

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., :
FOREST LABORATORIES HOLDING, :
LTD. and H. LUNDBECK A/S, :
 :
Plaintiffs, :
 :
v. : Civil Action No. 03-891-JJF
 :
IVAX PHARMACEUTICALS, INC., :
and CIPLA LTD., :
 :
Defendants. :

John M. Desmarais, Esquire; Peter J. Armenio, Esquire; Gerald Flattman, Esquire and Ellen Scordino, Esquire of KIRKLAND & ELLIS LLP, New York, New York.

Melanie K. Sharp, Esquire and Andrew Lundgren, Esquire of YOUNG CONAWAY STARGATT & TAYLOR, Wilmington, Delaware. Attorneys for Plaintiffs.

Jeffrey S. Ward, Esquire and Thomas P. Heneghan, Esquire of MICHAEL BEST & FRIEDRICH LLP, Madison, Wisconsin. Attorneys for Defendants.

Richard D. Kirk, Esquire and Ashley B. Stitzer, Esquire of THE BAYARD FIRM, Wilmington, Delaware.

MEMORANDUM OPINION

March 15, 2007
Wilmington, Delaware.


Farnan, District Judge.

Pending before the Court is Defendants' Motion For Summary Judgment Of No Willful Infringement And For Summary Disposition Of Exceptional Case Issue (D.I. 647). Pursuant to the Court's January 12, 2007 Order, Plaintiffs have filed a Counter-Statement Of Disputed Facts In Opposition To Defendants' Motion (D.I. 652) contending that genuine issues of material fact exist with respect to Defendants' Motion, and therefore, summary judgment is not appropriate.

I. PARTIES' CONTENTIONS

By their Motion, Defendants contend that Plaintiffs cannot establish a claim of willful infringement as a matter of law. In support of their argument, Defendants rely on Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350-1351 (Fed. Cir. 2004) for the proposition that willful infringement cannot be established in a Hatch-Waxman Act case where, as here, there has been no commercial activity by Defendants. Defendants further contend that allowing a claim of willful infringement to proceed would undermine the purposes of the Hatch-Waxman Act.

Defendants also contend that the issue of whether this case is exceptional under 35 U.S.C. § 285 so as to justify an award of attorneys' fees, should be decided summarily, on the record and without the need for an evidentiary hearing. Defendants contend that Plaintiffs cannot prove by clear and convincing evidence

that Defendants intentionally or recklessly acted in bad faith during the course of this litigation. Thus, Defendants contend that Plaintiffs' exceptional case allegations fail as a matter of law.

In response, Plaintiffs contend that Glaxo does not foreclose a finding of willful infringement under the facts of this case. Specifically, Plaintiffs contend that Defendants filed and maintained a baseless ANDA application, admitted infringement of all asserted claims, and deliberately copied Plaintiffs' methods and products. Thus, Plaintiffs contend that this case is distinguishable from Glaxo.

With respect to the issue of exceptional case, Plaintiffs cite to the same alleged misconduct supporting their willful infringement claim and further contend that Defendants engaged in abusive and vexatious litigation tactics during this case, particularly during the discovery process before the Special Master. Plaintiffs contend that these issues raise genuine issues of material fact with respect to Defendants' Motion, and therefore, summary disposition of the exceptional case issue is inappropriate.

II. STANDARD OF REVIEW

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure a party is entitled to summary judgment if "the pleadings, depositions, answers to interrogatories, and

admissions on file, together with the affidavits, if any, show that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In making this determination, the Court must review all of the evidence and construe all inferences in the light most favorable to the non-moving party. However, a court should not make credibility determinations or weigh the evidence. Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the non-moving party must show more than "some metaphysical doubt as to the material facts.... In the language of the Rule, the non-moving party must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986) (quoting Fed. R. Civ. P. 56(c)). Accordingly, a mere scintilla of evidence in support of the non-moving party is insufficient for a court to deny summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986).

III. DISCUSSION

A. Willful Infringement

In support of their claim for willful infringement and in response to Defendants' Interrogatories requesting Plaintiffs to identify the basis for their willful infringement claim,

Plaintiffs alleged that:

Ivax and Cipla had relevant and constructive notice of the '712 patent at all relevant times, and despite this actual and constructive notice, and without any reasonable basis for doing so, deliberately copied Plaintiffs' patented product, jointly infringed the '712 patent and sought to capture the majority of the market for the patented product with their infringing copy.

(D.I. 647, Exh. 3 at 3.) As Plaintiffs point out, they reserved the right to supplement this response, which was given in July 2004; however, as evidenced by the characterization of their willful infringement claim in their Counter-Statement Of Disputed Facts, the heart of Plaintiffs' position remains relatively unchanged. Specifically, Plaintiffs allege that a finding of willful infringement is not precluded by Glaxo in the circumstances of this case where "Defendants filed a baseless ANDA, maintained that ANDA throughout the course of the litigation despite fact and expert discovery, claim construction and rulings of the Court all confirming the baseless nature of the filing; admitted infringement of all of the applicable asserted claims; and deliberately copied Plaintiffs' patented methods and products." (D.I. 652 at 2.) In other words, Plaintiffs' willful infringement claim still rests on Defendants' alleged frivolous ANDA filing and alleged copying of Plaintiffs' patent, the only change being that Plaintiffs now add that Defendants maintained the allegedly frivolous ANDA filing

throughout the various stages of this litigation so as to challenge the validity of Plaintiffs' patents.

The Court of Appeals for the Federal Circuit has recognized that the filing of an ANDA is an "artificial act" of infringement that gives rise to limited consequences. Glaxo, 376 F.3d at 1351 (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990)) (quotations omitted). In Glaxo, the Federal Circuit specifically held 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)." Id. at 1350-1351. In reaching this conclusion, the court harkened back to its decision in Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1346 (Fed. Cir. 2000). In Yamanouchi, the Federal Circuit recognized that a baseless ANDA filing could support a finding of exceptional case, but the Federal Circuit declined to conclude that such conduct rose to the level of willful infringement. Indeed, the Federal Circuit cautioned trial courts against elevating ANDA certifications into findings of willful infringement, and the Federal Circuit continued that line of reasoning in Glaxo. Since that time, trial courts have heeded the Federal Circuit's warning and dismissed claims of willful infringement based on allegations of baseless ANDA filings. See e.g., Aventis Pharma Deutschland GmbH v. Lupin Ltd., 409 F. Supp.

2d 722, 729 (E.D. Va. 2006); Celgene Corp. v. Teva Pharms. USA, Inc., 412 F. Supp. 2d 439, 445 (D.N.J. 2006); Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc., 355 F. Supp. 2d 586, 590-592 (D. Mass. 2005). At least one court has further concluded in light of Glaxo and Yamanouchi, that allegations of deliberate copying in combination with the alleged filing of a baseless ANDA cannot support a claim of willful infringement. Wyeth v. Ranbaxy Labs., Ltd., 448 F. Supp. 2d 607, 612 (D.N.J. 2006).

In this case, the Court has precisely that which the Court in Wyeth addressed - allegations of a baseless ANDA filing along with allegations of deliberate copying. Plaintiffs have not alleged any commercial activity on the part of Defendants, and the Court concludes that Plaintiffs have not alleged any other conduct sufficient to take this case outside of the rationale espoused by the Federal Circuit in Glaxo and Yamanouchi insofar as willful infringement is concerned. Plaintiffs remaining allegations concerning Defendants' litigation conduct go to the issue of exceptional case, and Glaxo does not foreclose a court from concluding that such circumstances amount to an exceptional case. However, any findings and/or conclusions the Court may make with respect to the issue of exceptional case cannot rest on willful infringement. Accordingly, the Court concludes that Plaintiffs cannot, as a matter of law, maintain a claim for

willful infringement under the circumstances of this case, and therefore, the Court concludes that Defendants are entitled to summary judgment on Plaintiffs' claim of willful infringement.¹

B. Exceptional Case

Plaintiffs also advance a claim for attorneys' fees under 35 U.S.C. § 285 on the basis that this is an exceptional case. To make this determination, the Court must consider (1) whether Plaintiffs have presented clear and convincing evidence that this case is exceptional; and (2) whether an award of attorneys' fees to the prevailing party is appropriate. Exceptional cases include cases involving "[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).

The filing of a baseless ANDA application together with allegations of litigation misconduct can support an "exceptional

¹ The Court recognizes that it reaches this conclusion without the benefit of a full Answering Brief from Plaintiffs on this issue as contemplated by the Court's January 12, 2007 Order, indicating that if summary judgment is appropriate full briefing will be permitted. However, the Court is persuaded that Plaintiffs' Counter-Statement sufficiently addresses the question of willful infringement to lead the Court to conclude that no genuine issues of material fact exist on this issue, and therefore, judgment as a matter of law in favor of Defendants on Plaintiffs' claim of willful infringement is appropriate.

case" determination, even though such allegations are insufficient to establish willful infringement. The Court understands that discovery related to the exceptional case determination is on-going. In the circumstances of this case, the Court will allow summary judgment applications to be filed on the issue of exceptional case following the close of discovery. Accordingly, at this juncture, the Court will cancel the proceedings scheduled for April 13 and April 16, 2007, and allow summary judgment briefing on the question of exceptional case. Upon conclusion of the briefing, the Court will expeditiously schedule a proceeding for the presentation of relevant evidence, if needed.

IV. CONCLUSION

For the reasons discussed, Defendants' Motion For Summary Judgment Of No Willful Infringement And For Summary Disposition Of Exceptional Case Issue will be granted on the issue of willful infringement and reserved on the question of whether summary disposition of the exceptional case issue is warranted.

An appropriate Order will be entered.

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O R D E R

At Wilmington, this 15 day of March 2007, for the reasons set forth in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1. Defendants' Motion For Summary Judgment Of No Willful Infringement And For Summary Disposition Of Exceptional Case Issue (D.I. 646) is GRANTED as to the issue of willful infringement and RESERVED as to whether summary disposition of the exceptional case issue is appropriate.

2. Judgement will be entered in favor of Defendants and against Plaintiffs on Plaintiffs' claim of willful infringement upon resolution of the exceptional case issue.

3. Concurrent applications for summary judgment along with opening briefs, if any, shall be filed **no later than March 30, 2007**. Further briefing on any applications shall proceed in accordance with D. Del. L.R. 7.1.2.

4. The Pretrial Conference scheduled for April 13, 2007, and the Trial scheduled to commence on April 16, 2007 are **CANCELLED**.


UNITED STATES DISTRICT JUDGE