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.	C.A. No. 04-968-GMS

PLAINTIFFS' BRIEF IN OPPOSITION TO ALCON'S MOTION FOR LEAVE TO AMEND ITS ANSWER

FISH & RICHARDSON P.C.
William J. Marsden, Jr. (marsden@fr.com)
Sean P. Hayes (hayes@fr.com)
919 N. Market Street, Suite 1100
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: (302) 652-5070

Jonathan E. Singer
Michael J. Kane
Deanna J. Reichel
FISH & RICHARDSON P.C., P.A.
3300 Dain Rauscher Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 335-5070

Juanita Brooks
W. Chad Shear
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070

Attorneys for Plaintiffs
ALLERGAN, INC. and ALLERGAN SALES, LLC

DATED: August 9, 2005

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I. INTRODUCTION

Consistent with its history of attempting to sandbag Allergan and other litigation opponents[1]—and without reference to the "good cause" standard to which its motion is subject—Alcon now moves to amend its answer more than eight months after the deadline set in the Court's Scheduling Order by adding 12 pages of "allegations" in which Alcon offensively and outlandishly contends that both of the patents-in-suit in this case, as well as a parent patent, are products of a vast conspiracy by Allergan, one of the inventors of the patents-in-suit, and one of the attorneys prosecuting the patents-in-suit to "defraud" the United States Patent Office and to "suppress" allegedly material prior art. Apparently believing that its non-infringement and written description defenses have not panned out, Alcon is now resorting to slinging mud, plain and simple.

This Court should reject Alcon's last-minute efforts. Alcon's motion fails basic standards of timeliness, diligence and good faith, and, at bottom, reflects a continuing attempt to win this case through gamesmanship, and not on the merits. Written fact discovery has closed, the summary judgment motion deadline has passed, and expert reports are due shortly. It is simply too late and would be manifestly unfair to indulge Alcon's wild-eyed scramble to find a new defense.[2] Alcon's motion should be summarily denied.

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[1] *See* D.I. 93 (Order striking argument in Alcon's summary judgment brief as outside the scope of issues for which it received permission to move for summary judgment and also striking argument raised by Alcon for the first time in its reply brief); *see also Advanced Medical Optics, Inc. v. Alcon, Inc.*, 361 F.Supp. 2d 404, 418, n.8 (D. Del. 2005) (refusing to consider Alcon's arguments which were raised for the first time in its reply brief).

[2] Because Allergan would be severely prejudiced if Alcon's motion is granted, Allergan is filing herewith a Provisional Motion to Amend the Scheduling Order. In the event Alcon's motion is granted, Allergan's Provisional Motion seeks to move the remaining dates in the Scheduling Order back three months, including discovery deadlines,

II. BACKGROUND FACTS AND PROCEDURAL HISTORY

A. Alcon Filed its Motion Eight Months After the Deadline for Amending Pleadings, Just Seven Days Before the Close of Written Fact Discovery, and Eight Days Before the Deadline for Allergan to Request Permission to File a Summary Judgment Motion

With the guidance of the Court, the parties in this case stipulated to the schedule set forth in the Court's scheduling order. Under that schedule, motions to amend the pleadings were due on December 1, 2004 and fact discovery in this case closed on August 1, 2005. Opening and rebuttal expert reports were originally due on August 15 and September 2, 2005, respectively, though because of scheduling conflicts regarding depositions that did not permit their conclusion by August 1, the parties have agreed to serve the reports on September 15 and September 29, 2005, respectively.[3]

As the Court is aware, this schedule granted Alcon special permission to file two early summary judgment motions, one on non-infringement of the '337 patent and one on lack of written description of the '874 patent. These motions were briefed by the parties in May of this year and taken under advisement by the Court in June.

Because of the stated significance of those motions, Allergan focused its discovery efforts in large part on those motions, serving contention interrogatories regarding each of them, as well as taking depositions of personnel at Alcon relevant to these defenses. Allergan relied in good faith on Alcon's representations that it had legitimate issues that it felt warranted early court consideration, and proceeded accordingly.

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summary judgment deadlines, expert report deadlines, and pretrial and trial dates, to allow Allergan sufficient time to address Alcon's newly raised defenses.

[3] Because of scheduling conflicts, the parties have agreed to conduct depositions through August 31, 2005.

Allergan was repaid for its efforts by Alcon filing a summary judgment motion on written description that had little to do with the motion Alcon had been granted permission to file. Allergan believes that Alcon changed the defense due to the discovery efforts of Allergan, which had demonstrated that the original grounds raised for summary judgment had no basis in fact.

As a consequence, and in response to an Allergan motion that demonstrated all of the above, the Court struck the portions of Alcon's summary judgment motion relating to the arguments Alcon had not been granted permission to make. (D.I. 93, at 3.) The Court also struck certain reply briefing of Alcon as amounting to "impermissible sandbagging." (*Id.*)

In contrast to the above, Allergan has not been granted permission to file any summary judgment motions in this case. Instead, Allergan, if it desired to move for summary judgment, was required to file a letter with the Court by August 2, 2005 seeking permission to file any such motion. (D.I. 30, at 4.) Rather than being suggested by the parties, as most of the discovery schedule was, this deadline was requested by the Court. According to the Court, the Court required significant time between any letter seeking permission to file a summary judgment motion and the scheduling of trial, currently set for March 6, 2006, so that it would have a fair opportunity to consider any summary judgment motion it might permit Allergan to file. (Declaration of Sean P. Hayes in Support of Plaintiffs' Opposition to Alcon's Motion for Leave to Amend its Answer ("Hayes Dec."), Ex. A, at 28.)

This deadline for requesting permission to file a summary judgment motion passed, not coincidentally, just eight days after Alcon filed its motion requesting

permission to amend its answer and counterclaims. As a consequence, Allergan would have no opportunity even to consider filing a summary judgment motion on Alcon's alleged new defenses were the Court to allow them. Likewise, Allergan would have no ability to: 1) serve contention discovery on Alcon's alleged defenses or requests for admission regarding those defenses; 2) depose relevant Alcon witnesses on technical aspects of the alleged defenses; or 3) meaningfully consult with its experts on the allegations made by Alcon. In short, just as it did with its written description defense, Alcon's proposed "inequitable conduct" defenses seek to change the rules of the game at the last minute, to the decided tactical advantage of Alcon.

B. Alcon Has Made No Effort to Diligently Pursue The Discovery in this Case Related to its Proposed Defenses, Instead Choosing to Delay Deposition Discovery Until After Summary Judgment Briefing Was Concluded

Discovery in this case commenced in late November, 2004, after the Rule 26(f) conference between the parties held on November 22, 2004. Thereafter, each party served written discovery requests, including document requests and written contention interrogatories. Alcon served its first set of document requests and first set of interrogatories on Allergan on November 24, 2004. Since then, Alcon has served four additional sets of document requests, and two sets of interrogatories.

In contrast to its prompt use of written discovery tools, Alcon has foot-dragged on taking depositions in this case, and, in particular, delayed for months in taking the depositions of the two individuals whose good names it proposes to sully in its amended pleading: inventor Orest Olejnik and prosecuting attorney Carlos Fisher. Not until April, 2005 did Alcon counsel even contact Allergan counsel requesting a deposition date for Dr. Olejnik. (Hayes Dec., Ex. B.) And after being provided multiple opportunities to

depose Dr. Olejnik in May, Alcon canceled his deposition scheduled for May 25 at the last minute. Ultimately, Alcon finally took Dr. Olejnik's deposition on June 23, 2005, just one month before the close of discovery.

As for Mr. Fisher, Alcon did not even request his deposition until after deposing Dr. Olejnik. (*Id.*, Ex. C.) Allergan provided a deposition date quickly thereafter, and Alcon deposed Mr. Fisher on July 20, 2005, just five days before filing its motion to amend its pleading.

The lengthy delays in taking these depositions are not due to any actions of Allergan. To the extent Alcon was waiting for documents, Allergan completed the vast majority of its document production by late March, three months before Dr. Olejnik's deposition was finally taken, and four months before Mr. Fisher's. Moreover, the bulk of Alcon's proposed amended pleading relates to alleged false statements in the file histories of the patents-in-suit, and alleged failures to disclose prior art, for which no discovery from Allergan was even necessary. On this score, Alcon has delayed not just since discovery began, but since before this case began. At his recent deposition, in-house counsel for Alcon, Patrick Ryan, testified that Alcon reviewed the file histories of the patents-in-suit well in advance of sending Allergan notice in July, 2004 of Alcon's generic drug application. (*Id.*, Ex. D, at 52-53, 82-83). Mr. Ryan also testified that Alcon conducted a "thorough" prior art search at that time. (*Id.*, Ex. D, at 55.)

Accordingly, the basic materials relevant to Alcon's proposed inequitable conduct charges—the file histories and the prior art search—were in its hands over a year ago. Alcon had every opportunity to make its charges when it filed its answer in August of last year, but chose instead to focus its efforts on its summary judgment issues. Having now

apparently lost faith in the merits of its position on those issues—and with one of the positions having already been rejected by the Court in the *Markman* process—Alcon now seeks to burden this Court and to sandbag Allergan with inflammatory and specious charges of inequitable conduct, which Allergan would have no opportunity to challenge except at trial. This Court should reject Alcon's motion on any of the grounds specified below.

III. ARGUMENT

A. Because the Deadline for Amending Pleadings has Passed, Alcon Must Show "Good Cause" to Amend its Answer and Counterclaims

The deadline to amend the pleadings in this case was December 1, 2004. (D.I. 30, at 1.) Because that deadline has long since passed, Alcon's motion to amend is subject to the "good cause" standard of Rule 16(b), and not the more liberal Rule 15(a) standard set forth in Alcon's motion. *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).

In its motion, Alcon does not even bother to cite, let alone address this standard. That is because Alcon cannot meet the standard. "Good cause" requires the party seeking to amend its pleadings at the last minute to show "diligence" in attempting to meet the original deadline. *Gonzales*, 2004 WL 2009366, at *1. A party may not simply sit on its hands having chosen one set of defenses, and then, when those do not pan out, move to another set of unpled defenses at the last minute, and expect a Court simply to allow it.

And even before the deadline to amend has passed, courts may deny leave to amend under Rule 15(a) on a number of grounds, including undue delay in seeking the amendment, undue prejudice to the opposing party, bad faith or dilatory motive on the part of the movant, and futility of the amendment. *Foman v. Davis*, 371 U.S. 178, 182 (1962).

All of the above reasons for denying Alcon's motion are present here.

B. Alcon Did Not Show Diligence in Pursuing Discovery and Unduly Delayed in Bringing its Proposed Affirmative Defenses and Counterclaims

As demonstrated above, Alcon has delayed since the inception of this case in bringing forth its proposed charges of inequitable conduct. Alcon conducted a prior art search over a year ago, yet only now brings forward Allergan's alleged failure to disclose material prior art—prior art that, to date, Alcon has not disclosed in its discovery responses.[4] Alcon analyzed the file histories of the patents-in-suit over a year ago, as well, yet only now, after its prosecution disclaimer argument has been rejected, does it state that numerous statements in those file histories were "false."

Alcon's efforts to justify this delay are half-hearted at best. Without citing the "good cause" standard, Alcon points to the depositions of Dr. Olejnik and Mr. Fisher in June and July, respectively, and claims that these depositions are the reason it is bringing its motion now. But nowhere in its motion does Alcon even state, much less show, that it would not have been able to bring its new defenses prior to those depositions. Indeed, given that the defenses relate to failures to disclose prior art and alleged false statements in the file history, there is no reason Alcon could not have come forward earlier.

[4] Indeed, Allergan continues to wait for Alcon's invalidity contentions, which Alcon initially refused to provide because it was still "reviewing" the prior art. (Hayes Dec., Ex. E.)

In fact, Alcon does not even once cite the transcripts of the depositions which it would have the Court believe provided the necessary information for its new defenses.[5] That is because the depositions are merely a pretext. If Alcon could have pointed to specific deposition testimony as revealing the facts on which its new allegations are based, it undoubtedly would have. That Alcon did not even make the attempt speaks volumes.[6]

Even if it were true that the depositions provided the basis for Alcon's new defenses—and it is not—that still would not excuse Alcon's undue delay in seeking to amend. Alcon could have deposed Dr. Olejnik and Mr. Fisher months ago, but for tactical reasons known only to it chose to wait until discovery had almost closed.[7]

This pattern of delay does not even come close to satisfying the diligence that the "good cause" standard requires. Alcon's motion should be denied on this basis alone. *See Gonzales*, 2004 WL 2009366 at *1; *see also Samick Music Corp. v. Delaware Music Ind., Inc.*, Civ. A. No. 91-23-CMW, 1992 WL 39052, *7 (D. Del. 1992) (denying leave to amend for failure to provide a reasonable explanation for delay); *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1269-70 (Fed. Cir. 2002) (affirming denial of motion for

[5] By contrast, in *Enzo Life Sci., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484 (D. Del. 2003), cited by Alcon, the defendant presented specific testimony from recent depositions on which its proposed inequitable conduct defense was based. *Id.* at 488. The defendant also presented evidence that its delay in bringing the defense was attributable to the plaintiff's delay in providing discovery and making witnesses available. *Id.* at 486.

[6] Having elected not to cite any evidence in its opening papers, Alcon cannot now cite evidence for the first time in its reply and thereby deprive Allergan of the opportunity to refute it. *See* D.I. 93; *see also Advanced Medical Optics, Inc.*, 361 F.Supp. 2d at 418, n.8.

[7] Allergan suspects that Alcon thought the depositions might raise fact issues or otherwise interfere with its motion for summary judgment. Alcon had previously declared that this case could be resolved on the issues raised in its summary judgment motion without any discovery. (*See* Hayes Dec., Ex. A, at 7-8, 18, 20.)

leave to add inequitable conduct charge for lack of good cause where defendant did not pursue it in a timely manner).

C. Allowing Alcon to Amend at this Late Stage Would Severely Prejudice Allergan

Alcon's assertion that Allergan would not be prejudiced by its amendment is preposterous. Written fact discovery is already closed in this case. Allergan would have no opportunity at all to propound interrogatories and other written discovery regarding Alcon's new defenses and counterclaims, discovery which is necessary for Allergan both to understand the alleged defenses and to avoid the continual surprise that seems to be Alcon's stock in trade. Nor would Allergan be provided a meaningful opportunity to take deposition discovery or consult with its experts on this defense given the current case calendar. In short, just as it did with its surprise written description defense, Alcon seeks to have its new defenses go essentially unchallenged in the discovery process.

Incredibly, Alcon argues that Allergan would not be prejudiced by the proposed amendment because "Allergan needs no discovery with respect to its own conduct before the United States Patent and Trademark Office and no discovery with regard to the inventorship on the '834 patent." (D.I. 107, at 3.) That is akin to Allergan asserting a new patent against Alcon at this stage 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).

Moreover, the August 2, 2005 deadline for Allergan to seek permission to file summary judgment motions has passed, so Allergan would have no opportunity to dispose of Alcon's new defenses on summary judgment. (D.I. 30, at 4.) Whether or not that was Alcon's intent in bringing these defenses so late—and Allergan believes that it was—the prejudice to Allergan is unmistakable.

In short, if Alcon's motion is 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); *see also Crest Hill Land Development, LLC v. City of Joliet*, 396 F.3d 801, 804 (7th Cir. 2005) ("'Surprises' such as new arguments or defense theories propagated after the completion of discovery and filing of summary judgment are wisely discouraged.").

D. Alcon's Proposed Defenses and Counterclaims are Specious

Finally, we note that Alcon is not attempting to raise a specific, well-founded defense in its proposed amended pleading. Rather, it is throwing everything it can think of at Allergan, apparently hoping that something might stick.

With regard to U.S. Patent No. 6,627,210 (which is not even in suit), Alcon accuses Allergan of making five different allegedly false statements during prosecution, "on information and belief" failing to disclose the best mode of carrying out the invention, and "on information and belief" failing to disclose a variety of information including three different publications. With regard to U.S. Patent No. 6,641,834, Alcon accuses Allergan of making two different allegedly false statements, "on information and belief" failing to disclose the best mode, and "on information and belief" failing to disclose a variety of information including six different publications. With regard to U.S.

Patent No. 6,673,337, Alcon accuses Allergan of making two different allegedly false statements, "on information and belief" failing to disclose the best mode, and "on information and belief" failing to disclose information including the nine publications Alcon identified in connection with the other two patents.[8]

It is absurd to raise all of these allegations this late in the litigation. With the disclaimer "on information and belief," Alcon admits that even now, at the close of discovery, it does not have the evidence it needs to support the allegations. Alcon identifies the statements it claims to be false, but does not explain why they are false, why they are material, or on what basis it asserts that Allergan intended to deceive the Patent Office. Similarly, Alcon identifies the publications which it contends that Allergan should have disclosed to the Patent Office, but does not explain why they are material or on what basis it asserts that Allergan knew of them or that Allergan intended to deceive the Patent Office by not disclosing them. These elements are the crux of any inequitable conduct defense,[9] and all Alcon can come forward with after a year of discovery are bare, conclusory allegations. Alcon assures the Court that "[a]dditional discovery is being sought which may provide further evidence of Allergan's breach of its duty of candor, the materiality of the breaches at issue, and Allergan's fraudulent intent," (D.I. 107, at 3), but Alcon's wishful thinking is an insufficient basis for granting its motion at this stage of the litigation.

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[8] The nine publications on which Alcon's inequitable conduct defenses are based were not even produced to Allergan in discovery. Apparently, Alcon has been withholding this prior art on the basis of privilege. (*See* Hayes Dec., Ex. F, entries beginning at 2 labeled "publications selected by attorney re patent prior art".)

[9] *See, e.g., Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed. Cir. 2003).

Alcon's motion does not even discuss its proposed "unclean hands" defense, and its amended answer does not allege any facts that would support an "unclean hands" defense apart from those it alleges to constitute inequitable conduct. Thus, Alcon's "unclean hands" defense is as groundless as its inequitable conduct defense.

Likewise, Alcon fails to provide any information on its inventorship defense—for example, failing to identify who it was that should or should not have been joined. And from the paragraph in Alcon's motion that addresses the proposed inventorship defense, it appears that it is nothing more than a variation of Alcon's written description argument that the "0.15%" limitation is not disclosed in the specification. In any event, "the burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence." *Bd. of Educ.. v. Am. Bioscience, Inc.*, 333 F.3d 1330, 1334 (Fed. Cir. 2003). At the close of discovery, Alcon is nowhere near meeting that burden.

Alcon contends that granting its motion "would be consistent with sound public policy" because courts have recognized the public interest in seeing that patents are not obtained through inequitable conduct. But the inequitable conduct defense is highly disfavored. *See Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against each other on the slenderest grounds . . . ."). Specific fact-based pleadings are required under Rule 9(b) to prevent abuse of the defense. *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2004). Surely public policy does not require the Court and

Allergan to accommodate Alcon's thirteenth-hour attempt to assert wholesale charges, without basis, at the close of fact discovery and long after the deadline to amend has passed.

This case is serious business, and Allergan, for one, is tired of the gamesmanship to which Alcon has repeatedly resorted. This Court should reject Alcon's last-minute attempt to add over ten pages of inequitable conduct allegations in complete disregard of the schedule in this case.

IV. CONCLUSION

For the foregoing reasons, Allergan respectfully requests that the Court deny Alcon's untimely motion for leave to amend its answer.

Dated: August 9, 2005

FISH & RICHARDSON P.C.

By: /s/ *Sean P. Hayes*

William J. Marsden, Jr. (#2247)
Sean P. Hayes (#4413)
919 N. Market Street, Suite 1100
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: (302) 652-5070

Jonathan E. Singer
Michael J. Kane
Deanna J. Reichel
FISH & RICHARDSON P.C., P.A.
3300 Dain Rauscher Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 335-5070

Juanita Brooks
W. Chad Shear
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070

Attorneys for Plaintiffs
ALLERGAN, INC. and ALLERGAN SALES, LLC

CERTIFICATE OF SERVICE

I hereby certify that on August 9, 2005, I electronically filed **PLAINTIFFS' BRIEF IN OPPOSITION TO ALCON'S MOTION FOR LEAVE TO AMEND ITS ANSWER** with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Josy W. Ingersoll
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building, 17th Floor
1000 West Street
P.O. Box 391
Wilmington, DE 19899-0391

I hereby certify that on August 9, 2005, I have sent via Federal Express, the document(s) to the following non-registered participants:

Brian D. Coggio
Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103-0001

/s/ *Sean P. Hayes*
Sean P. Hayes