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

DEFENDANTS SICOR INC. AND SICOR PHARMACEUTICALS INC.'S REPLY IN SUPPORT OF THEIR MOTION TO DISMISS COUNT III OF THE COMPLAINT

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Dated: September 6, 2005

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DEFENDANTS SICOR INC. AND SICOR PHARMACEUTICALS INC.'S REPLY IN SUPPORT OF THEIR MOTION TO DISMISS COUNT III OF THE COMPLAINT

Defendants Sicor Inc. and Sicor Pharmaceuticals, Inc. (collectively "Defendants") submit the following reply in further support of their Motion to Dismiss Count III of Plaintiffs' Complaint. Plaintiffs' Opposition to the Motion to Dismiss offers no support for the assertion of Count III and instead appears to be based on a misreading of the Federal Circuit's decision in *Glaxo Group, Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004), as well as Plaintiffs' Complaint.

With respect to the relevant law, Plaintiffs argue incorrectly that the statements from *Glaxo* on which Defendants rely are mere *dicta*. In particular, Plaintiffs state that "the certification question was not part of the *Glaxo* decision and is obviously *dictum.*" Opposition at 3. Plaintiffs have misread *Glaxo*. Plaintiffs' incorrect characterization of the *Glaxo* decision is refuted by the decision itself in which the Federal Circuit stated "***we now hold*** that the mere fact that a company has filed an ANDA application ***or certification*** cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." *See Glaxo*, 376 F.3d at 1350-51 (emphasis added). Accordingly, Defendants' Motion is supported by the clear holding in *Glaxo*. *Id.*

With respect to the substance of the allegations that purportedly are the basis for Count III, Plaintiffs have also incorrectly characterized their Complaint. In particular, Plaintiffs assert that the question of whether filing a "deficient" certification can constitute willful infringement is still open. *See* Opposition at 4. Plaintiffs ignore that the act alleged as "willful" in Count III for Willful Infringement is the "infringement," *i.e.*, filing the ANDA, not filing the certification. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-670, 676 (1990); 35 U.S.C. §

271(e)(2) (artificial act of infringement is filing the ANDA). Moreover, even if it were correct that an allegation of a deficient Paragraph IV certification could support a claim of willful infringement — and it is not[1] — Plaintiffs' Complaint contains no allegation that Defendant's certification is deficient. *See generally*, Complaint. The only allegation concerning the certification is in the general background section and states merely that "Sicor Pharma has filed an amendment to ANDA 77-425 containing a purported certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)." *See* Complaint, ¶ 26. Plaintiffs' mischaracterizations of Defendants' ANDA in their opposition (*see, e.g.*, Opposition at 3-4) are an after-the-fact attempt to salvage a deficient pleading. Had Plaintiffs intended to allege in Count III that the Paragraph IV certification was deficient and that the purported deficiency was a basis for their willfulness allegations, they plainly could have done so. They did not, and they should not be allowed to rewrite their Complaint in their opposition to Defendants' Motion to Dismiss Count III.[2] At any rate, Plaintiffs' attempt to rewrite their Complaint is to no avail, as Plaintiffs cite no legal authority that the claim of "deficient certification" they apparently now wish they had made is a basis for a claim of willful infringement. Further, to the extent that Plaintiffs suggest that a baseless Paragraph IV certification could support a claim for "exceptional case," this argument should also be rejected. Once again, Plaintiffs' Complaint does not even allege that the certification was "deficient" let alone that it was "baseless." Instead, Plaintiffs' Count III fails to state a claim upon which relief can be granted and should be dismissed.

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[1] Although not relevant to the present motion because not pleaded by Plaintiffs, Defendants note that Plaintiffs may not challenge any alleged deficiency in the Paragraph IV certification or notice in this context. In *Minnesota Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002), the Federal Circuit held that the Hatch-Waxman notice letter requirements "cannot be enforced by a private party in a patent infringement action . . . ." 289 F.3d at 777. Likewise, a federal court may not review the adequacy of a notice letter in the context of a patent infringement case. *See id.*, at 784 n.5.

[2] Moreover, for the reasons described in footnote 1, any attempt to amend the complaint to assert such allegations would be futile.

More importantly, the "exceptional case" issue that Plaintiffs seek to inject at this time is premature and cannot be litigated until after trial and a determination on the merits. On its face, 35 U.S.C. § 285 applies only to a "prevailing party." *See* 35 U.S.C. § 285 ("the court in exceptional cases may award reasonable attorney fees ***to the prevailing party***.") (emphasis added). There can be no "prevailing party" until there is a judicial determination on the merits. The Federal Circuit has recognized this by vacating attorney fee awards under § 285 where the merits are not yet determined, and has instructed whichever party ultimately prevails to pursue an award "at the close of the proceedings:"

> Because the case has not yet been resolved and the prevailing party has not yet been determined, we necessarily vacate the district court's decision regarding exceptional case status. [Defendant] ***may renew its claim for attorney's fees under 35 U.S.C. § 285 at the close of the proceedings***, should it be the "prevailing party" as that term is used in the statute.

DH Technology, Inc. v. Synergystex Int'l, Inc., 154 F.3d 1333, 1344 (Fed. Cir. 1998) (emphasis added); *see also Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1369 (Fed. Cir. 2004) ("at the pretrial stage, there is no prevailing party, and thus, any claim for attorneys' fees would be premature").

Finally, it bears noting that, while Defendants disagree with Plaintiffs' characterizations of the litigation conduct to date, these allegations concerning litigation conduct — made only in Plaintiffs' Opposition and not their Complaint — are not relevant to any willfulness inquiry or to the determination of whether the count alleging willfulness should be dismissed. At most, Plaintiffs' musings about potential litigation conduct may go to an analysis under 35 U.S.C. § 285. The mere fact that Plaintiffs assert that they may seek relief under § 285 does not save Count III from being dismissed. To the extent that Plaintiffs are seeking to preserve the right to seek a remedy under § 285, they have done so in their prayer for relief.

WHEREFORE, for the reasons set forth above and in their Motion to Dismiss, Defendants Sicor Inc. and Sicor Pharmaceuticals Inc. respectfully request that the Court grant their Motion and dismiss Count III of the Complaint.

Respectfully submitted,

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Dated: September 6, 2005

CERTIFICATE OF SERVICE

I, D. Fon Muttamara-Walker, Esquire, hereby certify that on September 6, 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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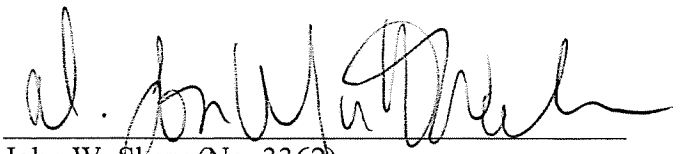
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