IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CIMA LABS, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. No. 11-821-SLR
	)	
SANDOZ, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 1st day of March, 2012, having reviewed defendant's motion to dismiss and the papers filed in connection therewith;

IT IS ORDERED that said motion (D.I. 9) is denied, for the reasons that follow:

1. **Background.** Plaintiff Cephalon, Inc. ("Cephalon") is the holder of approved New Drug Application ("NDA") No. 21-947 for FENTORA®-brand fentanyl citrate buccal tablets. (D.I. 1 ¶ 20) In conjunction with the approval of its NDA, Cephalon listed U. S. Patent Nos. 6,200,604 ("the '604 patent") and 6,974,590 ("the '590 patent") in the publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book")[1] for FENTORA®.

2. In January 2010, Cephalon received a letter from defendant Sandoz, Inc. ("Sandoz"), notifying Cephalon that Sandoz had filed Abbreviated New Drug Application ("ANDA") No. 200676 with a Paragraph IV certification alleging that the '604 and '590

[1]The Orange Book must list "each drug which has been approved for safety and effectiveness through an NDA." *See* 21 U.S.C. §§ 355(j)(A)(ii).

patents are invalid and/or will not be infringed by Sandoz's generic version of FENTORA®. On February 16, 2010, Cephalon filed suit in this court alleging that Sandoz infringes the '604 and '590 patents. *Cephalon, Inc. v. Sandoz, Inc.*, Civ. No. 10-123-SLR ("*Sandoz I*").

3. *Sandoz I* was scheduled to commence trial on June 6, 2011. On May 5, 2011, the court granted Cephalon's motion to stay *Sandoz I* pending the appeal of *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, Civ. No. 08-330-SLR, another lawsuit in which Cephalon alleged infringement of the '604 and '590 patents by generic versions of FENTORA®. *See Sandoz I*, 2011 WL 1750446 (D. Del. May 5, 2011).

4. United States Patent Nos. 7,862,832 ("the '832 patent") and 7,862,833 ("the '833 patent") issued on January 4, 2011, a year after Sandoz filed its ANDA, and were listed by Cephalon on April 25, 2011 in the Orange Book as patents covering FENTORA®. Pursuant to 21 C.F.R. § 314.94(a)(12)(vi)(1995),

> [i]f a patent on the listed drug is issued and the holder of the approved application for the listed drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted an abbreviated new drug application for that drug that contained an appropriate patent certification before the submission of the patent information is not required to submit an amended certification.

Sandoz, therefore, was not required to filed an amended Paragraph IV certification as to the '832 and 833 patents.

5. On June 3, 2011, Cephalon advised Sandoz of its intent to assert the '832 and '833 patents and asked if Sandoz would stipulate to amend the pleadings in *Sandoz I* to add these patents. (D.I. 21, ex. 1) By email dated August 11, 2011, Sandoz declined to so stipulate. (*Id.*, ex. 3) On September 15, 2011, Cephalon filed its

complaint against Sandoz in the instant litigation, alleging that Sandoz infringes the '832 and '833 patents.

6. Sandoz has filed a motion to dismiss on jurisdictional grounds, as well as for failure to state a claim. With respect to jurisdiction, Sandoz argues that "a district court does not have subject matter jurisdiction over an infringement action against an ANDA application under 35 U.S.C. § 271(e)(2) where, as here, the two asserted patents were late-listed in the FDA's Orange Book and the defendant's ANDA does not contain a Paragraph IV certification with respect to those late-listed patents." (D.I. 10 at 1) Sandoz grounds this argument on the proposition that "the artificial act of infringement under § 271(e)(2) consists of filing an ANDA with a Paragraph IV certification;" therefore, "[t]o establish this 'artificial act of infringement' under § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question." (*Id.* at 5) Sandoz asserts in this regard that jurisdiction under the Declaratory Judgment Act is not available under the circumstances at bar. Finally, Sandoz contends that Cephalon cannot state a cause of action for infringement before Sandoz brings its generic to market, in the absence of a Paragraph IV certification. (*Id.* at 10)

7. Cephalon responds that the court has jurisdiction over the dispute at bar pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201(a), regardless of whether § 271(e)(2) is applicable to the facts of record. According to Cephalon, "[t]he Declaratory Judgment Act authorizes any United States court, upon a showing of actual controversy within its jurisdiction, to declare the rights and other legal relations of any interested party seeking such declaration." (D.I. 20 at 5) (citing 28 U.S.C. § 2201(a)) An actual

controversy exists where the dispute is "'definite and concrete, touching the legal relations of parties having adverse legal interests;'" the dispute must be "'real and substantial . . . admit[ting] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" (D.I. 20 at 5) (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)) The facts at bar, which present an actual controversy between the parties, satisfy the pleading requirement of Fed. R. Civ. P. 12(b)(6). (*Id.* at 15)

8. **Standards of review.** Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. *See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir. 2000). Under Rule 12(b)(1), the court's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *See* 2 James W. Moore, Moore's Federal Practice § 12.30[4] (3d ed. 1997). Under a facial challenge to jurisdiction, the court must accept as true the allegations contained in the complaint. *See id.* Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or . . . is wholly insubstantial and frivolous.'" *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-09 (3d Cir. 1991) (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)). Under a factual attack, however, the court is not "confine[d] to allegations in the . . . complaint, but [can] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997); *see also Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891-92 (3d Cir. 1977). In such a situation, "no presumptive truthfulness attaches to plaintiff's

allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group*, 227 F.3d at 69 (quoting *Mortensen*, 549 F.2d at 891). Although the court should determine subject matter jurisdiction at the outset of a case, "the truth of jurisdictional allegations need not always be determined with finality at the threshold of litigation." 2 Moore § 12.30[1]. Rather, a party may first establish jurisdiction "by means of a nonfrivolous assertion of jurisdictional elements and any litigation of a contested subject-matter jurisdictional fact issue occurs in comparatively summary procedure before a judge alone (as distinct from litigation of the same fact issue as an element of the cause of action, if the claim survives the jurisdictional objection)." *Jerome B. Grubart, Inc. v. Great Lakes Dredge & Dock Co.*, 513 U.S. 527, 537-38 (1995) (citations omitted).

9. In reviewing a motion filed under Federal Rule of Civil Procedure 12(b)(6), the court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). A court may consider the pleadings, public record, orders, exhibits attached to the complaint, and documents incorporated into the complaint by reference. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384-85 n.2 (3d Cir. 1994). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007) (interpreting Fed.R.Civ.P. 8(a)) (internal quotations omitted). A complaint does not need detailed factual allegations; however, "a plaintiff's obligation to

provide the 'grounds' of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 545 (alteration in original) (citation omitted). The "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Id.* Furthermore, "[w]hen there are well-ple[d] factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1950 (2009). Such a determination is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Id.*

10. **Discussion.** Sandoz argues that the administrative paradigm created under the auspices of the Hatch-Waxman Act provides the exclusive means to resolve this dispute prior to market entry of the generic drug. Without reciting the full history and structure of the Hatch-Waxman Act, suffice it to say that the Act "created 'an important new mechanism designed to guard against infringement of patents relating to pioneer drugs.'" *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1136 (Fed. Cir. 1995) (citation omitted). In this regard, the generic manufacturers were given a safe harbor in which to develop their products without threat of patent litigation. *See* 35 U.S.C. § 271(e)(1).[2] To balance that freedom to operate, Congress deemed the filing of

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[2]35 U.S.C. § 271(e)(1) provides in relevant part as follows:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .

an ANDA "a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). *See* 35 U.S.C. § 271(e)(2).[3]

11. This statutory construct is implemented through a complex administrative process that has been explained in great detail in many opinions. *See, e.g., Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 675-78 (1990). In general, a pioneer drug manufacturer has the obligation to list those patents covering the pioneer drug in the Orange Book (21 U.S.C. §§ 355(b)(1)), and the generic drug manufacturer has the reciprocal obligation to give notice through a certification process as to which patents listed in the Orange Book, if any, are implicated in its ANDA (21 U.S.C. §§ 355(b)(2)(A), 355(j)(2)(A)(vii)). If a generic drug manufacturer certifies that a patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (a Paragraph IV certification), *id.*, the holder of the patent has 45 days in which to file suit to resolve the issues of infringement and/or invalidity. If suit is filed, the FDA may not approve the ANDA until expiration of the patent, resolution of

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[3]35 U.S.C. § 271(e)(2) provides in relevant part as follows:

> It shall be an act of infringement to submit -
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> (A) 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 the use of which is claimed in a patent before the expiration of such patent.

the lawsuit, or 30 months after the patentee's receipt of the notice, whichever is earlier.

12. In sum, § 271(e)(2) creates an "artificial" act of infringement for the "very limited and technical purpose" of permitting "patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004) (citing *Eli Lilly*, 496 U.S. at 676). To put the point another way, § 271(e)(2) "makes it possible for the district court to exercise its § 1338(a) jurisdiction[4] in the situation in which an ANDA has been filed." *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003).

13. **Jurisdiction.** As noted above, the '832 and '833 patents issued after Sandoz filed its ANDA and, because Cephalon failed to timely list the '832 and '833 patents in the Orange Book,[5] Sandoz was not required to amend its Paragraph IV certification. Sandoz, relying primarily on the opinion issued in *Eisai Co. v. Mutual Pharm. Co.*, Civ. No. 06-3613, 2007 WL 4556958 (D.N.J. Dec. 20, 2007) ("*Eisai*"), argues that the court's authority to exert subject matter jurisdiction over the instant dispute is narrowly limited by the administrative paradigm described above – put more simply, no Paragraph IV certification, no jurisdiction.

14. In coming to a contrary conclusion, I read the analysis in *Eisai* as follows. The court in *Eisai* first recognized that the statute, § 271(e)(2), does not specifically tie its jurisdictional trigger to a Paragraph IV certification. *Id.* at *9. The court nevertheless

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[4]28 U.S.C. § 1338(a) provides that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents. . . ."

[5]Missing the administrative deadline by 81 days.

concluded that the extended discussions of Paragraph IV certification in such cases as *Eli Lilly*, 496 U.S. at 676-77, and *Bristol-Myers Squibb,* 69 F.3d at 1131,[6] should be interpreted to mean, **as a matter of law**, that the patentee could not maintain an infringement action pursuant to 35 U.S.C. § 271(e)(2) "where the allegedly infringed patent was not listed in the Orange Book for the drug at issue and the ANDA contained no Paragraph IV certification against the patent." *Eisai*, 2007 WL 4556958 at *14. Against this broad conclusion are two important findings by the court: (1) "the Paragraph IV certification serves to protect the patent holder in that it enables notice of potential infringement," *id.* at *13; and (2) Eisai, the patentee, should "blame itself for its predicament" "by its repeated oversights in filing the wrong forms and wrong information with the FDA," *id.* at *14. What I take from these findings is that, despite the fact that the Paragraph IV certification was meant to protect the patent holder, in *Eisai*, the patent holder's conduct was so egregious that its ability "to take advantage of § 271(e)(2)" was forfeited.[7] The court in *Eisai* went on to hold that the patentee could not maintain an infringement action pursuant to the Declaratory Judgment Act because "§ 271(e)(2) provides the jurisdictional peg for infringement actions brought prior to ANDA approval and, in the absence of this jurisdictional hook, jurisdiction is lacking." *Id.* at

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[6]As a point of interest, I note that these cases were decided soon (taking into account how slowly the judicial review process works) after passage of the Hatch-Waxman Act in 1984. The fact that the complicated new scheme was described in great detail, perhaps, was more to inform than to narrowly circumscribe the scope of jurisdiction.

[7]This, despite the fact that the generic had filed Paragraph IV certifications against four other patents which also were not listed in the Orange Book. *Eisai*, 2007 WL 4556958 at *14.

*20.

15. While I take no position vis a vis the *Eisai* court's holding that the patent holder there should have been limited in its ability to resolve its infringement disputes with the generic manufacturer before the generic drug came to market, I respectfully disagree with the sweeping conclusion that the absence of a Paragraph IV certification limits, as a matter of law, the court's subject matter jurisdiction under both 35 U.S.C. § 271(e)(2) and 28 U.S.C. § 2201. With respect to § 271(e)(2), the sole purpose of the Paragraph IV certification in the artificial world of the Hatch-Waxman Act is to provide notice of what patents may be implicated by the ANDA, in order to trigger suit. In reality, however, "the inquiry truly begins because the ANDA filer seeks approval to market a patented drug prior to the expiration of the relevant patent." *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp.2d 572, 582 (D.N.J. 2001).

16. Where, as here, the jurisdictional trigger was properly pulled by the filing of an ANDA and the initial Paragraph IV certification by Sandoz, the court's jurisdiction should not be confined simply because Sandoz was not required to filed an amended Paragraph IV certification. Clearly, Sandoz was put on notice of the '832 and '833 patents. It would be ironic, indeed, if the absence of an amended Paragraph IV certification[8] precluded suit, when the certification provisions exist for the benefit of the patentee.[9] I decline to elevate form over substance where the purpose of the

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[8]I note in this regard that, as far as I can discern, Sandoz could have filed an amended Paragraph IV certification to reflect the '832 and '833 patents, but was not required to under 21 C.F.R. § 314.94(a)(12)(vi)(1995).

[9]As we learned from *Eisai*, a Paragraph IV certification is not limited to those patents listed in the Orange Book. Although patentees certainly have the obligation to

administrative process has been served and conclude that jurisdiction under § 271(e)(2) has been established.

17. Even if I were to conclude otherwise, I do not understand the administrative paradigm of the Hatch-Waxman Act to preclude a patent holder from establishing jurisdiction under 28 U.S.C. § 2201(a). "A patentee may seek a declaration that a person will infringe a patent in the future." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d at 1570. Consequently, so long as there is an actual controversy, that is, there is "a sufficient allegation of immediacy and reality," "the exercise of jurisdiction over such an action is within the discretion of the district court." *Id.* According to the Federal Circuit,

> when a patentee seeks a declaratory judgment against an alleged infringer, the patentee must demonstrate that two elements are present: (1) the defendant must be engaged in an activity directed toward . . . an infringement charge . . . or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming.

Id. at 1571. There can be no dispute that Sandoz is "systematically attempting to meet the applicable regulatory requirements while preparing to [manufacture] its product." *Id.* Importantly, the "protected status" of Sandoz's activities leading to the submission of its ANDA to the FDA "does not by itself prevent the district court from considering [a] request for declaratory relief because such relief is directed to the time after the ANDA

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list their patents in the Orange Book, it would be contrary to the underlying purpose of the statutory scheme to allow the ANDA filers to control the fact and scope of litigation by the fact and scope of their Paragraph IV certifications. *See, e.g., Novo Nordisk Inc. V. Mylan Pharm. Inc.*, Civ. No. 09-2445, 2010 WL 1372437 at *11 (D.N.J. 2010) (noting that "[i]t is possible that [an infringement] inquiry could begin even if the ANDA included no Paragraph IV certification at all, so long as a Paragraph IV certification should have been included.").

is approved, when § 271(e)(1) no longer provides a shelter against infringement liability." *Id.*

18. **Conclusion.** The underlying purposes of the Hatch-Waxman Act have been satisfied by the administrative process undertaken by the parties to date. Sandoz was given the freedom to develop its generic version of FENTORA®, pursuant to 35 U.S.C. § 271(e)(1). Sandoz left the safe harbor of § 271(e)(1) when it filed its ANDA and Paragraph IV certification as to the '604 and '590 patents. The parties have engaged in litigation, pursuant to 35 U.S.C. § 271(e)(2), to resolve the infringement and invalidity issues raised by Sandoz in connection with the '604 and '590 patents. Both parties are on actual notice of the potential entry of another generic and of the potential obstacle to that entry by the "832 and '833 patents. Given that the artificial infringement paradigm of the Hatch-Waxman Act was designed to protect the patent holder by promoting the judicial resolution of infringement actions before generic products come to market, I decline to hold that the administrative misstep on the part of Cephalon serves, as matter of law, to forfeit that protection. Indeed, if I were to dismiss this case for lack of subject matter jurisdiction, Sandoz would be given an advantage not contemplated under the careful balancing act of the statutory scheme, to wit, the ability to market its generic as soon as its ANDA is approved by the FDA without responsibly resolving all the patent issues related to said product.

19. For the reasons stated above, I conclude that the court has jurisdiction over

the above captioned litigation pursuant to 35 U.S.C. § 271(e)(2) and/or 28 U.S.C. § 1338(a). The motion to dismiss filed by Sandoz is denied.[10]

United States District Judge

[10]Because Sandoz bases its argument for dismissal pursuant to Fed. R. Civ. P. 12(b)(6) on the same reasoning rejected above for lack of jurisdiction, to wit, the complaint fails to state a cause of action for infringement because Sandoz's ANDA does not contain a Paragraph 4 certification with respect to the '832 and '833 patents, its motion to dismiss on this ground likewise is denied.