

Federal Court



Cour fédérale

Date: 20110407

Docket: T-1787-08

Citation: 2011FC436

BETWEEN:

APOTEX INC.

Plaintiff

and

SHIRE CANADA INC.

Defendant

REASONS FOR ORDER AND ORDER

Overview

[1] In the context of this action by Apotex Inc. (“Apotex”) for damages pursuant to Section 8 of the *Patented Medicines (Notice of Compliance) Regulations* (the “*NOC Regulations*”), Shire Canada Inc. (“Shire”) seeks leave to amend its statement of defence for the third time, to add a substantial new defence of infringement and to introduce a counterclaim for damages for patent infringement and an injunction.

[2] Although expert reports have yet to be filed and a pre-trial conference has yet to be held, a schedule has been set for those steps and dates have been fixed for a four-week trial to be held in this matter beginning on April 16, 2012.

[3] If Shire's proposed amendments are granted, the trial will have to be delayed. While Apotex concedes that the proposed amendments (subject to necessary particulars as to certain aspects) disclose a serious defence and counterclaim, it argues that allowing the amendments at this stage will cause it prejudice not compensable by costs, is an abuse of the Court's process, and is contrary to the interest of justice.

The facts

[4] Shire is a licensee under Canadian Patent No. 2,201,967, owned by Cephalon Inc. ("Cephalon", not a party to this action), for the medicinal ingredient modafinil. Shire also holds a Notice of Compliance permitting it to sell in Canada a medicine containing modafinil, commercialized under the name Alertec.

[5] Apotex desired to sell a generic version of Alertec in Canada. Because the '967 Patent had been listed in relation to Alertec on the patent register maintained by the Minister of Health pursuant to the *NOC Regulations*, Apotex was required to either await the expiration of the patent or assert that its modafinil product would not infringe the '967 Patent or that the '967 Patent was invalid before it could obtain a Notice of Compliance. Apotex therefore served on Shire, in 2006, a Notice of Allegation in which it asserted that the '967 Patent was invalid. No allegation of non-infringement was made.

[6] Shire and Cephalon commenced an application under the *NOC Regulations* for an order prohibiting the Minister from issuing a Notice of Compliance to Apotex until the expiration of the '967 Patent. That application was dismissed by this Court on April 25, 2008, the Court finding that

Apotex's allegations of invalidity of the '967 Patent were justified. Apotex received its Notice of Compliance in May 2008.

[7] In November 2008, Apotex filed the present action against Shire, claiming damages for having been kept off the market by reason of Shire's unsuccessful application for a prohibition order. Such a claim is contemplated by Section 8 of the *NOC Regulations*.

[8] Shire filed its first statement of defence in January 2009. That defence raises various reasons why Apotex's claim should be dismissed or substantially reduced, but does not raise infringement of the '967 Patent as a defence.

[9] On April 17, 2009, Cephalon filed an action against Apotex in a different Court file, claiming damages for Apotex's infringement of the '967 Patent. Shire is not a party to that action, and the action was given file number T-609-09.

[10] On May 1, 2009, the Court issued a notice to the parties and to the profession whereby it invited litigants in complex actions that were subject to case management to request trial dates early in the action, and offered to endeavour, where possible, to have the action tried within two years of its commencement.

[11] On July 24, 2009, Apotex wrote to the Court to request case management of this action and that trial dates be fixed in the early part of 2011. I was assigned as case management Judge and the action was designated as a specially managed proceeding on August 6, 2009.

[12] A first case management conference was held on September 16, 2009, in the course of which a schedule for all steps to the completion of the first round of discoveries was set, with a further case management conference contemplated in June 2010 to fix a schedule for all remaining steps, including fixing a trial date.

[13] In December 2009, Shire sought leave to amend its statement of claim to add, as a defence, that Apotex would not have been in a position to begin selling its modafinil product in 2006, as alleged, because of the difficulties in manufacturing this product on a commercial scale. No mention was made of the Cephalon action or of a defence based on the infringement of the '967 Patent. Shire was granted leave to amend in January 2010 and the schedule was extended by three months as a result.

[14] On April 23, 2010, Shire again moved to amend its statement of defence. This time, the amendment sought to add two new defences: The first, a defence of "grave consequences" in relation to a Notice of Allegation served by Apotex in relation to a different patent listed in respect of Alertec and the second, a defence based on Cephalon's infringement action against Apotex in T-609-09. That latter defence was to the effect that, if Cephalon is successful in the T-609-09 action, then Apotex should not be allowed to recover against Shire damages for loss of sales ultimately found to be infringing.

[15] An order issued on June 4, 2010 allowing the former but not the latter amendment. The reasons for order were issued on August 19, 2010 (2010 FC 828). Paragraph five of these reasons read as follows:

“[5] Instead of directly asserting as a defence against Apotex’s action a plea that the ‘967 Patent is valid and infringed and that Apotex should therefore not be entitled to recover damages based on the loss of infringing sales, Shire proposes to rely on the outcome of a separate infringement action commenced by Cephalon and to which it is not a party. Thus, it does not propose to bring any evidence in this action as to the validity or infringement of the ‘967 Patent so that the Court could make a direct determination of these issues in the context of this action. Rather, it proposes to rely strictly on the outcome of Cephalon’s action, as a fact. The allegations, as proposed, recognize clearly that the Cephalon action was only begun in April 2009 and has yet to be determined. The outcome of the Cephalon action, upon which depends the success of the proposed defence, is therefore clearly an uncertain future event which is not susceptible of being determined or even influenced in the context of the present action. In essence, Shire is alleging that if a certain event comes to pass (upon which neither the Court nor the parties have any control or any way of determining in the context of this action), then it will have a valid defence. This is the essence of a speculative and hypothetical pleading and ought to be struck (see *Bell Canada v. Pizza Pizza Ltd.* (1993), 48 C.P.R. (3rd) 129). Furthermore, if these allegations were allowed to be introduced in the Statement of Defence, the issues they raise could not be determined unless and until the proceedings brought by Cephalon against Apotex in that other Court file were resolved. This would unreasonably delay, embarrass and prejudice the trial of the present action.”

(Emphasis mine)

[16] That order was upheld on appeal, by order of the Honourable Justice Pinard on October 8, 2010 (2010 FC 1001), the Court writing, *inter alia*, as follows:

“2. A pleading which purports to import a separate proceeding involving different parties is baldly deficient and should not be permitted. As presently framed, the pleading fails to plead material facts in support of the defence of infringement and fails to permit Apotex the opportunity to defend the allegation of infringement on the merits in this proceeding. If Shire is of the view that it has a valid defence to Apotex’s section 8 claim herein, on the basis that Apotex’s product would, in the hypothetical period, have been infringing, it should have put forth a plea for infringement in accordance with the prescribed practice. It cannot circumvent the requirement to plead properly and in accordance with the *Federal*

Courts Rules, 1998, SOR/98-106, in particular Rules 174 and 181, which require that every pleading contain “a concise statement of the material facts on which the party relies, and particulars of every allegation contained therein”.

3. Because Shire is not a party to Court File No. T-609-09, which is an action only begun in April 2009 and has yet to be determined, and because Shire has failed to plead any material facts whatsoever as to the validity or infringement of the ‘967 Patent, the Court would likely be faced with issues upon which it could not make any direct determination. This would unreasonably delay, embarrass and prejudice the trial of this action.”

(Emphasis mine)

[17] Meanwhile, I had also been assigned as case management Judge to the Cephalon action. In a case management telephone conference held in August 2010, Cephalon advised of its intention to bring a motion to consolidate its action with this one. I issued an order requiring Cephalon to serve and file its motion record by October 15, 2010, and I informed Shire and Apotex of that development at a case management conference held on September 15, 2010. Notwithstanding Cephalon’s intended motion, I acceded to Apotex’s request that dates for a trial of this matter be considered at a case management conference to be held after Cephalon had filed its motion record on the consolidation motion, hoping that the motion would have, by then, been determined.

[18] In late September, however, the parties in the Cephalon action sought to extend the schedule for filing their records on the consolidation motion. In granting the extension, I warned as follows:

“The Court is amenable to granting the extension sought. However, the parties should note that the proceedings in T-1787-08 are continuing, and that trial dates are in the process of being considered and set. The status of the proceedings in T-1787-08, including whether trial dates have been set, will likely be a relevant consideration on any motion to consolidate. The parties should therefore govern themselves accordingly.”

(Emphasis mine)

[19] Cephalon eventually filed its motion record on the motion to consolidate on October 29, 2010. A joint case management telephone conference was held on November 12, 2010, to set dates for the hearing of Cephalon's consolidation motion and, for this action, to set a schedule for all remaining steps, up to and including the trial, which was then fixed to begin on April 16, 2012.

[20] Despite the fact that the stated purpose of the case management conference was to fix trial dates in this matter, notwithstanding Cephalon's pending motion for consolidation, despite the content of Cephalon's motion record, which had by then been served on Shire some two weeks previously, and despite the reasons rendered by Justice Pinard and myself on Shire's motion to amend to rely on Cephalon's action as a defence, Shire did not express or imply, at any time, an intention to amend its statement of defence to plead infringement directly.

[21] It is only on January 21, 2011, one week after Cephalon had withdrawn its motion for consolidation in the course of it being heard, that Shire served on Apotex its notice of motion on the present motion to amend. As mentioned, Shire now wishes to directly plead that Apotex currently infringes, and would have infringed the '967 Patent if it had come to market in 2006, such that Apotex should not be awarded damages under Section 8 of the *NOC Regulations* and should, further, compensate Shire for the infringement occurring after it did come to market.

Other relevant considerations

[22] It is worth noting that, with the exception of some delays due to Shire's first amendment and difficulties in scheduling motions arising out of the first round of discoveries, this matter has been proceeding apace and that the parties are on track for completing the second round of discoveries in May 2011, as scheduled, and for completing all necessary steps to be ready for trial in 2012.

[23] Conversely, the Cephalon action has hardly moved past the pleading stage. Apotex, not unexpectedly, has defended the Cephalon action on the basis of the invalidity of the '967 Patent, on grounds of anticipation, obviousness, insufficient disclosure, overbreadth, inutility and misleading specification. Motions for further and better affidavits of documents have been filed by both parties and even though the initial schedule called for these motions to be heard in the fall of 2010, the parties have consented to several extensions of time, such that the hearing was delayed to the end of March 2011.

[24] Apotex and Shire, the parties herein, are no strangers to litigation before this Court. Their counsel are experienced litigators in complex pharmaceutical patent litigation. The parties and their counsel are taken to be familiar with the Court's recent initiative to streamline complex litigation and bring them to trial within two years by fixing early trial dates and of the consequent necessity, for the parties, to act with foresight and diligence.

[25] While Shire in this case did not join in Apotex's request for an early trial, it was well aware of Apotex's intention to proceed expeditiously to trial. The schedules that have been set and followed here to date have been firm but not compressed. Shire has never complained that it was given insufficient time to consider or develop its case. In fact, despite Apotex's expressed desire for the trial to be fixed in early 2011, the Court adopted a more deliberate pace, ultimately fixing dates in 2012, with a schedule leaving ample time for each pre-trial step.

[26] Even so, allowing Shire's amendment would lead to the adjournment of the trial. Shire's proposed amendment does not merely add a new defence. It seeks to introduce an entirely new and complex litigation into this action. As it is, the only issues raised in this action pertain to Apotex's

readiness to enter the market, the conduct of the prohibition proceedings which led to this action, the effect of Apotex's breach of undertaking relating to the '287 Patent and the quantification of Apotex's loss. There is currently no issue as to the construction, infringement or validity of the '967 Patent. If Shire pleads as a defence and counterclaim the infringement of the '967 Patent, Apotex will inevitably attack the validity of the patent, as it did in the prohibition proceedings and in the Cephalon action.

[27] Although the Court has, in the past, successfully managed pharmaceutical patent infringement and invalidity actions to a trial within as little as 19 months, none has ever taken as little as 13 months, as would be necessary if the current trial dates are to be met. Contrary to Shire's argument at the hearing, the fact that the same allegations and issues have been raised in the Cephalon action does not give Shire's proposed new defence and counterclaim a head start or result in shaving six months off the best estimate of the time required to get such issues ready for trial, as the Cephalon action is only barely past the pleading stage. Further, the time set aside for the trial, while sufficient for the issues as they are currently framed, would certainly be insufficient to try a full infringement and invalidity action.

[28] Finally, the reasons why Shire has chosen not to raise directly the issue of the infringement of the '967 Patent as a defence until now remains unexplained on the record before me.

[29] Shire argued at the hearing, but without supporting evidence, that it could not know, or could not show, that there were reasonable grounds to believe that Apotex's product infringed the '967 Patent until Cephalon filed, as part of its motion record for consolidation, the expert affidavit of Dr. Bugay. That affidavit reports on intricate testing performed on Apotex's tablets to determine

whether the particle size distribution of the modafinil active pharmaceutical ingredient therein infringes the claims of the '967 Patent. Even if I were to accept Dr. Bugay's report as evidence of the facts stated therein (to which Apotex objects because the report is only attached to a clerk's affidavit as "a report filed by Cephalon in support of its motion for consolidation"), it would still not explain Shire's delay in proposing this defence.

[30] There is no evidence and no reason to believe that Shire could not have commissioned from Dr. Bugay the same tests and analysis as he performed for Cephalon at any time following the institution of this action (assuming even that it was reasonable for Shire to wait until explicit evidence of infringement was available before pleading same as a defence, a finding which I decline to make). Further, Shire had in its possession the report of Dr. Bugay as early as October 29, 2010, two weeks before the case management conference specifically convened to fix trial dates, yet failed to advise Apotex or the Court that it could and would amend its statement of defence to plead infringement. I therefore find that the disclosure of Dr. Bugay's report does not explain or justify Shire's belated decision to seek to amend its statement of defence to plead infringement.

[31] Shire having provided no explanation as to why it failed to propose a defence of infringement earlier, the inference must be made that it was a deliberate choice on the part of Shire.

Discussion

[32] The legal test to be applied in determining this motion is well known and was recently considered and applied by the Federal Court of Appeal in *Bristol-Myers Squibb Co. v. Apotex Inc.* 2011 FCA 34:

“[4] The parties substantially agree on the legal test to be applied in assessing whether Apotex should be granted leave to amend its pleadings. A pleadings amendment should be allowed for the purpose of determining the real questions in controversy, provided that allowing the amendment would not result in an injustice to the other party that is not capable of being compensated by an award of costs and the amendment would serve the interests of justice: *Canderel Ltd. v. Canada*, [1994] 1 F.C. 3 at page 10 (C.A.).

[5] The burden is “heavier when the amendments at issue purport to withdraw substantial admissions and would result in a radical change in the nature of the questions in controversy”: *Merck & Co., Inc. v. Apotex Inc.*, 2003 FCA 488 at paragraph 32, [2004] 2 F.C.R. 459. In *Merck* at paragraph 33, this Court emphasized that a Judge or Prothonotary, faced with a motion to amend, “has the duty to consider all relevant factors.”

[33] It is clear that Shire's proposed amendments would introduce into this action a radically new defence, and that as a result, Shire's burden to satisfy the Court that it is in the interest of justice to allow the amendment is heavier. The Court does not accept Shire's argument to the effect that the proposed amendments are not radically new because Shire announced its intention to rely on the infringement of the '967 patent in its previous, unsuccessful, motion for leave to amend. Shire's motion was not granted and the issue never therefore became part of this litigation. Further, even as then proposed, Shire's amendments were clearly never intended to introduce in this action infringement as an evidentiary issue.

[34] Allowing the amendment at this stage would, further, cause prejudice to Apotex that cannot be compensated in costs. Allowing the amendments at this time would, as mentioned above, necessarily result in the adjournment of the trial and delay the expeditious trial of this matter. This Court has already found, in determining Shire's previous motion to amend, that an amendment that would rely on the outcome of the Cephalon action would unreasonably delay the trial of this action,

in view of the fact that that action was far less advanced than the present one. The situation has not changed and introducing the bulk of the issues raised in the Cephalon action directly into this action would have the same effect as was anticipated when Shire's previous motion was determined.

Although the trial is a little over a year away, the amendments are so substantial that allowing them at this stage would likely delay the trial of this action by a further nine months at least. Judging by the glacial pace at which the Cephalon action has been proceeding, the delay could even be longer. It was held in *Montana Band v. Canada* 2002 FCT 583, at paragraph 7, that an award of costs cannot compensate for the substantial damages that an ultimately successful party suffers by being denied what is due to it for a further period of months or years.

[35] There is also the interests of justice to be considered here. This Court has invited parties who are serious in proceeding diligently with complex actions such as this one to apply for early trial dates, and has committed to bringing such actions to trial within two years where possible. Apotex accepted that invitation almost as soon as it had been extended, has made its intention to move to an expeditious trial clear and explicit to Shire at all times since and has conducted itself in a manner designed to achieve that result. Shire, for its part, chose to sit on its rights, to deliberately not to assert them until after a trial date had been set and to wait until these trial dates would necessarily be compromised before asserting those rights. This is conduct consonant with a deliberate attempt to derail the carefully planned and managed conduct of this litigation.

[36] As stated by the Court of Appeal in the case of *Bristol-Myers-Squibb v. Apotex, supra*:

“[37] Complex, high-stakes intellectual property proceedings are governed by procedural rules aimed at fairness, full and timely disclosure, and efficiency. Purposeful, strategic conduct involving non-disclosure, non-clarification or inaction, as the Prothonotary

and the Federal Court judge found here, disrespects these rules and their aims. Those who disrespect the rules and their aims can hardly expect courts to smile upon them when they look for a favourable exercise of discretion under those rules.”

[37] In the same way that it was noted by the Court of Appeal, at paragraph 52 of *Merck & Co. et al. v. Apotex Inc.*, 2003 FCA 488, as a relevant consideration in denying a late amendment: “this is not the case of negligent conduct of litigation by counsel but a case, rather, of a party attempting to derail litigation which has been pursued for several years by adding a defence which, it knows very well, does not reflect the true questions in controversy”. In coming to that conclusion, I do acknowledge that a defence of infringement in this case would constitute a triable issue. However, it is not, and has never been, a true question in controversy in this litigation. As mentioned above, even Shire's attempt to introduce that defence indirectly by reference to the Cephalon action carefully avoided bringing the question of infringement as a live factual issue in this action.

[38] Even if this were the case of negligent conduct of litigation, the *dicta* of Lord Griffiths in *Ketteman v. Hansell Properties Ltd.*, [1988] 1 All E. R. 38, at page 62, cited with approval in *Canada (Minister of National Revenue) v. Canderel Ltd.*, [1994] 1 F.C. 3 and in *Merck & Co.*, *supra*, would remain applicable:

“Another factor that a judge must weigh in the balance is the pressure on the courts caused by the great increase in litigation and the consequent necessity that, in the interests of the whole community, legal business should be conducted efficiently. We can no longer afford to show the same indulgence towards the negligent conduct of litigation as was perhaps possible in a more leisured age. There will be cases in which justice will be better served by allowing the consequences of the negligence of the lawyers to fall on their own heads rather than by allowing an amendment at a very late stage of the proceedings.”

[39] Shire argues that the decisions in *Bristol-Myers-Squibb* and *Merck & Co.* should not be followed here because the trial is over a year away, that discoveries have not been closed, that expert reports have not been filed and that a pre-trial conference has not been held. It is true that the representations of the parties at the pre-trial conference were an important consideration for the Court in *Bristol-Myers-Squibb*. However, it does not appear that those factors were present in *Merck & Co.* Further, the present case has in common with the latter two the following factors: that the proposed new defences admittedly would have raised a triable issue, that they constituted, nevertheless, a radical change in the pleadings, that they had a prejudicial effect on the opposing party and that the moving party had displayed purposeful, strategic conduct in failing to bring the new issues to the fore at the appropriate time. I cannot see how the cases differ in principle just because the trial dates set in this matter are a year away.

[40] To allow Shire to succeed on this motion, to derail the conduct of this litigation and to force the adjournment of the trial for months, if not years, by deliberately refraining from asserting a substantial defence in a timely manner would be to condone an abuse of process. I am therefore satisfied that it would not be in the interest of justice to allow Shire to amend its statement of defense to plead infringement as a defense and counterclaim.

Other matters

[41] Shire's motion also sought to introduce, by with amendment, a defense of failure to mitigate, which arises from issues raised on discovery. Apotex does not object to these amendments and Shire's motion will be granted for that limited purpose. As Shire was unsuccessful on the contested aspects of its motion, costs will be awarded in favor of Apotex.

ORDER

IT IS ORDERED THAT:

1. Shire Canada Inc. is granted leave to amend its statement of defense by adding paragraphs 56E-F of the proposed defense attached as schedule "A" to its notice of motion.
2. Shire's motion is otherwise dismissed, with costs in favour of Apotex Inc.

“Mireille Tabib”

Prothonotary

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1787-08

STYLE OF CAUSE: Apotex Inc. and Shire Canada Inc.

PLACE OF HEARING: Ottawa, Ontario

DATE OF HEARING: March 3, 2011

REASONS FOR ORDER: TABIB P.

DATED: April 7, 2011

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