IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., and ALLERGAN SALES, LLC, Plaintiffs, v. ALCON INC., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD., Defendants.	)	Civil Action No. 04-968 (GMS)

ORDER

1. Allergan, Inc. and Allergan Sales, LLC (collectively, "Allergan") filed the above-captioned action against Alcon Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively, "Alcon") on August 24, 2004. Allergan filed this suit for patent infringement pursuant to 35 U.S.C. § 271(e)(2).[1] The complaint alleges that Alcon infringes U.S. Patent No. 6,673,337 (the "'337 patent") and U.S. Patent No. 6,641,834 (the "'834 patent") because it submitted a § 505(b)(2) application, or paper New Drug Application ("paper NDA"), to the Food and Drug Administration ("FDA"),

[1] Section 271(e)(2) states, in pertinent part:

> [i]t shall be an act of infringement to submit – 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 if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A).

seeking approval of its proposed generic brimonidine tartrate ophthalmic drug product.[2] (Compl. ¶¶ 14-15, 17.) The complaint further alleges that Alcon acted without a reasonable basis for believing that it would not be liable for infringement of the '337 and '834 patents and, as such, its infringement of the '337 and '834 patents is willful. (*Id.* ¶¶ 19, 23.) Allergan requests injunctive relief and attorney's fees, pursuant to 35 U.S.C. § 285.[3] The issue presently before the court is whether Allergan may assert a claim for willful infringement.

2. Allergan contends that a willfulness claim is proper based on the totality of the circumstances. Allergan further contends that the totality of the circumstances comprises many factors, including whether Alcon intentionally copied ALPHAGAN® P, whether Alcon exercised due care to avoid infringing Allergan's patents, whether Alcon relied on competent legal advice, and Alcon's behavior as a party to the litigation. (D.I. 64, at 2.) According to Allergan, its claim of willfulness is based the following: (1) Alcon's Paragraph IV certification was filed without reasonable basis; and (2) Alcon's conduct in the litigation demonstrates its lack of reasonable basis. (*Id.* at 3). Lastly, Allergan contends that the Federal Circuit's holding in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004) does not foreclose a claim for willful infringement in Abbreviated New Drug Application ("ANDA") or paper NDA cases. (*Id.*)

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[2] Alcon also filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4), or Paragraph IV Certification, alleging that the '337 and '834 patents are invalid and/or not infringed by its product.

[3] Section 285 provides: "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." The Federal Circuit has recognized willful infringement as a type of misconduct that creates an exceptional case. *See Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1365 (Fed. Cir. 2000) (citing *Beckman Instruments, Inc. v. LKB Produkter AB*, 894 F.2d 1547, 1151 (Fed. Cir. 1989)).

3. Alcon asserts that the only act of infringement alleged in the complaint is the filing of its paper NDA with the FDA. According to Alcon, in light of the Federal Circuit's holding in *Glaxo*, "Allergan's conclusory allegation – standing alone – cannot support a charge of willful infringement." (D.I. 75, at 2.)

4. The Federal Circuit first 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 found that "[a]n ANDA [or paper 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. Nonetheless, the court held that the case was exceptional and awarded attorney fees to the plaintiff, based on the defendant's "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed. . . ." *Id.*

5. The Federal Circuit addressed the 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. In the *Glaxo* opinion, the court explained that in *Yamanouchi* it "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. According to the court, "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.*

6. In the present case, Allergan has not pointed to anything which would support a finding of willful infringement. The only act of infringement alleged in Allergan's complaint is Alcon's allegedly baseless paper NDA filing and Paragraph IV Certification with the FDA. Because a paper NDA filing cannot be considered willful, Allergan's complaint does not state any basis under which it could assert a claim for willful infringement. Allergan, however, maintains that Alcon's change in position with respect to its written description defense set forth in its summary judgment motion, combined with the paper NDA filing, permits a claim for willful infringement. The court disagrees. 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, but a finding of willful infringement cannot. Accordingly, the court will not permit a claim for willful infringement in this case. That being said, the court will not foreclose Allergan from, at the appropriate time, seeking to prove additional facts that would support its claim of an exceptional case for which the court should award attorney's fees. *See Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586, 592-93 (D. Mass. 2005).

Therefore, IT IS HEREBY ORDERED that:

1. A claim for willful infringement is not permitted in this case.

2. Allergan's claim for willful infringement shall be stricken from the complaint.

Dated: July 26 , 2005

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE