Federal Court  Cour fédérale

Date: 20120619

Docket: T-2021-10

Citation: 2012FC787

Ottawa, Ontario, June 19, 2012

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

TEVA CANADA LIMITED

Plaintiff

and

NOVARTIS AG

Defendant

REASONS FOR ORDER AND ORDER

[1] In the context of Teva's action for impeachment of Canadian Patent 2,093,203 covering the drug imatinib, commercialized by Novartis under the brand name GLEEVEC, Teva brings a motion to amend its statement of claim.

[2] These reasons should be read in conjunction with the reasons issued in *Apotex Inc. v Novartis AG*, 2012 FC 786, as some of the amendments proposed by Teva in its motion were identical to those proposed by Apotex and the reasons in *Apotex* apply to and provide the reasons for granting or refusing these amendments. For the reader's convenience I have reproduced in these

reasons (with minor changes to reflect the fact that Teva is the plaintiff herein) the preliminary discussion of the applicable law and relevant circumstances that informed the determinations made in the *Apotex* case and, by extension, the determination of the amendments in this case. As I later turn to considering the specific categories of amendments, reference will more summarily be made, where applicable, to the reasons given in the *Apotex* case.

[3] The Federal Court of Appeal's decision in *Apotex v Bristol-Myers Squibb Co. et al.*, 2011 FCA 34, emphasizes that when faced with a motion to amend, the Court "has the duty to consider all relevant factors" (paragraph 5). The relevant factors are not confined to whether the proposed amendments constitute a radical change to the pleadings and will result in an injustice to the other side that cannot be compensated in costs. Notably, and as per the test in *Canderel Ltd. v Canada*, [1994] 1 FC 3, the question of whether the amendments should be allowed "for the purpose of determining the real question in controversy" and "would serve the interest of justice" must be addressed, and requires consideration of all of the circumstances of the case (see paragraphs 14, 33 and 34 of *Apotex v Bristol Myers Squibb*, *supra*).

[4] The following circumstances are, in my view, relevant to that enquiry:

[5] Teva challenged the validity of the patent at issue through the present impeachment action, filed in December 2010.

[6] Apotex then, on February 18, 2011, challenged the validity of the same patent through service of a Notice of Allegation pursuant to the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 (the *PM (NOC) Regulations*) on February 18, 2011.

[7] Shortly thereafter, Teva served its own Notice of Allegation on Sanofi, citing the same grounds of invalidity as set out in this action.

[8] Novartis challenged both notices of allegations by bringing applications for a prohibition order (T-599-11 and T-679-11, respectively).

[9] When Teva moved to stay the application proceedings and Novartis moved to consolidate the schedule for all three proceedings (the action in T-2021-10 and the two applications), Apotex quickly instituted its own impeachment action, raising the same grounds of invalidity as appear in its Notice of Allegation. It then moved for its action to be consolidated with Teva's action and the applications to be stayed.

[10] The considerations for the order resulting from the motions read in part as follows:

> "**CONSIDERING** that all parties are in agreement that the just, most expeditious and least expensive determination of the issues on these proceedings on their merits is for the actions to proceed to trial together and that, subject to relevance in light of the NOAs, the findings in the actions be determinative of the issue of whether the allegations of the NOAs are justified.
>
> **CONSIDERING** that all parties consider it essential to their agreement that the issues of whether the allegations of the NOAs are

> justified and whether the NOAs are valid be determined on a substantive basis at the same time as the actions, rather than by a finding of mootness and/or at a later date."

[11] The actions were, accordingly, consolidated, but with the pleadings remaining separate. The applications were ordered to be heard by the same Judge and at the same time as the actions, on the evidence led at the trial of the actions "subject to the evidence's relevance for the purpose of the applications".

[12] At the time I made that order as Case Management Judge, the factual basis for the invalidity allegations raised by Teva and Apotex differed somewhat, Apotex's being broader, but raised substantially the same grounds. The invalidity allegations of each generic's action matched exactly their respective Notices of Allegations in respect of the compound and use claims of the patent. As I recall, the provision "subject to the evidence's relevance for the purpose of the applications" took into account the fact that there were differences between Apotex's and Teva's notices of allegation, and that the actions covered allegations not relevant to the notices of allegations (for example, allegations of invalidity in respect of process claims and abuse of process defences expected to be raised by Novartis. Potential amendments to the actions that would see invalidity allegations common to each generic's action and Notice of Allegation diverge were neither discussed nor contemplated.

[13] The provisions of the order requiring pleadings to remain separate, even though the rest of the actions would be consolidated, were primarily designed to avoid the complications and confusion that might arise from drafting fresh pleadings, and to address Novartis' concerns that the timing and order in which the pleadings were filed should remain apparent to the trial Judge, as they

formed part of its defence. Although I do not recall it being specifically raised or discussed at the time, keeping the pleadings separate also avoided unnecessary delays and complications arising from an attempt to reconcile, in the actions, the difference between Teva's and Apotex's allegations, keeping those distinctions constant through the actions and the NOAs.

[14] Avoiding delays and complications was indeed paramount: The actions were instituted with barely more than two years left before the expiration of the patent (April 1, 2013). Teva and Apotex insistently requested that a trial date be fixed in the fall of 2012. Even the 24 month period provided in the *PM (NOC) Regulations* for the determination of Novartis' applications was insufficient to ensure that a decision could issue before the patent expired (the first of the applications, relating to Apotex's Notice of Allegation, was filed on April 8, 2011)!

[15] The relevance of this latter factor cannot be overstated. I reiterate here the admonishment I made in *Apotex Inc. v Sanofi-Aventis*, 2010 FC 77 and repeated in the same case at 2010 FC 182.

> "**7** The Court's early trial initiative was a response to the frustration expressed by a significant number of litigants and members of the bar, very notably in the specialized field of intellectual property, that matters were taking too long to get to trial. As the Court began experimenting with this initiative on a case-by-case basis a few years ago, it quickly became obvious that it is not realistic, practical or reasonable to merely shorten the time between the filing of a statement of claim and the start of the trial if the parties and their counsel do not also adapt their litigation practice and strategies to the shorter time frames. Litigation that dragged on for five years or more typically featured three or more "rounds" of discoveries as well as numerous amendments to pleadings, often resulting in more discoveries and affidavits of documents. Attempting to shoe-horn into two years the never-ending discovery and amendments process that used to take five to

> ten years is simply unsustainable for most litigants and most lawyers, not to mention the limited resources of the Court.
>
> **9** I make these lengthy observations because they inform and highlight the consequences of both parties' expressed intention to avail themselves of the Court's streamlining and early trial initiative. In pressing for and committing to a trial in the spring of 2011, intended to last five weeks, the parties and their counsel have committed to a schedule that does not allow infinite time for discoveries and to a trial of fixed duration. The parties themselves are extremely sophisticated litigants, with extensive experience before this Court. Their respective counsel are knowledgeable and experienced trial lawyers. One expects and must demand from such parties that with a trial expected to begin in less than 15 months, with pleadings now closed and with the known history of litigation in this and other jurisdictions over the drug at issue, they have a clearly developed and articulated theory of their respective case, of what is required to prove it at trial, and how they intend to do so. There is no time in this schedule - and indeed, precious little trial time - for embarking on fishing expeditions, for cobbling up a strategy as one goes or for being unable to articulate a coherent theory of the case until all discoveries are completed or until the eve of trial.
>
> **10** In ruling on these motions, I have assumed from the parties that level of professionalism, and I intend, in managing this case to trial, to consistently expect this higher standard. The parties themselves should be able to expect and rely upon the same standard from their opponent. How that assumption will impact the case management of this matter will become apparent as I deal with the various aspects of these motions."
>
> (Emphasis mine)

[16] Another relevant factor to be considered is the nature of the invalidity allegations raised in these proceedings. The centerpiece of Teva's and Apotex's attack on validity is inutility, lack of demonstrated utility and lack of sound prediction. In turn, the cornerstone for any such argument is the construction of the promise of the patent. Shift that cornerstone, and the entire edifice of the invalidity attack shifts.

[17] Finally, a few notes on the chronology and conduct of the litigation:

a. The trial is set to begin on September 24, 2012.

b. Scheduling orders contemplated that discoveries were to be concluded on or about March 8, 2012.

c. March 15, 2012 was the date by which all documents or information could be produced for the purposes of Rules 232 and 248, except with consent of the other party or leave of the Court.

d. Expert reports in chief were to be served by March 30, 2012 and responding reports by June 15, 2012.

e. The pre-trial conference was to be held on June 20, 2012.

f. Apotex and Teva chose to serve joint expert reports, rather than distinct reports for their respective cases.

g. Apotex and Teva first advised Novartis of their intention to amend on or about May 10, 2012. The schedule for briefing and hearing the present motions was set on May 25, 2012, culminating in the hearing held June 14 and 15, 2012.

[18] I now turn to consider each category of proposed amendments:

Category 1 – Pleadings as to the promised utility of the patent

[19] Teva proposed the same amendments as Apotex to paragraph 20(b) of its Statement of Claim, whereby the allegation that the compounds of the patent are promised to:

> "have valuable pharmacological properties such that they can be used, for example, as anti-tumoral drugs to treat atherosclerosis".

would be changed to:

> "have valuable pharmacological properties such that they can be used to treat hyperproliferative disorders associated with the dysregulation of [PKC, signalling through PDGF-receptor kinase and signalling through abl-kinase]."

[20] Teva's arguments were essentially the same as Apotex's and indeed, counsel for Teva adopted counsel for Apotex's oral submissions on these issues at the hearing. In respect of these specific amendments, and for the reasons given in *Apotex*, *supra*, the amendments as initially proposed will not be permitted.

[21] Teva, at the hearing, proposed the same alternative wording for the amendments as Apotex, and for the same reasons as there given, that modified amendment will be permitted.

[22] The proposed amendments of Teva under this category, however, are more extensive than Apotex's. Namely, they seek to add, as paragraph 21A, five additional specific promises. These promises were not alleged in Teva's original pleading or in its Notice of Allegation. They were, however, textually alleged in Apotex's original Statement of Claim and Notice of Allegation.

[23] Teva's stated purpose in proposing these amendments is simply "to be consistent with Apotex, its co-plaintiff".

[24] As mentioned in the first part of these reasons, and even though it was not specifically discussed at the time the consolidation order was made, there was then, and there still is, a benefit to leaving in place the differences that originally existed between Apotex's and Teva's actions. To attempt to erase those distinctions now would trigger the need for Novartis to amend its Statement of Defence, an unwelcome and needless distraction in the lead up to trial.

[25] Given that Notices of Allegation cannot be amended, the amendment sought to be made by Teva to its Statement of Claim may bring its pleadings in line with Apotex's pleadings, but they would then make its Statement of Claim diverge from its Notice of Allegation. I cannot see how the interest of justice is served by achieving consistency in one respect and introducing inconsistency in another.

[26] Nor can I see that the amendment is necessary or useful to determine the real issue in controversy between the parties. That issue here is the validity of the '203 Patent, as informed by the promise of the patent. Because of the consolidation order, the evidence to be adduced at trial will be common to both actions, regardless of the pleadings. Evidence adduced by Apotex to support its wider pleading of promised utility will form part of the record, whether Teva's pleadings support it or not. And because construing the promise of a patent is a question of law (*Mylan v Pfizer*, *supra*), it is not possible for the Court to apply a different construction to the patent as between the actions of Apotex and Teva. Necessarily, the Court will determine both actions in accordance with the same construction, regardless of the pleadings. There is no usefulness in the amendment for the purpose of construing the promise of the patent.

[27] The evidence led at trial will, as per the consolidation order, be used to determine whether each of Teva's and Apotex's allegations of invalidity, as set out in their respective Notice of Allegations, are justified. For that purpose, the relevance of the evidence to the applications will be considered. In this exercise, it is arguable that Teva's narrow construction of the promise, as contained in its Notice of Allegation, would justify a different result on the application than in Apotex's case. If that is the case, it would likely be a unique situation and raise novel issues of law, the consequence of which may either give rise to, preclude, or fundamentally impact a future claim for damages based on Section 8 of the *PM (NOC) Regulations*. The Court should refrain, where proposed amendments are not otherwise useful to the determination of the issues in an action, from permitting amendments that may lead to unforeseen and unintended legal consequences in other related litigation. Further, parties should be discouraged from proposing amendments late in the litigation when these amendments are not required for the purpose of determining the real issue in controversy between the parties, as such motions serve to distract the opponent's energies and focus from the preparation of trial and waste scarce judicial resources. In the result, I am not satisfied that it is in the interest of justice to allow those amendments.

Category 2 – "Small changes in structural compounds could lead to large changes in activity"

[28] Novartis at the hearing removed its objection to a similar amendment proposed by Apotex on the basis that similar allegations were already present elsewhere in Apotex's initial pleadings and therefore would not cause it prejudice. In the case of Teva, however, Novartis maintains its objection, as the allegation is not otherwise pleaded in Teva's original Statement of Claim.

[29] This does not mean that the evidence tendered jointly by Teva and Apotex on this particular allegation will not, absent amendment, be admissible for the purposes of determining the validity of the patent within Teva's impeachment action. Since both Apotex's and Teva's actions are consolidated for the purposes of trial, evidence admissible and adduced as falling within the scope of Apotex's pleadings will form part of the consolidated evidence and will be considered in the determination of both actions.

[30] Again, the amendment appears to be proposed solely for the sake of the pleadings being consistent across both actions, which is unnecessary. In seeking that consistency, the amendment introduces an inconsistency between Teva's action and its Notice of Allegation, with unknown and potentially serious consequences. On that basis, I am not satisfied that the interests of justice will be served by allowing the amendment.

Category 3 – Negative *in vivo* results

[31] For the same reasons as given in *Apotex*, *supra*, these amendments will not be allowed.

Category 4 – Only 29 compounds tested

[32] At the hearing, counsel for Teva agreed to remove from its proposed amendments at paragraphs 31 and 33, the words "types of", to remove any suggestion that the pleadings might somehow expand the existing pleadings. On that basis, and for the same reasons as given in *Apotex*, *supra*, these amendments will be allowed.

Categories 5 and 6 – Addition of "prior art" in relation to claim 44 of the patent and "prior to April 1, 1993"

[33] For the reasons given in *Apotex*, *supra*, these amendments are also permitted.

Costs

[34] Even though success on this motion was divided, the costs of an amendment should be borne by the party making the amendment. It is therefore reasonable that the costs of this motion be awarded in favour of Novartis. Further, the motion required significant work by both parties and required more than 6 hours of hearing. The complexity of the motion dictates an elevated award of costs. Finally, the Court's general disapproval of the conduct of Teva in bringing a motion to amend so close to trial, in the midst of the period provided for Novartis to prepare its responding expert reports and with no apparent justification for having failed to bring this motion earlier, can also appropriately be expressed by an award of elevated costs.

ORDER

THIS COURT ORDERS that:

1. Teva has leave to serve and file an amended Statement of Claim in the form set out in Schedule "A" of its Notice of Motion, with the following exceptions:

   a) Proposed paragraph 20(b)i is to be modified so as to replace "hyperproliferative disorders" with the words "tumors and atherosclerosis ("hyperproliferative disorders")".

   b) Proposed paragraph 21A; the sentence in proposed paragraph 25 beginning with "Rather" and ending with "utility."; the words "types of" in paragraphs 31 and 33; and proposed paragraph 34 may not be included.

2. Teva's undertaking, as set out in paragraph 36 of the Reasons for Order in *Apotex v Novartis*, 2012 FC 786 is noted and is to be given effect to.

3. With costs in favour of Novartis at the high end of Column V of the Tariff.

"Mireille Tabib"

Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2021-10
STYLE OF CAUSE:	TEVA CANADA LIMITED v NOVARTIS AG
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	June 14 & 15, 2012
REASONS FOR ORDER:	TABIB P.
DATED:	June 19, 2012

APPEARANCES:

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