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 **PUBLIC VERSION**

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR REARGUMENT OR RECONSIDERATION OF ITS MOTION FOR LEAVE TO AMEND ITS ANSWER

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I. INTRODUCTION

Alcon refuses to take "no" for an answer. After receiving the Court's Order denying its motion to amend its answer, including an amendment to add a defense based on misjoinder of inventors, Alcon proceeded to include the rejected inventorship defense in the Pretrial Order. Indeed, Alcon does not even seek reargument for the inventorship defense. Instead, Alcon apparently believes that it can ignore the Court's Order and proceed to put on its inventorship defense at trial without permission of the Court. [*See* Tab 3 of the Parties' Joint Pretrial Order, D.I. 162].

Now Alcon files this ill-conceived motion for reargument regarding it proposed inequitable conduct defense, but this Court has repeatedly noted that motions for reargument in this district should be granted only in very limited circumstances:

> In this district, these types of motions are granted ***only*** if it appears that the court has patently misunderstood a party, has a made a decision outside the adversarial issues presented by the parties, or has made an error not of reasoning, but of apprehension.

Kerr-McGhee Chemical, LLC. v. Kemira Pigments, 2004 WL 345463, *1 (D. Del. 2004) (emphasis added); *Waters Tech. Corp. v. Applera Corp.*, 2004 WL 57217, *1 (D. Del. 2004); *Springer v. Henry*, 2004 WL 2127172, *6 (D. Del. 2004); *ISCO Intern., Inc. v. Conductus, Inc.*, 2003 WL 881005, *1 (D. Del. 2003).

Because it cannot meet this standard, Alcon's motion does not even bother to mention it, just as Alcon did not bother to mention the "good cause" standard of Rule 16(b) in its original motion to amend. Instead, Alcon simply provides additional arguments not contained in its original briefing and effectively begs the Court's forgiveness for having failed to include these arguments in the first place. The only reason proffered that the Court should do this is that Alcon did not believe that Rule 16(b) could possibly apply because the amendment deadline passed in December, as had been stipulated to by Alcon. [*See* Scheduling Order, D.I. 30]

Alcon's failure to understand that Rule 16 applied to its original motion is not a basis for reconsideration. Alcon cannot and has not shown that the Court patently misunderstood Alcon or made a decision outside of the adversarial issues presented by the parties. Nor did the Court make any error in applying Rule 16(b) to Alcon's motion. Moreover, Allergan would be extremely prejudiced by the addition of four new defenses less than four weeks before trial, and Alcon's footnoted claim that Allergan would not is "contrary to logic." *See Samick Music Corp. v. Delaware Music Ind. Inc.*, 1992 WL 39052 at *7 (D. Del. 1992). Alcon cannot and does not meet the high standard for motion for reconsideration and its motion should be denied.

II. BACKGROUND

The deadline to amend the pleadings in this case was December 1, 2004. [Scheduling Order, at 1, D.I. 30] Notably, this was not a deadline requested by the Court, but stipulated to by Alcon, and then entered by the Court in its Scheduling Order.

Some eight months later, on July 25, 2005, and just a week before the close of fact discovery, Alcon moved the Court to allow it to amend the pleadings to add four new affirmative defenses, including the highly disfavored defense of inequitable conduct. Despite the length of time between the amendment deadline and Alcon's motion to amend, Alcon failed even to mention Rule 16 or the good cause standard in its papers.[1] Those opening papers also failed to provide any evidence that supported either the new claims or the reasons that Alcon had delayed so long in bringing the motion.

In response to Alcon's motion, Allergan noted these glaring omissions and also demonstrated the prejudice that would occur if such a late amendment were allowed. As demonstrated by Allergan, that prejudice would be threefold: 1) the inability of Allergan to conduct any contention or fact discovery; 2) the inability of Allergan to submit expert

[1] Alcon's motion to amend was clearly subject to the "good cause" standard of Rule 16(b), not merely the Rule 15(a) standard set forth in Alcon's brief. *See Gonzales v. Comcast Corp.*, No. Civ.A. 03-445-KAJ, 2004 WL 2009366, *1 (D. Del. Aug. 25, 2004); *Eastern Minerals & Chem. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000).

testimony on the issues; and 3) the inability of Allergan to request to move for summary judgment on the new defenses.

On January 17, 2006, the day the Pretrial Order in this case was due, the Court denied Alcon's motion to amend. Because Alcon had failed properly to address the "good cause" standard, the Court framed its denial around this failure, without addressing Allergan's prejudice arguments:

> Here, the defendants argue that they could not have pleaded these defenses and counterclaims until after the deposition of the first-named inventor of the patents, and the deposition of the plaintiffs' former in-house counsel because those depositions revealed previously-unknown information. If the defendants are correct, it would seem that their motion should be granted. However, the defendants' opening brief points to no specific deposition testimony to back their argument. In fact, the defendants waited to submit any exhibits (other than the proposed amended answer) until they filed their reply brief – the very definition of sandbagging.[2]

[Court's Order Denying Alcon's Motion to Amend (D.I. 158) at 2.] The Court's Order then went on to preclude Alcon from asserting the defenses of:

> (1) unenforceability of U.S. Patent No. 6,641,834 . . .; (2) unenforceability of U.S. Patent No. 6,673,337 . . .; (3) unenforceability of the '834 patent and/or the '337 patent for unclean hands; and (4) invalidity of the '834 patent for the misjoinder of an inventor.

[*Id.* at 1.]

Now, merely rehashing old arguments, Alcon asks the Court to reconsider its earlier motion. However, Alcon falls well short of meeting any of the required criteria for reconsideration and still well short of the requisite "good cause" standard. Accordingly, the Court should deny Alcon's motion for reconsideration.

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[2] In this case, Alcon has been found by the Court to have engaged in "sandbagging" twice. [Court's June 13, 2005 Order, p. 3, (D.I. 93) and the Court's January 17, 2006 Order, p. 2 (D.I. 158)]

III. ARGUMENT

A. The Court has not made an error of law that might serve as the basis for reconsideration – Alcon must meet the "good cause" standard of Fed. R. Civ. P. Rule 16, not the more liberal standard of Rule 15.

As this Court has repeatedly noted:

> As a general rule, motions for reconsideration should be granted ***only sparingly***. In this district, these types of motions are granted ***only*** if it appears that the court has patently misunderstood a party, has a made a decision outside the adversarial issues presented by the parties, or has made an error not of reasoning, but of apprehension. Moreover, even if the court has committed one of these errors, there is no need to grant a motion for reconsideration if it would not alter the court's initial decision. Finally, motions for reconsideration should not be used to rehash arguments already briefed.

Waters Tech. Corp. v. Applera Corp., 2004 WL 57217 (D. Del. 2004) (internal citations omitted). "This Court's opinions are not intended as mere first drafts, subject to revision and reconsideration at a litigant's pleasure." *Id.* citing *Quaker Alloy Casting v. Gulfco Industries, Inc.*, 123 F.R.D. 282, 288 (N.D.Ill.1988).

Because Alcon did not bother citing this standard, Allergan is left to guess as to under what prong of the reconsideration standard Alcon moves.[3] From its papers, it appears that Alcon is not arguing that the Court patently misunderstood Alcon's arguments, nor is it arguing that the Court made a decision outside of the adversarial

[3] Allergan is likewise left to guess as to which portions of Alcon's amended pleading Alcon seeks to keep in the case through its motion. As the Court noted in its Order denying Alcon's original motion for leave to amend, Alcon's proposed amended answer added 14 pages of new factual allegations. [Order at 1, D.I. 158] However, in its motion for reconsideration, Alcon only attempts to connect "evidence" to support its argument that the '337 patent is unenforceable because of alleged misrepresentations by Dr. Olejnik. Alcon fails entirely to mention any of the other grounds on which it sought to render the patents in suit unenforceable or invalid. For example, Alcon fails to provide any support for its allegation that the patents are unenforceable for unclean hands or invalid for misjoinder of an inventor. Alcon further fails entirely to address the Court's correct conclusion that most of what Alcon cited to in support of its original motion was publicly-available prior art and new drug applications. [*Id.* at 2.] Therefore, Allergan only responds factually to the assertions regarding Dr. Olejnik.

issues raised by the parties. Rather, Alcon appears to be arguing that the Court made some error in applying Rule 16(b) to Alcon's motion. But from the Court's Order that is clearly not the case; rather, Alcon just did not like the result.

"A schedule shall not be modified except upon a showing of good cause . . ." Fed. R. Civ. P. 16(b), Order at 1 (D.I. 158); *see Gonzales v. Comcast Corp.*, No. Civ.A. 03-445-KAJ, 2004 WL 2009366, *1 (D. Del. Aug. 25, 2004) (applying "good cause" standard in denying motion to amend complaint filed seven months after deadline set by Scheduling Order); *see also Eastern Minerals & Chem. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000) (affirming district court's denial of motion to amend complaint filed six months after deadline set in Scheduling Order based on failure to meet "good cause" standard). The Court's Scheduling Order plainly states "All motions to join other parties and amend the pleadings shall be filed on or before December 1, 2004." [Scheduling Order, at 1 (D.I. 30)] There are no exceptions or caveats. Accordingly, Alcon had to amend the pleadings by December 1, 2004, or show good cause as to why it was unable to do so. Alcon has done (and did) neither.

As demonstrated by the case law, the Court made no error in its determination that Rule 16(b) applied, nor did it make any error that Alcon could not make the requisite "good cause" showing. There was no failure of apprehension and the Court did not patently misunderstand Alcon's argument. Rule 16(b) applied and Alcon could not meet it.

Because the law is against it, Alcon also appears to argue that Rule 16(b) should not be applied because of an alleged belief that the Court's Scheduling Order was not applicable to Alcon. Alcon's argument defies both credulity and logic. Alcon's only support for the claim that Rule 16 should not apply to it is a claim that the "Third Circuit requires that Rule 16 be applied in light of Rule 15." [Alcon's Br. at 5 [D.I. 178], citing *Deakyne v. Comm'rs of Lewes*, 416 F.2d 290, 297-298 (3rd Cir. 1969).] But *Deakyne* most certainly does not stand for the proposition that Alcon implies: namely, that Rule

16(b) must be read in light of Rule 15(a)'s liberal amendment of the pleadings standard to abrogate scheduling deadlines. In fact, *Deakyne* has nothing to do with Rule 15(a) at all. Rather, *Deakyne* addresses Rule 15(b) and states that Rule 16(b) should be read in light of Rule ***15(b)***. *Id.* This holding is a far cry from the "requirement" that Alcon makes it out to be. Rather, this rule makes perfect sense when one considers that Rule 15(b) addresses the situation where parties have together consented to try an issue that was not in the original pleadings. In that situation, Rule 15(b) allows for the pleadings to be amended after the Pretrial Order has been filed to conform to the evidence. That has most certainly not occurred here.[4] Accordingly, the Court made no error of law in applying Rule 16(b), just as other courts have done in the identical situation. *See Gonzales*, 2004 WL 2009366; *Eastern Minerals & Chem. Co.*, 225 F.3d 330.

B. Allowing Alcon to amend at this late stage would severely prejudice Allergan

Trial is less than four weeks away. Alcon's assertion that Allergan would not be prejudiced by its amendment is, on its face, incredible. Discovery closed months ago, expert reports are in, and the Pretrial Order has been filed. Allergan would have no opportunity at all to propound interrogatories and other written discovery regarding Alcon's new defenses and counterclaims. Nor would it be able to prepare and present expert testimony if necessary. Lastly, it would have no ability to move for summary judgment on the defense, an opportunity that was granted to Alcon in this case with respect to two of its other defenses.

Alcon's implication that the Court somehow rejected prejudice as a basis for its ruling is unfounded. Alcon's initial motion failed to get over the first hurdle—namely, satisfying the good cause standard. That the Court did not mention the prejudice to

[4] Indeed, the opposite has occurred here. Apparently pretending that the Court ruled in some other fashion, and over Allergan's vigorous objections to the contrary, Alcon is still attempting to assert that the inventorship of the '834 patent was somehow improper, claiming that the validity of the patent under 102(f)—the section relating to inventorship—is still in issue. [*See* Tab 3 of the Parties' Joint Pretrial Order, D.I. 162]

Allergan is no reason simply to dispense with it as an independent basis for the Court's ruling. Indeed, Alcon's continued claim that Allergan would not be prejudiced by the proposed amendment because

REDACTED is fanciful.

[Alcon's Br. at 6.] As we stated previously, that is akin to Allergan asserting a new patent against Alcon and arguing that Alcon needs no discovery with regard to its own infringement. Of course, each party is entitled to take discovery regarding the other's contentions, and Allergan would obviously be prejudiced if it were not allowed to take discovery regarding Alcon's inequitable conduct and other defenses. *See Samick Music Corp.*, 1992 WL 39052 at *7 (rejecting as "contrary to basic logic" defendant's argument that plaintiff would not be prejudiced by addition of fraud claim after the close of discovery since plaintiff knew of its own fraud).

In short, if Alcon's motion were granted, the prejudice to Allergan would be severe, and that alone justifies denying the motion. *See Acosta-Mestre v. Hilton Intern. of Puerto Rico*, 156 F.3d 49, 52-53 (1st Cir. 1998) (finding prejudice to be a sufficient basis for the denial of a motion to amend).

C. Alcon's purported evidence, explained for the first time in its brief in support of its motion for reconsideration, fails to identify anything that was learned during the depositions that would warrant Alcon's eight month delay.

In its original briefing, Alcon offered nothing to support its claim that the depositions of Carlos Fisher and Orest Olejnik resulted in newly found evidence justifying its new claims. Instead, as the Court noted, Alcon merely offered "vague representations" as to what it learned. [Order at 2, D.I. 158] "Moreover, the heart of the defendants' amendments, found at paragraphs 70 through 72 of the proposed amended answer, appear to mention nothing material regarding the deposition testimony of either the inventor or the attorney." [*Id.*]

Alcon does not argue, nor can it, that the Court made some error of apprehension — the Court understood Alcon's submissions, but what the Court correctly concluded from those submissions was that Alcon had failed to meet the good cause requirement of Rule 16. Rather, with its additional briefing, Alcon hopes to further supplement its original briefing in the hope that the Court will grant the original motion. Even putting aside that this is no basis for reconsideration—and the Court should not do so— Alcon's newly presented theory of what took place at Dr. Olejnik's deposition still falls well short of meeting the "good cause" standard. With respect to Mr. Fisher, Alcon attaches portions of his deposition to its motion, but does not even cite the deposition in its argument.

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As to the second alleged "contradiction," it simply confirms the lack of "good cause" here.

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[*See*

Declaration of William J. Marsden, Jr. (hereinafter "Marsden Decl.") submitted herewith, Ex. A – United States Patent No. 6,627,210 patent at col. 6, ll. 9-11; col. 8, ll. 15-20.] So, according to Alcon, Dr. Olejnik failed to live up to his duty of candor by not telling the patent office something that was plainly stated in the patent specification. This is nonsense.

Next, Alcon argues that Allergan's arguments regarding the mucoadhesive properties of CMC were "plainly deceitful because the patent claims have nothing to do with mucoadhesion." [Alcon Br. at 4, D.I. 178]. Alcon's argument, like so many of its arguments, simply ignores the controlling law. Allergan made the argument regarding mucoadhesive advantages of CMC, the preferred anionic SEC which was the subject of the pending claims, to overcome a § 103 obviousness rejection by the examiner. As Allergan pointed out in its summary judgment briefing:

> The totality of the record must be considered when determining whether a claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded.

[Marsden Decl. Ex. B – MPEP 716.02(f) (8th ed. 2004)]; *see also In re Chu*, 66 F.3d 292, 299 (Fed. Cir. 1995) ("We have found no cases supporting the position that a patent applicant's evidence or arguments traversing a § 103 rejection must be contained within the specification."). Allergan's arguments regarding the mucoadhesive advantages of CMC were completely proper under the case law and patent office rules.

Moreover, the additional matters Alcon fails to point out speak volumes. Left unsaid by Alcon is that the alleged inequitable conduct relates not to one of the patents in suit, but to the '210 patent, with claims that were narrower, not broader, than the patent-in-suit, a fact that was well known to the examiner. And the Federal Circuit has recently clarified that inequitable conduct in one patent does not somehow automatically apply to a related patent. *See Pharmacia Corp. v. Par Pharmaceutical, Inc.*, 417 F.3d 1369 (Fed.

Cir. 2005). Likewise, the case on which Alcon has rested its inequitable conduct contentions, the *Purdue Pharma L. P. v. Endo Pharm. Inc.*, 410 F.3d 690 (Fed Cir. 2005), was recently withdrawn, vacated, and remanded by the Federal Circuit to the district court for reconsideration. *Purdue Pharma L. P. v. Endo Pharm. Inc.*, No. 04-1189 (Fed. Cir. Feb. 1, 2006).

Accordingly, through its various motions, Alcon is attempting to inject into this case the enforceability of a patent not in suit, the '210 patent, on the most tenuous of legal footings in an effort to extend the inequitable conduct to a patent that could not possibly have been based on the allegedly offending declaration because the patent in suit, the '337 patent, had broader, not narrower, claims. And, at the same time, Alcon asks the Court's forgiveness in doing so, by asking the Court to ignore: 1) Alcon's failure to mention or meet the obviously applicable standards of Rule 16(b) in its opening brief; 2) Alcon's "sandbagging" of Allergan by waiting until its reply brief to submit any "evidence"; 3) the clear prejudice to Allergan that would result from the late amendment; and 4) Alcon's failure either to cite or meet the high standard for re-argument in its currently filed papers. Alcon simply asks too much. Its motion for re-argument should be summarily denied.

IV. CONCLUSION

For the foregoing reasons, Allergan respectfully requests that the Court deny Alcon's motion for reconsideration.

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