Federal Court  Cour fédérale

Date: 20160624

Docket: T-1844-14

Citation: 2016 FC 720

Ottawa, Ontario, June 24, 2016

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

APOTEX INC.

Plaintiff

and

ALCON CANADA INC.

Defendant

ORDER AND REASONS

[1] This motion for bifurcation is better understood if placed within the full context of multiple proceedings between the parties relating to Apotex's Apo-Travoprost Z topical ophthalmic solution.

[2] In 2012, Alcon held an NOC and had two patents listed on the Patent Register in respect of travoprost Z, an ophthalmic solution sold under the brand name Travatan Z. Apotex, wishing to come to market with a generic version of travoprost Z, served on Alcon Notices of Allegation

pursuant to the *PM(NOC) Regulations* (SOR/93-133), in respect of each of these two patents, namely, the '287 and '370 Patents. The prohibition proceedings instituted by Alcon in response to Apotex's Notices of Allegation were dismissed in the summer of 2014, the Court finding that Apotex's allegations of invalidity in respect of both patents were justified. Apotex obtained its NOC for Apo-Travoprost Z on August 13, 2014 and immediately started offering it for sale. Within less than a month, on August 29, 2014, Alcon filed a Statement of Claim against Apotex in Court file T-1885-14, alleging that Apo-Travoprost Z infringes the '370 Patent and seeking an injunction and damages; in response to this action, Apotex again raises the invalidity of the patent. No proceedings were begun by Alcon in respect of the '287 Patent, or any other patent allegedly covering Apo-Travoprost Z.

[3] Almost simultaneously, Apotex instituted the present action, seeking damages against Alcon pursuant to section 8 of the *PM(NOC) Regulations*, for having been delayed entering the market as a result of Alcon's unsuccessful prohibition proceedings. By way of defence, Alcon has raised the infringement of the '370 Patent, but also of the '287 Patent as well as one other patent that had not been listed on the Patent Register against travoprost Z: The '172 Patent. Apotex in reply denies infringement of the '172 Patent and alleges that all three patents are invalid.

[4] Alcon's infringement action moved swiftly to the close of pleadings in December 2014. In November 2015, the parties consented to a bifurcation order severing the liability and quantification issues. Discoveries were held in the spring of 2016 and Alcon has requested that early trial dates be fixed for the fall of 2017.

[5] By contrast, the progress of the present section 8 action was significantly delayed at the pleading stage, with numerous amendments being made by both sides. Pleadings only closed in February 2016 and affidavits of documents were finalized in May 2016. Examinations for discovery have yet to begin.

[6] Apotex now wishes to bifurcate this section 8 action along the following lines: It wants Alcon's allegations of hypothetical infringement of the '287 and '172 Patents, including Apotex's allegation of invalidity of those patents, determined separately from and before any other issue. The parties are *ad idem* that infringement and validity issues as regard the '370 Patent are already essentially bifurcated, in that they can and will be fully determined in the context of Alcon's infringement action, and that the Court's findings in respect of infringement and validity will be binding and applicable for the purpose of the section 8 action.

[7] Alcon opposes Apotex's motion, largely it seems, because it fears that Apotex is manoeuvering to then move to consolidate the trials of the hypothetical infringement of the '287 and '172 Patents with the trial of the infringement of the '370 Patent, and thus delay the latter, and with it Alcon's hoped-for injunction. To be fair, Alcon's fears were legitimately raised by Apotex's suggestion last year, repeated in its written argument on the motion, that the bifurcation would permit consolidation of the infringement and validity issues for all three patents. At the hearing of the motion, however, Apotex made it clear that its request for a bifurcation is not contingent on joinder, consolidation or a joint hearing of the issues relating to the '370 and the other two patents.

[8] Alcon also argued that the issues of infringement in this section 8 action cannot practically be severed from other section 8 issues, particularly the identification of the relevant period, because Apotex's pleadings do not indicate whether its formulation or mode of manufacture might have varied in the hypothetical period; any variation would make the identification of the relevant periods crucial. To address this concern, Apotex offers to stipulate that the composition, manufacture, packaging, information and interchangeability requests in respect of Apo-Travoprost Z would have been the same in the hypothetical world as in the real world. Such a stipulation would render the identification of a specific period irrelevant to the effectiveness or usefulness of any determination of the infringement and invalidity issues.

[9] With this context, I now turn to consider the factors that the case law has recognized as relevant, all with the ultimate goal of determining whether bifurcation is more likely than not to lead to the just, expeditious and least expensive determination of the proceeding on its merits. (See *Merck and Co. v Brantford Chemicals Inc.*, 2004 FC 1400, at paragraph 5).

[10] The issues to be tried in each of the proposed stages of the bifurcated trial are very complex. The proposed line of bifurcation as between the hypothetical infringement defences, including invalidity arguments on the one hand, and all other issues, including the relevant period, Apotex's ability to enter the market, generic competition and quantification on the other hand, are very clearly separated. The factual structure is not extraordinary or exceptional as compared to other section 8 actions, but the fact that parts of Alcon's section 8 defences are *de facto* being determined separately in a bifurcated infringement action is notable. The trial of the first phase will not improve the trial judge's ability to deal with or appreciate the issues in the

second phase, however, nor would trying all issues together in a single trial improve the judge's ability to try and appreciate all issues. The issues to be severed are quite distinct and easy to separate, they likely call for different witnesses. The Court is capable of trying this matter expeditiously, whether the issues are bifurcated or not. If one accepts, as I do, that bifurcation does not entail a joinder with the liability phase of Alcon's infringement action or a delay of that trial, then there is no clear advantage or disadvantage to either party in having the hypothetical infringement issues decided first. In terms of cost savings, the issues in the two phases are so clearly distinct and defined that, if both phases proceed, bifurcation will not likely result in substantial additional costs, nor substantial savings. If both phases proceed, then bifurcation would also likely result in additional delays, as split trials do involve two sets of discovery, trial and potential appeals. However, if the second phase does not proceed, then obviously, substantial savings of costs and time will be achieved. The determinative questions are therefore whether, or to what degree, severance might facilitate or lead to the settlement of the remaining issues, or put an end to the action.

[11] The law as it stands is to the effect that hypothetical infringement is not a complete defence to a section 8 claim, but that it is a significant factor to be considered in assessing compensation, and that it can indeed reduce damages to zero (*Apotex Inc. v Merck & Co.*, 2012 FC 620). The law however may continue to evolve, and Alcon does take the position that infringement in this case would constitute a full defence or would reduce any damages to nil. Given Apotex's concession to the effect that its product's composition, manufacture and use would have been the same throughout the hypothetical period as in the real world, there is a very high likelihood that a finding of hypothetical infringement would be effectively dispositive of the

second phase or very likely lead to a settlement. While the parties disagree as to the dollar value of Apotex's claim, it is still clear that, at its maximum, the claim is modest in comparison with other pharma litigations. This reinforces my conclusion that bifurcation would likely enable the most important aspects of Alcon's defences to be substantively determined earlier, and in a more cost effective manner, and that the remaining issues would stand a greater chance of being resolved by settlement.

[12] I add that my determination on this motion is also influenced by the fact that Alcon's related infringement action is already bifurcated. Had that not been the case, and had the proceedings in both actions been at the same stage, it is quite possible that the most appropriate way forward for the Court and both parties would have been the consolidation of both actions, without any bifurcation. However, the Court must take the proceedings as they currently are. As a result of the bifurcation of the infringement action, issues of quantification in that proceeding will not be subject to discovery or trial until the liability phase is determined, and then only if Alcon is successful. As mentioned, it is more likely than not that if Alcon is successful in the infringement action or on any of the hypothetical infringement defences, the remainder of the section 8 claim, including quantification, will settle. However, in the event it does not, quantification issues in the infringement case and in the section 8 case will necessarily overlap and become intertwined to a significant degree. While the likelihood of this occurring is, as mentioned, very low, the waste and duplication that would result if this did occur is significant. Without bifurcation, the section 8 action would immediately proceed to discovery and eventually to trial in respect of Apotex's "real world" profits on the sale of Apo-Travoprost Z, as a proxy for its losses in the "but for world". If, subsequently or concurrently to this, Alcon were to be

successful on its infringement action, then discoveries and an eventual trial as to Apotex's profits and/or Alcon's losses in the same period would ensue, with the obvious risks of duplication or even contradictory findings. Bifurcation would obviate this risk, and in the unlikely event that they both proceed, even permit the quantification phases to proceed to discovery and trial concurrently or jointly in both actions.

[13] For these reasons, and in the particular circumstances of this case, I am satisfied that bifurcating the issues of the hypothetical infringement and validity of the '287 and '172 Patents is more likely than not to lead to the just, most expeditious and least expensive determination of the issues on the merits than would otherwise be the case.

ORDER

THIS COURT ORDERS that:

1. Apotex's following stipulation is to be considered as, and shall have the same effect as, particulars to its Statement of Claim:

   "Apotex's claim for damages is based on the allegation that it would have sold Apo-Travoprost Z commencing on November 14, 2013, where Apo-Travoprost Z is the same in all respects to the Apo-Travoprost Z that it commenced selling on August 14, 2014, that the composition would have been the same, the process to manufacture it would have been the same, it would have been bottled and packaged in the same manner, it would have had the same product monograph, it would have been sold with the same patient leaflet, and Apotex would have sought the same interchangeability status for it with provincial formularies."

2. The following issues are to be determined separately from and prior to any other issues in this matter: Whether Apotex's hypothetical sales of Apo-Travoprost Z would have infringed the '287 or '172 Patent, and whether the said patents are invalid.

3. The parties are to proceed to a trial of these issues without having discovery or leading evidence as to any matter that relates solely to the other issues in this matter.

4. Necessary documentary and oral discoveries and a trial in relation to the other issues shall be conducted following the determination of the trial on the infringement and validity issues.

5. Costs of this motion shall be in the cause and are fixed in the amount of $3,750.00 inclusive of disbursements.

"Mireille Tabib"

Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1844-14
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