IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IN RE: CYCLOBENZAPRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULE PATENT LITIGATION	)	Civ. No. 09-MD-2118-SLR

MEMORANDUM ORDER

At Wilmington this 15th day of March, 2012, having considered Impax's motion to reargue and modify injunction (D.I. 366), plaintiffs' cross-motion for declaratory and injunctive relief (D.I. 372), and Impax's motion to enforce settlement agreement (D.I. 381), as well as the papers filed in connection therewith;

IT IS ORDERED, for the reasons discussed below, that the injunction remains in effect:

1. **Background**. This action arises out of the filing of an Abbreviated New Drug Application ("ANDA") by Mylan Pharmaceuticals, Inc. ("Mylan"), Barr Laboratories, Inc. ("Barr"), Impax Laboratories, Inc. ("Impax") and Anchen Pharmaceuticals, Inc. ("Anchen") to market a generic version of the pain drug AMRIX® proprietary to Eurand, Inc. and exclusive licensee Anesta AG (collectively "plaintiffs"). The active ingredient in AMRIX® is cyclobenzaprine hydrochloride in an extended release formulation, which is protected by, *inter alia*, U.S. Patent Nos. 7,387,793 ("the '793 patent") and 7,544,372 ("the '372 patent"). Upon receiving notification of the filing of Mylan's ANDA, plaintiffs

brought a suit for infringement of the '793 and '372 patents pursuant to 35 U.S.C. § 271(e)(2)(A). (D.I. 234 at 3-4) Plaintiffs filed similar suits against Barr, Impax and Anchen.[1] (*Id.*) Impax counter-sued for a declaratory judgment of non-infringement. (D.I. 8 in 09-18) The court notes, however, that Impax was not an active litigant, in that it did not participate in discovery, and it settled on the eve of trial.

2. Impax and plaintiffs reached a settlement agreement on October 7, 2010. (D.I. 105 in 09-18). Under the terms of the agreement, Impax admitted infringement, agreed not to challenge the validity of plaintiffs' patents, granted a release to plaintiffs and agreed to the dismissal of the lawsuit. (D.I. 367 at Ex. A) In exchange, plaintiffs released Impax and granted it a license to sell its ANDA or a generic version of AMRIX® upon the earliest of certain events. Specifically, under section 3.2(c), the settlement permitted Impax to begin selling on "the same entry date that any Third Party which is not entitled to First to File Exclusivity is licensed or authorized by [plaintiffs] to being selling Generic Equivalent Product." (*Id.*) A Third Party is defined as "a party that is neither Anesta, Eurand nor Impax." (*Id.*)

3. On May 12, 2011, after a bench trial on the merits, the court concluded that defendants infringed but plaintiffs' patents were invalid. (D.I. 254; 255) After this judgment, defendant Mylan undertook an at-risk launch of its generic. In response, plaintiffs did two things. First, they began to sell their own generic through a company called Watson Pharmaceuticals ("Watson"); the parties agree that Watson was

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[1] On December 2, 2009, the cases were consolidated by order of the United States Judicial Panel on Multi-District Litigation. (D.I. 1) The court presumes familiarity with the issues in this case, as detailed in its prior opinion (D.I. 254), and focuses the remainder of this background section on those issues relevant to the motions at issue.

plaintiffs' sales agent (D.I. 409 at 14) Second, they sought to enjoin Mylan from selling its generic pending the outcome of the appeal.

4. On May 24, 2011, the court issued an injunction; under its terms, neither Mylan nor plaintiffs could sell their generics. (D.I. 290) The injunction stated:

> 1. Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively, "Mylan"), its officers, agents, servants, employees, and attorneys, and other persons who are in active concert or participation with them are enjoined from engaging in the commercial use, offer to sell, or sale of the generic extended release cyclobenzaprine products that are the subject of Mylan's Abbreviated New Drug Application No. 90-738.
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> 2. Plaintiffs Anesta AG, Cephalon, Inc. and Eurand, Inc. (collectively, "plaintiff"), their officers, agents, servants, employees, and attorneys, and other persons who are in active concert or participation with them, shall not engage in the commercial use, offer for sale, or sale within the United States, or authorize or license, any generic cyclobenzaprine extended release product.

(*Id.*)

5. On November 8, 2011, paragraph 2 of the injunction was amended, as follows, to specifically bar Impax from selling a generic:

> 2. Plaintiffs Anesta AG, Cephalon, Inc. and Eurand, Inc. (collectively, "plaintiff"), their officers, agents, servants, employees, and attorneys, any person in privity with Cephalon, Eurand or Anesta via license, settlement, contract, including Impax Laboratories Inc., any company in privity with Teva/Barr via the transfer of Barr's ANDA - *i.e.*, Par Pharmaceutical - and any other persons who are in active concert or participation with any of these persons, shall not engage in the commercial use, offer for sale, or sale within the United States, or authorize or license, any generic cyclobenzaprine extended release product.

(D.I. 363)

6. In response to the injunction modification, Impax filed a motion for reargument and to modify injunction. (D.I. 366) In that motion, Impax argues that the modified injunction improperly binds a non-party (i.e., Impax) and fails to maintain the status quo.

(D.I. 366) Specifically, with respect to the later argument, Impax argues that the injunction alters the status quo by prohibiting it from taking advantage of section 3.2(c) of their settlement agreement with plaintiffs. (*Id.* at 7) According to Impax, Watson was a Third Party seller that triggered Impax's ability to enter the market under section 3.2(c). (*Id.* at 8) The motion also asserts that, should the injunction stand, plaintiffs are required, under F. R. Civ. P. 65(c), to post a bond that would protect Impax against damages sustained in the event that the injunction was improperly ordered. (*Id.* at 9)

7. Mylan responded to Impax's motion, claiming that Impax was properly restrained under F. R. Civ. P. 65(d) and the injunction does maintain the status quo. (D.I. 370) Plaintiffs responded with a cross-motion for declaratory and injunctive relief. (D.I. 372) In that motion, plaintiffs also argue that F. R. Civ. P. 65(d) allows Impax to be restrained and the injunction maintains the status quo. (D.I. 373) Additionally, plaintiffs assert that section 3.2(c) of their settlement agreement with Impax has not been triggered. (*Id.*) Impax responded to Mylan's response and plaintiffs' motion with its motion to enforce settlement agreement. (D.I. 381)

8. **Standard of Review**. The purpose of a motion for reconsideration is to "correct manifest errors of law or fact or to present newly discovered evidence." Max's *Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3rd Cir. 1999). Accordingly, a court may alter or amend its judgment if the movant demonstrates at least one of the following: (1) a change in the controlling law; (2) availability of new evidence not available when [] judgment was granted; or (3) a need to correct a clear error of law or fact or to prevent manifest injustice. *See id.*

9. Settlement agreements are interpreted according to contract principles and contracts are construed to "effectuate the parties' intent." *Lorillard Tobacco Co. v. American Legacy Found.*, 903 A.2d 728, 739 (Del. Supr. 2006); *E.I. du Pont de Nemours and Co., Inc. v. Shell Oil Co.*, 498 A.2d 1108, 1113 (Del. 1985) ("The basic rule of contract construction gives priority to the intention of the parties."). "In upholding the intentions of the parties, a court must construe the agreement as a whole, giving effect to all provisions therein." *Id.* at 1113.

10. Under Fed. R. Civ. P. 65(c), "[t]he court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained."

11. **Discussion**. Impax asks this court to amend its injunction in light of the parties' settlement agreement and the supposed triggering event that occurred under its terms. In response to an Email Request for Emergency Relief, the court held oral argument on the parties' competing motions. (D.I. 409) At oral argument, the parties agreed that the crux of their dispute was whether, under the terms of the settlement agreement, Impax was clearly permitted to go to market with its generic; if not, the equities favor retaining the injunction as is. (*Id.* at 5-7)

12. Having reviewed the contract on the whole, it is clear that the parties did not intend for Impax to receive any sort of windfall whereby it became the sole generic company on the market. Instead, the settlement agreement contemplates a scheme whereby Impax can enter the market on the same date or shortly after a third party's

generic enters the market.[2] Plaintiffs' use of a sales agent to market **its own product**, a common industry custom as Impax readily admits, would not trigger section 3.2(c) because plaintiffs can sell **their own generic** without triggering Impax's right to enter the market.

13. Because the court concludes that the settlement agreement did not grant Impax the right to enter the market, the equities favor maintaining the injunction. Accordingly, the injunction modification dated November 8, 2011 remains in effect. The court, however, notes that the injunction is not necessary to keep Impax off the market. As discussed above, the parties' settlement agreement does that. Accordingly, it is unnecessary for the court to require plaintiffs to post a bond under Fed. R. Civ. P. 65(c).

14. **Conclusion**. For the reasons discussed above, the court: 1) denies Impax's motion to reargue and modify injunction (D.I. 366); 2) denies Impax's motion to enforce settlement agreement (D.I. 381); and 3) grants plaintiffs' cross-motion for declaratory and injunctive relief (D.I. 372) to the extent that the November 8, 2011 version of the injunction remains in effect.

United States District Judge

[2] Specifically, Impax is permitted to enter the market, at the latest, one year before plaintiffs' patent expires; however, Impax can enter sooner if certain triggering events occur. These triggering events include circumstances in which a third party is permitted to enter the market. As plaintiffs' counsel explained at oral argument: "So the negotiation here wasn't a circumstance where we're negotiating with someone who is an aggressive challenger of the patent and we're willing to give up something. . . . We agreed to a settlement and we got one thing out of that settlement. We got the ability to say to Impax, you cannot come onto the market unless there are other people on the market." (D.I. 409 at 20)