IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., and ALLERGAN SALES, LLC., Plaintiffs, v. ALCON INC., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD., Defendants.	**Civil Action No: 04-968-GMS** **CONFIDENTIAL** **FILED UNDER SEAL**

DEFENDANT ALCON'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR REARGUMENT OR RECONSIDERATION OF ITS MOTION FOR LEAVE TO AMEND ITS ANSWER

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INTRODUCTION

Defendants Alcon Inc., Alcon Laboratories, Inc., and Alcon Research Ltd. (collectively, "Alcon") respectfully submit this memorandum of law in support of their motion, pursuant to Fed. R. Civ. P. 59(e) and 60(b), and Local Rule 7.1.5, for reconsideration of Alcon's Motion for Leave to Amend its Answer, which was denied by Court Order dated January 17, 2006 (D.I. 107) ("Order").

Alcon sought to amend its answer principally to add allegations that the patents-in-suit were procured by inequitable conduct before the United States Patent and Trademark Office ("PTO"). Inequitable conduct is a serious allegation of fraud, and as such it must be pleaded with particularity. Alcon acted responsibly by deposing the individuals (named inventor Orest Olejnik, and attorney Carlos Fisher) whose conduct is at issue before charging them with fraud on the PTO, and it would be inappropriate to penalize Alcon for deliberateness and care in amassing support before pleading fraud. Had Alcon made such grave assertions at the outset of this case based simply on dubious statements in Dr. Olejnik's declaration and Mr. Fisher's attorney argument, which Allergan submitted to the PTO to overcome rejections, Allergan could have been expected to argue that Alcon's assertions were boilerplate allegations, reflexively pleaded.[1] Instead, Alcon waited until it could depose Dr. Olejnik and Mr. Fisher, both to complete Alcon's investigation and to provide those individuals with the opportunity to offer non-fraudulent explanations for their statements to the PTO.

At those depositions, (i) it became apparent that false statements had knowingly been made to the PTO

REDACTED

[1] The Federal Circuit has observed that "[t]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague." Burlington Indus. Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed Cir. 1988).

REDACTED

and

(ii) Allergan's inventor and attorney offered no explanations for their statements that would be inconsistent with fraud, and indeed simply chose to stonewall rather than justify their conduct. See infra at 4. That combination provides clear and convincing evidence of Allergan's intent to deceive the PTO. Having learned that Allergan had procured its patents through false statements made with deceptive intent, and with Allergan unable or unwilling to provide any non-fraudulent explanation for its behavior, Alcon was able to plead inequitable conduct, and to do so with particularity. Accordingly, Alcon moved to amend its answer promptly thereafter.[2]

Allergan has engaged in serious misconduct. The basis for Alcon's allegations of misconduct may not have been apparent to the Court based upon Alcon's initial motions, but they were fully known to Allergan, which had attended and defended each of the depositions that made the misconduct apparent.

Alcon respectfully submits that reconsideration is warranted under these circumstances because it would be manifestly unjust to prevent Alcon from conforming its pleadings to allege Allergan's intentional lack of candor before the PTO, and because Alcon's decision to wait until it deposed Dr. Olejnik and Mr. Fisher was appropriate.

FACTS

The patents-in-suit concern, among other things, the use of certain well-known viscosity enhancers, rechristened by Allergan as "solubility-enhancing components" ("SECs"), to

[2] The Court denied Alcon's motion to amend, but recognized that if Alcon could not have made the proposed amendments to its Answer prior to the depositions of Dr. Olejnik and Mr. Fisher, "it would seem that [the] motion should be granted." Order at 2. The Court held that specific citation to relevant deposition testimony was required to show "good cause" for the proposed amendments under Fed. R. Civ. P. 16(b). Id. The Court also noted that Alcon had failed to submit exhibits in support of its motion until its reply brief – a failure the Court characterized as "sandbagging" – and that the exhibits ultimately submitted did not show that Alcon needed the deposition testimony before it could plead inequitable conduct. Id.

increase the solubility of brimonidine tartrate in ophthalmic formulations. In order to overcome prior art cited during prosecution of the patents, Allergan and its named inventor, Dr. Olejnik, led the PTO reasonably to believe that (1) certain substances were not SECs; and (2) Allergan had conducted testing to determine whether those substances were SECs and whether they had "mucoadhesive" properties that would promote adherence to the surface of the cornea. (See infra at 4.) At the deposition of Dr. Olejnik, Alcon learned that representations to the PTO in that regard were false. Mr. Fisher, who represented Allergan before the PTO, provided no testimony to rebut the inference of fraudulent intent that flows from Dr. Olejnik's false and misleading testimony.

ARGUMENT

A court may reconsider a decision where "there has been an intervening change in the controlling law, when new evidence has become available, or where there is a need to correct a clear error or prevent manifest injustice." NL Indus., Inc. v. Commercial Union Ins. Co. 65 F.3d 314, 324 n.8 (3d Cir. 1995). "[T]he Court should not hesitate to grant the motion when compelled to prevent manifest injustice or to correct clear error." Brambles USA, Inc. v. Blocker, 735 F.Supp. 1239, 1241 (D. Del. 1990). Alcon respectfully submits that the Court should reconsider its Order to prevent manifest injustice and to correct a clear error of law.

I. IT WOULD BE MANIFESTLY UNJUST TO PRECLUDE AMENDMENT OF ALCON'S ANSWER IN VIEW OF SPECIFIC DEPOSITION TESTIMONY SUPPORTING THE PROPOSED AMENDMENTS

Allergan's actual beliefs at the time it made the representations at issue to the PTO, as conceded in deposition testimony, are of central importance to its inequitable conduct claims, because an "inequitable conduct" defense requires an intent to mislead, see Burlington Indus., Inc., 849 F.2d at 1421, and must be pleaded with particularity under Rule 9(b), see

Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1344 (Fed. Cir. 2003).

Dr. Olejnik's and Mr. Fisher's testimony concerning their actual knowledge and beliefs with respect to certain representations to the PTO thus provided critical support for the proposed inequitable conduct allegations. The most relevant evidence concerning Dr. Olejnik's misrepresentations to the PTO can be summarized as follows:

Representations to PTO	Allergan's Actual Knowledge/Belief
"I have discovered as a result of work done and/or directed by me at Allergan that CMC possesses the surprising advantage [over other vehicles mentioned in the prior-art Burke patent] of both increasing the solubility of brimonidine in solution . . . and causing such solutions to have superior adherence to cell surfaces [i.e., mucoadhesion]." Ex. A., Proposed Amended Answer at ¶ 63; see also Ex. D, Mar. 17, 2003 Declaration of Orest Olejnik, Ph.D., at ¶ 7 (emphasis added).	**REDACTED**
"It is . . . my belief that brimonidine solutions made using the other vehicles mentioned in the Burke patent would not possess this surprising combination of advantages" [i.e, the solubility-enhancing and mucoadhesive properties referenced above]. Ex. D, Olejnik Declaration at ¶ 8 (emphasis added).	**REDACTED** instead stated that they would not increase solubility and be mucoadhesive. Ex. A, ¶¶ 70-72. This is plainly deceitful because the patent claims have nothing to do with mucoadhesion. Thus the very point that was germane to the prior art (i.e., whether they increased solubility) was replaced by one that was not relevant (whether they increased solubility and were mucoadhesive).

The Court's Order suggests that the Court may believe that waiting for those depositions was inappropriate because "the depositions yielded no fruit." Order at 2. Alcon respectfully disagrees, and, as described, the deposition testimony of Dr. Olejnik and Mr. Fisher

clearly supports and provided the necessary predicate for the proposed amendments to Alcon's Answer that were attached to the motion to amend. It would be a manifest injustice if Alcon were prevented from making the proposed amendments merely because specific page citations to the relevant deposition testimony – from depositions that Allergan defended – were not set forth in earlier briefing.[3]

II. THE LIBERAL STANDARD UNDER RULE 15(a) FOR PERMITTING AMENDMENTS TO PLEADINGS SHOULD NOT BE DISREGARDED

Fed. R. Civ. P. 15(a) requires that leave to amend "shall be freely given when justice so requires." As set forth in Alcon's opening brief in support of its amendments, the Supreme Court has made clear that this proscription is a "mandate" that "is to be heeded." Foman v. Davis, 371 U.S. 178, 182 (1962). Similarly, the Third Circuit requires that Rule 16 be applied in light of Rule 15. See Deakyne v. Comm'rs of Lewes, 416 F.2d 290, 297-98 (3d Cir. 1969). Under Rule 15, "[d]elay in of itself will not serve as a basis for denying a motion to amend unless the defendant is prejudiced," because "prejudice to the non-moving party is the touchstone for the denial of an amendment." CenterForce Techs., Inc. v. Austin Logistics Inc., 2000 WL 652943, at *4 (D. Del. 2000) (citing Lorenz v. CSX Corp., 1 F.3d 1406, 1414 (3d Cir. 1993).

The Court's Order makes no reference to Rule 15(a) at all and makes no finding that Allergan would be prejudiced by the proposed amendments. The Court's Order instead rests

[3] The Order also indicates that the Court discounted evidence of Allergan's stonewalling in discovery, in part because the Court saw the attachment of evidentiary exhibits to Alcon's reply brief as "sandbagging." Alcon submitted those exhibits with its reply brief, however, directly in response to Allergan's assertion in its opposition brief that "Alcon has foot-dragged on taking depositions in this case." Allergan Opp. Br. at 4. The submission of evidence demonstrating Alcon's diligent pursuit of discovery in the face of Allergan's stonewalling was necessary to rebut Allergan's preposterous charge of foot-dragging – which was not raised until Allergan submitted its opposition to the Motion to Amend, and which could not reasonably have been foreseen.

exclusively on the requirement of Rule 16(b) that a party demonstrate "good cause" when seeking to modify a scheduling order.[4] Alcon submits that it has shown good cause, but that in any event this is a clear error of law and that, if the "good cause" requirement of Rule 16 is considered in light of the liberal standard of Rule 15(a) – as it must be – allowance of the proposed amendments is clearly warranted. The proposed amendments have a substantial basis in fact, and the Court has not found that allowance of the amendments would unduly prejudice Allergan.[5] Under these circumstances, leave to amend should be freely given. See Foman, 371 U.S. at 182; CenterForce Techs., 2000 WL 652943, at *4; Fed. R. Civ. P. 15(a).

[4] Evaluating Alcon's motion exclusively under Rule 16's provisions for modifying a Scheduling Order would have a particularly harsh effect where, as here, the moving party had no understanding that the Scheduling Order required modification. This arose from Alcon's good-faith belief that the Scheduling Order's date for amending pleadings (nine days after the Rule 16 conference) would not intended to preclude amendments based on evidence developed during discovery.

[5] Allergan's assertions that it was deprived of the opportunity to obtain discovery on inequitable conduct is without merit, as the accuracy of Dr. Olejnik's and Mr. Fisher's representations, and their intention to deceive or not, are known to Allergan.

CONCLUSION

For all the foregoing reasons, Alcon respectfully requests that the Court reconsider its Order denying Alcon's motion for leave to amend, set aside the Order and grant the motion to amend.

Respectfully submitted,

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