Federal Court  Cour fédérale

Date: 20130618

Docket: T-1048-07

Citation: 2013FC677

Ottawa, Ontario, June 18, 2013

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

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

Plaintiffs
(Defendants by Counterclaim)

and

NOVOPHARM LIMITED

Defendant
(Plaintiff by Counterclaim)

REASONS FOR ORDER AND ORDER

[1] By the present motion, the Defendant/Plaintiff by Counterclaim, Teva Canada Limited ("Teva") seeks to amend its Statement of Defence and Counterclaim after the first phase of this bifurcated action has been heard and determined in its favour, but before the start of discoveries on the second phase of the litigation.

[2] Teva also seeks a scheduling order that would see the trial of the second phase begin approximately 18 months following the determination of its motion.

[3] One of the (many) complicating factors on this motion is the fact that Teva, rather than proposing an amended pleading in which the amendments are underlined, as required by Rule 79(1), has submitted a "Fresh as Amended Statement of Defence and Counterclaim", in which some of what was already pleaded is entirely reworked and incorporated into what is newly pleaded, with additions, deletions and variations in the particular facts pleaded and vocabulary used sometimes difficult or impossible to identify with certainty. The stated purpose of the amendments does not render the task of identifying material changes any easier: Teva submits that its amendments "remove certain claims, particularize its section 8 claim, and add a *Trade-Marks Act* claim". As will be seen below, it is not always clear which is which, and in many instances, new paragraphs purporting to particularize the existing section 8 claim also inextricable entwine the particulars of the existing claim with the allegations supporting the proposed new claims. The Plaintiffs/Defendants by Counterclaim, Eli Lilly Canada Inc. ("Lilly Canada"), Eli Lilly and Company ("Lilly US"), Eli Lilly and Company Limited ("Lilly UK") and Eli Lilly SA ("Lilly SA"), (hereafter jointly referred to as "Lilly") also charge that in rewriting certain allegations, Teva is also impermissibly withdrawing certain admissions, and that rather than particularizing the section 8 claim, Teva's amendments improperly seek to widen and expand its claim and re-open the evidentiary phase of the first trial. To the extent the amendments do go to quantum, Lilly submits that they claim inadmissible losses and fail to plead those losses with sufficient particularity.

[4] Another complicating factor is the fact that although the bifurcation order issued in this matter contemplated that all issues of liability in Teva's section 8 claim would be heard and determined at a first trial, with only quantification issues remaining to be determined in a second trial or reference, the Trial Judge elected to defer the determination of some liability issues to the second trial. Thus, the question arises as to whether any amendments proposed by Teva that can be said to go to liability issues rather than to quantification issues should be viewed as amendments made after trial but before judgment, rather than amendments made before trial, and to what extent such a distinction should affect the Court's determination on this motion.

[5] As further discussed below, I find that any and all amendments going to liability issues, including the new *Trade-Marks Act* claims, should be considered as amendments made after trial and should, in the circumstances of this case, be refused. Further, because it is impossible for the Court to separate, in many of the proposed amendments, those parts that impermissibly go to liability issues and those that go to quantification issues, and because those amendments that could be allowed are insufficiently particularized, Teva's proposed pleading cannot be allowed as currently drafted.

Procedural History:

[6] Teva acquired and merged with Novopharm Limited in the course of the events set out below, continuing the litigation originally instituted by Novopharm Limited under its own name. For ease of understanding, only the name "Teva" will be used in this order, even when referring to actions taken in the name of or against Novopharm Limited, as it then was.

[7] In response to a Notice of Allegation from Teva dated August 5, 2004, Lilly Canada instituted a prohibition proceeding pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations* ("*PM(NOC) Regulations*") (SOR/93-133), seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance to Teva in respect of its generic olanzapine product until the expiration of Canadian Patent No. 2,014,113 (the '113 Patent) (Court file T-1734-04).

[8] In April 2005, Teva withdrew its Notice of Allegation, prompting Lilly to discontinue its Application. On July 20, 2005, Teva served Lilly Canada with a second Notice of Allegation concerning the same olanzapine product. Lilly responded by again instituting prohibition proceedings (Court file T-1532-05).

[9] In the course of a contested motion to dispose of the costs of the first discontinued application (T-1734-04), Teva acknowledged that by withdrawing its first Notice of Allegation and serving another, it had also abandoned its right to claim damages pursuant to section 8 of the *PM(NOC) Regulations* for the period covered by the first proceeding.

[10] The second prohibition proceeding (T-1532-05) was dismissed after a full hearing on June 5, 2007. Teva obtained its NOC for olanzapine the next day, on June 6, 2007 and began selling its product.

[11] The same day, Lilly commenced the present proceedings, seeking an injunction and a declaration that Teva's sale of olanzapine infringes the '113 Patent. Lilly also applied under a new

initiative of this Court to have its action case managed and set down for a trial within two years of its inception.

[12] Teva responded to Lilly's action by filing a counterclaim seeking both a declaration of invalidity of the '113 Patent, and damages pursuant to section 8 of the *PM(NOC) Regulations* for the period it was prevented from selling its olanzapine product by reason of Lilly Canada's prohibition proceedings in T-1532-05. Teva also resisted Lilly's efforts to obtain an early trial date.

[13] In September 2007, Lilly moved for a bifurcation order whereby the issues of quantum on both its infringement action and on Teva's section 8 claim would be severed from the issues of liability and subjected to discoveries and a second trial or reference only after liability had been determined by a first trial. Teva opposed Lilly's motion.

[14] By order dated September 25, 2007, I granted Lilly's motion. The relevant part of the formal disposition of the order reads as follows:

> "1. Pursuant to Rule 107 of the *Federal Courts Rules*, this matter is to proceed to trial without requiring the parties to adduce evidence at trial, or to conduct discoveries, or make production on any issue of fact where such evidence, discovery or production relates solely to:
>
> (a) The quantum of the loss that the Plaintiffs' are claiming in this action;
>
> (b) The quantum of the Defendant's profits which are being claimed by the Plaintiffs; and

> (c) The quantum of the Defendant's damage claim pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*.
>
> 2. A hearing under Rules 107 and / or 153 of the *Federal Courts Rules* shall be conducted following the trial herein, if it then appears that such issues are required to be decided, to determine the procedure to be followed for the determination of such issues, including necessary documentary and oral discovery. The question of whether such hearing (if any) shall be by way of further trial or reference, and the procedure to apply in respect of any such proceeding shall be determined by the trial judge."
>
> (Emphasis mine)

[15] The first phase of the trial was held in November and December 2008, and further hearings were held in the spring of 2009. By judgment issued October 5, 2009, the Trial Judge held that the relevant claims of the '113 Patent were invalid and thus dismissed Lilly's action and granted Teva's counterclaim.

[16] The formal judgment reads as follows (*Eli Lilly Canada Inc. v Novopharm Ltd.*, 2009 FC 1018):

> "1. The claims of the '113 patent in issue are invalid;
> 2. Lilly's action for patent infringement is dismissed;
> 3. Novopharm [Teva] is entitled to relief under s. 8 of the Patented Medicines (Notice of Compliance) Regulations to be determined in a separate proceeding, and to its costs."

[17] The Court did not, either in its reasons for judgment or in the formal judgment, determine the period of time for which Teva could claim compensation for its losses, or identify which of the Lilly entities were liable to Teva.

[18] In December 2009, following a case conference convened to discuss the procedure to be followed for the second phase of the trial, the Trial Judge clarified that these issues of liability would be decided at the hearing on remedies, at which he would preside.

[19] On appeal of the October 5, 2009 judgment, the Federal Court of Appeal found that the Trial Judge had erred in respect of certain issues relating to the validity of the Patent, and returned the matter to the Trial Judge. Teva was once again successful at the re-hearing of the trial on the validity issues and Lilly's subsequent appeals were dismissed.

[20] This motion is brought as the first step in the second phase of the trial.

Teva's proposed amendments:

[21] The allegations of fact found in Teva's initial Statement of Defence and Counterclaim were directed primarily to the invalidity of the '113 Patent, as a defence to the main action for infringement. The only allegations relating to its section 8 claim were made an integral part of the remedies sought in the counterclaim and held in only two paragraphs.

[22] Teva proposes to remove the entirety of the original defence as being irrelevant to the counterclaim, and to remove a claim for disgorgement of the profits made by Lilly during the time Teva was prevented from obtaining an NOC. Lilly does not oppose these proposed redactions.

[23] The proposed new pleadings in relation to the section 8 claim would also:

- Remove the previously pleaded particulars of the period of claim and allege that, had Lilly not commenced the prohibition proceedings, Teva would have taken steps to expedite the approval of its ANDS and would have been in a position to obtain its NOC prior to the date certified by the Minister.

- Add claims for losses suffered as a result of Lilly listing other patents on the Registry with respect to olanzapine and continuing proceedings under the *PM(NOC) Regulations*, including in relation to a prohibition proceeding begun and discontinued before the start of the period as previously alleged.

- Add claims for losses relating to other products and loss of "enterprise value".

- Add allegations that Lilly US and Lilly UK had direct or indirect responsibility for, involvement in, or direction of the listing of the '113 Patent, the filing of the NDS, and the prosecution of prohibition proceedings, including those relating to another patent.

[24] Teva's proposed pleadings would also add a new cause of action based on sections 7(a) and 22 of the *Trade-Marks Act*.

[25] In relation to that *Trade-Marks Act* claim, Teva alleges that, beginning in June 2007 (that is, after Teva had obtained its NOC), Lilly made statements to provincial formularies, distributors and pharmacies to the effect that the '113 Patent was valid and that Teva's generic olanzapine product

was infringing and liable to be removed from the market regardless of an NOC having been obtained. Teva alleges that these statements were false and misleading and tended to discredit Teva's wares and services (contrary to s. 7(a) of the *Trade-Marks Act*) and that because the statements were made using Teva's registered trademark "Novopharm", it constituted an unauthorized use of the trademark having the effect of depreciating the value of the goodwill attached to it (contrary to s. 22 of the *Trade-Marks Act*). Teva therefore claims damages resulting from loss of sales, of profits and of enterprise value.

[26] At this point of the analysis, it would seem that the contested amendments proposed by Teva fall into distinct categories that can relatively easily be considered and dealt with: amendments going to the liability and quantum aspects of the section 8 claim, and amendments adding a cause of action under the *Trade-Marks Act*, based on facts arising after the section 8 period.

[27] Where the lines blur and the task of assessing what amendments might be permissible is rendered more difficult is in the manner in which Teva particularizes and claims its damages for both the section 8 claim and the *Trade-Marks Act* claims. Paragraph 65 of the proposed pleadings demonstrates the ultimate aim of the amendments, which is to link into a single, continuous and compensable loss, all of the losses suffered by Teva in relation to the olanzapine market:

> "65. The defendants knew and intended or at the very least ought to have known that their conduct would cause loss and damage to Teva far beyond the date of the order dismissing their application under the *Regulations*. It would be unfair and unjust for the defendants to be permitted to avoid compensating Teva for all of such loss and damages. The combination of Teva's claims under section 8 of the *Regulations* and section 7(a) of the *TMA* (as pleaded

> below) entitle Teva to recover for all of its losses to date as described herein."

[28] Teva's claim for damages also prominently brings into play agreements entered into by Lilly with provincial agencies and ministries in British Colombia, Manitoba, Saskatchewan and Ontario which, it is alleged, either blocked or significantly reduced Teva's ability to sell its products in these provinces after it obtained its NOC. The only dates provided in the proposed pleadings for when these agreements were negotiated is with respect to Ontario, where it is said the first agreement was entered into in December 2006 and amended in May 2007, (i.e., within the period covered by the section 8 claim). From the allegations concerning the other provinces, it appears however that those agreements postdate Teva's obtention of its NOC, and would fall outside the relevant period for the section 8 claim, although the allegations are open-ended. The proposed pleadings present losses suffered by Teva as a result of those agreements as recoverable both under its section 8 claim and its *Trade-Marks Act* claim. The pleadings allege that Lilly could only have succeeded in negotiating these agreements because of Teva's exclusion from the market during the prohibition proceeding. As to why these losses are recoverable under the *Trade-Marks Act* claim, the pleadings are ambiguous, but Teva explains in its motion materials that the agreements resulted from the false and misleading statements Lilly made as to the infringing nature of Teva's products. Lilly, for its part, submits that Teva's claim for losses resulting from the agreements is but a disguised claim based on the tort of conspiracy. It argues that this Court has no jurisdiction to hear such a claim. Lilly further submits that this claim is barred by the principles of *issue estoppel* as concerns the agreement with British Columbia, because Teva has already taken an action against British Columbia over the agreement with that province, based on the tort of conspiracy and naming Lilly Canada as a co-conspirator, which action was eventually dismissed on consent, as if after a full trial.

The effect of the bifurcation order, of the first trial and of the judgment:

[29] The *Federal Courts Rules* contemplate the possibility of amending pleadings at any time, even during or after a hearing, up to the time a judgment is rendered. However, Rule 75(2) imposes specific conditions to amendments sought during or after a hearing:

"75. (2) No amendment shall be allowed under subsection (1) during or after a hearing unless	« 75 (2) L'autorisation visée au paragraphe (1) ne peut être accordée pendant ou après une audience que si, selon le cas :
(*a*) the purpose is to make the document accord with the issues at the hearing;	*a*) l'objet de la modification est de faire concorder le document avec les questions en litige à l'audience;
(*b*) a new hearing is ordered; or	*b*) une nouvelle audience est ordonnée;
(*c*) the other parties are given an opportunity for any preparation necessary to meet any new or amended allegations."	*c*) les autres parties se voient accorder l'occasion de prendre les mesures préparatoires nécessaires pour donner suite aux prétentions nouvelles ou révisées. »

[30] In addition, the jurisprudence of this Court has consistently recognized that the timing of requests to amend in relation to a trial is of paramount importance. In *Canderel Ltd. v Canada*, [1994] 1 FC 3, the Federal Court of Appeal cautioned that "the nearer the end of trial a motion to amend is made, the more difficult it will be for the applicant to get through both the hurdles of injustice to the other party and interests of justice". This Court has also held that amendments proposed at or near a trial which substantially change the factual basis on which the parties have

proceeded to or prepared for trial and require the parties to revise their case, cause the kind of prejudice that cannot be compensated in costs: see *Valentino Gennarini SRL v Andromeda Navigation Inc.*, 2003 FCT 567, at par. 33:

> "[33] Finally, and contrary to the Defendant's contention, the proposed amendments would inevitably delay an expeditious trial since an amended reply would presumably have to be filed by the Plaintiff and fresh examinations for discovery would have to be undertaken on the basis of the Amended Statement of Defence. In *Montana Band v. Canada*, [2002] F.C.J. No. 774 (QL) (F.C.T.D.), this Court held that an amendment that substantially changes the factual basis of the claim, made on the eve of a lengthy trial and requiring the parties to revise their legal opinions, pleadings, discovery and production should be refused because it inflicts a prejudice that cannot be compensated for by an award of costs."

[31] In assessing both the prejudice to the opposing party and the interest of justice, the Court of Appeal, in *Canderel*, above, has recognized that both the Court and the parties have a legitimate expectation in litigation coming to an end, which must be weighed in the balance:

> "12 As regards interests of justice, it may be said that the courts and the parties have a legitimate expectation in the litigation coming to an end and delays and consequent strain and anxiety imposed on all concerned by a late amendment raising a new issue may well be seen as frustrating the course of justice.[16] The principles were in our view best summarized by Lord Griffiths, speaking for the majority, in Ketteman v. Hansel Properties Ltd:[17]
>
> > This was not a case in which an application had been made to amend during the final speeches and the court was not considering the special nature of a limitation defence. Furthermore, whatever may have been the rule of conduct a hundred years ago, today it is not the practice invariably to allow a defence which is wholly different from that pleaded to be raised by amendment at the end of the trial even on terms that an adjournment is granted and that the defendant

> pays all the costs thrown away. There is 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.
>
> Whether an amendment should be granted is a matter for the discretion of the trial judge and he should be guided in the exercise of the discretion by his assessment of where justice lies. Many and diverse factors will bear on the exercise of this discretion. I do not think it possible to enumerate them all or wise to attempt to do so. But justice cannot always be measured in terms of money and in my view a judge is entitled to weigh in the balance the strain the litigation imposes on litigants, particularly if they are personal litigants rather than business corporations, the anxieties occasioned by facing new issues, the raising of false hopes, and the legitimate expectation that the trial will determine the issues one way or the other. Furthermore, to allow an amendment before a trial begins is quite different from allowing it at the end of the trial to give an apparently unsuccessful defendant an opportunity to renew the fight on an entirely different defence."
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> (Emphasis mine)

[32] Needless to say, the admonition of the House of Lords, as approved by the Federal Court of Appeal, applies with even more force after the parties have declared their evidence closed and the trial is finished.

[33] On this motion, Teva takes the position that its amendments should not face the same heightened level of scrutiny as amendments proposed at or after trial, as the net effect of the Trial Judgment is to defer, regardless of the bifurcation order, the entirety of its section 8 claim to the second phase of this proceeding, which has barely yet begun.

[34] Teva's position incorrectly assimilates the Trial Judge's decision to defer the determination of specific issues of liability to the second phase of the trial to a decision to vary the bifurcation order and to defer the trial of these liability issues to the second phase.

[35] It is beyond question that the bifurcation order contemplated that the parties should proceed to discoveries and to the first phase of the trial on all issues in the proceedings except those that go solely to quantum. It is also beyond question that the question of which of the Lilly entities should be considered a "first person" and be liable for Teva's section 8 losses, and the question of the appropriate start and end dates for the section 8 losses, were intended to be tried as part of that first phase. At page 6 of the bifurcation order, I specifically refer to the issues of the identity of the "first person" and of the start of the period of time for which damages can be claimed as issues that could narrow the scope of the second trial if determined in the liability phase. The Trial Judge himself, in his December 2009 order, recognized that the start and end date of Teva's losses, as well as other issues "directly related to s. 8 relief", could have been determined as part of his judgment on the first phase of the trial. Indeed, the parties conducted themselves in accordance with the bifurcation order: They conducted discoveries on these issues, and led evidence and made argument at trial on these issues. Moreover, and as mentioned in the bifurcation order, Lilly had at one point argued that Teva's section 8 claim in its entirety should be deferred to a second trial, a suggestion that Teva specifically opposed and which I declined to adopt on the basis of Teva's objection.

[36] The Trial Judge, in his order of December 16, 2009, referred to the bifurcation order and clearly determined that, in deciding to defer his determination of certain liability issues, he was following, rather than varying, the bifurcation order. He interpreted the bifurcation order as

specifying the categories of evidence that the parties were not required to present at the first trial – not the issues that were required to be determined by the Judge:

> "I agree with Lilly's submission that there are some issues relating to remedies that could have been decided during the liability phase of the trial (*e.g.* the start and end date of any losses suffered by Novopharm). However, there was no requirement for me to do so. I determined that the question of the duration of any losses, and other issues directly related to s. 8 relief, should be decided at a hearing on remedies, and so ordered. Contrary to Lilly's submission, the bifurcation order did not specify the issues to be decided at the liability stage; it identified categories of evidence that should *not* be presented."

[37] By necessary implication, while the Trial Judge was not required by the bifurcation order to decide all liability issues at the first trial, the parties were nevertheless required to present all their evidence going to these issues at the first trial, so as to enable the Judge, if he so chose, to determine the issues. At no time before, during or after the first trial did the parties request, or the Judge suggest, that the bifurcation order should be amended or varied to dispense the parties from putting their case on the section 8 liability issues at the first trial. It is one thing for the Trial Judge to exercise the latitude given to him by a bifurcation order to defer his determination of certain issues to a later date; it is quite another to interpret this exercise of discretion as an order varying the terms of a previously made order when that variance has not been requested by the parties, when the parties were not provided with an opportunity to be heard and when no justification for the variance is given.

[38] Teva suggests that the Trial Judge's decision to defer his determination of the liability issues implies and almost requires that the evidentiary phase relating to these issues should remain open,

because of the necessity for the parties to address issues that can arise between the two trials, because issues of liability and quantum are intertwined, and because context may be missing to finalize the liability case. Teva therefore suggests that it would be unfair, would unnecessarily complicate discovery and the conduct of the second trial, and would be unworkable, to require the Court to tease out the permissible new evidence from the "frozen" evidence led in the first phase. Teva refers to other cases where the Court considered the necessity or possibility of varying a bifurcation order to allow the parties to present evidence relating to liability issues during the quantification phase of the trial: *Jag Flocomponents N.A. v Archmetal Industries Corp.*, 2010 FC 627, affirmed at 2011 FCA 235 and *Eurocopter v Bell Helicopter Textron Canada Ltée*, 2012 FC 113.

[39] These cases do not assist Teva. In *Eurocopter,* the Court in its discussion recognized that, where issues are left for determination years after the trial in which the evidence was presented, it may be necessary to permit the parties to present new evidence, or even to order a new trial if the trial judge is not in function anymore. This discussion does not establish a presumption that new evidence should be permitted or a new trial should be ordered every time issues are deferred or there is a significant delay between the close of trial and the deferred determination. On the contrary, *Eurocopter* implicitly confirms that the evidence led at the first trial is to be considered closed and may only be reopened where the particular circumstances of the case require it. In *Jag Flocomponents*, the Court found that damages was an essential element for the determination of the claim before it, and clearly found that the evidence to be led at the damages phase was necessary for it to make a final determination on liability. This case therefore also stands for the proposition that

the evidentiary phase of a bifurcated trial is to be considered closed on liability issues, even if the determination is deferred, unless it is explicitly left open.

[40] Teva's argument on the present motion merely assumes, but without demonstrating, that there is, in this case, confusion or overlap between the liability and quantification issues, or that events occurring in the intervening period between the two trials are, in the circumstances of this case, relevant to the undecided liability issues. That, however, is clearly not the case. The unresolved liability issues relate solely to the start of the section 8 period and to the identity of the "first person". As considered and confirmed by the bifurcation order, they are very clearly distinct from the quantification issues. Nor can the determination of these issues be informed by any event that might have occurred after Teva obtained its NOC. There is, further, no indication that the Trial Judge based his decision to defer determination on the liability issues on the lack or insufficiency of evidence on these issues, or on any expectation or understanding that further evidence to be led at the second trial might inform the determination he might have come to on the evidence adduced by the parties at the first trial, as was the case in *Jag Flocomponents*.

[41] Teva seeks support for its position in the fact that very little of the trial time was taken in adducing evidence or making submissions on issues going to liability for the section 8 claim. That, however, merely shows that the issues as engaged in the pleadings and the evidence that Teva chose to gather and present at trial were very narrow and focused. It does not demonstrate or indicate any intent on the part of the parties or of the trial judge to defer the presentation of the evidence on these narrow issues to a second phase of discovery and trial.

[42] Teva also relies on the judgment of the Federal Court of Appeal on a motion for reconsideration of its judgment allowing the appeal of Lilly (2010 FCA 219), and on the judgment of the Federal Court on Teva's motion for a "Mareva" injunction following the 2009 judgment (2010 FC 241). Teva argues that both of these judgments have interpreted the Trial Judge's December 16, 2009 order as meaning that the entirety of the section 8 claim is to be dealt with in the second phase of this proceeding. I disagree. These two judgments merely refer to the Trial Judge's decision of December 2009 and note that, as the decision clearly says, the determination of the issues of liability was deferred to the second phase. They do not purport to interpret the Trial Judge's decision in light of the bifurcation order, much less to determine whether the Trial Judge's stated intention to determine the issues at the second trial implied an intent to re-open the evidence on these issues. The Trial Judge's ultimate intention was immaterial to either of the decisions upon which Teva seeks to rely, and it is not appropriate to parse the language used by the Courts for meaning that was not intended.

[43] None of the circumstances set out above can lead to any other conclusion than that the trial on all liability issues is concluded, including on the issues of the identity of the "first person" and of the period during which Teva's losses can be compensated, and that only the determination of the Trial Judge on the evidence presented to him at the first phase of the trial was deferred to the second phase of the trial. Teva's proposed amendments going to liability issues must therefore be considered as amendments proposed after a hearing but before a judgment is rendered.

Amendments going to liability issues:

[44] The amendments proposed by Teva going to the start of the section 8 period and to the identity of the "first person" are, as determined above, to be treated as amendments proposed after a hearing. The amendments introducing a new cause of action pursuant to the *Trade-Marks Act* must equally be treated as amendments after a hearing, since they clearly introduce new liability issues, and since the bifurcation order required the parties to adduce all their evidence at the first trial, with the exception only of evidence going solely to quantification issues.

[45] As the jurisprudence set out earlier in these reasons clearly shows, amendments that change the questions in controversy and require reopening discoveries after the parties' cases are ready to proceed to trial or have, as in this case, been presented at trial, are inherently unjust and cause the kind of prejudice that cannot be compensated in costs. Clearly, Teva's amendments fall within that category.

[46] There can be no suggestion whatsoever that the amendments do not radically change the case that was presented at trial or that they would not require extensive discoveries and new evidence: Teva initially pleaded that the beginning of the section 8 period was February 9, 2006. At trial, it relied solely on the approvable date of March 3, 2006, as certified by the Minister. It led no other evidence to suggest an earlier start date. It now wishes to change this to plead that it could have expedited approval of its ANDS to an unknown, earlier date and to recover section 8 damages for other, earlier prohibition proceedings. Teva initially pleaded that the Lilly entities constituted a common enterprise, expressly relying only on the facts alleged by Lilly to support its claim for infringement. Teva led no additional evidence at trial and argued that on the basis of five pages of

the transcript of Lilly's evidence, Lilly US controlled Lilly Canada in respect of olanzapine products and of the litigation. It now wishes to change this to allege that Lilly UK also controlled these aspects of Lilly Canada's business and that Lilly US and Lilly UK controlled Lilly Canada's regulatory filings and intentionally took steps to delay the proceedings. As for the *Trade Marks Act* claim, it introduces an entirely new cause of action, based on entirely new facts that have never even been hinted at previously. None of the allegations have been the subject of any discovery, evidence or argument in the first phase of the trial.

[47] Teva has not attempted to show or argue that any of these proposed amendments do not drastically alter the issues to be determined, or that they will not require Lilly to alter the position it may have taken in the litigation so far or at the first trial. Teva's argument that the amendments will not cause prejudice to Lilly that cannot be compensated in costs is based entirely on the premise that the few days the parties have spent presenting their case and argument on these issues at trial are *de minimis*, and can merely be ignored and discounted altogether in favor of the extensive new discoveries and evidence that would now be allowed in the second phase. This ignores the prejudice and disruption caused from frustrating a party's legitimate expectation that there will be an end to litigation, and that when the evidence on the trial is closed, it will not be reopened without serious reasons. To suggest that this principle should apply with less vigor because the first trial was straightforward and short is to invite abuses of the Court's process, whereby the parties could put forward a skeleton, "disposable" case, that they can later ignore with impunity when they decide to bring in their full case.

[48] Teva has not met its burden of establishing that the proposed amendments will not cause prejudice to Lilly that cannot be compensated by costs.

[49] The Federal Court of Appeal recognized in *Canderel* that the courts are also legitimately entitled to expect that litigation will come to an end, such that amendments that would have the effect of delaying, adjourning or reopening a trial without justification are not in the interest of justice. It was Teva's burden to establish that allowing the proposed amendments in the present circumstances would nevertheless be in the interest of justice. Teva's only argument to that effect is based on the same unproven an incorrect assumption that the issues of liability left to be determined after the first trial could not, in any event, be determined without fresh evidence at the second trial, and that there would be confusion and overlap between the evidence led on those issues in the first trial and the evidence to be led at the second trial. Such an assumption, as discussed above, is unwarranted in the circumstances of this case.

[50] Teva suggests that recent decision relating to section 8 claims have clarified the law and that it is important that a more complete record be presented to the Trial Judge to enable him to apply these rulings with the full context. However, Teva chose, in 2007, to proceed to litigate the liability issues of its section 8 claim as part of the first phase, knowing that the jurisprudence on the proper interpretation of this section was embryonic. It chose the facts on which it wished to proceed to trial. Clarification of the law is not an excuse for a party to retroactively modify the factual basis of its case to make the facts fit the law.

[51] Teva has not attempted to otherwise justify why allowing the amendments at this time might be in the interest of justice. From the record before me, it seems that Teva was aware of all the facts relating to the new liability allegations, including those relating to the *Trade-Marks Act* claim, as early as the summer of 2007, and in any event, well before the first trial. Teva has not attempted to provide any explanation or reason why it waited until after the trial to raise these issues.

[52] For the reasons given above, I conclude that the amendments proposed by Teva that go to liability issues should not be permitted as they are not in the interest of justice and as Teva has not established that they would not cause prejudice to Lilly that cannot be compensated in costs.

[53] Having come to that conclusion, I do not need to consider or determine Lilly's argument that the proposed amendments do not disclose a reasonable cause of action. I do, however, make the following observations in respect of the *Trade-Marks Act* claim, without of course determining whether the allegations disclose a breach of the *Trade-Marks Act*: The proposed amendments do not contain any particulars about what specific damages or losses were caused to Teva by Lilly's alleged misrepresentations and use of Teva's trademark. The pleadings, as framed, clearly attribute the damages, lost sales and loss of enterprise value occurring after June 2007 to the agreements between Lilly and the provinces, but contain no material facts to support a finding that there is a causal link between the conclusion of the agreements and the alleged misrepresentations and misuse of the trademark. In the absence of a discernible causal connection between the alleged breaches of the *Trade-Marks Act* and the conclusion of the agreements, the proposed amendments appear to be a thinly disguised claim for losses caused by the agreements, based on the tort of conspiracy. It is clear that this Court has no jurisdiction to hear or determine a claim based on the common law tort

of conspiracy. Had I not concluded, on other grounds, that Teva's proposed amendments going to liability issues could not be granted, I would not have permitted the amendments to go in as they are currently drafted.

Amendments going to quantum:

[54] In addition to proposed amendments to add the *Trade-Marks Act* claim, extend the relevant date for section 8 damages and expand the grounds for fixing liability for section 8 damages on entities other than Lilly Canada, the proposed amended pleadings significantly expand the allegations relating to the damages suffered by Teva. Because discoveries have not commenced on the quantification issues, there is no prejudice to Lilly if substantial amendments are made to the heads of damages claimed. Amendments going to quantum should therefore be permitted, so long as they are reasonably arguable and are not otherwise defective.

[55] Some of the new claims and allegations, on their face, relate to losses suffered before and after the dates originally pleaded by Teva as framing the relevant section 8 period. Because Teva will not be allowed to plead a different start and end date for the section 8 period, and will therefore not be able to lead evidence to establish a different timeframe, it is plain and obvious that Teva cannot succeed on any claim for compensation for losses suffered before February 9, 2006 or after June 6, 2007. Any amendments relating to losses alleged to have been suffered before or after those dates are bound to fail and must therefore be denied. This would include allegations related to the listing and prosecution of prohibition proceedings on patents other than the '113 Patent, which, on their face, predate February 9, 2006, to expenses incurred in defending the appeals of the prohibition proceedings giving rise to the present claim, which, on their face, were taken after June 6, 2007, to

all losses alleged to result from Lilly's misrepresentations and unauthorized used of Teva's trademarks, which on the face of the pleadings, occurred after June 7, 2007, and to all losses arising from the alleged agreements between Lilly and the provinces, where it has not been pleaded that the agreement was entered into prior to June 6, 2007.

[56] That said, even though Teva cannot independently claim compensation for losses resulting from the agreements between Lilly and the provinces, I do not exclude the possibility that the existence of the agreements and their effect on Teva's share of the market would be relevant to the assessment of Teva's section 8 claim. This is because, in order to assess the sales a generic would have made in the relevant section 8 period, market shares and sales actually achieved in the subsequent period are often used as a proxy for predicting what would have happened in the section 8 period. Lilly acknowledged that it might argue that, had Teva been in a position to obtain an NOC in March 2006, Lilly would have entered into the very same agreements with the provinces at an earlier date, with the same resulting market shares for Teva. It also does appear that the agreement with Ontario was in place prior to June 2007, and could have affected Teva's sales in the relevant period. Accordingly, Teva's argument that Lilly could not have entered into the agreements with the provinces but for its exclusion, and that these agreements should therefore not be taken into account to reduce Teva's claim for section 8 damages, could be relevant to the quantification of Teva's section 8 claim, as originally pleaded. Lilly does not seriously contest this. However, I note that Teva's possible argument that its properly claimable section 8 losses cannot be reduced by taking these agreements into account may be premature at this point and might be more appropriately pleaded in an eventual reply. Indeed, only the agreement with Ontario was in effect in the relevant period, and Lilly and has yet to allege that it would have reached agreement with the other

provinces earlier if Teva had obtained its NOC when it was approvable. Unless Lilly formally pleads those facts in an amended defence to counterclaim, the existence of agreements with provinces other than Ontario after June 7, 2007 would be irrelevant.

[57] Teva argues that it is not making claims for losses due to the previous prohibition proceedings, but is merely alleging these proceedings as part of the background context to its claim for losses within the allowable period. Presumably, the same argument applies to Teva's allegations relating to Lilly's alleged "anti-generic" conduct generally, and cannibalization of its olanzapine market in favor of "other" Lilly products, such as Zyprexa Zydis orally dispersible tablets. Teva, however, has not articulated how conduct and events occurring before and after the relevant section 8 period can be relevant to the assessment of Teva's losses. On the other hand, the allegations relating to Lilly's allegedly "harmful, unlawful and/or anti-generic actions" before, during and after the relevant period were clearly intended to be relevant to the intentional aspects of Teva's claim under the *Trade-Marks Act*, and to the suggestion that the combination of Teva's claims under section 8 and under the *Trade-Marks Act* entitles it to recover for "all its losses to date". These allegations were also clearly intended to support a new claim for punitive, aggravated or exemplary damages. As section 8 has been interpreted by the Federal Court of Appeal in *Merck Frosst Canada Ltd. et al. v. Apotex Inc.* 2009 FCA 187, it is clear that its aim is purely compensatory. Punitive or exemplary damages, by their very nature, are intended to punish or deter conduct on the part of a defendant where compensation to the plaintiff is not sufficient to achieve these aims. As such, punitive or exemplary damages clearly cannot legitimately be claimed in a section 8 action and could only form part of Teva's claim under the *Trade-Marks Act*. As I have concluded that Teva cannot amend its pleadings to add a cause of action under the *Trade-Marks Act* or for compensation

arising from Lilly's agreements with the provinces, and as the proposed amendments are explicitly drafted for the purpose of linking all losses and claims related to section 8 claims and to the new claims as a globally recoverable loss, the amendments, as currently proposed, are designed to support a cause of action that cannot succeed at trial. The proposed amendments going to Lilly's alleged "anti-generic" conduct therefore do not disclose a reasonable cause of action.

[58] It might be that, if stripped of elements that are irrelevant to a proper section 8 claim, some of the new allegations could be relevant and allowable. However, as the allegations are currently drafted, it cannot be understood which of the numerous facts pleaded might be relevant to the assessment of Teva's section 8 claim, and how these facts might legitimately go to the assessment of quantum. Teva has not attempted, on this motion, to tease out from its proposed amendments those that go solely to the section 8 claim and those that go to the *Trade-Marks Act* claim or to linking the two claims. Amendments made without a discernible purpose are of a nature to embarrass, prejudice and delay the conduct of proceedings and should not be allowed.

[59] The proposed new pleadings specifically seek compensation for losses suffered by Teva in the section 8 period relating to other products and to its overall market share, losses which the jurisprudence recognizes as potentially recoverable in a section 8 proceeding (*Teva Canada Limited v. Janssen Ortho Inc.* 2010 FC 329). Lilly's objection to these proposed amendments, with which I agree, is based on the lack of any particulars as to the other products in relation to which such losses are claimed or the customers in relation to which Teva's inability to offer olanzapine has negatively affected negotiations. Absent such particulars, Lilly's defence can only be the vaguest denial. At this point of the proceedings, where the sole issues for discovery and trial concern the quantum of

the damages, and where all of the relevant facts are, on the face of the record, within the peculiar knowledge of Teva, allowing amendments that go only to introducing vague an open-ended heads of damages is not in the interest of justice. It would only invite a motion for particulars, and absent such particulars, the scope and subject matter of discoveries cannot adequately be defined and will likely result in protracted and inefficient discoveries. Teva's original pleadings already very generally state a claim for "loss (including lost sales and market share (...))". Allowing Teva to amend these pleadings to specify that this general loss includes losses relating to other products would serve no useful purpose unless the amendments provide particulars of the other products at issue and of the material facts upon which losses of sales or market share in relation to these other products were suffered in the relevant period and can be attributed to Teva's inability to market olanzapine in that period.

[60] Teva also seeks to add allegations to the effect that its recoverable losses include the loss of value of Teva's overall enterprise, and the loss of opportunity to invest and reinvest the proceeds of the claimable lost sales and market share. This Court, in *Sanofi-Aventis Canada Inc. et al. v. Teva Canada Limited* 2012 FC 552, considered whether an alleged claim for loss of business value based on the capitalization of the generic's business value as at the end of the section 8 period was a claim for losses suffered in the period or a claim for future profits, which is not recoverable under section 8. On the facts before it, the Court held that the alleged loss of business value was in fact a claim for lost profits. The manner in which Teva's proposed pleadings are phrased use the term "loss of enterprise value" rather than "loss of business value", and add the assertion that this loss "was realized during the period", but otherwise provided no material facts as to the basis on which that loss is to be calculated and the circumstances in which it was allegedly "realized". The inadequacy

of these pleadings is apparent when one considers the comments made in respect of such pleadings in *Sanofi-Aventis*, above, at paragraph 248:

> "[248] I appreciate that, in this action, Teva has pleaded harm due to [r]eduction in the overall value of the business due to being held off the market with respect to Teva's generic ramipril" (Seventh Amended Statement of Defence and Counterclaim at para 76(h1)(ix)). Sanofi did not move to strike this statement, in spite of the fact that it successfully moved to strike other paragraphs referring to future profits (see *Sanofi 2010*, above). The fact that Sanofi did not move to strike paragraph 76(h1)(ix) does not mean that that paragraph in the pleadings and the evidence allegedly related to it become relevant to a s. 8 claim. The problem with Teva's argument is that it ignores the reality that Sanofi could have had no idea of how Teva intended to "prove" lost business value. It is quite possible that, had Sanofi understood the scope of this pleading, it would have moved to strike it. Until Sanofi (and this Court) had an opportunity to review the evidence in support of this claim, the claim was capable of many interpretations. Only upon reviewing Ms. Loomer's expert report in light of all the evidence on this issue was everyone able to fully understand the meaning of this claim."
>
> (Emphasis mine)

[61] While I appreciate that Teva is not required to plead the evidence by which it will prove the allegations made, it is required to plead the material facts which it intends to prove. In light of this Court's specific findings in *Sanofi-Aventis*, unless Teva pleads the material facts on which the calculation of its loss of enterprise value will be based, the pleadings can only reasonably be interpreted as impermissibly alleging a loss based on the capitalization of its expected future market share and revenues, as of the end of the relevant period. It is also relevant to note that, because the pleadings were drafted with a view to rolling into one, indivisible and recoverable loss, all of the losses suffered during and after the relevant period, the inference that the alleged loss of enterprise value includes loss of future profits is entirely justified. In the circumstances, the proposed

pleadings would, on their face, require particulars and should not be allowed unless they include those particulars.

[62] Finally, the proposed amendments reiterate Teva's earlier claim for expenses incurred in defending the prohibition proceedings giving rise to its section 8 claim, to the extent not recovered as costs in those proceedings. Lilly did not previously move to strike these claims but now objects to their inclusion in the amended pleadings. Lilly argues that costs have already been awarded by the Court in these proceedings, and could have been, but were not, awarded on a solicitor and client basis. Lilly submits that an attempt to claim the un-awarded costs is an attempt to circumvent the Court's final order on costs and is barred on the principles of issue estoppel, *res judicta* and abuse of process. Lilly relies on an unreported decision of one of my colleagues, *Eli Lilly Canada Inc. v. Teva Canada Limited* (August 30, 2010, Court file T-607-10, per Milczynski P.), for that proposition. Although my colleague's reasoning in that case is compelling, it also appears to rely on the specific facts of the case before her, which included the fact that the parties had entered into an agreement to settle "all costs in this matter". It is always delicate to rely on endorsed or speaking orders as authoritative determinations of issues of law, as these kinds of orders are intended only to inform the parties expeditiously of the reasons for the decision at issue, and are often based in large part on the particular circumstances of the case, with which the parties are familiar and which therefore need not be explained at length.

[63] On the record before me, and while Lilly has made a strong argument that these losses should not be recoverable at law, I have not been persuaded that the matter is entirely free from doubt and that the existing allegation should not be allowed to be retained in the amended pleadings,

as confined of course to expenses incurred in relation to the prohibition proceedings in T-1532-05 during the relevant period, which excludes in this case any appeals.

Conclusion:

[64] At this stage of the proceedings, Teva cannot amend its pleadings to reopen, in any way, the liability phase of the trial that has been held in this matter, including to allege new causes of action. It may amend to add particulars as to the losses alleged to have been suffered as a result of the prohibition proceedings in T-1532-05, but only in the period between February 9, 2006 and June 6, 2007, as originally pleaded, and only if it provides the particulars of those losses and sufficient material facts to support the conclusion that the losses were suffered in the relevant period and are attributable to the prohibition proceedings. Where Teva intends to plead facts that may be relevant to the assessment of the amount of those losses, it should provide sufficient particulars as to the causal relationship between those facts and the amounts claimed. As presently drafted, the proposed amended pleadings do not meet these requirements and cannot be filed.

[65] Teva's motion also requested that the Court establish an expeditious schedule for the steps to be taken in this matter, up to and including trial dates. As a result of Teva's motion to amend and of the present decision on that motion, the scope of the pleadings, of the documentary and oral discoveries that will be required and the length of the expected trial cannot be ascertained, and a schedule cannot be established as requested.

ORDER

THIS COURT ORDERS that:

1. Teva's motion is dismissed, with leave to reapply.

2. Teva may serve on Lilly a new proposed amended statement of defence and counterclaim in accordance with these reasons, and Lilly shall have 14 days from service of the proposed pleading to advise whether it consents to the amendments. Upon Lilly's consent, the proposed amended pleading may be served and filed without further order of this Court. If Lilly objects to the proposed amendments, it shall, within the same delay, advise Teva and the Court of the grounds for its objections, and include in its communication to the Court a copy of the proposed amended pleading.

3. Counsel for both parties shall, no later than June 26, 2013 provide the Court with their mutual dates of availability to participate in a case management telephone conference after July 15, 2013 for the purpose of setting a schedule for the next steps to be taken in these proceedings.

4. Costs of this motion shall be payable by Teva to Lilly.

"Mireille Tabib"

Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1048-07
STYLE OF CAUSE:	ELI LILLY CANADA INC., ELI LILLY AND COMPANY, ELI LILLY AND COMPANY LIMITED AND ELI LILLY SA v NOVOPHARM LIMITED
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	January 10, 2013 & February 5, 2013
REASONS FOR ORDER AND ORDER:	TABIB P.
DATED:	June 18, 2013

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