Federal Court  Cour fédérale

Date: 20160722

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

Citation: 2016 FC 865

Ottawa, Ontario, July 22, 2016

PRESENT: The Honourable Mr. Justice Zinn

T-1409-04

BETWEEN:

ASTRAZENECA CANADA INC. AND AKTIEBOLAGET HÄSSLE

Plaintiffs
(Defendants by Counterclaim)

and

APOTEX INC.

Defendant
(Plaintiff by Counterclaim)

T-1890-11

BETWEEN:

ASTRAZENECA AB AND AKTIEBOLAGET HÄSSLE

Plaintiffs
(Defendants by Counterclaim)

and

APOTEX INC.

Defendant
(Plaintiff by Counterclaim)

ORDER AND REASONS

[1] Apotex Inc. [Apotex] infringed Canadian Letters Patent 1,292,693 [the 693 Patent] and parties are now proceeding to a reference into the Plaintiffs' [AstraZeneca] damages or Apotex's profits, as AstraZeneca may elect.

[2] AstraZeneca commenced the reference by Statement of Issues delivered on June 1, 2015. That pleading has been amended three times: July 28, 2015, February 3, 2016, and May 17, 2016. The last two amendments were with the consent of Apotex.

[3] Apotex delivered its Responding Statement of Issues on July 10, 2015. That pleading has been amended twice: August 5, 2015, and April 1, 2016. The latest amendment was made partially with the consent of AstraZeneca.

[4] AstraZeneca filed its Reply Statement of Issues on July 17, 2015. That pleading has been amended twice: August 10, 2015, and April 11, 2016.

[5] One of the defences plead by Apotex in its Responding Statement of Issues is that at the time of the infringement, it had available to it non-infringing alternatives [the NIA plea] which would reduce or eliminate the damages or profits available to AstraZeneca on the reference.

[6] The reference is set for 30 days commencing January 16, 2017. AstraZeneca has not yet made its election between damages and an accounting of profits but is scheduled to do so by August 12, 2016. Expert reports are to be exchanged by August 26, 2016, with responding and reply reports to be exchanged by November 7, 2016, and December 30, 2016, respectively.

[7] On May 26, 2016, Apotex sought the consent of AstraZeneca to amend its NIA plea at paragraph 46 of its Second Amended Responding Statement of Issues. On June 9, 2016, AstraZeneca advised Apotex that it did not consent to the amendments sought. This motion followed, seeking the amendments to paragraph 46, as underlined and set out in the Amended Notice of Motion, as follows:

> 46. In addition, and in any event, Apotex states that it is only required to account for the incremental benefit it received, if any, as a result of its infringing activities, as opposed to carrying out the same activities in a non-infringing manner. Apotex states that it realized no incremental benefit and AstraZeneca suffered no incremental damage as a result of Apotex's infringing activities, because the following non-infringing alternatives were available to Apotex at all material times:
>
> (a) Removal of magnesium hydroxide from the core of Apotex's formulation, with or without: (i) an increase in the amount of mannitol or another inert ingredient in its place, and/or; (ii) with a subcoat applied between the core and the enteric coating, and/or; (iii) in anhydrous conditions (i.e., using organic solvents in place of water);
>
> (b) Substitution of a binder in place, or the removal, of the polyvinylpyrrolidone (PVP) from the core of Apotex's formulation, with or without the removal of the magnesium hydroxide. One

example of such a binder substitution would be hydroxypropyl cellulose (HPC). However, other cellulosic binders could have also been employed;

(c) Change of the coating material in Apotex's formulation or the formulations described in sub-paragraphs (a) and (b) above from methacrylic acid copolymer to coating selected from hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, or a methanol-based methacrylic acid copolymer;

(c.1) Employing the same ingredients and process as was employed by Apotex for its Apo-Omeprazole capsules or the formulations described in (a), (b) and (c) above, but using dry granulation instead of wet granulation;

(d) A microtablet with a core containing omeprazole, with one or more of the following ingredients: lactose (anhydrous), carboxymethylcellulose (crosslinked), magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, magnesium oxide, and colloidal silicon dioxide; and an enteric coating layer containing one or more of the following ingredients: methacrylic acid copolymer, hydroxypropyl methylcellulose phthalate, polyvinyl acetate phthalate, hydroxypropyl methylcellulose acetate succinate, sodium bicarbonate and triethyl citrate;

(e) Employing the same process as was employed by KUDCo in the United States or a related process which did not include an intermediate layer between the core and the enteric coating;

(f) Employing the same process as was employed by Mylan in the United States or a related process which did not include an intermediate layer between the core and the enteric coating; and

(g) Employing the same process as was employed by Lek in the United States or a related process which did not use a solvent during the manufacture.

[8] This motion was scheduled to be heard at the Court's General Sittings in Toronto in the afternoon of July 12, 2016. That morning Apotex sent a letter to the Court advising that "Apotex is no longer pursuing the amendments at subparagraph 46(d) of its Responding Statement of Issues."

[9] Accordingly, the amendments now sought by Apotex relate only to paragraphs 46 (b),(c), and (c.1), dealing with the NIA plea as follows:

> (b) Substitution of a binder in place, or the removal, of the polyvinylpyrrolidone (PVP) from the core of Apotex's formulation, with or without the removal of the magnesium hydroxide. One example of such a binder substitution would be hydroxypropyl cellulose (HPC). However, other cellulosic binders could have also been employed;
>
> (c) Change of the coating material in Apotex's formulation or the formulations described in sub-paragraphs (a) and (b) above from methacrylic acid copolymer to coating selected from hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, or a methanol-based methacrylic acid copolymer;
>
> (c.1) Employing the same ingredients and process as was employed by Apotex for its Apo-Omeprazole capsules or the formulations described in (a), (b) and (c) above, but using dry granulation instead of wet granulation;

[10] Apotex filed an affidavit from Michael J. Cima, Ph. D., who reviewed the existing Responding Statement of Issues and that proposed by this motion, and attested that "the minor changes would not call for any different testing methodology" [emphasis added]. Counsel for Apotex submitted that the impact of the proposed amendments on testing "was maybe more, but nothing different, and even if the number of [formulations to be tested] was 1 before, it's 13 now."

[11] Apotex submits at paragraphs 60-72 of its memorandum that AstraZeneca will suffer no prejudice if these amendments are permitted because "it has long been aware of the scope of Apotex's NIA plea as reflected in the proposed amendments, through Apotex's discovery answers and its disclosure in the context of inter partes testing."

[12] It is over-reaching for Apotex to say that AstraZeneca has "long been aware" of the items above; however, it is clear that AstraZeneca has known of Apotex's position as reflected in many if not all of the proposed amendments for some time.

[13] AstraZenca, citing *Merck & Co v Apotex Inc*, 2003 FCA 488 [*Merck v Apotex*] and *Teva Canada Limited v Gilead Sciences Inc*, 2016 FCA 176 [*Teva v Gilead*], submits that on a motion to amend there is a threshold question to be asked: "Does the proposed amendment have a reasonable prospect of success?"

[14] In *Merck v Apotex*, Apotex sought an amendment to its Statement of Defence that the Federal Court of Appeal described as one that "would add a totally new defence to the Statement of Defence." Whereas Apotex had previously admitted that apo-lisinopril would infringe the relevant patent, it sought an amendment to withdraw that admission because it had discovered that the active compound in the Merck drug was lisinopril dehydrate, a compound not disclosed in the patent. The proposed amendment was described by the court as a "dramatic departure from the position until now advanced by Apotex in its pleadings."

[15] AstraZenca submits that the amendments proposed by Apotex in this motion also constitute a new defence, not previously plead by Apotex. I am unable to accept that submission. It is common ground that Apotex has plead from the beginning of the litigation involving the 693 Patent that it had available to it a NIA. What it seeks to do by way of this amendment is to increase the number of formulations of NIAs available to it. This is not adding a new defence; this is expanding the evidence on which it hopes to prove that defence.

[16] In *Teva v Gilead*, some two years after Teva issued its claim seeking to have the patent at issue found to be invalid for obviousness, double patenting, overbreadth, lack of utility and ambiguity, Teva sought an amendment to include an allegation that the patent had been fraudulently obtained by misleading the Patent Office, and thus it was invalid on this ground as well. The motions judge found that the proposed amendment was not supported by the evidence submitted in support of the motion, and thus lacked a reasonable prospect of success. The Federal Court of Appeal observed that the proposed amendments "advance new grounds supporting the relief sought" and further observed that "if the grounds do not have some reasonable prospect of success, allowing them into the litigation does nothing other than to complicate and protract it needlessly and pointlessly."

[17] The situation in *Teva v Gilead* is not similar to that here. Here the NIA plea has been engaged from day-one. As stated above, what is new is the evidence that Apotex wishes to rely on to prove that plea. If the NIA plea had not been previously advanced and Apotex was seeking at this late stage to amend to raise a NIA plea, then the observations in *Teva v Gilead* would be apposite. In short, in that circumstance, it would be appropriate for the Court to inquire as to whether the NIA plea has a reasonable prospect of success.

[18] AstraZeneca submits that the same examination ought to be done here; the Court ought to ask whether the proposed amendment adding new formulations to prove the NIA plea has a reasonable prospect of success. It submits there is no reasonable prospect of success for two reasons. First, Apotex's own testing protocol is such that by the commencement date of the trial, it will not have completed the stability testing and thus it cannot establish that the 13

formulations to be tested are true substitutes. Second, it submits that Apotex cannot establish at trial that any of these new formulations were reasonably foreseeable by it twelve years ago because it has only recently conceived of them, as evidenced by the recent motion to amend.

[19] When I examine these submissions, I am led to ask whether when an amendment is sought that neither adds a new defence nor seeks to withdraw an admission, the "reasonable prospect of success" test is the appropriate starting point.

[20] It may well be that at trial that Apotex will be unable to prove on a balance of probabilities that one or more of the 13 formulations is not a true substitute because there is inconclusive evidence of stability. As counsel for Apotex put it – that is his issue and he may have to lead expert evidence that the stability testing done prior to trial shows, to an expert, that it is more likely than not that the formulation is stable. It may also be that the trial judge may find that none of these 13 formulations is a NIA that Apotex "would" have used 12 years ago because there is no evidence that any of them were in its mind at the time, but were only recently thought of. Apotex submits that the proper question to ask when determining if something is or is not a NIA is this: "If you put Apotex in the position it … is today, 12 years ago, would it have made exactly the same alternatives as its making now?" These are legal and evidentiary issues that are best dealt with by the trial judge. It is impossible at this stage in the process, without the benefit of a witness testifying and being cross-examined and with no evidence of the results of testing, to make any informed assessment as to whether the amendments sought have a reasonable chance of success.

[21] In my view, when what is sought is an amendment to an existing plea expanding the scope of the evidence available to prove the plea, the better expression of the threshold question is that set out by Prothonotary Lafrenière in his April 8, 2011 Order in this very action. In allowing a motion by AstraZeneca to amend its Second Amended Statement of Claim he observed:

> On a motion for leave to amend, the court must assume the facts pleaded in the proposed amendment are true. As a general rule, an amendment should be allowed at any time unless an injustice would result to the opposing party that is not compensable in costs. An amendment must be refused, however, if it would not survive a motion to strike. [emphasis added]

That decision was upheld by Justice Mosley on appeal (2011 FC 598) and by the Federal Court of Appeal on further appeal (2012 FCA 68).

[22] Apotex submits, and I agree that AstraZeneca would not be successful in striking the proposed amendments if they had been in the original Responding Statement of Issues, because, as Apotex notes, it has plead NIA from the beginning, without objection by AstraZeneca. Moreover, there is no submission made by AstraZeneca that the amendment sought is so deficient that it would be subject to a motion to strike.

[23] The Federal Court of Appeal in *Bauer Hockey Corp v Sports Maska Inc (cob Reebok-CCM Hockey)*, 2014 FCA 158 at para 15, observed that the *Federal Courts Rules* provide a "liberal approach to amendments" and that the applicable principles a Court is to apply when considering whether to grant an amendment are set out in *Canderel Ltd v Canada*, [1994] 1 FC 3 (CA) at para 13:

> [W]hile it is impossible to enumerate all the factors that a judge must take into consideration in determining whether it is just, in a given case, to authorize an amendment, 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.

[24] In *Abbvie Corp v Janssen Inc*, 2014 FCA 242, the Federal Court of Appeal stated that the application of the test "is taught by" *Continental Bank Leasing Corp v Canada*, 93 DTC 298 at page 302:

> I prefer to put the matter on a broader basis: whether it is more consonant with the interests of justice that the withdrawal or amendment be permitted or that it be denied. The tests mentioned in cases in other courts are of course helpful but other factors should also be emphasized, including the timeliness of the motion to amend or withdraw, the extent to which the proposed amendments 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. No single factor predominates nor is its presence or absence necessarily determinative. All must be assigned their proper weight in the context of the particular case. Ultimately it boils down to a consideration of simple fairness, common sense and the interest that the courts have that justice be done.

[25] Apotex must first establish that the proposed amendment is necessary to determine the real question in controversy between it and AstraZeneca. In my view, this burden has been met. Counsel submits that there are "hundreds of millions of dollars" potentially at issue on the reference. The NIA plea if successful will mitigate the amount Apotex will be required to pay

and the NIA plea is one of the significant questions in controversy between these parties and has been engaged from the beginning.

[26] Next, Apotex has the burden of showing the Court: (1) that the amendment will not create an injustice or prejudice to AstraZeneca that is not compensable in costs; and (2) that the amendment would serve the interests of justice.

[27] Apotex argues that AstraZeneca will suffer no prejudice. It will accommodate any request by AstraZeneca for further examinations and it is seeking no amendment or extension to the existing schedule for the exchange of notices of experimental testing and expert reports relating to the NIA plea and is not itself seeking any additional discovery. It submits:

> [A]ny complaints of prejudice or delay advanced by AstraZeneca cannot meet the high threshold of non-compensable prejudice. This is particularly so when considered in the context of recent case law, which holds that amendments may be granted "very late in the trial", or even after trial and judgment. The recent decision of the Federal Court of Appeal in *Janssen Inc. v. Abbie Corp.*, 2014 FCA 242 is apposite in this regard.

[28] AstraZeneca submits that "the scale of the proposed amendments would require a tremendous amount of discovery." At paragraph 68 of its memorandum of argument it writes that "there are thousands of new NIAs." That may have been the case if Apotex continued to pursue the proposed amendment to paragraph 46(d); but it is not the case now. In fact, it is accepted by both parties that the proposed amendments encompass only 13 new formulations which are listed in Apotex's Notice of Testing delivered just prior to this motion.

[29] There is no evidence filed by either party as to what the scope of any discovery occasioned by granting the amendments would be. It is evident that some additional discovery will be required but the Court cannot accept the submission of AstraZeneca, without evidence, that the scope of discovery would either result in a delay of the trial or the curtailing of its right to discovery.

[30] Aside from the additional discovery that the amendments may occasion, there is the additional testing that is required. The time required for that testing, as set out in the Notice of Testing served by Apotex is approximately one month. That is not an excessive amount of time such that one can infer that the testing will have any material impact on the steps to be taken in the litigation or the trial date.

[31] The best argument advanced by AstraZeneca of prejudice is that it may not have completed the newly required discovery prior to August 12, 2016, the deadline set for it to make its election whether it is seeking damages or Apotex's profits. The Prothonotary in her Order of December 9, 2013, ordered that AstraZeneca "need not make any election until after they have conducted all necessary documentary and oral discovery for all issues identified in paragraph 1 above." The issues so identified relate to "the quantum of damages arising from any infringement," "the defendant's profits arising from any infringement," and "the defendant's asserted experimental and regulatory use defences." However, it is noted that there is no evidence before the Court that any additionally required discovery cannot or is unlikely to be completed before August 12, 2016, nor is there anything to suggest that the August 12th date

could not be changed if necessary by the trial judge to a somewhat later date, without impacting the trial date set for January 2017.

[32] Given the assurances of Apotex that it will fully cooperate regarding any further discovery, the absence of any evidence that such discovery will impact the current schedule, except possibly the date of AstraZeneca's election which can be moved without consequence if required, the Court is satisfied that Apotex has shown that AstraZeneca will not suffer any prejudice that cannot be compensated for in costs.

[33] AstraZeneca submits that the proposed amendments are not in the interests of justice because "they are radical, they are not timely, and Apotex's conduct militates against their allowance."

[34] It says that where there is a radical change then the burden on the moving party is higher: *Merck v Apotex* and *Apotex v Bristol-Myers Squibb Company*, 2011 FCA 34 [*BMS*]. However it is clear from paragraph 5 of *BMS* that it was not just the fact that the amendment constitutes a "radical change" that results in the heavier burden, it was that the amendment proposed "would result in a radical change in the nature of the questions in controversy" [emphasis added]. It was found that the proposed withdrawal of a substantial admission in *Merck v Apotex* and the raising a new defence in *BMS* each constituted a radical change in the nature of the questions in controversy. As the existence of a NIA has been a significant question in controversy from the commencement of this action, I cannot find, as AstraZeneca asks, that the addition of some 13 different possible NIA compounds changes the nature of the questions in controversy without

some evidence to explain how this is so. Here there is none from AstraZeneca, and Apotex's expert says that his examination of the NIA formulations pre and post amendment leads him to attest that these are "minor changes."

[35] In any event, this is not a situation like *BMS* where the parties were some six months away from trial and seeking to raise entirely new defences nearly 10 years after the litigation had begun. There, unlike here, the moving party took the position that it would require further discovery and affidavits from the opposing party. Here, it is the opposing party that will require that. AstraZeneca submits that the proposed amendments "would require a tremendous amount of discovery" but it has offered no evidence to support that bald assertion in its memorandum. As noted, the Court has nothing before it that suggests that any of the dates for pre-trial steps, let alone the trial date, would have to be changed to accommodate the "burden" of additional discovery. If AstraZeneca believed such to be the case, then it could and should have filed an affidavit from a person knowledgeable about this litigation to that effect. Having failed to do so, it is not unfair for the Court to draw an inference that such a statement could not be sworn.

[36] AstraZeneca says that the motion to amend is not timely because of the stage of the current litigation. Again, it observes that additional discovery and testing will be required; however, as noted above, the Court is not convinced that additional discovery cannot be accommodated within the current trial schedule, and testing will account for no more than an additional 30 days, which can be accommodated in the current schedule.

[37] AstraZeneca also points to the conduct of Apotex in this litigation and says that its NIA plea is a "moving target" up to and including the date the motion was heard. There is merit to that observation; however, the Court finds that the Notice of Testing (of 13 formulations) served by Apotex a few days prior to this motion does serve to identify precisely the formulations on which Apotex will be relying to prove its NIA plea. The date of that notice was set by the trial judge, knowing the scheduled trial date. The parameters of the NIA plea in terms of the formulations to be tested to provide evidence in support of that plea were long known by the parties. Thus, to some extent the exact range of formulations was always a bit of a moving target; although it is may be a greater range of movement with the amendment sought.

[38] I am satisfied that Apotex has met its burden in this case, and the motion will be granted. I shall not give Apotex its costs of this motion, as is requested. The very late withdrawal of its amendment to paragraph 46(d) and the moving target it has created are not to be rewarded with costs.

ORDER

THIS COURT ORDERS that Apotex is granted leave to deliver a Fresh as Amended Responding Statement of Issues in the form set out in Schedule A to its Amended Notice of Motion, with the exception of the proposed amendments to paragraph 46(d), which were withdrawn.

"Russel W. Zinn"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1409-04
STYLE OF CAUSE:	ASTRAZENECA CANADA INC ET AL v APOTEX INC
AND DOCKET:	T-1890-11
STYLE OF CAUSE:	ASTRAZENECA AB ET AL v APOTEX INC
PLACE OF HEARING:	TORONTO, ONTARIO
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ORDER AND REASONS:	ZINN J.
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