IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC., ASTELLAS US LLC, and ASTELLAS PHARMA US, INC. Plaintiffs, v. SICOR INC. and SICOR PHARMACEUTICALS, INC., Defendants.	Civil Action No. 05-337 SLR

DEFENDANT SICOR'S REPLY IN SUPPORT OF ITS MOTION FOR LEAVE TO AMEND ITS ANSWER

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I. INTRODUCTION

The opposition submitted by plaintiffs King Pharmaceuticals Research and Development, Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively "plaintiffs") fails to set forth any legitimate basis for this Court to deny the motion to amend made by defendants Sicor Inc. and Sicor Pharmaceuticals, Inc. (collectively "Sicor"). Instead, plaintiffs rely on irrelevant cases in unrelated areas of law in an attempt to cloud the real issue to be decided here and to cobble together an argument supporting their opposition. Plaintiffs' efforts fail, however, because the weight of judicial precedent favors freely granting leave to amend pleadings, especially to amplify a defense that has already been asserted, as is the case here.

The core of Plaintiffs' opposition is their argument that the word "enforceable" in Sicor's proposed amendment is an attempt to assert a stand-alone defense of inequitable conduct. Plaintiffs are plainly wrong. Sicor is well aware of the particularized pleading requirements for an assertion of fraud in obtaining a patent, and there is no doubt that is not the meaning of Sicor's proposed amendment. The word "enforceable" in Sicor's proposed amendment simply conveys the notion that an invalid claim is not enforceable as a matter of law. *See*, *e.g.*, 35 U.S.C. § 282. Plaintiffs' opposition wholly mischaracterizes Sicor's proposed amendment, apparently to create a straw man that Plaintiffs can knock down in the absence of any substantive reason for opposing Sicor's motion.

Nor is Sicor's amendment futile or prejudicial, as Plaintiffs assert. Sicor's proposed amendment merely clarifies the non-infringement defense that it previously asserted in its August 8, 2005 answers in this action, as is plain from the redlined version of Sicor's proposed amended answer attached to Sicor's motion as Exhibit B.

II. ARGUMENT

This Court has previously indicated that motions to amend defenses that have been previously asserted (like Sicor's proposed amendment to its non-infringement defense) are precisely the types of motions to amend that should be granted:

> [*T*]*he clearest cases for leave to amend are* correction of an insufficient claim of defense and ***amplification of previously alleged claims or defenses.***

See France Telecom S.A. v. Novell, Inc., No. 02-437 GMS, 2002 U.S. Dist. LEXIS 19967, at *3 (D. Del. Oct. 17, 2002)(emphasis added). Indeed, plaintiffs do not cite any cases holding otherwise. Instead, the few cases cited by plaintiffs on this point are readily distinguishable from the factual circumstances in this case and blur the distinction between a motion to amend a complaint and a motion to amend a defense.

Both the Federal Rules of Civil Procedure and the weight of the case law regarding motions to amend are absolutely clear – leave to amend the pleadings should be freely granted when justice so requires (Def. Mot. at 2). The United States Supreme Court emphasized that the liberal mandate of Rule 15(a), Fed. R. Civ. P., is to be heeded by the lower courts, and the courts of the District of Delaware have faithfully followed this mandate for over four decades (Def. Mot. at 2-3).

The strong tendency of the courts in this District to grant motions to amend is evidenced by the scant support for plaintiffs' contrary position. Each and every district and appellate court case cited by plaintiffs in their discussion of motions to amend (Pl. Opp'n at 4) concerns amendment of a ***complaint*** – not an answer or an affirmative defense. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410 (3d Cir. 1997)(investor class action alleging claims for securities fraud, in which the district court's denial of plaintiffs' motion for leave to amend its complaint was reversed in part); *Massarsky v. Gen. Motors Corp.*, 706 F.2d 111 (3d Cir.

1982)(action for age discrimination, in which plaintiffs moved to amend complaint); *Lewis v. Foster*, No. 04-1350 GMS, 2006 U.S. Dist. LEXIS 4548 (D. Del. Feb. 7, 2006)(*pro se* civil rights action alleging violations of constitutional rights, in which the plaintiffs' motion for leave to amend its complaint was granted in part). Moreover, none of these cases involve patent infringement, and instead concern unrelated causes of action (*e.g.*, securities fraud) against which an affirmative defense of non-infringement is unavailable as a matter of law.

In support of their opposition, Plaintiffs cite inapposite cases in which inequitable conduct is discussed in connection with a motion to dismiss or a motion for a more particular pleading (Pl. Opp'n at 4-5) – not a motion to amend. *See Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327 (Fed. Cir. 2003)(affirming the district court's finding that an "improper revival" claim was not proper where inequitable claim was not alleged in the complaint); *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261 (D. Del. 1996)(granting the defendant's motion for a more definite statement regarding the allegations of inequitable conduct set forth in plaintiff's complaint). None of these cases concerned a motion to amend an answer or an affirmative defense to amplify previously-asserted allegations. Nor does any of these cases provide any basis for Plaintiffs' strained argument that Sicor's proposed amendment purports to assert a defense of inequitable conduct.

Lacking relevant legal authority to support their opposition, plaintiffs resort to obscuring the real issue with irrelevant arguments (Pl. Opp'n at 3-5). Plaintiffs' musings about Sicor's noninfringement contentions have no bearing on Sicor's motion to amend its answer or its affirmative defenses, and should be disregarded by the Court.

The Court's determination must be based on the established four-part test used to determine whether a motion to amend should be granted (Def. Mot. at 3-4). Not surprisingly, plaintiffs give only cursory treatment to this test.

First, plaintiffs are simply wrong in asserting that Sicor's motion to amend is not timely (Pl. Opp'n at 5). As Sicor previously discussed (Def. Mot. at 3), Sicor filed its motion to amend in accordance with the Court-ordered deadline to amend pleadings (*i.e.*, March 30, 2006).

Second, plaintiffs incorrectly assert that Sicor's amendment is futile "in that Sicor neither admits nor denies infringement" (Pl. Opp'n at 5). However, in its proposed amended answer, Sicor expressly denies infringement, as well as the other allegations of paragraph 30 (Def. Mot. at Ex. B, ¶ 30). Furthermore, plaintiffs' argument that Sicor is attempting to "conflate" the issues of invalidity and non-infringement ignores the fact Sicor already set forth affirmative defenses directed to each of these issues its original answer. In amending its answer to clarify that its non-infringement defense is asserted with respect to "any asserted valid and enforceable claim," Sicor is merely tailoring its defense to respond to the claims subsequently identified by plaintiffs in their non-infringement contentions.

Third, and notwithstanding their apparent misunderstanding of the meaning of "prejudice" in connection with a motion to amend,[1] plaintiffs' argument that Sicor's proposed amendments will "severely prejudice" plaintiffs (Pl. Opp'n at 5) is disingenuous. Plaintiffs argue that Sicor's proposed amendments will force them to continue to take and respond to discovery on the issue of inequitable conduct, but fact discovery will close as scheduled on

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[1] As Sicor stated in its motion, "[p]rejudice for the purpose of Rule 15(a) does not concern potential prejudice resulting from the nature of claims sought to be added; it concerns only the prejudice resulting from the fact of adding new claims at a later date." *See Centerforce Tech., Inc.*, No. 99-243 MMS, 2000 U.S. Dist. LEXIS 6924, at *19. Sicor's amendment serves only to clarify a defense that was previously asserted, not to add a new claim.

April 21, 2006, the day after Sicor's reply is filed.[2] Moreover, plaintiffs argue that Sicor's proposed amendments will require plaintiffs to prepare expert reports and prepare to address the issue of infringement at trial – in spite of the fact that plaintiffs would presumably undertake both of these tasks regardless of whether Sicor's previous defense of non-infringement was amended.

Plaintiffs fail to address the final factor to be considered in the four-part test – whether Sicor's motion to amend is in bad faith or the result of any dilatory motive. Presumably, plaintiffs could not rebut Sicor's argument with respect to this factor (Def. Mot. at 3-4), given that Sicor's proposed amendments will not lead to any postponement in the deadlines for discovery or the date that has been set for trial.

WHERETOFORE, for the reasons set forth above and in its Motion to Amend, defendant Sicor respectfully requests that the Court grant its Motion for Leave to Amend its Answers.

Respectfully submitted,

Dated: April 20, 2006

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[2] Due to issues concerning witness availability, the parties have agreed that certain fact depositions will occur during the week following the close of discovery.

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CERTIFICATE OF SERVICE

I, Monté T. Squire, Esquire, hereby certify that on April 20, 2006, 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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