

Federal Court



Cour fédérale

Date: 20111013

Docket: T-1787-08

Citation: 2011 FC 1159

Ottawa, Ontario, October 13, 2011

PRESENT: The Honourable Mr. Justice Near

BETWEEN:

APOTEX INC.

Plaintiff

and

SHIRE CANADA INC.

Defendant

REASONS FOR ORDER AND ORDER

[1] This is a motion brought by the Defendants, Shire Canada Inc. (Shire), under Rule 51 of the *Federal Court Rules*, SOR/98-106 appealing the Order of the Case Management Prothonotary, dated April 7, 2011. The Prothonotary denied leave to Shire to amend its Statement of Defence and plead infringement as a defence and counterclaim.

I. Background

[2] Shire is a licensee of Canadian Patent No. 2,201,967 (the '967 Patent), owned by Cephalon Inc. (Cephalon), for the medicinal ingredient modafinil. Shire also holds a Notice of Compliance (NOC) permitting it to sell a medicine containing modafinil in Canada under the name Alerte.

[3] On March 15, 2006, Apotex Inc. (Apotex) served a Notice of Allegation (NOA) on Shire alleging invalidity of the '967 Patent. In response, Cephalon and Shire commenced an application under section 6 of the *Patented Medicines Regulations* for an Order prohibiting the Minister of Health from issuing a NOC to Apotex. That application was dismissed by this Court on April 25, 2008.

[4] Accordingly, Apotex (the Plaintiff) filed the present action against Shire on November 18, 2008 under section 8 of the *Regulations* claiming damages for having been kept off the market by Shire's unsuccessful application for a prohibition order. On January 23, 2009, Shire delivered its Statement of Defence. Apotex wrote to the Court requesting case management and a trial date fixed for the early part of 2011. Prothonotary Tabib was appointed as the case manager on August 6, 2009.

[5] Meanwhile, Cephalon commenced a separate patent infringement action against Apotex on April 17, 2009 (Court File No. T-609-09). Shire is not a party to that action. Cephalon brought a

motion on October 29, 2010 to consolidate that action with the current proceedings but it was subsequently withdrawn.

[6] Shire has brought two previous motions to amend its Statement of Defence in these proceedings:

- (1) In December 2009, Shire sought leave to add as a defence that Apotex would not have been in a position to sell its product in 2006 because of difficulties in manufacturing for commercial sale. Shire was granted leave to amend in January 2010 but this extended the schedule by three months.
- (2) On April 23, 2010, Shire again moved to add a defence of grave consequences as well as a defence based on Cephalon's infringement action against Apotex. The Prothonotary dismissed this motion stating that the proposed amendment "would unreasonably delay, embarrass and prejudice the trial of the present action." This Order was upheld on appeal on October 8, 2010 (2010 FC 1001, [2010] FCJ no 1245). Justice Yvon Pinard suggested that if Shire thought it had a valid defence to the section 8 proceedings on the basis that Apotex's product would have been infringing; it should have brought forward a plea for infringement in accordance with the prescribed practice.

[7] The appeal before this Court arose out of Shire's third motion to amend its Statement of Defence on January 21, 2001. Shire sought to allege infringement directly (instead of basing it on the Cephalon action) and to counterclaim for damages and an injunction.

II. Order of the Prothonotary

[8] The Prothonotary determined that it would not be in the interests of justice to allow Shire to amend its Statement of Defence to plead infringement as a defence and counterclaim. The proposed amendment would introduce a radically new defence into the action. Shire therefore had a heavier burden of establishing that it was in the interests of justice.

[9] As the Prothonotary stated, allowing the amendment at this stage would cause prejudice to Apotex that could not be compensated by costs. It would lead to an adjournment and delay of at least nine additional months. This was particularly disconcerting given that Shire's previous motion to amend had been denied because it would cause an unreasonable delay. Moreover, costs could not compensate for damages suffered by denying a successful party what was due for a period of months.

[10] The Prothonotary also noted that the Court has encouraged parties to apply for early trial dates, as Apotex did in this instance. By contrast, Shire was seen as deliberately waiting until after a trial date had been set to assert its rights. The Prothonotary was not convinced by Shire's claims that it did not know there were reasonable grounds to argue infringement until after receiving an expert report because this information could have been acquired earlier. As a consequence, Shire's

conduct was seen as derailing the litigation. To allow the motion, according to the Prothonotary, would be to condone an abuse of process.

III. Issues

- (a) What is the appropriate standard of review for the Prothonotary's Order?
- (b) Should Shire be granted leave to amend its pleadings to include infringement as a defence and counterclaim?

IV. Standard of Review

[11] It is well-established that the Court should not disturb the discretionary order of a prothonotary unless she has decided on a question vital to the final issue of the case, or made an order that is clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts (*Merck & Co v Apotex Inc*, 2003 FCA 488, [2004] 2 FCR 459 at para 19).

[12] The importance of deference is particularly stressed in the case management context. As a prime example, the Federal Court of Appeal stated in *Montana Band v Canada*, 2002 FCA 331, [2002] FCJ no 1257 at para 7:

[7] We would like to emphasize once again the heavy burden upon litigants seeking to overturn an interlocutory order of a case management judge. This Court is loathe to interfere with interlocutory orders in any case due to the delay and expense which

such appeals add to any proceeding. This is all the more so where an appeal is taken from an interlocutory decision of a case management judge who is intimately familiar with the history and details of a complex matter. Case management cannot be effective if this Court intervenes in any but the “clearest case of misuse of judicial discretion.” [...]

[13] Shire argues that Prothonotary Tabib’s Order should nonetheless be reviewed *de novo* as the questions raised are vital to the final issue. An amendment advancing additional claims or new causes of action to the existing claim has been recognized as vital by this Court in the past (see *Merck & Co*, above, para 18). In addition, an amendment which adds a new defence going directly to the issue of the case should be considered vital and requiring a *de novo* review (see *Banks of the West v Weldga* 281596, 2007 FC 1112, [2007] FCJ no 1433 at para 6). Shire notes that Apotex and the Prothonotary acknowledged the importance of the proposed amendment as constituting a serious defence and triable issue.

[14] Alternatively, Shire argues that the Order was based on a wrong principle and misapprehension of the facts. Specifically, Shire claims that the Prothonotary erred in finding that Shire’s attempt to add a defence of infringement in April 2010 was not evidence of an intention to raise it and therefore Shire was abusing the process by introducing a radical new defence at a late stage. Shire also insists that delays in the trial date could be compensated by costs being awarded to Apotex.

[15] Apotex contends that there should be deference for the factual findings of the Prothonotary. It bases this argument on comments made in a recent decision of the Federal Court of Appeal, *Bristol-Myers Squibb Co v Apotex Inc*, 2011 FCA 34, [2011] FCJ no 147 at paras 8-9.

Justice David Stratas suggested that he was attracted to submissions promoting a deferential stance on factual findings and assessments of prothonotaries, akin to the normal standard of appellate review, even where they raise a question vital to the final issue of the case. However, Justice Stratas reached no definitive conclusion on this issue that would justify altering the established approach to reviewing a prothonotary's order.

[16] I am therefore persuaded by Shire's submissions that since the proposed amendment is adding a new defence, it would be a question vital to the final issue in the case and should be reviewed *de novo*.

V. Leave to Amend Pleadings

[17] Amendments to pleadings are governed by the decision in *Canderel Ltd v Canada*, [1994]

1 FC 3, [1993] FCJ no 777 at para 9:

[9] [...] The general rule is that an amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties, provided, notably, that the allowance would not result in an injustice to the other party not capable of being compensated by an award of costs and that it would serve the interests of justice.

[18] An amendment that would lead to a radical change in the nature of the questions in controversy places a heavier burden on the moving party to establish that it is in the interests of justice (*Merck & Co*, above, para 32). This heavier burden applies to Shire's amendment because it would insert a full infringement action into the pre-existing section 8 proceedings. As Apotex

asserts, the real questions in controversy are determined by the pleadings and would be altered in this case.

[19] Relevant factors in determining the interests of justice include the timeliness of the motion to amend, the extent to which the proposed amendment would delay the expeditious trial of the matter, the extent to which a position taken originally by one party has led another party to follow a course of action in the litigation which it would be difficult or impossible to alter and whether the amendments sought will facilitate the court's consideration of the true substance of the dispute on its merits (*Merck & Co*, above, para 30).

[20] Shire submits that the issue of infringement was put forward as early as April 2010 before discoveries had closed. It also asserts that allowing the amendment would promote efficiency and raise a serious and novel issue within the section 8 action.

[21] Even if the Court accepts that the issue of infringement was put into play somewhat earlier in the proceedings, this does not imply that the motion is timely and would not delay an expeditious trial or allow for consideration of the “true substance” of the dispute. Justice Pinard’s comments in assessing Shire’s previous motion to amend should not have been viewed as an invitation to introduce further delays by raising a defence of infringement in a different manner. Shire should have raised the issue of infringement much sooner. Moreover, the infringement aspect is not necessarily the “true substance” of section 8 proceedings directed at damages of Apotex being kept off the market. Any potential basis for infringement could be pursued by way of a separate action

or by Shire joining the Cephalon proceedings already in progress without delaying a section 8 resolution.

[22] In addition, it is evident that the proposed amendments will cause significant delays in the expeditious trial of the matter, an objective pursued by Apotex since the commencement of proceedings. As Apotex asserts, it will cast the matter back to the pleadings phase. Apotex has also provided persuasive evidence of delays measured in years currently plaguing section 8 proceedings when an infringement allegation is included.

[23] While this Court has recognized that a delay of a couple weeks or months may not be sufficient to deny a request to amend (*Drolet c Stiftung Gralsborchaft*, 2007 FC 1347, [2007] ACF 1737 at para 6), it has also made clear that certain delays close to a trial date could not be compensated by costs because they are prolonging the opportunity to have the matter resolved by the Court. As stated in *Montana Band v Canada*, 2002 FCT 583, [2002] FCJ no 774 at para 7, aff'd 2002 FCA 331:

[7] [...] Every amendment to pleadings will of course cause some delay but some delays are far more consequential than others. Where one is virtually on the eve of a lengthy and major trial, whose date has been known and anticipated for many months, the preparation for which has been the subject of close and intensive cooperation between counsel and the Court extending over a period of years and where the issues are many and complex and the proceedings involve numerous parties, there is simply no way in which an order for costs could possibly provide adequate compensation for the loss of the trial date. Indeed, even the attempt to assess the costs that would have been thrown away by the anticipated delay of this trial would be well-nigh impossible. And costs, even on the highest scale, can, as their name implies, only compensate for the moneys spent in preparing for and conducting the trial; they cannot include 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.

[24] Since the proposed amendments will lead to significant delays and the loss to Apotex of having the matter dealt with expeditiously cannot be fully remedied with costs, the Court should not grant leave. Shire should have brought the issue of infringement forward in its initial pleadings and not sought an alternative way to introduce it into the action when its previous request was denied with reference to the potential for delay.

VI. Conclusion

[25] The Defendant's motion is dismissed with costs awarded to the Plaintiff.

ORDER

THIS COURT ORDERS that the Defendant's motion is dismissed with costs awarded to the Plaintiff.

“ D. G. Near ”

Judge

FEDERAL COURT
SOLICITORS OF RECORD

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STYLE OF CAUSE: APOTEX INC. v. SHIRE CANADA INC.

PLACE OF HEARING: OTTAWA

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**REASONS FOR ORDER
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