Federal Court  Cour fédérale

Date: 20131115

Docket: T-1151-12

Citation: 2013 FC 1165

Toronto, Ontario, November 15, 2013

PRESENT: Kevin R. Aalto, Esquire, Case Management Judge

BETWEEN:

ALLERGAN INC. AND ALLERGAN, INC.

Applicants

and

THE MINISTER OF HEALTH AND APOTEX INC.

Respondents

REASONS FOR ORDER AND ORDER

[1] This proceeding is an application under the *Patented Medicines (Notice of Compliance) Regulations* (*Regulations*). There is a partial reversal of evidence. The patent in suit relates to the drug bimatoprost ('691 Patent).

[2] As is the approach in proceedings under the *Regulations*, the Respondent, Apotex Inc. (Apotex) in its NOA provided a detailed statement of the positions it was taking regarding the '691

Patent. As is often the approach of the patent holder, the notice of application in this case is bereft of any real detail as to the positions being taken to support the validity of the '691 Patent.

[3] Apotex has brought this motion pursuant to Rule 312 of the *Federal Courts Rules* for leave to file Reply Affidavits of three of their experts: Dr. Arthur Kibbe (Kibbe Reply); Dr. Ian Grierson (Grierson Reply); and, Ms. Lea Katsanis (Katsanis Reply)(collectively the Replies).

[4] Prior to the hearing of the motion, the Applicant (Allergan) advised that it was not opposing Apotex's motion with respect to the Katsanis Reply and limited parts of the other Replies. Essentially, the Katsanis Reply responds to issues raised by Allergan relating to the LUMIGAN RC™ market, provincial formulary listings and, the data source used.

[5] The portions of the other Replies which Allergan does not oppose relate to another patent referred to by an Allergan expert and preservative free preparations. However, Apotex argues that the remainder of the Replies should also be permitted.

[6] Allergan opposes primarily on the grounds that, objectively, Apotex should have known and understood that the three documents referred to by Allergan's experts were "available" and known to Apotex at the time it filed its evidence and it should therefore have referred to those documents. Those documents are: the 004 Study; the '289 Patent (apparently a teaching away patent); and, the '233 Patent (the Documents). While Allergan argued during the hearing that it was opposed to Apotex's Reply to the '289 Patent, in fact, the letter of October 21, 2013 states that Allergan does not oppose paragraphs 1 – 11 of the Kibbe Reply of which paragraphs 4 – 6 deal with the '289

Patent. In any event, whether Reply to the '289 Patent is or is not opposed, it does not matter as for the reasons that follow I am of the view that the Replies are proper.

[7] This was an application in which there was an agreed partial reversal of evidence. Thus, Apotex put in its evidence without knowing the case of Allergan and did not comment or refer to the Documents. Thus, the request to serve the Replies.

[8] Allergan argues that the Documents all were known to and could have and should have been referred to by Apotex in its initial affidavit evidence. Allergan argues that because two other generic companies, Mylan and Cobalt, referred to the Documents in their NOA's or evidence then it is axiomatic that Apotex could and should have known about them and therefore referred to them. As argued by Allergan: "The conduct of similarly-placed generics in respect of the same patent for the same drug at the same time is the best objective evidence available and disproves Apotex's assertion that reliance on the study could not be anticipated". Thus, it is argued that on an objective basis Apotex could have anticipated Allergan's responding evidence and that while Apotex was aware of the Documents it chose not to refer to them in support of their case and that by now trying to reply they are splitting their case.

[9] Quite apart from the prescience of other generics in referring to the Documents, Allergan also points to bits and pieces of the expert affidavits and the Apotex NOA to argue that Apotex would have had to have known that the Documents should be dealt with.

[10] For its part, Apotex points to the paucity of any real information that Allergan puts forward regarding its case in its notice of application. In all, the notice of application, as is often the case, is a collection of denials of the positions in Apotex' NOA without any detail or substantive information about why Apotex' NOA is wrong. Some examples are illustrative: "none of the references cited by Apotex to support its allegation of obviousness formed part of the common general knowledge or were disclosed made available to the public prior to the relevant date"; "Apotex's allegation regarding the identification of the inventive concept of the claims of the '691 Patent are incorrect and not justified and are premised on an incorrect application of the law"; and, "Each and every allegation of obviousness is unjustified . . .". There is no detail to support any of these allegations.

[11] By comparison, Allergan knows with exactitude the position of Apotex regarding the '691 Patent as it is spelled out in detail in the NOA. In light of this, Apotex argues it could not know what Allergan believes is relevant and it is idle speculation to try and divine what Allergan will argue and what prior art or other documents its experts might rely upon. This is particularly so as the Documents are not specifically referred to anywhere in the NOA or the notice of application. Allergan was only able to point to the most oblique references in the NOA to suggest that it was obvious that Apotex not only knew about them but should have referred to them.

[12] In large part, the position of Allergan is putting the cart before the horse. How can one know what the other side believes relevant until they put it in play? If the expectation is that if any piece of prior art or document is known to a party and they do not refer to it in their evidence then they cannot reply because they knew of it – this is an invitation for a party to include every single

piece of known prior art and document so as not to be prevented from commenting on it. Such an approach will only lengthen and complicate what are already very complex proceedings. Precision, not guesswork is required in these proceedings. However, that is not the way the litigation plays out.

[13] This motion raises issues that frequently haunt Rule 312 motions. The allegation of the opposing party usually revolves around the "availability" of the evidence and that the Reply is, in effect, a "splitting" of the case. The "availability" argument flows from the well-known Federal Court of Appeal case of *Atlantic Engineering Ltd. v. Lapointe Rosenstein*, 2002 FCA 503.

[14] Rule 312(a) of the *Federal Courts Rules* permits this Court to grant leave to "file additional affidavits to those provided for in Rules 306 and 307". In *Atlantic Engraving*, the Federal Court of Appeal described four requirements that must be met before this Court may permit additional affidavits:

> [8] Pursuant to Rule 306 of the *Federal Court Rules, 1998*, an applicant has thirty days from the filing of its notice of application to file its supporting affidavits and exhibits (appeals under section 56 of the *Trade-marks Act* fall within Part 5 of the Rules entitled "Applications" (Rules 300 to 334) and therefore must be commenced by way of a notice of application). By exception, rule 312 allows a party, with leave of the Court, to file additional affidavits. Under that rule, the Court may allow the filing of additional affidavits if the following requirements are met:
>
> > i) The evidence to be adduced will serve the interests of justice;
> > ii) The evidence will assist the Court;
> > iii) The evidence will not cause substantial or serious prejudice to the other side (see *Eli Lilly and Co. v. Apotex Inc.* (1997), 76 C.P.R. (3d) 15 (T.D.); *Robert Mondavi Winery v. Spagnol's Wine & Beer Making Supplies Ltd.* (2001), 10 C.P.R. (4th) 331 (T.D.)).

> [9] Further, an applicant, in seeking leave to file additional material, must show that **the evidence sought to be adduced was not available prior to the cross-examination of the opponent's affidavits**. Rule 312 is not there to allow a party to split its case and a party must put its best case forward at the first opportunity (see *Salton Appliances (1985) Corp. v. Salton Inc.* (2000), 181 F.T.R. 146, 4 C.P.R. (4th) 491 (T.D.); *Inverhuron & District Ratepayers Assn. v. Canada (Min. of Environment)* (2000), 180 F.T.R. 314 (T.D.)). [emphasis added]

[15] In *Deigan v. Canada (Industry)* 1999 CanLII 7761 (FC), (1999), 168 F.T.R. 277 (T.D.) aff'd 1999 CanLII 7910 (FC), (1999), 165 F.T.R. 121 (T.D.), a fifth requirement was enunciated: The evidence will not unduly delay the proceeding. These five criteria were applied in *Merck Frosst Canada & Co. v. Canada (Minister of Health*), 2003 FCT 287 at para. 12; and, *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FC 168 at para. 5.

[16] However, before slavishly applying these criteria it is important to consider the context in which they were developed and what the Court actually said. In *Atlantic Engineering*, which appears to be the seminal case upon which all others comment, the appeal related to a decision of the Trial Division arising from an appeal from the Registrar of Trade-marks who had expunged the appellant's trade-mark. The Judge who was hearing the matter on the merits determined that the affidavit evidence of the appellant was deficient and resulted from the ineptitude of counsel. The Hearings Judge of his own volition then granted leave to the appellant to file a further and better affidavit and adjourned the matter. This happened after all of the parties' evidence including cross-examinations had been put in.

[17] In the circumstances, the Federal Court of Appeal was rightly concerned with the "additional" affidavit for which the Hearings Judge granted leave to file. It was not a "reply" affidavit. Rather, it was a new affidavit to be provided in support of the case after all the evidence had been put before the Court. This was obvious "case-splitting".

[18] Is the need to reply to the Documents raised for the first time in Allergan's expert affidavits "case-splitting" as argued by Allergan? In my view, it is not.

[19] The Documents were not discussed in the Apotex NOA and were not referred to in the Allergan notice of application. They first came to light in this proceeding as part of Allergan's evidence. It can hardly be said that this is case splitting. Allergan's argument would have more weight if this were a case of eliciting "fresh evidence" as opposed to reply.

[20] It is strenuously argued by Allergan that the Documents must have been "known" to Apotex when it served its expert reports and therefore was "available" within the meaning of *Atlantic Engraving*. Thus, as it was "available" to Apotex when they served their expert reports they cannot now reply to it. To permit them to reply would be to "water down" the "available" requirement. Further, it is argued that as two other generics referred to this evidence Apotex must also have know about them.

[21] With respect, this argument makes no sense. In this day and age of instant internet searching virtually anything can be found. Lawsuits are not about what is available and can be found but rather what is relevant to make out the case of a party. Apotex may very well have

known about the Documents but made a decision based on the known Allergan evidence that it was not required. Now, after Apotex puts in its evidence, Allergan puts in play the Documents and they have taken on relevance. Just because Apotex may have known about the evidence does not make it relevant until a party seeks to put it before the Court as part of their case. Further, the fact that two other generics referred in their evidence to one or more of the Documents is not determinative of anything. Those generics cast their case as they saw fit to support the allegations they were each making. Similarly, so did Apotex without knowing what Allergan might put in play.

[22] This does not water down the "available" part of the *Atlantic Engraving* test nor will it create a "floodgate" of reply motions as argued by Allergan. For example, a generic that does not put in evidence prior art that is specifically referred to in its NOA in all likelihood will not get a right of reply if the patentee chooses to use such prior art in support of its case. Further, in *Atlantic Engraving*, the Court had before it a case where all of the evidence was in and the evidence in the new affidavit would undoubtedly be case-splitting as it is obvious that it was available prior to cross-examinations and the hearing. Here there is no such situation. Cross-examinations have not taken place and the hearing is several months away and it is Allergan that has decided to make the Documents part of its case. In this case, it is clear that Apotex should have right of reply.

[23] Granting a party an opportunity to reply, however, is not an invitation to that party to do a further "document dump" of materials that are not already in the record. Such a step simply invites sur-reply which should be avoided. Reply requires that the evidence be directed only at that which requires clarification by the expert and does not necessarily require any additional documentation to

be referred to. Reply should be succinct, precise and relevant only to an issue raised in the opposite party's evidence.

[24] While other arguments were raised during the course of the hearing they need not be addressed as the reasons given are sufficient to support a right of reply to Apotex.

[25] As Apotex was successful it is entitled to its costs.

ORDER

THIS COURT ORDERS that:

1. The Respondent, Apotex Inc., is granted leave to file the Reply Affidavits of Dr. Arthur Kibbe, Dr. Ian Grierson and Ms. Lea Katsanis attached to the Notice of Motion herein as Schedules "A", "B", and "C".

2. Costs of the within motion are payable to Apotex.

"Kevin R. Aalto"

Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1151-12
STYLE OF CAUSE:	ALLERGAN INC. AND ALLERGAN, INC. v. THE MINISTER OF HEALTH AND, APOTEX INC.
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