IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| ITEM DEVELOPMENT AB, ASTELLAS US LLC, and ASTELLAS PHARMA US, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civ. No. 05-336-SLR |
| SICOR INC. and SICOR PHARMACEUTICALS, INC., | ) | |
| Defendants. | ) | |
| KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT INC., ASTELLAS US LLC, and ASTELLAS PHARMA US, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civ. No. 05-337-SLR |
| SICOR INC. and SICOR PHARMACEUTICALS, INC., | ) | |
| Defendants. | ) | |

**MEMORANDUM ORDER**

At Wilmington this 31st day of March, 2006, having considered defendants' motions to dismiss count III of the complaint, as well as the papers submitted in connection therewith;

IT IS ORDERED that defendants' motions to dismiss count III of the complaint (Civ. No. 05-336-SLR, D.I. 5; Civ. No. 05-

337-SLR, D.I. 5)[1,2] is granted in part and denied in part for the reasons that follow:

1. **Standard of Review.** In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiff. See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." Id. Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiff cannot demonstrate any set of facts that would entitle it to relief. See Conley v. Gibson, 355 U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957). The moving party has the burden of persuasion. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409

[1]The D.I. numbers in this memorandum order refer to Civ. No. 05-336-SLR, unless otherwise noted.

[2]The motions filed by defendants in Civ. No. 05-336-SLR ("the '336 case") and Civ. No. 05-337-SLR ("the '337 case") are identical, except for the parties' names and other case-specific information which is inconsequential to the resolution of these motions. The responsive arguments made by the plaintiffs in the '337 case "mirror" those made by the plaintiffs in the '336 case. (Civ. No. 05-337-SLR, D.I. 1, n.1) Since the issues are identical and the arguments thereon are nearly identical, the court will address the issues and arguments regarding the motions in both cases in this single memorandum order.

(3d Cir. 1991).

2. With respect to their claim of infringement, plaintiffs assert that defendant Sicor Pharmaceuticals filed an ANDA and paragraph IV certification with the FDA to obtain approval for the manufacture, use and sale of Adenosine Injection, USP. (D.I. 1 at ¶ 23, 25) Plaintiffs in the '336 case assert that the use of Adenosine Injection, USP, according to its approved labeling, would "result in infringement of one or more claims of [its] '296 patent [U.S. Patent No. 5,731,296]." (D.I. 1 at ¶ 24) (Plaintiffs in the '337 case allege that the same acts would result in infringement with respect to U.S. Patent No. 5,070,877 ("the '877 patent").) Plaintiffs further allege that defendant Sicor Inc. has encouraged and induced Sicor Pharmaceuticals to file an ANDA and prepare to sell Adenosine Injection, USP pursuant to the ANDA. (D.I. 1 at ¶ 27) Count I of plaintiffs' complaint in the '336 case, entitled "Patent Infringement," restates the allegation that Sicor Pharmaceuticals infringes the '296 patent under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA to the FDA, as well as the allegation that Sicor Inc. induced Sicor Pharmaceuticals to file the ANDA application, prepare to sell Adenosine Injection, USP, and eventually sell it once approved by the FDA. (D.I. 1 at ¶¶ 29-30) (The same argument is offered by plaintiffs in the '337 case with respect to the '877 patent.) Count III of the complaint of

plaintiffs in the '336 case, entitled "Willful Infringement," asserts in paragraph 40[3] that the alleged infringement by defendants has been willful. (D.I. 1 at ¶¶ 38-41) (Plaintiffs in the '337 case make the same assertion in paragraph 41 of their complaint.)

3. Defendants move to dismiss count III of plaintiffs' complaint as failing to state a claim on which relief can be granted, pursuant to Fed. R. Civ. P. 12(b)(6). (D.I. 5) Defendants assert that plaintiffs' claim in count III of their complaint, alleging willful infringement, has no support in the facts since a patentee in an infringement action under 35 U.S.C. § 271(e)(2) may not prove that an accused infringer's conduct amounts to willful infringement. (Id.)

4. Plaintiffs argue that defendants' arguments with respect to § 271(e)(2) are incorrect and ignore the facts of this case. (D.I. 14 at 2-6) Furthermore, plaintiffs request that the court not strike those portions of count III which are not directed to willful infringement. (Id. at 6-7)

5. The Federal Circuit initially addressed the issue of willfulness in ANDA and paper NDA cases in Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339 (Fed. Cir. 2000). In Yamanouchi, the court noted that "[a]n ANDA [or paper

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[3]"On information and belief, Defendants' infringement has been willful." D.I. 1 at ¶ 40.

NDA] filing by its very nature is a 'highly artificial act of infringement,' therefore, the trial court need not have elevated the ANDA certification into a finding of willful infringement." 231 F.3d at 1347. Nevertheless, the court held that the case was exceptional and awarded attorney's fees to the plaintiff, based on defendant's "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed . . . ." Id.

6. The Federal Circuit addressed this issue again in Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004), holding 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)." 376 F.3d at 1350-51. The court noted that in Yamanouchi, it had "determined that a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding." Id. at 1350. The court continued, "in Yamanouchi, we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification." Id.

7. In the case at bar, plaintiffs have not offered any support for a finding of willful infringement. The only allegations of infringement by plaintiffs are that Sicor Pharmaceuticals filed an ANDA and paragraph IV certification for Adenosine Injection, USP, and that Sicor Inc. assisted, induced or encouraged Sicor Pharmaceuticals in those and related acts. Because the filings of Sicor Pharmaceuticals cannot support a claim of willful infringement, plaintiffs' complaint fails to state a claim on that basis. Paragraph 40 of count III of the complaint in the '336 case, and paragraph 41 of count III of the complaint in the '337 case, shall be dismissed. Plaintiffs assert that, even if the court strikes the allegations of willful infringement in count III, the allegations concerning exceptional case and attorney's fees should remain. The court agrees. As the Federal Circuit explained in Glaxo, a finding that a ANDA/paper NDA case is "exceptional" can be based on meritless filings combined with litigation misconduct, although a finding of willful infringement cannot. Glaxo, 376 F.3d at 1350-51. Plaintiffs shall have the opportunity to establish facts which support a claim for an exceptional case for which the court may award attorney's fees. Thus, the remaining paragraphs of count III (¶¶ 38, 39, 41 in the '336 case; ¶¶ 39, 40, 42 in the '337 case), including those relating to an exceptional case and

attorney's fees, shall not be dismissed.

United States District Judge