IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| IN RE: CYCLOBENZAPRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULE PATENT LITIGATION | ) | MDL No. 09-2118 (consolidated) |

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**MEMORANDUM OPINION**

Dated: March 12, 2010
Wilmington, Delaware

**ROBINSON, District Judge**

## I. INTRODUCTION

The dispute at bar in this consolidated patent infringement action concerns the submission of an Abbreviated New Drug Application ("the ANDA"),[1] and amendment thereto, by Anchen Pharmaceuticals, Inc. ("Anchen Pharmaceuticals") to manufacture and sell generic versions of AMRIX® (cyclobenzaprine hydrochloride extended-release capsules) ("the ANDA products), a skeletal muscle relaxant proprietary to plaintiffs Eurand, Inc. ("Eurand") and Anesta AG ("Anesta") (collectively, "plaintiffs").[2] In response to the ANDA, plaintiffs filed a suit against defendants Anchen Pharmaceuticals and Anchen, Inc. ("Anchen Holding") (collectively, "defendants") on July 7, 2009 for infringement of U.S. Patent No. 7,387,793 ("the '793 patent"). (D.I. 1)[3] Anchen Pharmaceuticals subsequently amended the ANDA, resulting in plaintiffs' second complaint against defendants, filed on September 9, 2009 and alleging the infringement of U.S. Patent No. 7,544,372 ("the '372 patent"). (Civ. No. 09-715-SLR,

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[1]ANDA No. 91-281.

[2]Plaintiffs have filed a total of six cases relating to AMRIX® and having common questions of fact: four actions in this district and two actions in the Central District of California. The Judicial Panel on Multidistrict Litigation has centralized these actions in this district for consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. (D.I. 28)

The individual captions of these actions are as follows: *Eurand, Inc., et al. v. Anchen Pharmaceuticals, Inc., et al.*, Civ. No. 09-4931 and *Eurand, Inc., et al. v. Anchen Pharmaceuticals, Inc., et al.*, Civ. No. 09-1098 in the Central District of California; and *Eurand, Inc., et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civ. No. 08-889, *Eurand, Inc., et al. v. Impax Laboratories, Inc.*, Civ. No. 09-18, *Eurand, Inc., et al. v. Anchen Pharmaceuticals, Inc., et al.*, Civ. No. 09-492 and *Eurand, Inc., et al. v. Anchen Pharmaceuticals, Inc., et al.*, Civ. No. 09-715 in the District of Delaware.

[3]The individual captions for the actions at bar are Civ. No. 09-492-SLR and Civ. No. 09-715-SLR. Unless otherwise noted, all citations are made to the record of Civ. No. 09-492-SLR.

D.I. 1)

Pending before the court are defendants' motions to dismiss. Anchen Holding moves to dismiss this action for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1) and for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). (D.I. 10; Civ. No. 09-715-SLR, D.I. 11) Anchen Pharmaceuticals likewise moves to dismiss for lack of subject matter jurisdiction and for failure to state a claim, as well as for lack of personal jurisdiction under Fed. R. Civ. P. 12(b)(2) and improper venue under Fed. R. Civ. P. 12(b)(3). (D.I. 12; Civ. No. 09-715-SLR, D.I. 11) The court has jurisdiction pursuant to 28 U.S.C. § 1338(a). For the reasons that follow, the court grants in part and denies in part the motions.

## II. BACKGROUND

### A. The Parties and Patents-in-Suit

Eurand, a Nevada corporation with a principal place of business located in Ohio, owns all title and interest in the '793 patent and the '372 patent (collectively, "the Eurand patents"). (Civ. No. 09-715-SLR, D.I. 1 at ¶ ¶ 16, 19) Eurand is engaged in the development, manufacture and commercialization of pharmaceutical and biopharmaceutical products. Anesta, a Swiss corporation having a principal place of business in Switzerland, is a wholly owned subsidiary of Cephalon.[4] Anesta obtained exclusive licenses to the Eurand patents pursuant to an Asset Purchase Agreement ("APA"). (*Id.* at ¶ ¶ 17, 20) The APA also transferred to Anesta all title and interest in

[4]Cephalon is an international biopharmaceutical company whose business is primarily directed to the development and commercialization of products in four therapeutic areas: central nervous system, pain, oncology and addiction.

approved New Drug Application ("NDA") No. 21-777 for cyclobenzaprine hydrochloride extended-release capsules in 15 mg and 30 mg doses, both sold under the tradename AMRIX®. (*Id.* at ¶ 17) The Orange Book of the Food and Drug Administration ("FDA") lists, inter alia, the Eurand patents as the unexpired patents associated with AMRIX®. (*Id.* at 22) AMRIX® is a muscle relaxant whose dosage form allows for the treatment of muscle spasms with a single daily dose. (D.I. 22, ex. 2)

Anchen Pharmaceuticals is a California corporation with a principal place of business in Irvine, California. (D.I. 1 at ¶ 5) The business of Anchen Pharmaceuticals is focused on the development and commercialization of extended release and niche generic products. Anchen Pharmaceuticals distributes these products throughout the United States, including the State of Delaware. Anchen Holding is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in Irvine, California. (*Id.* at ¶ 6) It is alleged that Anchen Holding has sold millions of dollars worth of pharmaceutical products within the United States generally, and the State of Delaware specifically, under its stylized "Anchen" trademark (serial no. 77037779). (*Id.*, exs. B, C)

While the pleadings do not specify the exact business relationship between Anchen Pharmaceuticals and Anchen Holding, the two entities share senior corporate officers, including Margaret Choy ("Ms. Choy"), Senior Vice President of Regulatory Affairs. (*Id.* at ¶ 7) Plaintiffs allege that defendants closely coordinate commercial activities and hold themselves out to the marketplace as one company. (*Id.*) For example, during prosecution of Anchen Pharmaceuticals' trademark application for the

work mark ANCHEN (serial no. 77051871), representatives for Anchen Pharmaceuticals stated that "Anchen Pharmaceuticals, Inc. and [Anchen Holding], through separate legal entities, constitute a single source to the relevant public, and there is unity of control with respect to the nature and quality of the goods." (*Id.*)

**B. The ANDA and the Instant Suit**

On May 29, 2009, Anesta (through Cephalon) received a letter dated May 28, 2009 from Anchen Pharmaceuticals regarding the ANDA. (*Id.* at ¶ 23) Eurand received the same notification letter on or about June 3, 2009 ("the first notification letters"). (*Id.* at ¶ 22) In the first notification letters, Anchen Pharmaceuticals stated its intent to engage in the commercial manufacture, use or sale of a generic equivalent of AMRIX® prior to the expiration of the '793 patent. (D.I. 22, ex. 3) Anchen Pharmaceuticals further alleged that the '793 patent was invalid, unenforceable, or would not be infringed by the ANDA products, and that it had certified as such to the FDA ("Paragraph IV Certification").[5] (*Id.*) Ms. Choy is designated by the first notification letters as the contact person in connection with the Paragraph IV Certification. (D.I. 1 at ¶ 7) Plaintiffs have acknowledged Anchen Pharmaceuticals' offer of access to the confidential information contained in the ANDA ("the offer of access"), but have declined to accept in light of allegedly unreasonable terms and conditions Anchen Pharmaceuticals has placed upon the receipt of this information.[6] (*Id.* at ¶ 26)

On July 7, 2009, after negotiations in connection with the offer of access faltered,

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[5]*See* 21 U.S.C. § 355(j)(2)(b)(i) and (ii).

[6]Plaintiffs allege that the terms and conditions in the offer of access exceed those that usually apply under a protective order.

and within the requisite 45-day period, plaintiffs filed Civ. No. 09-492-SLR pursuant to 35 U.S.C. § 271(e)(2)(A). This suit triggered a 30-month stay on the FDA's approval of the ANDA. *See* 21 U.S.C. 355(j)(5)(B)(iii).

Plaintiffs subsequently received a second set of notification letters from Anchen Pharmaceuticals on August 13, 2009, which provided notification of an amendment to the ANDA ("the second notification letters"). (Civ. No. 09-715-SLR, D.I. 17, ex. 3) In the second notification letters, Anchen Pharmaceuticals alleged that the claims of the '372 patent are invalid, unenforceable and/or will not be infringed by the ANDA products. (*Id.*) On September 23, 2009, plaintiffs instituted Civ. No. 09-715-SLR against defendants, alleging that defendants infringed the '372 patent by submitting the amended ANDA to the FDA, and that defendants will continue to infringe the '372 through the manufacture, marketing and/or sale of the ANDA products. (Civ. No. 09-715-SLR, D.I. 1)

## III. STANDARD OF REVIEW

In reviewing a motion filed under Rule 12(b)(1), the court must first identify whether the motion presents a facial or factual challenge to the court's subject matter jurisdiction. *See Samsung Elecs. Co., Ltd. v ON Semiconductor Corp.*, 541 F. Supp 2d 645, 648 (D. Del. 2008). Where the movant presents a facial challenge, the court must accept all factual allegations in the complaint as true and may only consider the complaint and documents referenced therein or attached thereto. *Id.* (citing *Gould Elecs., Inc., v. United States*, 220 F.3d 169, 176 (3d Cir. 2000)). Where the movant presents a factual challenge, the court need not confine its consideration to the

allegations of the complaint nor accept those allegations as true. *Mortensen v. First Fed. Sav. & Loan*, 549 F.2d 884, 891 (3d Cir. 1977). Rather, the court may consider evidence outside the pleadings, including affidavits, depositions, and testimony, "to resolve any factual issues bearing on jurisdiction."[7] *Samsung*, 541 F. Supp. 2d at 648 (citing *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997)). "[P]laintiff bears the burden of proving that [subject matter] jurisdiction exists." *Id.*

In reviewing a motion filed under Rule 12(b)(2), the court must accept all of a plaintiff's allegations as true and construe disputed facts in the plaintiff's favor. *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 368 (3d Cir. 2002) (quoting *Carteret Sav Bank, FA v. Shushan*, 954 F.2d 141, 142 n.1 (3d Cir. 1992)). A plaintiff still, however, bears "the burden of demonstrating the facts that establish personal jurisdiction."[8] *Id.* (citing *Mellon Bank (East) PSFS Nat'l Ass'n v. Farino*, 960 F.2d 1217, 1223 (3d Cir. 1992)).

Rule 12(b)(3) provides that a motion to dismiss may be made on the basis of improper venue. Fed. R. Civ. P. 12(b)(3). The purpose of venue, in most instances, "is to protect the defendant against the risk that a plaintiff will select an unfair or

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[7]Although the court should determine subject matter jurisdiction at the outset of a case, "the truth of jurisdictional allegations need not always be determined with finality at the threshold of litigation." *See* 2 James W. Moore, Moore's Federal Practice § 12 30[1] (3d ed. 1997). Rather, a party may first establish jurisdiction "by means of a nonfrivolous assertion of jurisdictional elements and any litigation of a contested subject-matter jurisdictional fact issue occurs in comparatively summary procedure before a judge alone (as distinct from litigation of the same fact issue as an element of the cause of action, if the claim survives the jurisdictional objection)." *Jerome B. Grubart, Inc. v Great Lakes Dredge & Dock Co.*, 513 U.S. 527, 537-38 (1995) (citations omitted).

[8]"[C]ourts are to assist the plaintiff [in meeting its burden] by allowing jurisdictional discovery unless the plaintiff's claim is 'clearly frivolous.'" *Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003).

inconvenient place of trial." *Cottman Transmission Sys., Inc. v. Martino*, 36 F.3d 291, 294 (3d Cir. 1994). Title 28 of the United States Code § 1400(b) provides that a "civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b) (2006). For the purposes of venue, a defendant "that is a corporation . . . reside[s] in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced." *Id.* at § 1391(c).

Finally, in reviewing a motion filed under Rule 12(b)(6), the court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff.[9] *See Erickson v. Pardus*, 551 U.S. 89 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp v. Twombly*, 550 U.S. 544 (2007) (interpreting Fed. R. Civ. P. 8(a)) (internal quotations omitted). A complaint does not need detailed factual allegations; however, "a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 1964-65 (alteration in original) (citation omitted). The "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that

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[9]"Generally, in ruling on a motion to dismiss, a district court relies on the complaint, attached exhibits, and matters of public record." *Sands v. McCormick*, 502 F.3d 263, 268 (3d Cir. 2007) (citing *Pension Benefit Guar Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)).

all of the complaint's allegations are true." *Id.* at 1959.

## IV. DISCUSSION

### A. Subject Matter Jurisdiction

Defendants allege that plaintiffs have admitted an inability to state a claim of infringement based upon presently possessed information, resulting in the absence of a justiciable case or controversy. Defendants cite to the complaints,[10] highlighting the sections in which plaintiffs aver the failed negotiations regarding the offer of access. (D.I. 1 at ¶¶ 28, 29; Civ. No. 09-715-SLR, D.I. 1 at ¶¶ 28, 30, 32) Defendants submit that, insofar as no case or controversy exists, the court has no Article III subject matter jurisdiction. Lacking the necessary confidential information in the ANDA, defendants argue, plaintiffs have resorted to an improper attempt to obtain discovery in order to satisfy the pre-suit obligations of Fed. R. Civ. P. 11 ("Rule 11"), to wit, whether plaintiffs have a sufficient basis to allege that the ANDA products infringe the Eurand patents.[11]

It is axiomatic that an actual case or controversy must exist at all stages of litigation. *Evans v. Holden*, 474 F. Supp. 2d 587, 589 (D. Del. 2007) (citing *United*

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[10](D.I. 1; Civ. No. 09-715-SLR, D.I. 1)

[11]Defendants contend that plaintiffs' Rule 11 deficiency is facially presented by the complaints, which state as follows:

> 32. Plaintiffs are not aware of any other means of obtaining information regarding [the ANDA products] within the 45-day statutory period. In absence of such information, plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that [the ANDA products] fall within the scope of one or more claims of [the Eurand patents].

(D.I. 1 at ¶ 29; Civ. No. 09-715-SLR, D.I. 1 at ¶ 32)

*States v. Kissinger*, 309 F.3d 179, 180 (3d Cir. 2002)). A case or controversy, in this instance, must be premised upon allegations of infringement. While it is clear that plaintiffs cannot determine, without prior examination of the confidential information contained in the ANDA, whether the ANDA products are likely to infringe the Eurand patents, plaintiffs have availed themselves of the "artificial" act of infringement created in 35 U.S.C. § 271(e)(2)(A). *See, e.g. Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). This section provides that

> [i]t **shall be an act of infringement to submit** – (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]

(emphasis added) When an ANDA is submitted, the applicant must wait for FDA approval before it can place any products covered by the ANDA onto the market. Accordingly, this "artificial" act of infringement is an acknowledgment that the usual methods of supporting an allegation for infringement (e.g., securing and evaluating the accused product) are not immediately available to the patentee. *See id.* (explaining that the inquiries in an ANDA case "are hypothetical because the allegedly infringing product has not yet been marketed").

In count I of the complaints, plaintiffs allege that "[defendants], acting jointly, submitted [the ANDA] and amendment thereto to the FDA" and that, "[b]y submitting [the ANDA] and the amendment thereto, [defendants], individually and collectively, committed an act of infringement with respect to [the Eurand patents] under 35 U.S.C. § 271(e)(2)(A)." (D.I. 1 at 31; Civ. No. 09-715-SLR, D.I. 1 at ¶ ¶ 24, 26) Defendants do not contend that the ANDA was not submitted to the FDA. Therefore, plaintiffs'

allegations of infringement, made pursuant to 35 U.S.C. § 271(e)(2)(A), present the court with a case or controversy sufficient to create Article III subject matter. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008) ("§ 271(e)(2) is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts.").

With respect to defendants' contentions that plaintiffs filed these actions to obtain improper pre-suit discovery, the Federal Circuit has rejected the notion that Rule 11 prohibits a patentee from bringing an infringement action based upon the submission of an ANDA where the patentee "is unable to obtain and set forth in [its] complaint facts showing infringement . . . ." *Hoffmann La Roche, Inc. v. Invamed Inc.*, 213 F.3d 1359, 1364 (Fed. Cir. 2000).[12] In *Hoffmann La Roche*, the patent at issue concerned a process for manufacturing a drug. The defendant-ANDA filer provided plaintiffs with a sample of the generic drug, but refused to disclose how it was manufactured. *Id.* at 1361. In the subsequently filed infringement action, plaintiffs averred - similar to the complaints at bar - as follows:

> In the absence of [defendant's manufacturing] information, plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that each and every defendant infringes one or more claims of the [asserted patents].

*Id.* at 1364. In affirming the district court's denial of sanctions, the Federal Circuit noted that "[i]t is difficult to imagine what else [plaintiffs] could have done to obtain facts relating to [defendant's] alleged infringement of their process patents." *Id.*

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[12]This decision was made within the context of a motion for sanctions following a voluntary dismissal of the complaint of infringement. *Id.* at 1362.

Defendants argue that *Hoffmann La Roche* is inapposite to the case at bar because the defendant-ANDA filer in that case utterly refused to supply its manufacturing information. Here, defendants contend that plaintiffs have not been refused access to the ANDA; rather, plaintiffs have refused to accept the offer of access. In light of the allegedly unreasonable restrictions and limitations attached to the receipt of this information, as well as defendants' refusal to accept conditions consistent with the Protective Order filed in the other member cases of this consolidated action, this is a distinction without difference. The above scenario would allow an ANDA filer to frustrate the Hatch-Waxman system by attaching unacceptable conditions to its offer of access, thereby unilaterally withholding information about its accused product until the 45-day window for filing suit lapses.

Plaintiffs made several attempts to obtain access to the ANDA, and expressed a willingness to observe the restrictions and limitations of the Protective Order existing in the other member cases. (Civ. No. 09-715-SLR, D.I. 17, exs. 4, 5, 9, 10, 13, 14) Defendants rebuffed these efforts, and did not respond to plaintiffs' final request to receive the entire ANDA under Delaware Local Rule 26.2. Accordingly, as was found in *Hoffmann La Roche*, plaintiffs did not run afoul of Rule 11 in bringing this infringement action.

**B. Ability to State a Claim Upon Which Relief May Be Granted**

**1. Defendants' liability under § 271(e)(2)**

Defendants advance two theories upon which it is alleged that plaintiffs have failed to state a claim for relief. The first subsumes defendants' contentions regarding

subject matter jurisdiction, i.e., because plaintiffs lack sufficient information upon which an allegation of infringement may be based, there is no ripe case or controversy, no subject matter jurisdiction and, accordingly, a failure to state a claim upon which relief can be granted. (D.I. 13 at 9) Insofar as the court has found, *supra*, that plaintiffs have properly brought claims pursuant to 35 U.S.C. § 271(e)(2)(A), plaintiffs have stated a claim for infringement against defendants.

The second line of arguments, if accepted by the court, would result in a dismissal of all or some of plaintiffs' claims against Anchen Holding. Defendants argue that Anchen Pharmaceuticals is the sole signatory to the ANDA and, therefore, Anchen Holding did not "submit" the ANDA within the meaning of 35 U.S.C. § 271(e)(2). Plaintiffs criticize this narrow reading of "submit," and respond that liability for filing an ANDA under 35 U.S.C. § 271(e)(2) may extend beyond the signatory entity. *See Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338 (D. Del. 2009).

The entities disputing liability for submitting the ANDA in *Cephalon* existed in the same corporate family as the signatory entity. Moreover, each disputing entity: (1) took part in the operations of the filing entity; (2) contributed employees to the teams who prepared the ANDA; (3) had multiple employees who signed various documents included in the ANDA; and (4) would eventually be involved in the marketing and distribution of the generic drug at issue if approved by the FDA. *Id.* at 349. In finding that each entity had "submitted" the ANDA within the meaning of 35 U.S.C. § 271(e)(2), this court held that "[p]arties 'actively involved' in preparing the ANDA are deemed to have 'submit[ted]' the ANDA, regardless of whether they are the named applicant[;] this

is especially true where the parties involved are in the same corporate family." *Id.* (internal citations omitted).

Here, plaintiffs have alleged in the complaints that: Anchen Holding and Anchen Pharmaceuticals are closely related; both companies take part in the generic division operations; employees from both companies are intermingled; and the companies collaborate in the manufacture, marketing, and sale of many pharmaceutical products, including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications. (D.I. 1 at ¶¶ 4 - 7) These pleadings do not rise to the level of certainty determined to exist in *Cephalon.* However, *Cephalon* is also clearly distinguishable on the basis that plaintiffs were forced[13] to file the complaints in the case at bar without the benefit of basic access to the ANDA. Insofar as defendants have unreasonably withheld such access, the court will not countenance such gamesmanship with a dismissal at this stage of the proceedings. Accordingly, defendants' motion to dismiss Anchen Holding's liability under 35 U.S.C. § 271(e)(2) is denied without prejudice to renew.

**2. Defendants' liability under § 271(b)**

Defendants likewise move to dismiss plaintiffs' inducement claim against Anchen Holding pursuant to 35 U.S.C. § 271(b). "Where an inducement claim is premised on the filing of an ANDA pursuant to § 271(e)(2), plaintiff . . . must allege acts to be committed after the ANDA is approved, such as manufacturing, marketing or selling the

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[13]Under the Hatch-Waxman Act, patent holders have a "strict 45-day window in which to file suit after the patent holder receives notice that a generic company has filed an ANDA . . . ." *Abbott Labs. v. Mylan Pharms., Inc.*, 2006 WL 850916, at *8 (N.D. Ill. March 28, 2006).

infringing products." *Id.* at 350 (citing *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007). Plaintiffs have alleged that Anchen Holding will be actively involved in the infringement of the '372 patent through the manufacture, marketing and sale of the ANDA products if the ANDA is approved. (Civ. No. 09-715-SLR, D.I. 1 at ¶ 39) This allegation is sufficient to raise Anchen Holding's active inducement above the speculative level with respect to the '372 patent. *See id.*

Similar allegations do not appear in the complaint for infringement of the '793 patent. Rather, plaintiffs' complaint states that "[Anchen Holding] actively induced Anchen Pharmaceuticals to submit [the ANDA] to the FDA . . . . By actively inducing submission of [the ANDA], [Anchen Holding] has committed an act of indirect infringement with respect to the '793 patent under 35 U.S.C. § 271(b)." (D.I. 1 at ¶ 34) Insofar as plaintiffs fail to allege any future acts of Anchen Holding that could contribute to the infringement of the '793 patent, this pleading fails to characterize Anchen Holding "as the prime mover in the chain of events leading to infringement." *Forest Labs.*, 501 F.3d at 1272. Thus, plaintiffs' claim of inducement against Anchen Holding with respect to the '793 patent (D.I. 1 at ¶¶ 33-35) is dismissed without prejudice.

**3. Declaratory judgment**

The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction." 28 U.S.C. § 2201(a) (2000). A plaintiff bringing an action for declaratory judgment must prove, by a preponderance of the evidence, that an actual controversy exists. *See Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 (Fed. Cir. 1992). An actual controversy exists where "the facts alleged,

under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Defendants argue that plaintiffs' traditional request for a declaration of infringement against Anchen Holding must fail because of the absence of a case or controversy.

A claim for declaratory judgment under 35 U.S.C. § 271 "is proper so long as plaintiffs can show the existence of real and immediate controversy." *Cephalon*, 629 F. Supp. 2d at 351. Moreover, "[i]n the context of a § 271(e)(2) infringement action, where the court is engaged in a forward-looking analysis of what defendants will do upon ANDA approval, defendants' declared intent is sufficient to make the controversy real and immediate. *Id.* To the extent that defendants' refusal to provide access to the ANDA has concealed the intent of Anchen Holding, the court will not consider dismissal of plaintiffs' request for declaratory judgment until such access has been granted. Consequently, defendants' motions for the dismissal of the declaratory judgment counts are denied without prejudice to renew.

**C. Personal Jurisdiction**

Defendants next argue that this action should be dismissed as to Anchen Pharmaceuticals for lack of personal jurisdiction. To establish personal jurisdiction, plaintiffs must show, by a preponderance of the evidence, that (1) "there is a statutory

basis for jurisdiction under the forum state's long arm statute"[14] and (2) "the exercise of jurisdiction comports with the defendant's right to due process." *L'Athene, Inc. v. EarthSpring LLC*, 570 F. Supp. 2d 588, 590 (D. Del. 2008) (citing *Time Share Vacation Club v. Atlantic Resorts, Ltd.*, 735 F.2d 61, 66 (3d Cir. 1984); *Reach & Assocs. P.C. v. Dencer*, 269 F. Supp. 2d 497, 502 (D. Del. 2003)).

Pursuant to the Delaware long arm statute, 10 Del. C. § 3104, a court may exercise personal jurisdiction over a defendant where the defendant or its agent, as provided in subsection (c)(1), "[t]ransacts any business or performs any character of work or service in the State" or, as provided in subsection (c)(4), "[c]auses tortious injury[15] . . . [and] regularly does or solicits business [in the State], engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State." 10 Del.C. § 3104(c). The long arm statute lists the subsection (c)(4) activities in the disjunctive, and the defendant need only engage in one for that subsection to apply. *Power Integrations, Inc. v. BCD*

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[14]The court applies the Delaware long arm statute consistent with Delaware state courts' interpretations. *Intel Corp. v. Broadcom Corp.*, 167 F. Supp. 2d 692, 700 (D. Del. 2001); *see also LSI Indus. Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1371 (Fed. Cir. 2000). Delaware state courts interpret the long arm statute as "confer[ring] jurisdiction to the maximum extent possible under the Due Process Clause." *Hercules Inc. v. Leu Trust & Banking (Bahamas) Ltd.*, 611 A.2d 476, 480-81 (Del. 1992); *LaNuova D & B S.p.A. v. Bowe Co., Inc.*, 513 A 2d 764, 768 (D. Del. 1986); *see also Boone v. Oy Partek Ab*, 724 A.2d 1150, 1156-57 (Del. Super. 1997), *aff'd*, 707 A.2d 765 (Del. 1998). As this district has before acknowledged, Delaware courts "liberally interpret the [long arm] statute in favor of exercising jurisdiction." *Jeffreys v. Exten*, 784 F. Supp. 146, 151 (D Del. 1992).

[15]Patent infringement is a tortious act for purposes of the Delaware long-arm statute. *Merck & Co., Inc. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 373 (D. Del. 2002).

*Semiconductor Corp.*, 547 F. Supp. 2d 365, 374 (D. Del. 2008) (citing *LaNuova*, 513 A.2d at 769).

If defendant is found to be within the reach of the long arm statute, the court then must analyze whether the exercise of personal jurisdiction comports with due process. *Shoemaker v McConnell*, 556 F. Supp. 2d 351, 354 (D. Del. 2008). The exercise of personal jurisdiction comports with due process where "the defendant's conduct is such that it should 'reasonably anticipate being haled into court there.'" *L'Athene*, 570 F. Supp. 2d at 591 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)). Personal jurisdiction may be either specific or general. *Vikoma Int'l, Ltd. v. Oil Stop, Inc.*, 1993 WL 14647, at *2 (D. Del. Jan. 14, 1993). For the court to exercise specific personal jurisdiction consistent with due process, plaintiff's cause of action must have arisen from the defendant's activities in the forum state. *Id.* (citing *Burger King Corp. v. Rudzewicz*, 471 U.S 462, 472 (1985); *Woodson*, 444 U.S. at 297) For the court to exercise general personal jurisdiction consistent with due process, plaintiff's cause of action can be unrelated to the defendant's activities in the forum state so long as the defendant has "continuous and systematic contacts with the forum state." *Applied Biosystems, Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1470 (D. Del. 1991); *Vikoma*, 1993 WL 14647, at *2. Subsection (c)(1) of the long arm statute requires a showing of specific jurisdiction. *See G & G LLC v. White*, 535 F Supp. 2d 452, 461 (D. Del. 2008). In contrast, subsection (c)(4) of the long arm statute requires a showing of general jurisdiction, that is, a showing that defendant or its agent, through more than minimum contacts, is "generally present" in the forum state. *See id.*;

*Shoemaker*, 556 F. Supp. 2d at 355.

Relevant to this analysis, a defendant company may be subject to personal jurisdiction in Delaware by virtue of the court's personal jurisdiction over the defendant company's affiliate pursuant to the "agency theory." *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 559 (D. Del. 1998). "Under the agency theory, the court may attribute the actions of a subsidiary company to its parent where the subsidiary acts on the parent's behalf or at the parent's direction." *Id.* at 560. This theory does not treat the parent and subsidiary as one entity, but rather attributes specific acts to the parent because of the parent's authorization of those acts. *Id.*; *see also Applied Biosystems*, 772 F. Supp. at 1464 (under the agency theory, "only the precise conduct shown to be instigated by the parent is attributed to the parent"). The agency theory may be applied not only to parents and subsidiaries, but also to companies that are "two arms of the same business group," operate in concert with each other, and enter into agreements with each other that are nearer than arm's length. *See Wesley-Jessen Corp. v. Pilkington Visioncare, Inc.*, 863 F. Supp. 186, 188-89 (D. Del. 1993).

Plaintiffs argue that the court should attribute the Delaware contacts of Anchen Holding to Anchen Pharmaceuticals under the agency theory. Because the allegations demonstrate a nearer than arm's length relationship, the court agrees. Plaintiffs have alleged that both entities share the same address and some of the same employees. Moreover, Anchen Pharmaceuticals' statements to the United States Patent Office made during the prosecution of its mark, noted *supra*, evince exactly this type of relationship. (*See* Civ. No. 09-715-SLR, D.I. 17, ex. 1 at ¶¶ 4-7) Defendants do not

dispute these facts. Consequently, Anchen Holding's Delaware contacts are attributable to Anchen Pharmaceuticals.

The court next evaluates the sufficiency of Anchen Pharmaceuticals' contacts under Delaware's long arm statute. Anchen Pharmaceuticals' activities in Delaware are not sufficient to establish specific personal jurisdiction because they do not relate to the patent infringement action brought against Anchen Pharmaceuticals and so do not satisfy subsection (c)(1) of Delaware's long arm statute. *See C.R. Bard*, 997 F. Supp. at 559 (citing *Applied Biosystems*, 772 F. Supp. at 1466) ("Section 3104(c)(1) provides for specific jurisdiction over a party, where that party's actions are linked to the cause of action.") (internal quotation marks omitted).

The court, however, concludes that general jurisdiction over Anchen Pharmaceuticals is present. Having previously established that Anchen Pharmaceuticals' submission of the ANDA constitutes an act of infringement, Anchen Pharmaceuticals has committed a tort within the meaning of 10 Del. C. § 3104(c)(4). While insufficient for specific jurisdiction, Anchen Pharmaceuticals' activities establish general personal jurisdiction because they show that Anchen Pharmaceuticals derives "substantial revenue" from Delaware drug sales. For example, Anchen Pharmaceuticals and Anchen Holding have sold millions of dollars worth of Buproprion and Divalproex generic drugs in Delaware. (Civ. No. 09-715-SLR, D.I. 1 at ¶ 8; *Id.* at exs. B and C) Revenue sheets indicate that Anchen Pharmaceuticals sold at least $1,079,202 worth of drug products in Delaware between June 2007 and May 2009. (Civ. No. 09-715-SLR, D.I. 17 at ex. 18) Thus, plaintiffs have shown a basis under Delaware's long arm statute for jurisdiction over Anchen Pharmaceuticals.

The court similarly finds that the exercise of general personal jurisdiction over Anchen Pharmaceuticals comports with Due Process. The substantial revenue relevant to the court's analysis under the Delaware long arm statute demonstrates Anchen Pharmaceuticals' purposeful contacts with Delaware. *See LSI Indus. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1375 (Fed. Cir. 2000) (holding that the Due Process Clause was satisfied "[b]ased on [defendant's] millions of dollars of sales of lighting products[16] in Ohio over the past several years and its broad distributorship network in Ohio . . . ."). Thus, Anchen Pharmaceuticals can reasonably expect to be "haled into court" in Delaware, and its motion to dismiss is denied.

**D. Venue**[17]

Because the court may exercise personal jurisdiction over Anchen Pharmaceuticals, venue, too, is proper in this district. *See* 28 U.S.C. § 1391(c).

With respect to defendants' request in the alternative to transfer this litigation to the Central District of California, 28 U.S.C. § 1404(a) provides that "[f]or the convenience of the parties and witnesses, in the interests of justice, a district court may transfer any civil action to any other district or division where I might have been brought." The Third Circuit has framed this analysis in terms of nonexclusive public and

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[16]As here, products unrelated to the product accused of infringement in the case. *Id.* at 1370.

[17]A 28 U.S.C § 1407 transferee court retains jurisdiction to determine motions regarding the propriety of venue. *Jack Winter, Inc. v Koratron Co.,* 326 F. Supp. 121 (1971, N.D. Cal.).

private interest factors.[18] *See Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879-880 (3d Cir. 1995). But "[i]t is black letter law that a plaintiff's choice of a proper forum is a paramount consideration in any determination of a transfer request, and that choice should not be lightly disturbed." *Shutte v. Armco Steel Corp.*, 431 F.2d 22, 25 (3d Cir. 1970).

Defendants allege that the relevant witnesses and documents are located in California. This concern over defendants' convenience is, at the very least, offset by the substantial interests held by plaintiffs in maintaining this action in Delaware. Anesta's parent, Cephalon, is incorporated in Delaware, and has already produced more than 600,000 pages of documents in the related cases before the court, and will be producing a number of witnesses for deposition. Defendants also take issue with the two protective suits[19] plaintiffs filed in the Central District of California, submitting that plaintiffs have effectively made this jurisdiction a "second choice" for this litigation. Notwithstanding any indicia of consent by plaintiffs to litigating in the Central District of California, defendants concede that plaintiffs' "first choice" for this litigation is the

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[18]The private interests include: (1) the plaintiff's choice of forum; (2) the defendant's preferred forum; (3) where the claim arose; (4) the convenience of the parties; (5) the convenience of the witnesses, and (6) the location of books and records. *Id.* With respect to public interests, courts may consider factors including (1) practical considerations that could make the trial easier, quicker, or less expensive, and (2) the trial judge's familiarity with the applicable law. *Id.* As movants, defendants bear the burden of establishing the need for a transfer. *Id.*

[19]With respect to the "strict 45-day window in which to file suit," the Hatch-Waxman Act is "silent [as to] whether the patent holder loses its right to sue for patent infringement in the event its suit is dismissed for lack of personal jurisdiction after the 45-day period has expired." *Abbott Labs.*, 2006 WL 850916, at *8. The court will not infer that plaintiffs have made a "choice" as to venue when prudence counsels the need for such protective measures to preserve rights in light of an ambiguous statute.

District of Delaware. Moreover, with respect to the public factors espoused by *Jumara*, practicality counsels against transferring these cases to California in light of the recent decision of the MDL Panel to centralize this litigation in Delaware. In sum, defendants have not demonstrated, within the *Jumara* framework, the propriety of transferring the actions back to the Central District of California; the court will not disturb plaintiffs' choice of venue.

## V. CONCLUSION

For the aforementioned reasons, the court grants in part Anchen Holding's motion to dismiss (Civ. No. 09-492, D.I. 10), denies Anchen Pharmaceuticals' motion to dismiss (Civ. No. 09-492, D.I. 12), and denies defendants' joint motion for dismissal or transfer (Civ. No. 09-715, D.I. 10) without prejudice to renew. An appropriate order shall issue.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| IN RE: CYCLOBENZAPRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULE PATENT LITIGATION | ) | MDL No. 09-2118 (consolidated) |

**ORDER**

At Wilmington this 12th day of March, 2010, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that:

1. Defendant Anchen, Inc.'s motion for dismissal (Civ. No. 09-492, D.I. 10) is granted in part, to wit:

a. Anchen, Inc.'s motion is granted as to plaintiffs' allegations of liability under 35 U.S.C. § 271(b).

b. Anchen, Inc.'s motion is otherwise denied without prejudice to renew regarding its allegation that plaintiffs fail to state a claim both for declaratory judgment against Anchen Inc., and that Anchen, Inc. is liable under 35 U.S.C. § 271(e)(2), subject to the following time line:

i. On or before May 17, 2010, plaintiffs shall receive access to ANDA No. 91-281 and any amendments thereto.

ii. On or before June 30, 2010, plaintiffs may file an amended complaint.

2. Defendant Anchen Pharmaceuticals, Inc.'s motion for dismissal (Civ. No. 09-492, D.I. 12) is denied.

3. Anchen, Inc.'s and Anchen Pharmaceuticals, Inc.'s (collectively, "defendants") joint motion for dismissal or transfer (Civ. No. 09-715, D.I. 10) is denied without prejudice to renew with respect to the allegation that plaintiffs fail to state a claim both for declaratory judgment against Anchen, Inc., and that Anchen, Inc. is liable under 35 U.S.C. § 271(e)(2), subject to the following time line:

a. On or before May 17, 2010, plaintiffs shall receive access to ANDA No. 91-281 and any amendments thereto.

b. On or before June 30, 2010, plaintiffs may file an amended complaint.

United States District Judge