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 12th day of January, 2012, having considered Anchen's motion for attorney fees pursuant to 35 U.S.C. § 285 (D.I. 309) and plaintiffs' motion to dismiss or defer Anchen's motion (D.I. 339), as well as the papers filed in connection therewith;

IT IS ORDERED, for the reasons discussed below, that Anchen's motion (D.I. 309) is granted and plaintiffs' motion (D.I. 339) is deemed moot:

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. (*Id.*) On December 2, 2009, the cases were consolidated by order of the United States Judicial Panel on Multi-District Litigation.[1] (D.I. 1)

2. On May 12, 2011, after conducting a seven day bench trial, the court issued an opinion which concluded that Anchen had not infringed. Specifically, the court explained:

> During trial, plaintiffs never put on evidence as to Anchen's infringement of the patents-in-suit. In fact, plaintiffs admit that Anchen's current formulation "does not explicitly include one of the plasticizers listed in the claims of the '793 and '372 patents and, thus, does not meet each and every limitation of any of the claims of [the patents]." Therefore, the court grants final judgment in favor of Anchen and against plaintiff[s].

(D.I. 254 at 3, n.3) (citations omitted) On May 25, 2011, plaintiffs filed notices of appeal. (D.I. 304; 305; 306; 307; 308)

3. On May 26, 2011, Anchen filed a motion for attorney fees pursuant to 35 U.S.C. § 285. (D.I. 309) Plaintiffs responded, and also filed a motion to dismiss Anchen's motion or defer judgment on it until the Federal Circuit had resolved the appeal. (D.I. 339)

4. Plaintiffs filed a motion to withdraw their appeals on August 19, 2011; the Federal Circuit granted the motion on August 31, 2011. Fed. Cir. Order Granting Mot.

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[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 Anchen's motion for attorney fees.

to Withdraw, Aug. 31, 2011.[2]

5. **Legal Standard**. Under 35 U.S.C. § 285, a court may, in "exceptional cases," award attorney fees to the prevailing party. A district court's determination of whether to award fees involves a two-step process. "First, a district court must determine whether the prevailing party has proved by clear and convincing evidence that the case is exceptional." *Eon-Net LP v. Flagstar Bancorp,* 653 F.3d 1314, 1323-24 (Fed. Cir. 2011). "Second, if the district court finds the case to be exceptional, the court must then determine whether an award of attorney fees is appropriate and, if fees are appropriate, the amount of the award." *Id.* Exceptional cases include: "[i]nequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1034 (Fed. Cir. 2002).

6. **Discussion**. In support of its motion for fees, Anchen emphasizes that the court resolved the issue of infringement against it in a three sentence footnote. (D.I. 310 at 1) On the basis of the court's summary resolution to Anchen's alleged infringement, Anchen claims that it was "beyond frivolous" to maintain such a "baseless" suit. (*Id.* at 2-3) More specifically, Anchen claims that plaintiffs "never even offered a basis for maintaining an infringement [action]" and used this suit to "improperly invoke

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[2] Given the withdrawals, plaintiffs' motion to defer is moot. Plaintiffs' motion to dismiss was based upon the court's May 25, 2011 order which stated, in part, that "The court will not entertain further communications with the parties, except as they identify matters which must be addressed before the Federal Circuit will take jurisdiction over this case." (D.I. 302) As there is no longer an appeal pending, this argument is also moot. The court now resolves the issue of fees on the papers submitted in connection with Anchen's motion.

an FDA stay of approval of Anchen's ANDA."[3] (D.I. 310 at 2-4)

7. With respect to Anchen's contention that plaintiffs' suit was baseless from the start, the court disagrees. While plaintiffs, in their brief in opposition, never argue that they had a basis for initiating the infringement suit,[4] plaintiffs' complaint provides the basis on which the suit was filed. Plaintiffs' complaint explains that "the Anchen Paragraph IV Notice letters . . . fail to comply with the requirements of 21 U.S.C. § 355(j)(2)(B)(iv)(II) because, **inter alia**, they contain very limited information about the generic formulation for which Anchen filed ANDA No. 91-281. For example, the Anchen Paragraph IV Notice letters do not list any of the ingredients in the proposed generic versions." (D.I. 1 at ¶ 25 in Civ. No. 09-492) Having been unable to come to an agreement with Anchen on the conditions under which they could procure or view a copy of ANDA No. 91-281, plaintiffs opted to file suit in order to obtain the information (and then prove that infringement was occurring as suspected). (*Id.* at ¶¶ 26-29) Anchen does not deny that plaintiffs were never given leave to review a copy of the ANDA prior to filing suit. (D.I. 29 at 28 in Civ. No. 09-492) Thus, Anchen's contention that plaintiffs' suit has been frivolous and baseless from the start is unfounded; the

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[3] Under the Hatch-Waxman Act, the mere filing of a infringement suit by the patent holder triggers a 30-month stay of the FDA's approval of an ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). In effect, the stay prevents the generic drug from coming to market and competing with the brand name drug.

[4] Anchen, in its reply to plaintiffs' brief in opposition, argues that plaintiffs have effectively conceded that their original complaint of infringement was baseless. (D.I. 349 at 1-2) According to Anchen, "Plaintiffs never state [in their brief in opposition] why the allegations they did make - infringement of the '372 and '793 patents - were ever warranted. Hindsight now shows that these allegation were in fact baseless from the start." (D.I. 349 at 2)

complaint provides a sufficient explanation for why this infringement suit was filed and proceeded to discovery.

8. Instead of justifying their reasons for filing suit, plaintiffs' brief in opposition emphasizes that ANDA infringement cases ask the factfinder "to determine whether the **drug that will be sold upon approval of the ANDA** will infringe the asserted patent" (D.I. 345 at 1) (citing *In re Brimonidine Patent Litigation*, 643 F.3d 1366, 1377 (Fed. Cir. 2011)) (emphasis in original), and then argues that Anchen was proceeding to trial on a formula that the Food and Drug Administration ("FDA") had already rejected.[5] (D.I. 345 at 1; D.I. 346 at Ex. A) According to plaintiffs, Anchen was proceeding to trial on this "sham" formula in order to "terminate the 30-month stay and potentially become the first generic product on the market."[6] (*Id.* at 1-2) Plaintiffs maintain that final judgment should not have been entered in Anchen's favor until it was determined which formula Anchen would be taking to market. (*Id.* at 2) According to plaintiffs, if a final judgment of noninfringement was granted to Anchen, "the Court would no longer have had jurisdiction to police Anchen's compliance with its promise not to reformulate, and

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[5] In a February 2010 letter, after explaining that Anchen's proposed formulation exhibited alcohol-induced dose-dumping, the FDA asserted that "such results are unacceptable" and then recommended reformulating the drug. (D.I. 346 at Ex. A) Dr. Grant Heinicke, Anchen's formulator, testified that the FDA's recommendation to reformulate was particularly "forceful" and uncharacteristically strong-worded. (D.I. 47, Ex. 6 at 52-54 in Civ. No. 09-492) In Dr. Heinicke's estimation, the letter meant that Anchen would have to start an entirely new development program (i.e., reformulate the drug). (*Id.*)

[6] The stay can be terminated by the entry of a final judgment by a district court finding that the patent is not infringed, invalid or otherwise unenforceable. 21 U.S.C. § 355(j)(5)(B)(iii)(I). By being the first generic to receive a final judgment of noninfringement, Anchen would receive 180 days of market exclusivity against other generic producers. 21 U.S.C. § 355(j)(5)(B)(iv).

Plaintiffs would have had no assurance that Anchen would not immediately reformulate its product in a manner that would infringe by, for example, simply copying Plaintiffs' product in order to obtain quick FDA approval." (D.I. 345 at 11)

9. Contrary to plaintiffs' assertions, there are safeguards against the end-run they feared. Under 21 U.S.C. § 355(j)(2), ANDA filers must provide a Paragraph IV Certification that the ANDA does not infringe; this certification must be sent to the patent holder and other interested parties so that they can decide whether or not to sue for infringement. 21 U.S.C. § 355(j)(5)(B)(iii). Likewise, when an ANDA filer makes an alteration or amendment to its application, for example, by changing the drug's formula, the FDA requires ANDA filers to provide a new Paragraph IV Certification and re-notice the patent holder and drug owner. *See e.g. Ben Venue Labs., Inc. v. Novartis Pharmaceutical Corp.*, 146 F. Supp. 2d 572, 580-81 (D.N.J. 2001); *Paddock Labs., Inc. v. Ethypharm S.A.*, Civ. No 09-3779, 2011 WL 149860, at *3 (D.N.J. Jan. 18, 2011). In the event Anchen changes its formula, plaintiffs should receive another certification notice and be given the opportunity to file an infringement action based upon the amended formulation.[7] *Id.*

10. While plaintiffs appear concerned that another Paragraph IV Certification may not be required by the FDA, plaintiffs have not explained why or under what circumstances they would not be re-noticed (and, thus, have another opportunity to sue for infringement) if Anchen reformulated its drug. Without some explanation of how this fear would become reality, the court declines to accept plaintiffs' justification for

[7] Especially in light of this litigation history.

maintaining suit.

11. Before the court was the issue of infringement. Well before trial, in September of 2010, plaintiffs agreed to stipulate to the fact that Anchen's product, as formulated in its ANDA, did not infringe. (D.I. 47 at Exs. 1 and 2 in Civ. No. 09-492) The decision to nevertheless maintain the suit in order to "police" against any possible reformulations by Anchen warrants a finding of "exceptional" in light of the FDA's requirement of re-certification once reformulation occurs. *See Astrazeneca AB v. Dr. Reddy's Labs.*, Ltd., No. 07 Civ. 6790, 2010 WL 1375176, at *5-6 (S.D.N.Y. Mar. 30, 2010) (explaining that maintenance of a suit despite a lack of evidence to support the infringement allegation makes a case an exceptional one); *see also*, *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1379 (Fed. Cir. 2008) ("If the patentee prolongs litigation in bad faith, an exceptional finding may be warranted."). Plaintiffs unjustified maintenance of this suit also makes an award of fees appropriate. Accordingly, Anchen's motion for fees is granted. Fees are assessed from September 2010, a date by which plaintiffs opted to maintain a suit with clear knowledge that Anchen's product, as formulated, did not infringe.[8] *See Phonometrics, Inc. v. Choice Hotels Int'l, Inc.*, 65 Fed. Appx. 284, 285 (Fed. Cir. 2003) (affirming a district court's finding that a case was exceptional where a party continued to litigate after it became apparent that the party would not prevail on the merits).

12. Anchen shall file with the court and supply to plaintiffs, on or before

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[8] As discussed, plaintiffs did not originally file a frivolous suit; the suit became unjustifiable once plaintiffs declined to acknowledge that there was no need to maintain the suit in order to police Anchen's conduct.

February 13, 2012, an itemization of fees spent in defense of this suit and a brief, no longer than ten (10) pages in length, in support of its requested fees. Plaintiffs may reply, on or before **March 12, 2012**, in a brief limited to no more than ten (10) pages.

13. **Conclusion**. For the reasons set forth above, the court grants Anchen's motion for fees pursuant to 35 U.S.C. § 285 (D.I. 309) and finds plaintiffs' motion to dismiss or defer (D.I. 339) to be moot.

United States District Judge