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

ALCON'S MOTION FOR LEAVE TO AMEND ITS ANSWER

Defendants, Alcon Inc., Alcon Laboratories, Inc., and Alcon Research Ltd. (collectively "Alcon"), respectfully submit this motion for leave to amend their Answer pursuant to Federal Rule of Civil Procedure 15(a). In accordance with Local Rule 15.1, Alcon's proposed First Amended Answer and one copy thereof are attached hereto as Exhibit A. A copy of the proposed First Amended Answer indicating how it differs from Alcon's original Answer is attached hereto as Exhibit B. Alcon waives an opening brief in support of its motion, relying on the argument contained herein. The changes brought about by the proposed Amended Answer include the addition of the following affirmative defenses and counterclaims: (1) unenforceability of the '834 patent for inequitable conduct; (2) unenforceability of the '337 patent for inequitable conduct; (3) unenforceability of the '834 and/or '337 patents for unclean hands; and (4) invalidity of the '834 patent for the misjoinder of an inventor(s).

Rule 15(a) mandates that leave to amend a pleading "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). "[T]his mandate is to be heeded." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

> In the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc. – the leave sought should, as the rules require, be "freely given."

Id.; *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3rd Cir. 1997) (following *Foman*).

On June 23 and 24, 2005, Alcon deposed the first-named inventor on the two patents-in-suit, Orest Olejnik, Ph.D. Based on concessions made at that deposition, it became apparent that Allergan orchestrated an elaborate scheme to defraud the United States Patent and Trademark Office during the prosecution of the patents-in-suit. The means by which this scheme was accomplished are pleaded with particularity in the proposed Amended Answer, but includes, in respect of both asserted patents, material misrepresentations and omissions concerning the testing of various compositions in connection with declarations submitted to the PTO to overcome obviousness rejections based on purportedly "unexpected results." *See Purdue Pharma L.P. v. Endo Pharm. Inc.*, 410 F.3d 690 (Fed. Cir. 2005) (patent held unenforceable for inequitable conduct based on patentees' misleading declaration of "surprising results," which implied the existence of testing that had not been performed.)

On July 20, 2005, Alcon deposed Carlos Fisher, Esq., the former in-house Allergan patent attorney responsible for the prosecution of the patents-in-suit. At that deposition, Allergan refused to offer any explanation inconsistent with the inference of fraud for certain arguments made to the PTO by Mr. Fisher that were intended to mislead the Examiner to believe

that compositions claimed in the parent application were novel, when Allergan knew that they were not. Alcon believes that the factual record developed to date is sufficient to render the patents-in-suit unenforceable by virtue of Allergan's inequitable conduct during prosecution of the patents-in-suit and related applications. Additional 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.

Similarly, Alcon has discovered that the inventorship of United States Patent No. 6,641,834 ("the '834 patent") is highly suspect. When both named inventors of the '834 patent-in-suit (Drs. Olejnik and Kerslake) were questioned about the claims' "0.15% (w/v)" limitation, neither took credit for that critical aspect of the invention. This adds to the mystery that already exists with respect to the 0.15% limitation – a limitation utterly absent from the specification and inappropriately added late in prosecution. While Alcon continues to seek discovery regarding the conception of the alleged invention, it appears from the record developed to date that the inventorship of the '834 is improper.

Allergan will not be prejudiced by the Court granting Alcon leave to amend. 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. Moreover, even if Allergan needs to gather any information, several weeks of fact discovery remain in this case, expert discovery has not yet begun, and the scheduled trial date is many months away.

The grant of Alcon's motion would be consistent with sound public policy. "The far-reaching social and economic consequences of a patent . . . give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope." *Precision Instrument*

Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). Consequently, courts often grant leave to add the defense of inequitable conduct. *See, e.g., Lucent Tech., Inc. v. Extreme Networks, Inc.*, No. 03-508 JJF (D. Del. Jan. 12, 2005) (order granting motion to file amended answer and counterclaims adding inequitable conduct allegation); *Enzo Life Sci., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 490 (D. Del. 2003) (granting motion to file amended answer adding inequitable conduct allegation); *see also Thompson-Hayward Chem. Co. v. Rohm & Haas Co.*, 745 F.2d 27, 33 (Fed. Cir. 1984) (recognizing strong public interest in enforcing adherence to the duty of candor in the Patent Office).

For at least the foregoing reasons, and those identified in Alcon's proposed Amended Answer, Alcon respectfully requests that the Court grant Alcon's Motion For Leave to Amend Its Answer.

Respectfully submitted,

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Dated: July 25, 2005

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ORDER

At Wilmington this _____ day of _____, 2005, having considered Alcon, Inc.'s, Alcon Laboratories Inc.'s, and Alcon Research, Ltd.'s ("Alcon") motion to amend its answer, IT IS HEREBY ORDERED that:

(i) Alcon's Motion for Leave to Amend its Answer is granted.

(ii) Alcon's proposed First Amended Answer and Counterclaims, in the form attached as Exhibit A to its motion, shall be deemed as having been filed and served as of the date of this Order.

_____
United States District Judge

CERTIFICATE OF SERVICE

I, Glenn C. Mandalas, Esquire hereby certify that on July 25, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on July 25, 2005, I caused a copy of the foregoing document to be served on the following non-registered participants in the manner indicated:

BY E-MAIL

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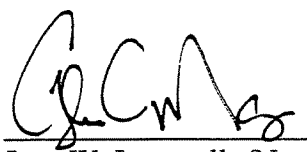

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