***NOT FOR PUBLICATION**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, et al.,	Civil Action No. 04-4030 (FLW)
Plaintiffs,	Civil Action No. 06-6154 (FLW)
v.	**OPINION**
TEVA PHARMACEUTICALS USA, INC.	
Defendant.	

WOLFSON, United States District Judge:

In this Hatch-Waxman Act patent infringement case, Defendant Teva Pharmaceuticals USA, Inc. ("Defendant" or "Teva") moves pursuant to Fed. R. Civ. P. 12(c) for judgment on the pleadings with respect to paragraph 24 of the Complaint by Plaintiffs, Celgene Corporation, Novartis Pharmaceuticals Corporation, and Novartis Pharma AG (collectively, "Plaintiffs"), alleging willful infringement.[1] Plaintiffs contend that Defendant's infringement of Plaintiffs' patent-in-suit has been, and continues to be, willful and deliberate, and goes beyond the mere filing of its abbreviated New Drug Application ("ANDA"), which it claims was so baseless so as to be filed in bad faith. The Court has considered the parties' moving, opposition, and reply papers. For the reasons that follow, the Court grants Teva's Motion for Judgment on the Pleadings regarding Plaintiffs' claim of willful infringement.

[1]This is a consolidated action involving two lawsuits, Celgene Corp., et al. v. Teva Pharmaceuticals USA, Inc., Civil Action No. 04-4030, and Celgene Corp., et al. v. Teva Pharmaceuticals USA, Inc., Civil Action No. 06-6154. In this motion, Teva seeks to strike paragraph 24 from Plaintiffs' Complaint in the second action. See Part I.B., infra.

I. Factual Background and Procedural History

A. The Hatch-Waxman Act

Plaintiffs filed suit under the Drug Price and Patent Term Restoration Act of 1984, more commonly referred to as the Hatch-Waxman Act, 35 U.S.C. § 271, which modified the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 ("FDCA"). The Hatch-Waxman Act was aimed at streamlining the approval process for generic pharmaceuticals. 35 U.S.C. § 271(e)(2). A company seeking to market a new brand-name drug must submit a New Drug Application ("NDA"), which is generally a lengthy application that includes information about the drug such as evidence of its safety and effectiveness, and information about the patents that cover or might cover it. 35 U.S.C. § 355(b)(1). The Hatch-Waxman Act permits a manufacturer seeking to market a generic equivalent of a previously approved Food and Drug Administration ("FDA") drug to file an ANDA with the FDA to obtain approval for its generic drug, which essentially "piggyback[s] on the safety-and-effectiveness information that the brand-name manufacturers submitted in their NDAs." Celgene Corp. v. Teva Pharms. USA, Inc., 412 F. Supp. 2d 439, 441 (D.N.J. 2006) (internal citations omitted).

As part of the application process, an ANDA applicant must provide a certification as to each patent covering the previously-approved drug. 21 U.S.C. § 355(j)(2)(A)(vii). An applicant files a "Paragraph IV Certification," named after its statutory sub-paragraph, if the applicant believes "to the best of his knowledge . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug from which the application is submitted[.]" 21 U.S.C. § 355(j)(2)(A)(vii)(IV). An

applicant that includes a Paragraph IV Certification must give notice to "each owner of the patent that is the subject of the certification . . . and . . . the holder of the approved [NDA]." 21 U.S.C. § 355(j)(2)(B)(iii). Upon receiving notice, a patent-holder has a forty-five-day period in which to bring an action for patent infringement. See Id. If a patent-holder does file a lawsuit, then the FDA will not approve the ANDA until the court rules that the patent is not infringed or until thirty months have passed, beginning on the date the patent-holder received notice of the ANDA, whichever occurs first. See Id.

A patent infringement claim is generally made against "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor[.]" 35 U.S.C. § 271(a). The Hatch-Waxman Act limits the potential patent liability for companies that seek FDA approval to market a generic version of the brand-name drug. See 35 U.S.C. §271(e)(1). Because a generic-drug manufacturer has not yet placed the drug into the market when it files an ANDA application, a patent-holder cannot make a claim for patent infringement under § 271(a). However, Section 271(e)(2)(A) "provides a jurisdictional basis for an infringement action against the applicant where it seeks approval to market a patented product before the expiration of the patent." Janssen, L.P. v. Barr Laboratories, Inc., No. 07-1515, 2008 U.S. Dist. LEXIS 7965, at *5 (D.N.J. Feb. 4, 2008); see also Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). Thereby, with this provision, Congress created an "highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the

new drug (none of which, of course, has actually occurred) violates the relevant patent." Janssen, 2008 U.S. Dist. LEXIS 7965 at *5 (quoting Eli Lilly, 496 U.S. at 678). Congress has extended the Court's jurisdiction over a hypothetical issue: whether the defendant's proposed generic drug would infringe on plaintiff's patent if the defendant's drug was on the market. See Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1366 (Fed. Cir. 2003).

B. Plaintiffs' Allegations

Plaintiffs allege that Defendants have infringed on two of their patents, specifically U.S. Patent Nos. 5,908,850 ("the '850 patent") and 6,355,656 (as reexamined) ("the '656 patent") (collectively, "patents-in-suit"), listed in the FDA's Orange Book in conjunction with FOCALIN® IR ("FOCALIN IR"), a product marketed by Novartis that is widely used in the treatment of Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder. On January 18, 2007, the Court consolidated the two actions brought by Plaintiffs involving Defendant's generic dexmethylphenidate immediate release drug product. In the first action, Civil Action No. 04-4030, Plaintiffs alleged that Defendant willfully infringed the '850 Patent, and Teva moved for judgment on the pleadings to strike that allegation because Plaintiffs' claim of willful infringement was based solely on Defendant's filing of its ANDA; the Court granted Defendant's motion. See Celgene Corp. v. Teva Pharms. USA, Inc., 412 F. Supp. 2d at 445 (the Honorable Stanley R. Chesler[2] held that the mere filing of an ANDA or Paragraph IV Certification cannot support a finding of willful infringement). Ten months after the

[2]The case was reassigned from Judge Stanley R. Chesler to Judge Freda L. Wolfson on July 10, 2006.

Court's order, Plaintiffs filed another lawsuit against Teva, Civil Action No. 06-6154, alleging that Teva had infringed on the '656 Patent, and again included a willful infringement claim as follows:

> Teva had notice of the '656 patent prior to undertaking its acts of infringement, and had notice of the reexamination proceedings and the [Patent and Trademark Office ("PTO")]'s Notice of Intent to Issue while continuing its act of infringement. Teva's Notice Letters fail to identify any prior art other than that considered by the PTO examiner at the time the PTO originally allowed the claims, and has since failed to identify any art or information other than the art considered by the PTO reexamination at the time the PTO issued its Notice of Intent to Issue. Teva otherwise had, and continues to have, no good faith belief in the invalidity of the '656 patent. Moreover, Teva has continued to pursue approval of its ANDA for marketing prior to expiration of the '656 patent even after having notice of the successful reexamination of that patent. Therefore, Teva's acts of infringement have been and continue to be willful and deliberate.

Compl. ¶ 24.

Teva asserts that Plaintiffs' claim of willful infringement is based solely on Teva's filing of an ANDA, and its accompanying Paragraph IV Certification,[3] and that this artificial act of infringement cannot constitute a claim for willful infringement. In response, Plaintiffs argue that they have sufficiently pled willfulness in this case because they have pled additional supporting evidence beyond the ANDA filing and allegedly baseless Paragraph IV Certification.

II. Discussion

A. Standard of Review

The standard that a court applies on a motion for judgment on the pleadings

[3]Teva notes that when Plaintiffs assert facts concerning Teva's alleged "baseless ANDA filing," Plaintiffs are referring only to Teva's Paragraph IV Certification.

pursuant to Rule 12(c) is the same standard that a court applies in deciding a motion to dismiss pursuant to Rule 12(b)(6). Turbe v. Government of Virgin Islands, 938 F.2d 427 (3d Cir. 1991); see also Spruill v. Gillis, 372 F.3d 218, 223 n. 2 (3d Cir. 2004). When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (internal citation and quotations omitted). In Bell Atlantic Corp. v. Twombly, 127 S.Ct. 1955 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Twombly, 127 S.Ct. at 1968 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 1965.

The Third Circuit has summed up the Supreme Court's Twombly formulation of the pleading standard as: "'stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." Phillips, 515 F.3d at 234 (quoting Twombly, 127 S.Ct. at 1965). The Court will grant a motion under Rule 12(c) if "it appears beyond doubt that no relief could be granted under any set of facts which could be proved consistent with the allegations[.]"

Celgene, 412 F. Supp. 2d at 443. "Therefore, the narrow issue before the Court is whether or not Defendant[s] could be found to have engaged in an act of willful infringement" in this case. Janssen, 2008 U.S. Dist. LEXIS 7965 at *9.

B. Willful Infringement

The Federal Circuit, in Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1349 (Fed. Cir. 2004), and this Court, in Celgene v. Teva Pharms. USA, Inc., 2008 WL 4858263, at *4 (D.N.J. Nov 10, 2008), found that an ANDA filing, without more, cannot support a claim for willful infringement. See also Janssen, 2008 U.S. Dist. LEXIS 7965 at *12. The Federal Circuit has cautioned that a "trial court need not . . . elevate[] the ANDA certification into a finding of willful infringement." Yamanouchi Pharm. Co., LTD v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000). Plaintiffs argue that they have pled additional facts that go beyond the mere act of "technical infringement," such as a mere filing of an ANDA, and thus their claim should be sustained. The Court disagrees.

Plaintiffs acknowledge that in Judge Chesler's earlier opinion in this case relating to Plaintiffs' allegations of willful infringement relating to the '850 Patent, Judge Chesler found that the "technical act of infringement," the mere filing of an ANDA or allegedly baseless Paragraph IV Certification, cannot constitute a claim for willful infringement. Nonetheless, Plaintiffs assert that they have pled additional facts beyond a mere ANDA filing to show that the ANDA or Paragraph IV Certification was filed in bad faith, and thus they may proceed on allegations of willful infringement. Plaintiffs contend that their '656 Patent was successfully reexamined, during which the "Patent Office addressed and rejected the very same prior art and invalidity arguments upon

which Teva now relies in this case. Teva has admitted that its generic product infringes the '656 Patent, and Teva's invalidity defenses have already been considered and rejected by the Patent Office." Pl. Opp. at 2 (emphasis in original). Plaintiffs argue that Teva's § 355 Statement in support of its Paragraph IV Certification "relied on prior art that was fully considered by the Patent Office – not once, but twice – and completely fails to explain why the Patent's Office's patentability determinations were allegedly erroneous." Pl. Opp. at 4. Thus, Plaintiffs allege that Teva willfully infringed on its '656 Patent because "Teva's Notice Letters fail to identify any prior art other than that considered . . . by the PTO reexamination at the time the PTO issued its Notice of Intent to Issue" and Teva "had, and continues to have, no good faith belief in the invalidity of the '656 patent," yet Teva continued to pursue approval of its ANDA "even after having notice of the successful reexamination of that patent." Compl. ¶ 24.

Plaintiffs maintain that these factual allegations serve as additional supporting evidence that the ANDA was filed without any basis and they cite to Glaxo, Yamanouchi, and cases in this District, to urge the Court to find that a claim for willfulness may be made when a Paragraph IV Certification of invalidity is so baseless that it was filed in bad faith. Plaintiffs made a similar argument in their motion to Judge Chesler: "[P]laintiffs argue[d] Teva obtained the idea for the accused product in violation of a confidential disclosure agreement, its Paragraph IV Certification is baseless, and it had not come forward with any better prior art." Celgene, 412 F. Supp. 2d at 443 (emphasis added). Judge Chesler rejected Plaintiffs' argument and Teva contends that the law is clear that this type of allegation – an allegedly baseless ANDA filing – is legally insufficient to state a claim of willful infringement.

Judge Chesler held that there can be no "willful infringement" in cases where the allegedly infringing conduct is limited to the highly technical act of infringement, such as filing of an ANDA or Paragraph IV Certification, sufficient to confer jurisdiction under the Hatch-Waxman Act. Celgene, 412 F. Supp. 2d at 445. In applying the Federal Circuit's decision in Glaxo, Judge Chesler found that filing of even an allegedly baseless ANDA or Paragraph IV Certification does not rise to the level of a literal act of patent infringement that could give rise to a finding of willful infringement. See Id. (citing Glaxo, 376 F.3d at 1351, and Aventis Pharma Deutschland GMBH v. Lupin Ltd., 409 F.Supp.2d 722, 729- 30, 2006 WL 141670, at *7 (E.D.Va.2006) ("[T]he fact that the appellate court in Glaxo emphasizes that the purpose of the ANDA process is to create an 'artificial' act of infringement for jurisdictional purposes strongly supports this Court's conclusion that even a baseless ANDA filing may never constitute willful infringement.")).

Defendant asserts, and the Court agrees, that Plaintiffs' "additional supporting evidence" amounts to no more than that Teva filed a baseless ANDA. Plaintiffs' allegations that Teva had notice of the reexamination of the '656 Patent and that Teva does not rely on any prior art that was not before the Patent Office during the reexamination do nothing more than go to the alleged baselessness of Teva's ANDA filing. Further, Plaintiffs' argument that Teva's Notice Letter, detailing why Teva's ANDA does not infringe Plaintiffs' patents, serves as additional evidence of willful infringement also fails. The Hatch-Waxman Act requires that Teva provide Plaintiffs with a Notice Letter, or a Paragraph IV Certification, as part of the application process. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Thus, the content therein only relates to the merit of

Teva's ANDA filing, i.e., whether or not Teva's ANDA was baseless.[4] As previously discussed, the mere filing of an allegedly baseless ANDA or Paragraph IV Certification is insufficient to sustain a willful infringement claim. See Celgene, 412 F. Supp. 2d at 445. Such allegations, however, may be evidence toward finding an "exceptional case" for purposes of awarding attorneys fees.

Consistent with this Court's earlier rulings, this holding does not prohibit Plaintiffs from seeking an "award [of] attorney's fees under section 285" if they later successfully argue that the instant case is "exceptional." 35 U.S.C. §§ 271(e)(4), 285; Celgene, 2008 WL 4858263 at *5; Celgene, 412 F. Supp. 2d at 445. In Glaxo, the Federal Circuit discussed its previous holding in Yamanouchi, and determined "that a baseless and 'wholly unjustified' Paragraph IV Certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding" for purposes of only awarding attorneys fees. Glaxo, 376 F.3d at 1350 (discussing Yamanouchi, 231 F.3d 1339 at 1346). In Yamanouchi, "the Court did not agree that the generic company['s ANDA filing constituted] willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed

[4]In their Opposition, Plaintiffs also argue that Defendant's actions go beyond the mere ANDA filing or Paragraph IV Certification because Defendant, inter alia, has shifted to an inequitable conduct claim and planned its generic launch before the date of the earliest entry listed in Defendant's private log. Regardless of the accuracy of these allegations, no post-filing conduct (i.e. allegations relating to Teva's launch) are pled in Plaintiffs' Complaint and therefore are not before the Court on this motion. See Mele v. FRB, 359 F.3d 251, 257 (3d Cir. 2004) ("In deciding a Rule 12(c) motion, the court does not consider matters outside the pleadings."). In addition, Plaintiffs dispute Defendant's reliance on In re Seagate, 497 F.3d 1360 (Fed. Cir. 2007) (discussing preliminary injunctive relief for a charge of willfulness based on post-filing conduct). But since Teva's post-filing conduct is not at issue on this motion, Defendant agrees that Seagate's application is moot.

numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification. Such unjustified litigation and misconduct has always justified a finding of an exceptional case." Glaxo, 376 F.3d at 1350. If Plaintiffs ultimately prevail in this litigation, it is at that point that a determination can be made whether this case is "exceptional" for purposes of seeking attorney's fees pursuant to 35 U.S.C. § 285; but such a claim is premature at this time. See Janssen, 2008 U.S. Dist. LEXIS 7965 at *14.

III. Conclusion

For the foregoing reasons, the Court grants Defendant's Motion for Judgment on the Pleadings regarding Plaintiffs' claim of willful infringement.

Dated January 12, 2009

/s/ Freda L. Wolfson
Honorable Freda L. Wolfson
United States District Judge