IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., ALLERGAN SALES, LLC, Plaintiffs, v. ALCON, INC., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD., Defendants.	Civil Action No. 04-968-GMS

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO STRIKE PORTIONS OF DEFENDANTS' SUMMARY JUDGMENT BRIEF

Dated: May 16, 2005

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I. INTRODUCTION

Allergan moves to strike Alcon's motion for summary judgment of non-infringement and invalidity to the extent it goes beyond the issues on which the Court gave Defendants permission to move for summary judgment.

The Court gave Alcon extraordinary permission to move for summary judgment on two specific issues only, one relating to non-infringement and one relating to invalidity. With respect to invalidity, Alcon sought and was given permission to move for summary judgment on "whether the claims of the '834 patent violate the written description requirement of 35 U.S.C. § 112 because they use the term '.15%'" (*See* Scheduling Order, D.I. 30, at 3-4.)

Much of Alcon's summary judgment motion, however, focuses not on whether there is written description support for the "0.15% (w/v)" limitation, but whether there is support for the 0.15% (w/v) concentration being "therapeutically effective," as recited in the preambles of the independent claims. For example, Alcon argues in its summary judgment motion:

> [N]owhere in the specification or the original disclosure of the application from which the '834 patent claims priority is 0.15% (w/v) identified as a therapeutically effective amount of active ingredient.

(Defendants' Opening Brief, D.I. 55, at 3.) That is an entirely different issue, and it is one for which Alcon neither sought nor was given permission to raise on summary judgment.

II. ARGUMENT

A. Alcon was Given Permission to Move for Summary Judgment of Invalidity on the Sole Issue of Whether there is Written Description Support for the Claimed "0.15% (w/v)" Concentration

As the Court may recall, Alcon argued vigorously for permission to move for early summary judgment on two specific issues. One was a non-infringement issue relating to Allergan's U.S. Patent No. 6,673,337. The other was an invalidity issue

relating to the '834 patent. Alcon's counsel described the invalidity issue at the November 22, 2004 scheduling conference as follows:

> The only issue is looking at the specification, does that support the revised claims which added the new matter of up to 0.15 percent. . . .We simply want to look at the claim and the spec and say there is no support for these claims because nothing in the claim relates to the amount. Indeed, everything in the specification is .2 percent or higher, every chart, every example. It would only teach one to use that much. There is nothing there that would even suggest that you would go to a lower amount.

(Marsden Decl, Ex. A, at 7.)

In a follow-up letter to Allergan, Alcon confirmed the statements it made at the scheduling conference:

> We can confirm that the summary judgment motion that Alcon intends to file be limited to two arguments: (1) the claims of the '834 patent are invalid for lack of written description under 35 U.S.C. Sec. 112 because there is no support for the limitation "up to about 0.15%," and, ...

(Marsden Decl., Ex. B.)

Alcon's description of the motion at the hearing on December 15, 2004, was consistent with its statements at the scheduling conference and in the follow-up letter:

> The second motion relates to an allegation of lack of written description about the term .15 percent. That is obviously a mathematical term. Everybody knows what .15 percent is. The question is whether or not the claimed limitations that use .15 percent are supported by the specification. . . . That's what the summary judgment process would be about.

(Marsden Decl., Ex. C, at 3.)

Alcon thus clearly and repeatedly represented to the Court and to Allergan that the issue on which it would seek summary judgment was whether there is support in the '834 patent for the "0.15% (w/v)" limitation in the claims. Based on Alcon's representations, the Court agreed to depart from its normal procedure and gave Alcon permission to file an early summary judgment motion on that issue:

> Defendants shall be permitted to file two summary judgment motions to be heard at the hearing on June 7, 2005. These motions shall be limited to: a) whether the claims of the '834 patent violate the written description requirement of 35 U.S.C. § 112 because they use the term ".15%"; and b) whether the limitation "solubility

> enhancing component" in the '337 patent should be limited to only anionic solubility enhancing components. . . . Defendants shall be permitted no other summary judgment motions in this case.

(Scheduling Order, D.I. 30, at 3-4.)

B. Prior to its Summary Judgment Motion, Alcon Never Raised the "Therapeutically Effective" Limitation in Connection with its Written Description Defense

Prior to filing its summary judgment motion, Alcon's written description defense did not rely on the "therapeutically effective" limitation recited in the independent claims. For example, in the Paragraph IV certification Alcon sent to Allergan on July 6, 2004, before this suit was filed, Alcon laid out its written description defense in detail. Noticeably absent was any reference to the "therapeutically effective" limitation on which Alcon's summary judgment motion now relies so heavily:

> The claims of the '843 patent are invalid under 35 U.S.C. § 112 for lack of written description because there is no support in the specification or the claims originally filed in the parent application for the claim term "up to about 0.15% (w/v)" or "0.15%." See, e.g., Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998). Allergan did not cite to any disclosure to support the term when it was introduced by preliminary amendment upon filing of the continuation application. Furthermore, the specification teaches away from a 0.15% limitation in that all concentrations of the drug referred to in the specification are 0.2% and higher.
>
> ***
>
> Thus, all of the claims of the '834 patent are invalid under 35 U.S.C. § 112 first and second paragraphs because there is no support for the 0.15% limitation in the specification or in the claims originally filed with the parent application.
>
> ***
>
> An invention requiring the 0.15% limitation is new matter unsupported by the disclosure of the parent application USSN 09/904,018.

(Marsden Decl., Ex. D, at 6-7.)

The same goes for Alcon's December 27, 2004, response to Allergan's first interrogatory, which sought the bases for Alcon's invalidity contentions:

> The claims of the '834 patent are invalid under 35 U.S.C. § 112 for lack of written description because there is no support in the specification or the claims originally filed in the parent application or the application for the '834 patent for the claim term "up to about 0.15%(w/v)", "about 0.15%(w/v)" or "0.15% (w/v)." Allergan did not cite to any disclosure to support the term when it was introduced by

> preliminary amendment upon filing of the continuation application. Furthermore, the specification teaches away from a 0.15% limitation in that all compositions disclosed in the specification have concentration of drug that is 0.2% (w/v) and higher. Thus, all of the claims of the '834 patent are invalid under 35 U.S.C. § 112 first paragraph because there is no support for the 0.15% (w/v) limitation in the specification or in the claims originally filed with the parent application.

(Marsden Decl., Ex. E, at 2.) Allergan relied on these statements made by Alcon and took the discovery necessary to respond to Alcon's arguments. Alcon's last second change to a new argument violates the Court's Scheduling Order and prejudices Allergan.

C. Alcon neither Sought nor Received Permission to Move for Summary Judgment on the "Therapeutically Effective" Issue

Having represented to the Court and to Allergan that it would seek summary judgment of invalidity on the sole issue of whether there is written description support for the "0.15% (w/v)" limitation, Alcon's summary judgment motion now improperly raises an entirely different issue. Much of the motion focuses ***not on whether there is written description support for the "0.15% (w/v)" limitation***, as Alcon had represented, but instead ***whether there is support for the fact that the claimed "0.15% (w/v)" concentration is "therapeutically effective."***

For example, Alcon now argues that the '834 patent is invalid on the grounds that:

> [N]owhere in the specification or the original disclosure of the application from which the '834 patent claims priority is 0.15% (w/v) identified as a therapeutically effective amount of active ingredient.

(Defendants' Opening Brief, D.I. 55, at 3.) Alcon neither sought nor received permission to move for summary judgment on this "therapeutically effective" issue.

It is clear that Alcon had second thoughts about the argument it represented it would make, and decided to focus on the "therapeutically effective" issue instead. The reason is evident: In support of its original argument, Alcon had proffered a claim construction limiting the claim term "about 0.15%" to "0.1499-0.1501%." (*See* Marsden Decl., Ex. F.) Alcon claimed that, since the specification did not disclose a concentration in the range of "0.1499-0.1501%," the claims were invalid for lack of written description.

(*See, e.g.,* Marsden Decl., Ex. E, at 2.) When it became clear from discovery (including from the deposition of Alcon's own witness, Ramon Espino) that Alcon's construction of "about 0.15%" was untenable, Alcon was forced to abandon its original claim construction. (*Compare* Ex. F *with* D.I. 53.) Once that happened, Alcon's original written description arguments had to be discarded and a new written description defense focusing on the "therapeutically effective" limitation constructed in its place.

As a result, the great majority of the invalidity argument in Alcon's summary judgment brief concerns the "therapeutically effective" issue, starting at page 18, where Alcon underlines the term in claim 1 for emphasis. (*Id.* at 18.) This emphasis permeates Alcon's invalidity argument:

- The invention claimed in the '834 patent includes a critical 0.15% (w/v) "therapeutically effective" concentration of active ingredient that is not mentioned anywhere in the specification and, indeed, is a wholly different invention from that described in the specification, which calls for compositions containing a solubility enhancing component and/or an oxy-chloro preservative. (*Id.* at 2-3.)

- The specification of the '834 patent does not teach a "therapeutically effective" amount. (*Id.* at 21.)

- Neither solubility study provides any indication as to what concentrations of active ingredient might be therapeutically effective. (*Id.* at 22-23.)

- It is beyond dispute that there is no teaching in the patent that 0.15% brimonidine tartrate is therapeutically effective. (*Id.* at 23.)

- But the portions of the specification to which Allergan referred contained absolutely no teaching of a therapeutically effective 0.15% brimonidine tartrate composition. (*Id.* at 25.)

- Even if one skilled in the art thought to perform experiments that would identify 0.15% as a therapeutic concentration of brimonidine . . . . (*Id.* at 27.)

Indeed, the only portion of Alcon's brief that actually makes the argument Alcon represented it would make appears on pages 27 and 28. The argument on those pages is based on *Purdue Pharma*—the case which Alcon indicated would be the basis of its motion. (Marsden Decl., Ex. A, at 7, 20-21, and 24-25)

Alcon's summary judgment motion also makes at least passing reference to still more invalidity arguments which are outside the scope of what was agreed upon. At one point, Alcon suggests that the '834 patent could be invalid for a best mode violation. (*See* Defendants' Opening Brief, at 26 n. 45, D.I. 55.) At other points, Alcon suggests that the invention disclosed in the specification must include either a solubility enhancing component or a preservative. (*See, e.g., id.* at 21.) These arguments are likewise improperly raised by Alcon.

D. The Improper Arguments in Alcon's Summary Judgment Motion should be Stricken

Because Alcon failed to live up to the representations it made to secure the extraordinary opportunity to file its early summary judgment motion, and violated the Scheduling Order by improperly moving for summary judgment based on the "therapeutically effective" issue, and has made other undisclosed invalidity arguments, the portions of Alcon's brief dealing with those issues should be stricken. *See* Rule 16(f) (the court may make such orders as are just with regard to a party's failure to obey the scheduling order, including "striking out pleadings or parts thereof" as provided in Rule 37(b)(2)(C)). While these new arguments are as futile as the one Alcon represented it would make, it was nevertheless improper for Alcon to raise them in its summary judgment motion.

III. CONCLUSION

Accordingly, Allergan respectfully requests the Court to strike the "therapeutically effective," best mode, and solubility enhancing component/preservative arguments in Alcon's summary judgment brief.

Dated: May 16, 2005

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I hereby certify that on May 16, 2005, I electronically filed with the Clerk of Court PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO STRIKE PORTIONS OF DEFENDANTS' SUMMARY JUDGMENT BRIEF using CM/ECF which will send notification of such filing(s) to the following:

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