Federal Court Cour fédérale

Date: 20160516

Docket: T-389-11

Citation: 2016 FC 552

Ottawa, Ontario, May 16, 2016

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

APOTEX INC.

Plaintiff

and

ASTRAZENECA CANADA INC.

Defendant

ORDER AND REASONS

[1] AstraZeneca brings this motion to amend its statement of defence in the context of Apotex's action for damages pursuant to Section 8 of the *PM (Notice of Compliance) Regulations*, (SOR/93-133);

[2] This motion was essentially prompted by my April 1, 2016 order ruling on a motion to determine objections arising out of discoveries, in which I held an ordered as follows:

Apotex argues that Astrazeneca may not properly have discovery on the issue of whether or not Astrazeneca would have launched an Authorized Generic in the "but for" world, because Astrazeneca has not pleaded this as a fact. I agree. However, I note that the pleadings of both parties are deficient. Apotex's pleadings contain no particulars as to what it alleges it would have done in the "but for" world. Astrazeneca's defence does plead that Apotex did not and was not able to launch until March 2011, because, in the real world, it only launched that date, nine months after receiving its NOC and then only in three provinces with limited inventory. It does not otherwise assert any other alternative scenario, including that it might have launched an authorized generic if Apotex had launched earlier, or in a broader fashion. Apotex's reply is limited to asserting that it was "at all times in a position to lawfully market" its product. This pleading is equivocal as to whether Apotex asserts that it would have launched at a certain date and in a broader manner than it launched in the real world.

The Court understands that Astrazeneca's position is that if Apotex were to assert that it would have launched differently in the "but for" world than in the real world, then it should be able to defend by asserting that it would, in such circumstances, have launched an Authorized Generic. Clearly, the pleadings need to be clarified; the parties cannot continue discoveries and go to trial without a clear understanding of what is pleaded.

As they stand, I find that Apotex's pleadings fail to sufficiently particularize what it asserts it would have done in the "but for" world, and that Astrazeneca does not plead that, had Apotex launched "differently", it would have launched an Authorized Generic or that other generics would have entered the market. As a result, questions that would go solely to the issues of what Astrazeneca would have done in terms of an Authorized Generic in the "but for" world or the entry of other generics would not be relevant on the pleadings as they stand.

That said, Astrazeneca's pleadings are clearly sufficient to put into play all the factors that went into Apotex's decision, actions and state of mind in launching in the real world, and how these factors might have influenced it in the "but for" world. Apotex's anticipation or "fear" of an Authorized Generic or of other competitors, and how that affected or may have affected its own conduct, is accordingly relevant on the pleadings as they stand.

In order to avoid any further controversy arising from insufficient pleadings, Astrazeneca shall seek the particulars it says are missing

> from Apotex's pleadings, and shall, if it feels it necessary, move to amend its pleading in accordance with a schedule to be established.
>
> (Emphasis added)

[3] In compliance with that order, AstraZeneca sought particulars of several aspects of Apotex's statement of claim. While Apotex objected to most, it did provide further particulars to the effect that, had AstraZeneca not invoked the *Regulations*, it would have entered the market as of the Patent hold date, in all provinces and with all dosage forms, having previously sought listings in all provinces, with full interchangeability and at a price at least as high as the one it sought in "the real world".

[4] AstraZeneca would seek to amend its statement of defence to add the following paragraphs:

> 1A. AstraZeneca objects to the baldness of Apotex's Claim, which does not set out the material facts on which Apotex relies. Apotex has not amended its Claim to address the deficiencies, despite having been provided an opportunity to do so. AstraZeneca will object to any attempt by Apotex to lead affirmative evidence at trial of any material fact that ought to have been pleaded therein. Without prejudice to the foregoing, AstraZeneca pleads as follows.
>
> (...)
>
> 15A. With respect to any hypothetical market entry in the "but for" world that Apotex may seek to rely on, that differs materially from Apotex's market entry in the real world (AstraZeneca denies there would have been any such difference), including with respect to one or more of: geographical territory; market entry dates in various markets; pack size; price; formulary listing dates; product specification; different market penetration rates; and, number and timing of entry of generic esomeprazole competitors, AstraZeneca would have responded appropriately to protect its esomeprazole market and business, including by authorizing a generic esomeprazole product and not opposing market entry by other generic competitors. Specifically, if Apotex seeks to rely on a

> hypothetical market in which it enters all material markets in Canada with no limits on its available inventory as of its alleged patent hold date, and subject to Apotex's pricing, AstraZeneca would have introduced an authorized generic sooner than it did in the real world and it would not have opposed the market entry of other generic products which would have competed with Apotex for market share.

[5] The first proposed paragraph is not a pleading of any fact material to the determination of the issues between the parties but the iteration of a complaint as to the propriety or sufficiency of Apotex's pleadings. The *Federal Courts Rules* provide procedural mechanisms to remedy such complaints. The Court specifically directed AstraZeneca to use the mechanism of particulars in order to obtain the clarifications it needed. Although AstraZeneca has not obtained all the particulars it sought, it chose not to make a motion to compel the provision of additional particulars. And despite obtaining some particulars, the proposed new pleading appears to ignore same in favour of keeping the controversy alive for trial. I cannot see how it can be in the interest of justice to allow an amendment designed solely to leave a procedural issue unresolved, in defiance of the Court's directions that the pleadings be clarified before the parties were to continue discoveries or go to trial

[6] So that matters are perfectly clear, I reiterate what I said at the hearing: the particulars provided by Apotex in response to AstraZeneca's request for particulars are as binding on Apotex as if they had been included in an amended statement of claim. They serve to narrow and particularise the allegations of the statement of claim and may not be modified without leave.

[7] The second proposed paragraph, as drafted, is on its face impermissibly vague and open-ended. Again, the proposed amendments seem to ignore the particulars that were provided in

favour of an approach that assumes the same uncertainties as to what Apotex may try to prove at trial and leaves the door open for AstraZeneca to invoke any defence or scenario it wishes. Only the last sentence seems to provide some, but still inadequate, particulars.

[8] The very vagueness of the proposed allegations initially seemed to support the view expressed by Apotex in its responding motion record to the effect that the pleading had "no air of reality" and was merely a ploy to delay the trial, scheduled to begin in May 2017. Apotex's responding record went even further, suggesting that AstraZeneca could not propose a properly particularized plea because there are no facts that could have been placed into evidence to give the proposed defence an air of reality. In oral argument, counsel for AstraZeneca wished to clarify that documents and information had been communicated on discovery to show that, in the real world, AstraZeneca did launch an authorized generic after the market had been genericized, and that AstraZeneca had in fact instituted prohibition proceedings in response to Notices of Allegation served by other generics. Counsel for AstraZeneca argued that its proposed amendments intended to allege that these "real world" events would have happened earlier if, as pleaded by Apotex, Apotex had entered the market as broadly as it suggests at an earlier date.

[9] Apotex objected to the clarification, arguing that counsel was improperly testifying and supplementing its record. I declined at the hearing to receive a copy of the documents AstraZeneca's counsel sought to produce, because there is in my view no general requirement, on a motion to amend, for the moving party to bring evidence to prove the existence of the facts proposed to be alleged. I did however accept the oral submissions of counsel for AstraZeneca as argument to the effect that the purpose of the proposed amendment is to allege that the specific

events that allegedly took place in the real world would have happened earlier if Apotex had entered the market in all provinces with all dosage strengths as soon as it received its NOC. Counsel for Apotex eventually conceded that the existence of the real world events (the launch of an authorized generic and the entry of other generics) was not a matter of controversy. Whether or not AstraZeneca can eventually prove that these real world events could have occurred earlier is disputed, but that is not a matter to be proven or determined at this stage.

[10] As mentioned above, the amendments, as drafted in AstraZeneca's motion record, are far too vague and imprecise, and I would not have allowed them in this form, this late into the proceedings. However, to the extent they are understood in light of counsel's clarifications at the hearing, and assuming that they can be proven at trial, they would clearly disclose a reasonable defence. The motion therefore cannot be summarily dismissed as frivolous, vexatious or speculative. I am satisfied that the issues AstraZeneca proposes to raise by amendment disclose a serious and viable defence, and I now turn to considering whether leave should be granted to include them, having regard to the interest of justice, fairness, and any prejudice that might be suffered by Apotex that cannot be compensated in costs.

[11] Apotex argues that AstraZeneca has not discharged its burden to show that the amendments are in the interest of justice and would not work an injustice. It argues that because the amendments constitute a radical departure from previous pleadings, the burden on AstraZeneca to show why the amendments were made so late and that they are not prejudicial is much greater. It submits that AstraZeneca's motion must fail because AstraZeneca has not explained at all why it did not move to amend earlier.

[12] Apotex's position that the amendments constitute a radical departure from previous pleadings is premised on the argument that the existence of other generics or of an authorized generic in a hypothetical market is, according to broadly accepted and well-established jurisprudence, an affirmative defence that must be pleaded. Accordingly, the fact that the defence was not pleaded specifically is to be taken as tantamount to an acknowledgement that the hypothetical world would not have included any other generic. I cannot agree.

[13] The legal premise on which Apotex's argument is based is of course now well-understood and established, but it was only stated with any degree of clarity for the first time in *Apotex Inc. v Sanofi Aventis et al.*, 2012 FC 553, a year after the statement of defence was filed in this matter. If one accepts Apotex's argument that the issuance of this decision required AstraZeneca to immediately revisit its pleadings in order to specifically plead the existence of other generics in the hypothetical market, then the same should apply to Apotex. The *Apotex v Sanofi* decision makes it clear that the primary burden is on the claimant to prove that it would have entered the market in the delay period and would have suffered damages. I reiterate that while Apotex's statement of claim asserts that Apotex suffered damages (to be particularized prior to trial), it contains no allegations to the effect that Apotex would have entered the market in the delay period. Apotex's statement of claim is limited to simply asserting that the obtention of its NOC was delayed, at best implying that it could have entered the market. On Apotex's own argument, without amending its pleading, it would not be permitted to bring evidence at trial to establish that it would have entered the market in the delay period and the burden would therefore never shift to AstraZeneca to establish that there would have been competition in the marketplace.

[14] Looking instead at the conduct of the parties, I note that while Apotex forcefully and explicitly raised the absence of specific allegations of generic completion in the course of the October 2015 discoveries, it is not at all clear that the parties had not previously contemplated or appreciated the relevance of "real world" events to the construction of the "but for world", including the entry of other generics. Indeed, at the direction of the Court, the parties filed, in late 2014, trial charts setting out the issues on which each party had the burden of proof, and the witnesses they foresaw calling. AstraZeneca's chart lists as an issue "AstraZeneca's approach to NEXIUM, and actions that it took in response to genericization of the Nexium market or would have taken in response to genericization had it occurred at an earlier date." and "Esomeprazole Magnesium market and impact of genericization on NEXIUM; market share allocation following genericization and in hypothetical scenarios;" . Apotex says that this shows that AstraZeneca did understand that Apotex was asserting it would have entered the market in the relevant period. That may be so, but as worded, this statement is also certainly wide enough to include as an issue for trial AstraZeneca's approval of an authorized generic or its decision to discontinue its opposition to the entry of other generics. There is no basis, on the record before me, to construe AstraZeneca's statement of issues as intentionally excluding from the "actions it took in response to genericization of the NEXIUM market" the actions that AstraZeneca took in respect of other generics. There is nothing to support the conclusion that Apotex might have believed this.

[15] While the primary burden on a motion to amend is on the moving party, and not on the responding party, evidence of what Apotex understood from the pleadings or the conduct of the parties is within Apotex's sole control. Apotex claims that the pleading is a radical departure from what the parties understood to be at issue in the litigation, and reproaches AstraZeneca for

its failure to bring evidence to explain this, but it has itself failed to bring any evidence to support its argument that the pleading constitutes a radical departure.

[16] It must be remembered that this motion is the culmination of the vigorous disagreement between the parties that came to light in the fall of 2015 as to what scenarios were properly at issue in this matter, and the Court's own determination that Apotex's pleadings were deficient and required particularization before AstraZeneca would be required to consider the necessity of amending to respond to the specific scenario put forward by Apotex. AstraZeneca's intended plea (as clarified at the hearing) is *prima facie* logically responsive to Apotex's particulars and discloses a reasonable cause of action. While I found that AstraZeneca's previous pleadings were insufficient as they stood to properly frame the issue of the entry of other generics in the "but for world" for discovery, I am satisfied that the issue was never previously ruled out as a relevant issue for trial by either party, implicitly or explicitly.

[17] In the end, it is a matter of doing justice between the parties, ensuring that an injustice does not result from the amendments and that the interests of justice be met. Here, both parties have been content to allow equivocal, open-ended or deficient pleadings to stand and to attack, block, or ambush each other in procedural wranglings rather than work towards a resolution or clarification of the issues. Apotex, as an equal participant in this behaviour, is not in a position to complain that the necessary clarification of both parties' pleadings comes late, and is, for that reason, unjust or imposes a higher onus on AstraZeneca. Only the likelihood that some prejudice not compensable by costs would befall Apotex should, in the circumstances, be considered a valid objection to the amendment.

[18] I agree that AstraZeneca's motion record is silent on the issue of prejudice. Indeed, with such ill-defined proposed amendments, it would seem that AstraZeneca hardly turned its mind to contemplating what, if any, additional discovery might be required as a result of its amendments and whether that additional work could reasonably be accomplished before the trial. Still, while Apotex in its responding record baldly affirms that the amendments are designed to delay the trial and are prejudicial, it stops short of backing up these complaints with any evidence, indication or cogent argument of the manner in which the amendments, if permitted, might work on it an injustice not compensable by costs. As mentioned, the lateness of the amendment is a result of the complacency and conduct of both parties. Where it comes to potential prejudice, it is not sufficient for Apotex to merely sit back and hope to defeat the motion to amend merely by pointing out that AstraZeneca has not brought evidence to rule out a potential prejudice. If Apotex believed that it could not reasonably prepare to address the proposed pleading before the trial, it was incumbent upon it to bring evidence to that effect.

[19] It seems inevitable that some further documentary production or discoveries might be needed, adding to the work to be accomplished in the limited time before trial. However, the burden of production will be on AstraZeneca and there is no indication that the amendments would give rise to further affirmative pleas from Apotex, such that it might be unable or unreasonably constrained in preparing for and meeting the defence framed by the amendments. I am satisfied that Apotex will not suffer prejudice from the amendments that cannot be compensated in costs.

[20] I am accordingly prepared to grant leave to AstraZeneca to amend its statement of defence to allege what it would have done if Apotex had launched in the manner set out in its particulars, including that AstraZeneca would have launched an authorized generic sooner than it in fact did and would not have opposed other generics coming onto the market. However, the plea must be much better particularized than the proposed pleading. It must allege specifically what actions AstraZeneca would have taken and when, and the date(s) on which AstraZeneca alleges that each specific generic would have entered the market.

[21] Although AstraZeneca was substantially successful on the motion, costs will be payable by AstraZeneca to Apotex. I make this order to express the Court's disapproval of the amendments as initially proposed by AstraZeneca. The ruling of the Court in its order of April 1, 2016 was crystal clear: the parties could not continue discovery and go to trial without a clear understanding of what is pleaded. AstraZeneca took advantage of the opportunity to seek particulars but refused to meaningfully engage with the clarifications they provided. It not only proposed amendments that would perpetuate the controversies arising out of the allegedly remaining deficiencies in Apotex's pleadings, but itself proposed unjustifiably vague and open-ended pleadings. In so doing, it as good as invited Apotex to oppose the pleading on technical grounds, deprived the Court of the opportunity to receive cogent and relevant submissions as to what the proposed amendments truly represented in terms of additional pleadings and documents, made its motion a moving target and unnecessarily lengthened the duration of the hearing. And while I recognize that AstraZeneca's conduct might have provoked Apotex's overly technical response, Apotex did not have to rise to the provocation. Apotex's determination to pursue the argument that the proposed amendments were unjustifiably late or

constituted a radical departure was also disingenuous and unnecessary given the Court's earlier ruling. AstraZeneca suggested a range of three to four thousand dollars, whilst Apotex suggested that five thousand dollars would be appropriate. Taking all matter into consideration, I am satisfied that costs in the amount of $2,000.00 should be awarded in favour of Apotex.

[22] Considering that it is the conduct of both parties that caused the need for clarifying amendments to be made at this late date, it is not appropriate to determine at this time which of the two parties should bear the costs of any additional step necessitated by the amendments. The allocation will be deferred to the discretion of the trial Judge.

ORDER

THIS COURT ORDERS that:

1. AstraZeneca has leave to amend its statement of defence no later than 10 days from the date of this order to add particularized pleadings as to what AstraZeneca would have done, including in respect of other generics, if Apotex had entered the market in the manner alleged in the particulars given by Apotex. The amended statement of defence shall include the dates on which AstraZeneca alleges that each specific generic would have entered the market as a result of its actions.

2. Apotex may serve and file an amended reply responsive to the amendments within 10 days of service of the amended statement of defence.

3. The parties shall communicate with each other to discuss the schedule for service of supplementary affidavits of documents arising from the amendments and provide the Court with submissions to the affect within 14 days of this order.

4. Costs, in the amount of $2,000, shall be payable by AstraZeneca to Apotex.

5. The allocation of any costs resulting from the amendments shall be determined by the trial Judge.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-389-11
STYLE OF CAUSE:	APOTEX INC. v ASTRAZENECA CANADA INC.
PLACE OF HEARING:	TORONTO, ONTARIO
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DATED:	MAY 16, 2016

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