbarali

COUNSEL: Nicholas Wong, for the Plaintiff

Benjamin Reingold, for the Defendants

HEARD: November 15, 2016.

ENDORSEMENT

Overview

[1] The defendants bring this motion under Rules 21.01(b) and 25.11 to strike portions of the plaintiff's statement of claim or, alternatively, for particulars under Rule 25.10. The parties to this litigation are pharmaceutical companies: on the one hand, a generic manufacturer, and on the other, originators. The claim seeks compensation for what the plaintiff generic manufacturer says are the damages it has suffered by reason of the defendants holding a patent that it claims is invalid.

[2] The patent at issue is Canadian Patent No. 2,195,094 (the "094 patent") which claims olopatadine solutions of varying concentrations, including an ophthalmic product - an eye drop - with a 0.1% olopatadine solution known by the brand name Patanol. The 094 patent is co-owned by the defendants Alcon Research, Ltd and Kyowa Hakko Kirin Co., Ltd. The defendant Alcon Canada Inc. markets, distributes and sells Patanol in Canada.

[3] The claim seeks relief pursuant to s. 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("PMNOC") promulgated under the *Patent Act*, R.S.C. 1985, c. P-4. Very simply described (but sufficient for these purposes), when a generic manufacturer seeks to bring a generic version of a drug to market, it must first obtain marketing authorization from Health Canada. Where the drug it seeks to copy is listed on the patent register, one option open to the generic manufacturer is to allege that the relevant patent is invalid. The originator can challenge the allegation of invalidity under s. 6 of the *PMNOC*, in what I refer to herein as a s. 6 proceeding. If the originator is unsuccessful in its s. 6 proceeding, the generic manufacturer can

commence a proceeding against the originator under s. 8 of the *PMNOC* to seek damages for its losses suffered due to the delay in taking its generic version of the drug to market by reason of the s. 6 proceeding. The plaintiff advances a s. 8 claim in this action.¹

[4] The claim also seeks relief under what has been called the *Statutes of Monopolies*, these consisting of *An Act concerning Monopolies, and Dispensation with penal laws, etc.*, R.S.O. 1897, c. 323 (the Ontario *Statute of Monopolies*) and *An Act concerning Monopolies and Dispensation with Penal Laws, and the Forfeitures thereof*, 1624, 21 Jac. I, c.3 (the UK *Statute of Monopolies*).²

Issues

[5] The issues before me can be described as follows:

1. Should the following portions of the statement of claim be struck:
 - a. the claims under the *Statutes of Monopolies* because an essential element of the claim is not present, in that no *in rem* declaration of invalidity of the 094 patent has been obtained, or even yet sought, by the plaintiff in the Federal Court which has exclusive jurisdiction to make such a declaration. In effect, the allegation is that the claims under the *Statutes of Monopolies* are premature;
 - b. the claims against the defendant Kyowa on the basis that it is not a first person under the *PMNOC* and does not exercise complete control over Alcon Canada, which is a first person under the *PMNOC*;
 - c. the “basket clause” claims, which seek “such further and other relief as this Honourable Court deems just” and “other losses, including those to which Actavis is entitled as a matter of equity, arising during the Relevant Period and which will be particularized as this matter proceeds to trial” on the basis that these claims are bald allegations and unsupported by assertions of fact capable of constituting a cause of action; and
 - d. the claim that the defendants undertook an “anti-competitive product switching campaign” on the basis that it is scandalous?

¹ Section 8 proceedings often proceed in the Federal Court. No argument was raised before me to suggest this court does not have concurrent jurisdiction to entertain a s. 8 proceeding.

² The UK *Statute of Monopolies* was before Dunphy J. in *Apotex Inc. v. Eli Lilly and Co.*, 2015 ONSC 5396, a motion to strike portions of a statement of claim raising similar issues to this case. Dunphy J. found that it was arguable that the UK *Statute of Monopolies* is a matter of property and civil rights and thus among the body of laws incorporated into Upper Canada in 1792 by the *Property and Civil Rights Act*, R.S.O. 1990 c. P. 29. He concluded it was not plain and obvious that the UK *Statute of Monopolies* is not in force in Ontario and other parts of Canada. See paras. 55-60. That particular issue is not raised before me; its final determination on the merits awaits another day.

2. Should particulars be ordered with respect to:
 - a. whether the plaintiff's claim under the *PMNOC* includes a trebling of damages;
 - b. whether the plaintiff pleads inconsistently with respect to the defendants' position about whether the defendants reached a settlement with another generic manufacturer, Apotex, in a separate proceeding under s. 6 of the *PMNOC* that was also related to the 094 patent;
 - c. how Kyowa exercised "complete control" over Alcon Canada Inc.;
 - d. the plaintiff's claim for damages due to lost competitive advantage;
 - e. the plaintiff's claims for damages related to lost sales of other products, lost profit due to increased promotional costs for other products, and lost business opportunities; and
 - f. the plaintiff's claims for damages due to loss of goodwill?

[6] Originally the motion also sought to strike the plaintiff's claim for damages consisting of unrecoverable legal expenses in relation to the proceeding brought under s. 6 of the *PMNOC*, the eventual result of which entitled the plaintiff to bring its claim herein to recover losses under s. 8 of the *PMNOC*. At the outset of the motion, counsel advised that the plaintiff has consented to striking that portion of its claim.

Analysis

Motion to Strike

[7] The test on a motion to strike under Rule 21.01(1) is not in dispute. A claim will only be struck if it is plain and obvious, assuming the facts pleaded to be true, that the pleading discloses no reasonable cause of action; that is, that it has no reasonable prospect of success: *Knight v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42 at para. 17. However, novel but arguable claims must be permitted to proceed to trial: *Imperial Tobacco, supra*, at para. 21.

[8] McLachlin C.J. described the underlying rationale of the rule:

[19] The power to strike out claims that have no reasonable prospect of success is a valuable housekeeping measure essential to effective and fair litigation. It unclutters the proceedings, weeding out the hopeless claims and ensuring that those that have some chance of success go on to trial.

[20] This promotes two goods — efficiency in the conduct of the litigation and correct results. Striking out claims that have no reasonable prospect of success promotes litigation efficiency, reducing time and cost. The litigants can focus on serious claims, without devoting days and sometimes weeks of evidence and argument to claims that are in any event hopeless. The same applies to judges and juries, whose attention is focused where it should be — on claims that have a reasonable chance of success. The efficiency gained by weeding out unmeritorious claims in turn contributes to better

justice. The more the evidence and arguments are trained on the real issues, the more likely it is that the trial process will successfully come to grips with the parties' respective positions on those issues and the merits of the case. (*Imperial Tobacco, supra*, at paras. 19-20)

[9] The defendants also rely on Rule 25.11 which allows a court to strike out all or part of a pleading on the ground that it is "scandalous, frivolous or vexatious". On a motion under Rule 25.11, I need not accept the facts pleaded as true, but am entitled to consider evidence.

[10] I have concluded that the claims under the *Statutes of Monopolies* and the "basket clause" claims must be struck. The s. 8 *PMNOC* claim against the defendant Kyowa and the claims about the "anti-competitive product switching campaign" should be allowed to proceed. I address each of these below.

Claims under the Statutes of Monopolies

[11] While there have been many cases in which plaintiff generic manufacturers have alleged violations under the *Statutes of Monopolies*, there has been no determination of such claims on their merits. Motions to strike claims under the *Statutes of Monopolies* have been unsuccessful, with courts taking the view that the claims are novel ones and should be allowed to proceed to trial.

[12] This case is different. Here, for the purposes of this motion, the defendants do not challenge the validity of a claim under the *Statutes of Monopolies*. However, they argue that the claim is premature.

[13] It is common ground between the parties that:

- an *in rem* declaration of invalidity is an essential element of a claim under the *Statutes of Monopolies*;
- pursuant to s. 60(1) of the *Patent Act* and s. 20(1)(b) of the *Federal Courts Act*, R.S.C. 1985 c F-7, the Federal Court has exclusive original jurisdiction to grant such a declaration of invalidity;
- there is currently no *in rem* declaration of invalidity respecting the 094 patent and no such declaration of invalidity has been pleaded. The plaintiff pleads only that the 094 patent was "improperly issued". The plaintiff undertook before me to commence an action in the Federal Court seeking an *in rem* declaration of invalidity but none has yet been commenced.

[14] I agree with the parties that an *in rem* declaration of invalidity is an essential element of a claim under the *Statutes of Monopolies*. In *Apotex Inc. v. Eli Lilly and Company*, 2015 ONSC 5396, at para. 44, Dunphy J described the "trigger" of a claim under the *Statutes of Monopolies*

as the originator “taking the voluntary step of procuring what is now proved to have been an unlawful monopoly by way of void letters patent and then putting that unlawful monopoly into use, exercise or execution in such a manner as to grieve or disquiet [the generic manufacturer]”.

[15] The importance of the *in rem* declaration of invalidity was also noted by the Federal Court of Appeal in *Apotex Inc. v. Warner Lambert Company LLC*, 2012 FCA 323. In that case, Apotex sought a declaration of invalidity in respect of a patent that had expired. The Federal Court of Appeal allowed the action to proceed despite the defendant’s argument that it was moot, finding that the declaration of the invalidity of the patent was a necessary condition to the success of the proceedings that Apotex intended to commence under the *Statutes of Monopolies*: see paras. 2-3.

[16] The plaintiff here argued that an *in rem* declaration of invalidity would mean the patent would be void *ab initio*, and as such, this claim could, in hindsight, have all its constituent elements. The plaintiff argues that the claims under the *Statutes of Monopolies* could be continued in tandem with an action in the Federal Court seeking the declaration.

[17] A statement of claim must disclose a presently existing, legally recognized claim against the defendant: *Gevaert v Arbuckle* (1998), 26 CPC 4th 207 (Ont Gen Div) at para. 18. At the moment, the most that can be said about the plaintiff’s claims under the *Statutes of Monopolies* is that they may arise if the declaration of invalidity is sought and granted. In argument, counsel for the defendants agreed that, if a declaration of invalidity is sought and granted by the Federal Court, any limitation period under the *Statutes of Monopolies* would begin to run at that time, and that no limitation period has yet begun to run. There is thus no prejudice to the plaintiff if its claims are struck.

[18] Of course, the s. 8 action will continue. Striking the claims under the *Statutes of Monopolies* thus runs the risk that, if the *Statutes of Monopolies* claims are brought again if a declaration of invalidity is granted by the Federal Court, there could be two proceedings in this court dealing with the same factual matters – this proceeding under s. 8 and another under the *Statutes of Monopolies*. Such a result raises the spectre of inconsistent findings. While I am troubled by this risk, I have concluded it is preferable to the risks of attempting to prosecute a novel action for damages when all the elements of the claim are not present. These risks include that the litigation will be expanded to encompass factual and legal issues, and in particular as they relate to damages under the *Statutes of Monopolies*, that may never need to be addressed if the declaration of invalidity is never granted. As such, there may be greater inefficiency in allowing the *Statutes of Monopolies* claims to proceed than in requiring them to be brought anew if and when the declaration of invalidity is granted.

[19] Accordingly, I strike paragraphs 1(b)-(d), 45-49 and 52 of the statement of claim. I do so based on Rule 21.01(b) because the claim does not plead that an *in rem* declaration of invalidity has been granted. Alternatively, if the plaintiff’s pleading that the patent was “improperly granted” were sufficient to plead to this element of the claim, I would have struck the claim under Rule 25.11, in reliance on the affidavit of the plaintiff’s representative to the effect that the plaintiff intends to bring an action in the Federal Court seeking a declaration that the 094 patent

is invalid, thus making clear that a key element of the cause of action - the *in rem* declaration of invalidity – is absent here.

The claims against Kyowa

[20] The defendants seek to strike the portions of the claim that allege that Kyowa was in “complete control” of Alcon Canada such that it is a first person for the purposes of the *PMNOC*. The defendants argue that the Alcon defendants are separate corporate entities from Kyowa, and that Kyowa does not control, and is not under common control with, the Alcon defendants. The defendants have filed an affidavit from senior legal counsel at Alcon Research, Ltd. to that effect. Because they rely on evidence to establish a lack of complete control by Kyowa, they rely on Rule 25.11 for this relief. In effect, they argue that the claim that Kyowa is a first person fails because the plaintiff cannot establish that Kyowa exercised “complete control” over Alcon Canada because the corporations are not in the same corporate family.

[21] I disagree that the claim that Kyowa is a first person for the purposes of the *PMNOC* is frivolous and vexatious. The question of who may be a first person under the *PMNOC* is not settled.

[22] In *Apotex Inc. v. Eli Lilly and Company and Eli Lilly Canada Inc.*, 2004 FCA 358 at para. 11-13, the Federal Court of Appeal suggested that the evidence that might emerge on discovery could reveal that the degree of control exercised by Lilly U.S. over Lilly Canada could be such as to make Lilly U.S. a first person. In that way, the Federal Court of Appeal allowed that a corporation could become a first person by exercising a degree of control over another corporation that was a first person.

[23] That decision was discussed recently by the Federal Court in *Teva Canada Limited v. Pfizer Canada Inc. et al*, 2014 FC 69. The Court concluded, at paras. 46-48, that the question in *Apotex* had been whether a first person could include a parent corporation who directed the submission of the patent list in the name of its subsidiary. However, the Federal Court found that *Apotex* left open the door for other considerations that are potentially relevant to determining whether each applicant for a prohibition order (i.e. an application under s. 6 of the *PMNOC* such as was brought here by the defendants) is also a first person.

[24] In *Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2010 FC 150 at para. 27, the prothonotary noted that whether a first person under the *PMNOC* can include persons other than the person who filed the New Drug Submission and patent list had not yet been fully canvassed at trial and had yet to be finally determined. She declined to strike Novopharm’s pleading that Sanofi-Germany was a first person. She struck Novopharm’s pleading that Schering Corporation was a first person because the allegations against Schering failed to meet the requirement of pleading sufficient material facts that would enable a court to find Sanofi Canada was an agent, acting as a nominal first person, directed and controlled by Schering.

[25] The law as to who can be a first person is thus unsettled. However, where allegations of complete control of a first person have been levied against a party who is also pleaded to be a first person, the claims have been allowed to proceed. Neither party here could point me to a case

that dealt squarely with an alleged controlling first person from a different corporate family. As I have already noted, the *Sanofi-Aventis* case is closest to the point but the pleading against Schering was deficient.

[26] At its essence the question is whether “control” for the purposes of being a first person under s. 8 of the *PMNOC* can only mean “control” in the traditional sense of corporate structure, or whether “control” can have a broader meaning in this context. In other words, if a corporation controls a corporation that is a first person by reason of something other than their corporate structures, is it frivolous to plead that the controlling corporation is also a first person?

[27] In its pleading, the plaintiff has alleged that Kyowa exercised complete control over Alcon Canada in that it controlled a number of matters relating to the marketing and sale of drug products, the listing of products on the patent list, and the proceedings that are or may be taken under the *PMNOC*. The allegations made by the plaintiff are strikingly similar to those made in *Apotex Inc. v Eli Lilly and Company and Eli Lilly Canada Inc.*: 2004 FCA 358 at para 9. Lilly U.S.’s motion for summary judgment was dismissed and the allegations against it allowed to proceed. While there, the allegations of control were made against a related company, there is nothing before me to suggest that complete control as pleaded can only occur when companies are related.

[28] Certainly where corporations are related, complete control may be easier to make out, but this is not a trial on the merits. I am not prepared to find, at this early stage, in the face of the pleading that Kyowa exerted complete control over Alcon Canada in respect of matters relevant to the *PMNOC*, that it is frivolous to claim that Kyowa is also a first person.

[29] The defendants indicated they were also moving on this ground in reliance on s. 21.01(1)(b). I would also dismiss the motion to strike Kyowa under this rule. It is not plain and obvious that the claim could not succeed.

The “Basket Clauses”

[30] The plaintiff’s claim seeks relief including “such further and other relief as this Honourable Court deems just”. It also pleads that its damages suffered include “other losses, including those to which Actavis is entitled as a matter of equity, arising during the Relevant Period and which will be particularized as this matter proceeds to trial”.

[31] The defendants attack the pleading on the basis that the claims are unsupported by assertions of fact capable of constituting a cause of action. They rely on *Apotex Inc. v Eli Lilly and Company*, 2012 ONSC 3808 at para. 53 and *Apotex Inc. v Schering Corporation*, 2016 ONSC 3407 at para 8, where similar “basket clauses” have been struck. The plaintiff resists on the basis that the *Courts of Justice Act* gives the court broad discretion to craft a remedy that is appropriate when determining the relief to which a party is entitled in equity. The plaintiff also argues that s. 8(5) of the *PMNOC* allows the court to consider matters of equity. Section 8(5) provides that, when assessing the amount of compensation to be awarded, the court “shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application

under subsection 6(1)". The plaintiff agrees that the "basket clauses" rise and fall together on this motion.

[32] The plaintiff's claim does not make out a claim for equitable relief. There is no need to look to equity when s. 8(5) of the *PMNOC* allows the court to consider any matter relevant to the assessment of damages.

[33] I can find no facts that support the "basket clause" claims pleaded and counsel could not point me to any. Accordingly, pursuant to Rule 21.01(1)(b) I order paragraphs 1(g) and 42(h) struck from the claim.

The "anti-competitive product switching campaign" claim

[34] The defendants seek to strike from the pleading the plaintiff's claims that they undertook an "anti-competitive product switching campaign". In effect, the allegation in the pleading is that the defendants undertook a campaign to direct prescriptions for Patanol towards an alternate product, Pataday, which campaign dried up the market for Patanol and any generic copy thereof. The defendants say this pleading accuses them of criminal behaviour. They argue it is a scandalous pleading, intended only for colour, and it ought to be struck under Rule 25.11(b).

[35] I disagree. The claim is a serious one but it is capable of proof and is potentially a matter a court could consider to be relevant to the assessment of the amount of damages under s. 8(5) of the *PMNOC*. I decline to strike this portion of the claim.

Motion for Particulars

[36] In the alternative to their motion to strike, the defendants seek particulars in respect of certain paragraphs of the plaintiff's statement of claim pursuant to rule 25.10. Particulars may be ordered if they are not within the knowledge of the party demanding them and if they are necessary to enable that party to plead: *Mezin v. HMQ*, 2016 ONSC 5171 at paras. 37-38. Typically, a motion for particulars requires an affidavit from a directly-involved representative of the party setting out in some detail the information required, the fact that it is not in their knowledge, and how it is required to enable the party to plead: *Sears Canada Inc. v. Pi Media Ltd.*, 2011 ONSC 2625 at para. 37.

[37] Here, the defendants have filed an affidavit from senior legal counsel at Alcon Research, Inc. which identifies paragraphs in the claim about which he says the defendants require particulars and which particulars are not within the defendants' knowledge. The affidavit does not provide information with respect to how the information sought is required to enable the defendants to plead.

[38] I will address each part of the claim for which particulars are sought.

Treble Damages

[39] The defendants argue that they require particulars as to whether paras. 1(a) and 49 of the claim together mean that the plaintiff is seeking treble damages in its claim under the *PMNOC*. Earlier in this decision, I have ordered that para. 49 be struck. In any event, I see no confusion or inconsistency in the plaintiff's claim. It is clear that the plaintiff was seeking treble damages in relation to its now-struck claims under the *Statutes of Monopolies*, not under the *PMNOC*. No particulars are ordered with respect to para. 1(a). They are not necessary to plead over.

The "Settlement" with Apotex

[40] The defendants argue that paras. 24 and 26 of the plaintiff's claim are inconsistent. They say that the plaintiff claims in para. 24 that the defendants were aware that there was no settlement with Apotex, and in para. 26 that the defendants took the position that a settlement had been reached with Apotex. There is no confusion in these paragraphs, which clearly speak to different points in time and the alleged discord between what the plaintiff pleads the defendants believed and what the defendants did in relation to the settlement of the s. 6 proceeding with Apotex. No particulars are necessary to plead over.

"Complete Control"

[41] The defendants argue they require particulars about how Kyowa exercised "complete control" over Alcon Canada as pleaded in paras. 35, 50 and 51. As I have already noted, the plaintiff has pleaded with some specificity the complete control which Kyowa is alleged to have exercised over Alcon Canada in para. 35(a) to (e) of its claim. No particulars are necessary to plead over.

Lost competitive advantage

[42] The defendants seek particulars of the plaintiff's claim in para. 39 that, had it been able to market its generic version of Patanol earlier, it would have secured a competitive advantage, resulting in an overall increase in sales, market share, profit and would have increased the value of its business. No particulars are necessary to plead over.

Lost profits, lost business opportunities

[43] The defendants seek particulars with respect to paras. 42(b) – (e) of the claim. These paragraphs allege that the plaintiff suffered losses including lost sales of other Actavis products that would have been bundled with the generic version of Patanol that Actavis would have brought to market; lost profits as a result of the need for increased promotional costs for other Actavis products; lost sales of other Actavis products that would have flowed from the increased market profile Actavis would have enjoyed; and lost business opportunities that would have been available if Actavis had access to revenues arising from the sale of its generic version of Patanol.

[44] In support of their request, the defendants rely on a decision of the Federal Court in *Eli Lilly Canada Inc. v. Novopharm Limited*, 2013 FC 677, where, after a bifurcated trial in a proceeding brought under s. 8 of the *PMNOC* determined liability, in the context of preparing to try damages, Novopharm sought to amend its claim to seek compensation for losses it suffered

relating to other products. The amendments were not allowed because they lacked particulars as to the other products in relation to which the losses were claimed.

[45] Particulars with respect to the other products with respect to which losses are claimed here should be provided. The information the defendants seek is not within their knowledge. To plead meaningfully to the allegations, they require particulars. With respect to what other products does the plaintiff claim it lost sales and profits?

[46] Similarly, the lost business opportunities that the plaintiff alleges are outside the defendants' knowledge and to plead meaningfully in response, the defendants are entitled to know what opportunities the plaintiff claims to have lost.

Lost Goodwill

[47] The defendants seek particulars of the plaintiff's claim in para. 42(f) that it suffered a loss of goodwill that would have flowed from being earlier to the Canadian market with its generic version of Patanol. In particular, the defendants' affidavit indicates that the defendants seek to know to whom the goodwill would have accrued. There is only one plaintiff in this case and the claim is for that plaintiff's losses. I disagree that any particulars are necessary.

Conclusion

[48] I therefore direct that the following paragraphs in the statement of claim be struck: paras. 1(b), (c), (d) and (g), 42(g) and (h), 45, 46, 47, 48, 49, 52.

[49] The plaintiff shall provide particulars of the other products referred to in para. 42(b), (c) and (c) of its claim in respect of which it claims it suffered lost sales and lost profits.

[50] The plaintiff shall provide particulars of the lost business opportunities it alleges it suffered in para. 42(e) of its claim.

[51] In addition, I am directing a case conference to be convened forthwith pursuant to Rule 50.13 of the *Rules of Civil Procedure*. The issues at stake in this proceeding are important; this litigation needs to move forward to its resolution. In addition, the progress of this litigation may be complicated by the proceeding the plaintiff intends to bring in the Federal Court for an *in rem* declaration of invalidity with respect to the patent 094.

Costs

[52] The parties agreed before me that costs of no more than \$10,000 would be appropriate in this motion, and that if success was divided, I should reduce the amount as appropriate. In view of the result of this motion, I order no costs.

The Honourable Madam Justice Akbarali

Date: November 18, 2016