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., SICOR PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD. Defendants.	)	Civil Action No. 05-337 SLR

DEFENDANTS SICOR PHARMACEUTICALS, INC.'S AND SICOR INC.'S MOTION TO DISMISS COUNT III OF THE COMPLAINT

Defendants Sicor Inc. and Sicor Pharmaceuticals, Inc. ("Sicor Pharma") (collectively "Defendants") hereby move to dismiss Count III of Plaintiffs' Complaint (the "Complaint").

This is a patent infringement action arising under the Hatch-Waxman Act, which governs the approval process of generic drugs by the U.S. Food and Drug Administration ("FDA"). The Complaint alleges patent infringement based on Sicor Pharma's filing of an Abbreviated New Drug Application ("ANDA") and paragraph IV certification, pursuant to § 355(j)(2)(A)(vii)(IV), for a generic version of Adenosine Injection, USP. In Count III Plaintiffs assert a claim that Defendants' alleged infringement is willful. The Federal Circuit, however, has expressly held that merely filing an ANDA application or certification cannot support a finding of willful infringement. *See Glaxo Group, Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004). Therefore, Count III of the Complaint should be dismissed for failure to state a claim on which relief can be granted, pursuant to

Rule 12 (b)(6), Fed. R. Civ. P. Sicor Inc. and Sicor Pharma waive their opening brief pursuant to Local Rule 7.1.2 and as further grounds for this Motion state as follows:

PLAINTIFFS' ALLEGATIONS

1. As to infringement, Plaintiffs allege only that Sicor Pharma filed an ANDA and paragraph IV certification with the FDA in connection with "Adenosine Injection, USP" for sale or use "as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately" and that "use of Sicor Pharma's Adenosine Injection, USP according to its approved labeling will result in infringement of one or more claims of the '877 patent." *See* Complaint, ¶¶ 24-26. With respect to Sicor Inc., Plaintiffs allege only that Sicor Inc. encouraged and induced Sicor Pharma in filing an ANDA and preparing to sell product pursuant to the ANDA. *See* Complaint, ¶ 28.

2. Count I, entitled "Patent Infringement," merely restates the allegation that Sicor Pharma has infringed the patent-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA to the FDA and the allegation that Sicor Inc. induced Sicor Pharma to file the ANDA and prepare to sell product pursuant to the ANDA.

3. Plaintiffs' Count III for "Willful Patent Infringement" asserts that the alleged infringement has been willful. *See generally* Complaint, ¶¶ 39-42.

THE RELEVANT LAW

4. The policy underlying the Hatch-Waxman Act, coupled with recent Federal Circuit and district court decisions, makes clear that the Plaintiffs' claim for willful infringement should be dismissed. The Hatch-Waxman Act provides that the manufacture, use, sale or offer for sale of a patented invention is not infringing if it is solely for uses reasonably related to the development and submission of information in an ANDA to the FDA. *See* 35 U.S.C. § 271(e)(1). However, the Act

has limited this safe harbor by creating "a new (and somewhat artificial) act of infringement for a very limited and technical purpose." *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-670, 676 (1990). This "artificial act" consists of the submission of an ANDA to the FDA to obtain approval to engage in marketing of a drug prior to expiration of the applicable patents. *See* 35 U.S.C. § 271(e)(2).

5. The creation of this "highly artificial act of infringement" allows a patentee to sue an ANDA applicant upon filing of an ANDA for a determination "as to whether commercial manufacture, use or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *See Eli Lilly* at 678. In this way, the Hatch-Waxman Act enables any alleged patent infringement to be resolved before the approval, and thus the commercial manufacture, use or sale, of any potentially infringing drug product. *See Bristol-Meyers Squibb Co. v. Royce Labs.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995) ("section 271(e)(2)(A) makes it possible for a patent owner to have the court determine whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent.").

6. The Federal Circuit discussed these unique aspects of an ANDA litigation in *Glaxo* before holding that the mere filing of an ANDA and certification cannot support a claim of willful infringement. *See Glaxo*, 376 F.3d at 1349-1351. There, the Federal Circuit noted that "the act of filing an ANDA constitutes a 'highly artificial' act of infringement under 35 U.S.C. § 271(e)(2)." *Id.* at 1349 (citing *Eli Lilly,* 496 U.S. at 678, 110 S.Ct. 2683). The Federal Circuit further noted that the artificial act of infringement is created by statute for a "very limited and technical purpose that relates only to certain drug applications." *Id.* at 1351 (citation omitted).

7. Relying on the purposes and nature of the statute, the Federal Circuit held in *Glaxo* 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)." *Id.* at 1350-1351.

8. The District of Massachusetts has since relied on *Glaxo* to grant judgment on the pleadings for a defendant on plaintiff's willful infringement claim. *See Aventis Pharma Deutschland GmbH v. Cobalt Pharma., Inc.*, 355 F. Supp. 2d 586, 592 (D. Mass. 2005). The only act of infringement alleged in the complaint in *Aventis* was defendant's filing of an ANDA and a paragraph IV certification with the FDA. *Id.* The District Court there held that "[b]ecause this artificial act of infringement cannot be considered willful, Plaintiffs have averred no facts that can support a finding of willful patent infringement." *Id.* Similarly, in a recent decision in this District, the Court struck a claim for willful infringement from the complaint where the only act of infringement alleged in the complaint was an "allegedly baseless paper NDA filing and Paragraph IV Certification with the FDA." *See Allergan, Inc. v. Alcon, Inc.*, C.A. No. 04- 968 (July 26, 2005 Order, ¶ 6).

COUNT III SHOULD BE DISMISSED FOR FAILURE TO STATE A CLAIM

9. Plaintiffs allege infringement in this case only under the artificial construct created by 35 U.S.C. § 271(e)(2)(A). Plaintiffs' allegations (taken as true only for purposes of this motion) are that Sicor Pharma filed an ANDA and paragraph IV certification for Adenosine Injection, USP, and that Sicor Inc. assisted or encouraged Sicor Pharma in related acts. As a matter of law, the "mere fact" that Sicor Pharma has filed an ANDA application with an accompanying Paragraph IV certification cannot support a finding of willful infringement. *See Glaxo*, 376 F.3d 1339, 1351. As in *Aventis*, because the artificial act of infringement under § 271(e)(2)(a) cannot be considered willful, here the allegation that Sicor Pharma filed an ANDA and Paragraph IV Certification cannot support a claim of willful infringement. *See Aventis Pharma*, 355 F. Supp. 2d at 592. And if the filing of an ANDA does not support a claim of willful infringement, then Sicor Inc.'s alleged

encouragement or assistance in filing an ANDA cannot support a claim. Accordingly, Count III should be dismissed pursuant to Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

WHEREFORE, Defendants Sicor Inc. and Sicor Pharmaceuticals Inc. respectfully request that the Court grant this Motion and dismiss Count III of the Complaint.

Respectfully submitted,



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Dated: August 8, 2005

CERTIFICATE OF SERVICE

I, D. Fon Muttamara-Walker, Esquire, hereby certify that on August 8, 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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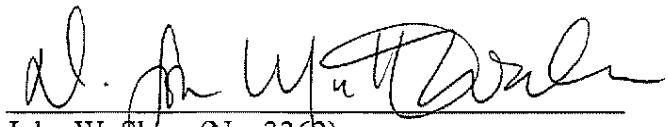
I further certify that on August 8, 2005, I caused copies of the foregoing document to be served by hand delivery on the above listed counsel of record and on the following in the manner indicated:

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