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.	)	Civil Action No. 05-337-SLR
SICOR, INC. and SICORPHARMACEUTICALS, INC.,	)	
Defendants.	)	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO
DEFENDANT'S MOTION FOR LEAVE TO AMEND ANSWER

Plaintiffs King Pharmaceuticals Research and Development Inc. ("King)", Astellas US LLC, and Astellas Pharma US, Inc. ("Astellas") oppose Sicor, Inc.'s and Sicor Pharmaceuticals, Inc.'s ("Sicor") Motion for Leave to Amend Its Answer. For months, in this action and in the related action of *Item et al. v. Sicor et al.*, D.Del (05-336), Sicor has resisted disclosing the factual and legal bases for its denial of infringement.[1] Sicor's current motion to amend its Answer merely continues this pattern. While ostensibly directed to the issue of infringement, Sicor's proposed amendment stating that it does not and will not infringe any "valid and enforceable claim" improperly attempts to inject the issues of validity and enforceability as part of the infringement determination. In addition, the amendment is improper in that Sicor is apparently attempting to reserve a right to plead unenforceability in the case without particularly

[1] Sicor has filed an essentially identical amendment in the related action, and Plaintiffs are filing a similar response. *See Item*, D.Del (05-336).

pleading that defense as required by Federal Rule of Civil Procedure 9(b). Furthermore, although described as a "clarification" of its infringement position, Sicor's proposed amendment would, in fact, substitute a cloud of ambiguity for an otherwise clear denial.

With less than 10 days of fact discovery remaining, Sicor must "fish or cut bait." If it has a good faith basis for maintaining its non-infringement pleading, no amendment is needed. If it lacks such a basis, the proper course is to admit infringement, not needlessly multiply the proceedings with an ambiguous amendment.

Under the circumstances, Sicor's proposed amendment would be futile and highly prejudicial to Astellas and King and should be denied.

I. BACKGROUND

Sicor sparked this lawsuit, and the related action, by filing a "Paragraph IV" certification with the FDA in April 2005, seeking permission to sell a generic version of Astellas' product Adenoscan®. In that certification, Sicor swore "to the best of its knowledge" that the sale of its copy product would not infringe U.S. Patent No. 5,070,877 (the patent-in-suit in this matter, hereinafter "the '877 patent") or that the patent was invalid or unenforceable. *See* 21 C.F.R. § 314.94 (a)(12)(i)(A)(4)(regarding the regulatory requirements for Paragraph IV certifications). Notably, in the accompanying "Detailed Statement of the Factual and Legal Bases" for Sicor's opinion, Sicor asserted non-infringement of only some, not all, of the claims of the '877 patent and relied on its invalidity theories to support its certification as to the remaining patent claims. Sicor offered no theory of unenforceability.

On May 26, 2005, Astellas and King filed their Complaint for patent infringement in this action, alleging infringement of "one or more claims of the '877 patent" by Sicor's filing of an Abbreviated New Drug Application ("ANDA") on a product "the use or sale of which would contribute to or induce the direct infringement of one or more claims of the '877 patent by

ultimate purchasers" (Complaint ¶¶ 30, 31). On August 8, 2005 Sicor filed its Answer, which denied infringement of the '877 patent (Def.'s Answer ¶¶ 30, 31).[2]

The parties negotiated a Scheduling Order, entered October 12, 2005, that required an exchange of contentions on infringement and validity in lieu of interrogatories (Sched. Order at 2). Plaintiffs complied with the Order on October 28, 2005 by providing preliminary infringement contentions. (Pl.'s Prel. Infring. Cont. at 4 - 20).

But Sicor asserted no position at all on non-infringement in its November 18, 2005 Preliminary Statement (Def.'s Stat. Prel. Non-Infring. Cont. at 2). During the December 2005 discovery conference, Sicor justified this action by stating that "defendants had been seriously looking at and assessing the development of a non-infringement position, but doing that requires some scientific analysis" (Disc. Tr. at 7, Dec. 8, 2005). The Court ordered Sicor to supplement its non-infringement contentions by January 17, 2006 (*id*. at 28), but Sicor ignored this order and produced nothing relating to non-infringement of the '877 patent.

Plaintiffs addressed Sicor's continual failure to follow the Court's Order during the next discovery hearing and noted that Sicor's failure to assert a position regarding non-infringement was prejudicial (Disc. Tr. at 4-7, Feb. 14, 2006). Sicor merely reiterated the same justification as before, but admitted that its failure to assert non-infringement contentions would constitute a waiver if Sicor did not provide them during discovery (*id*. at 8-10). The Court agreed and indicated that Sicor should provide non-infringement contentions by March 31 (*id*. at 32). Sicor ignored the March 31 deadline and has yet to provide any non-infringement contentions with

[2] Sicor's unequivocal denial of the allegation in ¶ 30 of the Complaint contradicts its current suggestion that its pleading was predicated on not knowing which claims were being asserted and that Sicor purportedly did not suspect until months into the litigation that King and Astellas would assert the patent claims for which Sicor had not offered a non-infringement position in connection with its Paragraph IV certification. *See generally* Motion at 2, 3-4.

respect to the '877 patent. Instead it has filed the instant motion.

III. ARGUMENT

Leave to amend pleadings, although permissive, is not automatic. Rule 15(a), Fed. R. Civ. P. According to *Foman v. Davis*, 371 U.S. 178, 182 (1962), denial of an opportunity to amend is allowed where there is: "bad faith . . . undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment." *See also In re Burlington Coat Fact. Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). Under Rule 15(a), the standard for determining the futility of an amendment is whether, accepting all the well pleaded facts as true, the amended claim of the complaint fails to state a claim upon which relief may be granted. *See Lewis v. Foster*, 2006 U.S. Dist. LEXIS 4548, *29-*30 (3rd Cir. 2006) (citing *Satellite Fin. Planning Corp. v. First Nat'l Bank of Wilmington*, 646 F. Supp. 118, 120 (D. Del 1986)); *See also Massarsky v. General Motors Corp.*, 706 F.2d 111, 125 (3rd Cir. 1983)(stating that a "trial court may properly deny leave to amend where **the amendment** would not withstand a motion to dismiss")(emphasis added), *cert. denied* 464 U.S. 937 (1983).

A. Sicor Cannot Raise the Issue of Unenforceability Without a Particularized Pleading of the Basis for Its Allegation

Sicor proposes to amend its Answer to aver that it does not infringe "any asserted valid or **enforceable**" claim of the '877 patent. (Def.'s Motion to Amend at 1, emphasis added). Yet it has never raised or pled any facts that would support a claim of unenforceability. Fed. R. Civ. P. 9(b) requires the pleading of fraud or mistake with particularity, and affirmative defenses of inequitable conduct carry the same requirements. *See Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003)(stating that inequitable conduct must be pled with particularity); *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996) (stating that the particularity requirement of Rule 9(b) applies to inequitable conduct

charges). Given the absence of any pled facts on the issue of unenforceability, Sicor's proposed amendment would violate the particularity requirements of Rule 9(b). Furthermore, because the time for amending pleadings set forth in the Scheduling Order has passed, Sicor cannot timely cure its failure to plead facts that would support an unenforceability claim.

Because its proposed amendment would violate Rule 9(b), Sicor's motion should be denied, or, at minimum, revised to delete any reference to unenforceability.

B. Sicor's Proposed Ambiguous Pleading on Infringement is Futile and Would Prejudice Astellas and King

Sicor's motion should be also be denied because it is futile and because it is prejudicial to Astellas and King. Sicor has ignored multiple Court-ordered deadlines to provide appropriate non-infringement contentions (Disc. Tr. at 28, Dec. 8, 2005; Disc. Tr. at 32, Feb. 14, 2006). Its inability to articulate a non-infringement position results from the simple fact that the sale of its proposed product would infringe the '877 patent. Sicor's request to amend its pleading to recite that it does not infringe any "valid and enforceable" claim is not a proper Answer to the Complaint. The proposed amendment is futile in that Sicor neither admits nor denies infringement, but merely attempts to conflate infringement and validity in the apparent hope of further delaying the consequences of its lack of an infringement defense.

Sicor's proposed amendment will also severely prejudice Astellas and King by requiring the Plaintiffs to continue to litigate infringement when Sicor clearly no longer believes it has a basis to deny the same. If Sicor has a basis for denying infringement, the denial set forth in the original answer is completely sufficient. But to allow Sicor to plead ambiguously that it does not infringe a "valid and enforceable" claim would force the Plaintiffs to continue to take and respond to discovery on the issue, prepare expert reports, and otherwise prepare for an infringement trial. Moreover, granting Sicor's motion would reward Sicor for what would

appear to be a strategic decision to plead non-infringement and then ignore Court-ordered dates for providing contentions.

IV. CONCLUSION

For the reasons discussed above, Plaintiffs respectfully submit that the Court should deny Sicor's Motion for Leave to Amend Its Answer.

Dated: April 13, 2006	
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CERTIFICATE OF SERVICE

I hereby certify that on the 13th day of April, 2006, I electronically filed the foregoing document, **PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR LEAVE TO AMEND ANSWER**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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