Federal Court  Cour fédérale

Date: 20170419

Dockets: T-1409-04
T-1890-11

Citation: 2017 FC 378

Ottawa, Ontario, April 19, 2017

PRESENT: The Honourable Mr. Justice Barnes

Docket: T-1409-04

BETWEEN:

ASTRAZENECA CANADA INC. AND AKTIEBOLAGET HÄSSLE

Plaintiffs
(Defendants by Counterclaim)

And

APOTEX INC.

Defendant
(Plaintiff by Counterclaim)

Docket: T-1890-11

AND BETWEEN:

ASTRAZENECA AB AND AKTIEBOLAGET HÄSSLE

Plaintiffs
(Defendants by Counterclaim)

and

APOTEX INC.

Defendant
(Plaintiff by Counterclaim)

ORDER AND REASONS

[1] This patent infringement proceeding has been underway in this Court since 2004. A liability determination was rendered in favour of the Plaintiffs [AstraZeneca] on March 16, 2015 and substantially upheld on appeal on January 12, 2017; see *AstraZeneca v Apotex*, 2015 FC 322, 252 ACWS (3d) 567, aff'd in part 2017 FCA 9, [2017] FCJ No 22 (QL). The quantification phase is presently being tried before me in Toronto. The presentation of evidence commenced on February 14, 2017 and only final argument remains outstanding. Numerous fact and expert witnesses have testified on behalf of the parties and the evidence has closed on the present pleadings. Nevertheless, Apotex seeks to further amend its Fresh as Amended Responding Statement of Issues in these proceedings by adding a new non-infringing alternative [NIA] in the following form:

> 46A. Apotex further states that, for sales of Apo-Omeprazole that were made into the U.S. market, Apotex had available to it the option of arranging for the manufacture and sale of all or some of such quantities in a non-Canadian jurisdiction by another pharmaceutical manufacturing company. Such an arrangement would have rendered any manufacture, use or sale of omeprazole, even if made in accordance with the manufacturing process employed by Apotex in the real world, non-infringing of the 693 Patent because the 693 Patent's territorial reach is limited to activities in Canada.
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> 46B. To Apotex's present knowledge, the following entities could have and would have entered into contract manufacturing arrangements with Apotex to effect such a non-infringing alternative:

- Intas Pharmaceuticals Ltd. and its affiliates; and
- Barr Laboratories, Inc. and its affiliates.

[2] This new allegation is in addition to Apotex's earlier amended pleading of an NIA defence based on several alternative formulations to be made either in-house or by third parties.

[3] A summary of the various motions to amend in this case can be found in the decision of Justice Russel Zinn dated July 22, 2016 and need not be repeated here: see *AstraZeneca v Apotex*, 2016 FC 865, [2016] FCJ No 1503 (QL). It is of some significance that Justice Zinn there permitted an amendment to Apotex's NIA pleading over AstraZeneca's objections based, in part, on his observation that the pending trial dates could still be accommodated.

[4] The proposed amendment was first brought to the attention of the Plaintiffs and the Court shortly before the commencement of trial. The motion was officially filed on February 27, 2017 and it was argued on April 12, 2017. Final argument in the trial is scheduled for the week of April 24th based on the evidence called by the parties to the close of evidence on April 7, 2017.

[5] To their credit, Apotex and its counsel acknowledge that the failure to seek this amendment on a timely basis was based on an oversight. According to the affidavits of Dr. Sherman and Mr. Radomski, this variation of Apotex's NIA defence was, over the several years of this litigation, simply overlooked. It was only recently considered by counsel in the course of a meeting on February 10, 2017 after which it was brought to the attention of the Court and counsel for the Plaintiffs.

[6] The primary thrust of this proposed amendment is that, after the expiry of AstraZeneca's United States patent on April 20, 2007, Apotex could have employed its Canadian-developed formulation in the United States provided that the product came from a jurisdiction outside of Canada where AstraZeneca did not enjoy similar patent protection (e.g. India). The proposed amendment is, nevertheless, intended to apply on some largely unarticulated basis to the entirety of the infringing period covering several years.

[7] With the amendment Apotex must, of course, establish a new hypothetical postulate: that it "could have and would have" obtained its approved formulation from a non-infringing source for sale into the United States market for the relevant period. Apotex acknowledges that the allowance of the amendment will, therefore, require the reopening of the trial for the marshaling of additional evidence including the likely amendment of some of the expert opinion evidence already tendered.

[8] Apotex describes its proposed amendment as merely a technical adjustment to its NIA pleading resulting in "inconvenience" to AstraZeneca. The asserted inconvenience will take the form of further discoveries, amendments to some of the extant expert reports and a trial delay of several months to permit the calling of new evidence. At this stage an accurate estimate of the additional days required to continue the trial cannot be made. However, based on the time taken to deal with Apotex's NIA defence to date, a further two weeks would not be out of the question. These things, Apotex says, do "not alter materially the contours of the trial or the analytical frameworks employed by the respective experts". Apotex also concedes that it ought to bear the additional expenses occasioned by the amendments.

[9] Not surprisingly, AstraZeneca takes a fundamentally different view of the logistical and evidentiary problems created by this proposed amendment. Some of the difficulties it identifies are not, it says, capable of being compensated by costs or interest.

[10] AstraZeneca's principal concern is that it made its election claiming profits on the strength of Apotex's pleaded NIA defence and the expert reports Apotex tendered in support of that case. According to some of the accounting analysis, AstraZeneca's claim to profits from Apotex's United States sales is substantially larger than its alternative claim to damages. AstraZeneca argues that this differential also informed its election and established the framework for much of the evidence called to date.

[11] Apotex contends that this argument ought to be ignored in the absence of any supporting affidavit evidence. Indeed, it says this failure to proffer some evidence of substantive prejudice supports the drawing of an inference that there will be no resulting prejudice.

[12] A recent and helpful discussion concerning pleading amendments in the context of patent litigation can be found in *Abbvie Corp v Janssen Inc*, 2014 FCA 242, 246 ACWS (3d) 337. That case involved an amendment before trial to add prior art references that were known to the parties and their experts. The Court described the test in the following way:

> [18] The jurisprudence on amendments teaches us that no single factor is determinative. The list of factors to be considered is not exhaustive. This is a balancing exercise and although no single factor predominates, proper weight has to be given to the relevant factors applicable to each particular case. In our view, the Judge misapplied the stated test and failed to give proper consideration to the relevant factors including the particularity of this case which involves novel technology with complex scientific and commercial

> realities going at the heart of the patent bargain between the inventor and the public. Had the Judge considered all of the relevant factors and applied them appropriately to the case at hand, he would have allowed the amendment. Once again, the interests of justice required that the Judge be in possession of the entire relevant prior art.
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> [19] In saying this, we are not suggesting that every amendment sought by a party within a few months or weeks of the commencement of a trial should be allowed. The delicate balancing exercise required to decide whether or not to allow the amendment sought by a party must be done on a case-by-case basis. We also realize the importance of this case for the parties and the inconvenience of going back to the Federal Court with this matter. But weighed against the other factors discussed above, we reach the same conclusion. The parties are experienced litigators and will, no doubt, find solutions to shorten the next hearing. As a result, the appeal will be allowed with costs.

[13] I do not read this decision as displacing the older authorities which place considerable weight on the timing of the motion to amend and the disruption to the legitimate expectations of the responding party. Decisions like *Continental Bank Leasing Corp v Canada*, [1993] TCJ No 18 (QL), 93 DTC 298 and *Montana Band v Canada*, 2002 FCT 583, [2002] FCJ No 774 (QL), continue to be applied in situations like the present one. For example in *Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2014 FCA 65, 238 ACWS (3d) 846, the Court upheld an amendment refusal brought a mere three months before trial. The Prothonotary was of the view that the amendment ran the risk of a trial adjournment and the likely alteration of already exchanged expert reports. In upholding the decision, the Court had this to say:

> [19] As I have already noted, the timing of a motion to amend is a relevant factor to be taken into account when considering whether the motion should be granted. As stated in *Canderel Ltd. v. Canada*, above at p. 11, "[a]s 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".

> [20] In this case, not only was the timing of Sanofi's motion tardy, it also almost certainly ensured that the trial would be considerably delayed had it been allowed. In this matter, I adopt the words of Hugessen J. in *Montana Band v. Canada*, 2002 FCT 583, [2002] F.C.J. No. 774 (QL) at para. 7:
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> > 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.
>
> [21] This, in my view, is sufficient to dispose of the appeal.

[14] Applying the above considerations to the circumstances relevant to this motion, I am not prepared to grant relief to Apotex. The complications arising from Apotex's failure to raise this NIA issue in a timely way are simply too profound to be remedied by monetary relief.

[15] The considerations that militate against the relief sought by Apotex include the following:

a) the proposed amendment did not arise from something beyond the control of Apotex or its counsel;

b) Apotex has already had the benefit of several amendments to its pleadings including a NIA amendment argued and allowed last July;

c) AstraZeneca made a profits election, prepared and fully presented its case based on Apotex's current pleadings;

d) evidence in the trial on the present pleadings is closed and only final argument remains outstanding;

e) the proposed amendment will require further documentary and oral discovery;

f) the proposed amendment will require new factual evidence to be led out of order;

g) the proposed amendment concerns a materially different NIA theory than those already pleaded; it is decidedly not a technicality;

h) some of the expert accounting reports will require amendment and additional opinion evidence about a different regulatory environment will probably be necessary;

i) the completion of the trial will be delayed by at least several months, creating a large gap in the hearing of evidence;

j) trial dates were assigned three years ago based on the parties' estimate of what was needed; and

k) the dates currently set aside for final argument will be wasted.

[16] Apotex contends that it was incumbent on AstraZeneca to lead evidence in proof of the prejudicial effects of these amendments, including evidence either from AstraZeneca's counsel or from someone providing instructions to counsel. In the absence of something substantive showing a step taken or avoided that cannot now be readily reversed, Apotex says the Court should infer an absence of irreversible prejudice.

[17] I do not agree that such an inference should be drawn in these circumstances. First of all, after hearing five weeks of evidence, I believe I have an informed appreciation of the impact that this amendment will have on AstraZeneca and the Court. I have no doubt that AstraZeneca's election of profits would have been informed, in part, by its appreciation of the merits of Apotex's pleaded NIA defence.

[18] The NIA formulation Apotex seeks now to advance is not just one more of several hypothetical and unapproved alternate formulations to Apo-omeprazole. Instead, Apotex now wants to assert Apo-omeprazole itself as an NIA – a formulation that has received regulatory approval in Canada and, perhaps more importantly, in the United States. This is a materially different NIA theory than those already presented to the Court.

[19] When evidence has been shaped and strategic choices made in response to a pleaded defence, I am not prepared to assume that the raising of a new and distinct issue at the very end of a lengthy trial will be effectively benign. In my view, to permit this amendment will be to renew the fight on an entirely different front: see *Canderel v Canada*, [1994] 1 FC 3 at para 12, [1993] FCJ No 777 (QL)(FCA).

[20] There are other problems with Apotex's argument that AstraZeneca's position is undermined by its failure to file a substantive affidavit explaining how the amendment would impair its litigation strategy and its strategic choices.

[21] To demand this type of evidence would almost inevitably put at risk AstraZeneca's claim to solicitor-client privilege. It is inconceivable that AstraZeneca's election of profits was not substantially informed by advice from its counsel about the merits of Apotex's as-pleaded NIA defence and the relative amounts of potential recovery from claims to damages versus profits from Apotex's United States sales. AstraZeneca should not be forced into the awkward position on this motion of justifying its position by putting its privileged communications at substantial risk.

[22] I note, as well, that Apotex has not stipulated on this motion that it would permit AstraZeneca to re-elect if the amendment is allowed. Needless to say a re-election would wreak havoc on the evidence already called. Added to this is that the kind of evidence Apotex would require of AstraZeneca is not fact evidence about something that occurred. Instead Apotex says AstraZeneca should provide evidence about what it would have done in the face of its proposed pleading. This is, in effect, a "but-for" situation requiring a knowledgeable affiant to speak to a hypothetical construct. Such an affidavit would inevitably be challenged as unreliable hindsight.

[23] A secondary consideration is the matter of judicial efficiency and, in particular, the management of increasingly scarce judicial resources. The interests of the litigants are always in the forefront of the Court's consideration of pleading amendments. But the Court is not at the total mercy of the parties before it. The public, too, has an interest in the preservation and allocation of Court time and resources: see *Sanofi-Aventis Canada Inc v Teva Canada Ltd*, *above*, at paras 16-17. When a proposed amendment would cause lengthy delay and use up significant unplanned trial dates, it is to be assumed that the adjudication of other pending

matters will be adversely affected. This case has already taken up many hearing days leading up to and throughout the trial. Trial dates were allocated three years ago based on the joint request of the parties. Suffice it to say that the proposed amendment would considerably disrupt the Court's schedule and split the trial into two distinct phases months apart. This bifurcation of the trial would be inefficient. Furthermore, delays of this duration are inevitably damaging to the Court's ability to give reasons that are responsive to the oldest evidence.

[24] There is clearly a need to bring some finality to cases like this one. This matter has been before the Court since 2004 and has absorbed a large amount of judicial resources. It is simply not good enough after 13 years to say that, in the scheme of things, another delay of some months is of no material consequence.

[25] The motion is, accordingly, dismissed with costs payable to AstraZeneca in the amount of $15,000.

ORDER

THIS COURT ORDERS that the motion is dismissed with costs payable to AstraZeneca in the amount of $15,000.

"R.L. Barnes"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-1409-04 AND T-1890-11
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