IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CIMA LABS, INC., Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. 11-0821-SLR

DEFENDANT SANDOZ INC.'S OPENING BRIEF
IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT

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I. NATURE AND STAGE OF PROCEEDINGS/SUMMARY OF ARGUMENT

The law is clear that a district court does not have subject matter jurisdiction for an infringement action against an ANDA applicant under 35 U.S.C. § 271(e)(2) where, as here, the two asserted patents were late-listed in the FDA's Orange Book[1] and the defendant's ANDA does not contain a Paragraph IV certification with respect to those late-listed patents. 35 U.S.C. § 271(e)(2) only provides a cause of action for patent infringement against an ANDA applicant where the ANDA is directed to a drug (or use of a drug) claimed in an Orange Book-listed patent and includes a Paragraph IV certification with respect to that same Orange Book-listed patent. Those facts are absent here.

On September 15, 2011, Plaintiffs Cephalon, Inc. and CIMA Labs, Inc. ("Plaintiffs") filed a new complaint ("Complaint") alleging that Defendant Sandoz Inc. ("Sandoz") infringed two late-listed U.S. patents. The Complaint contains two counts (Counts I and III) for patent infringement under 35 U.S.C. § 271(e)(2) and two counts (Counts II and IV) for Declaratory Relief of patent infringement under 35 U.S.C. § 271(a)–(c). However, the Complaint fails to allege that Sandoz filed a Paragraph IV certification as to the two late-listed asserted patents in this case. Consequently, the Court lacks subject matter jurisdiction for the infringement counts under § 271(e)(2).

The Complaint also fails to allege that Sandoz is engaging in any acts (*e.g.,* making, using, selling, offering for sale or importing a generic drug) that constitute infringement of the asserted patents under § 271(a)–(c), or how any such acts are not subject to the safe-harbor provision of § 271(e)(1). Because Plaintiffs cannot establish jurisdiction under § 271(e)(2) with

[1] The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* publication is commonly known as the "Orange Book."

respect to the asserted patents, Plaintiffs' allegations concerning preparations and development of a generic product, filing an ANDA and engaging in litigation are exempt under the Hatch-Waxman's safe-harbor provision of § 271(e)(1). Thus, the Complaint does not present a case or actual controversy to support declaratory judgment jurisdiction. Accordingly, the Complaint should be dismissed under Federal Rules of Civil Procedure ("FRCP") 12(b)(1) for lack of subject matter jurisdiction and FRCP 12(b)(6) for failure to state a claim upon which relief can be granted.

II. STATEMENT OF FACTS

A. Sandoz Filed Its ANDA With a Paragraph IV Certification Only With Respect To The '604 and '590 Patents, Which Are Not Asserted In This Action

Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 200676 with a Paragraph IV certification only with respect to U.S. Patent Nos. 6,200,604 ("the '604 patent") and 6,974,590 ("the '590 patent"), certifying that the '604 and '590 patents are invalid and/or will not be infringed. ***When Sandoz filed ANDA 200676, the '604 and '590 patents were the only patents listed in the Orange Book for FENTORA®***, the drug at issue in this case. In response to Sandoz's ANDA filing and Paragraph IV certification, Plaintiffs filed Civil Action No.10-123-SLR-MPT, entitled *Cephalon, Inc. and Cima Labs, Inc. v. Sandoz, Inc.* (the "Existing Action"), asserting infringement of the '604 and '590 patents under § 271(e)(2).

The Existing Action was set for trial on June 6, 2011. Prior to trial, however, the Court stayed the Existing Action pending the appeal of *Cephalon, Inc. et al. v. Watson Pharms., Inc. et al.*, Civil Action No. 08-330, wherein this Court found the '604 and '590 patents invalid and not infringed. (D.I. 114, May 5, 2011 Memorandum Order Granting Motion to Stay Proceedings, ¶¶ 2, 11.) In its Order staying the Existing Action, the Court noted that "[t]he FDA has not yet

approved [Sandoz's] ANDA and, until the 30-month stay expires in July 2012, Sandoz cannot enter the marketplace." (*Id.* at ¶ 7.)

B. Cephalon Listed The '832 And '833 Patents In The Orange Book After Sandoz Filed Its ANDA And After 30-Days Of Patent Issuance

In the instant action, Plaintiffs assert infringement of U.S. Patent Nos. 7,862,832 ("the '832 patent") and 7,862,833 ("the '833 patent"). (Complaint, ¶5.) The U.S. Patent and Trademark Office issued the '832 and '833 patents in January 2011 (*id.* at ¶¶ 18, 19), after the approval of Cephalon's New Drug Application ("NDA") No. 21-947 for FENTORA® and ***after Sandoz filed its ANDA***.[2] Thus, it would have been impossible for Sandoz to include a Paragraph IV certification against the '832 and '833 patents in its originally-filed ANDA because the '832 and '833 patents issued after Sandoz filed its ANDA.

The Hatch-Waxman Act requires patent holders to submit patent information to the FDA for publication in the Orange Book within 30 days of patent issuance. 21 U.S.C. § 355(c)(2) (requiring submission of patent information "not later than thirty days after the date the patent involved is issued"). If a patent owner submits patent information for Orange Book-listing more than 30 days after patent issuance, the patent is "late-listed." The purpose of this FDA regulation is to stop the improper extension of market monopoly by the branded drug company (*i.e.*, the NDA holder) by "delaying the entry of otherwise approvable generic drugs onto the market." *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 935-36 (N.D. Ill. 1995). In *Abbott Labs.*, the court stated that the FDA passed the above-quoted regulation to address the FDA's concern that NDA holders would delay listing new patents [in the Orange Book] until within 30 months

[2] In addition to being late-listed, the '832 and '833 patents are known as "pop-up patents" because they issued *after* Sandoz filed its ANDA.

of the latest-expiring patent already listed and, thereby, potentially unfairly extend its monopoly. *Id.* (citing FDA Decision regarding Docket No. 94 P-0144/CPI at p. 10).

The Complaint states that the '832 and '833 patents both issued on January 4, 2011. (Complaint, ¶¶ 18-19). During a meet and confer prior to filing this motion, Plaintiffs' counsel admitted to Sandoz's counsel that the '832 and '833 patents were not submitted to the FDA for publication in the Orange Book ***until April 25, 2011 – nearly four months after their issuance.*** (*See* Declaration of David H. Dolkas, counsel for Sandoz, ¶ 3, which is concurrently filed herewith.) Thus, the '832 and '833 patents are late-listed.

C. No Paragraph IV Certification Is Required For Late-Listed Patents

An ANDA applicant who previously filed its ANDA with an appropriate certification *before* the patent owner's untimely submission is not required to file an amended certification to the late-listed patent:

> Late submission of patent information. If 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.***

21 C.F.R. § 314.94(a)(12)(vi) (1995) (emphasis added).

Here, Plaintiff Cephalon failed to timely list the '832 and '833 patents (hereafter, the "Late-Listed Patents") within 30 days of patent issuance. Further, the Complaint does ***not*** allege that the Late-Listed Patents were timely filed and concedes that Sandoz's Paragraph IV certification was submitted ***before*** the Late-Listed Patents even issued. (Complaint, ¶28) ("The '832 and '833 patents had not issued at the time Defendant submitted its certification under § 505(j)(2)(A)(vii)(IV) . . . ."). Accordingly, under 21 C.F.R. § 314.94(a)(12)(vi), Sandoz is not

required to submit an amended Paragraph IV Certification to certify to the Late-Listed Patents, and, in fact, Sandoz has not done so. 21 C.F.R. § 314.94(a)(12)(vi).

III. ARGUMENT

A. Section 271(e)(2) Creates A Cause of Action Only When The Asserted Patent Is Subject To A Paragraph IV Certification

A district court does not have subject matter jurisdiction for an infringement action against an ANDA applicant under 35 U.S.C. § 271(e)(2) where the asserted patents were late-listed in the Orange Book and the defendant's ANDA does not contain a Paragraph IV certification with respect to those late-listed patents. The law relating to this aspect of the Hatch-Waxman legislation is well-settled and intended to foster and promote Congress' intent underlying Hatch-Waxman.

The U.S. Supreme Court has noted that the artificial act of infringement under § 271(e)(2) consists of filing an ANDA with a Paragraph IV certification. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). To 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. *Eisai Co. v. Mutual Pharm. Co.*, No. 06-3613, 2007 U.S. Dist. LEXIS 93585, at *35 (D.N.J. Dec. 20, 2007); *see also Abbott Labs. v. Zenith Labs., Inc.*, No. 94-6792, 1995 U.S. Dist. LEXIS 3256, at **27-28 (N.D. Ill. Mar. 15, 1995).

In *Eisai*, the challenged ANDA did not include a Paragraph IV certification with respect to the asserted patent because the asserted patent was not listed in the Orange Book when the ANDA was filed.[3] *Eisai*, 2007 U.S. Dist. LEXIS 93585 at *20. Although the court

[3] The patent asserted against the ANDA applicant in *Eisai* was eventually added to the Orange Book, but because the patent information was not submitted to the FDA within 30 days of issuance, the ANDA applicant was not required to file a Paragraph IV certification with respect to the patent. *See* 21 C.F.R. § 314.94(a)(12)(vi).

acknowledged § 271(e)(2) does not specifically mention Paragraph IV certifications, it nonetheless found dispositive the Supreme Court's and Federal Circuit's construction of § 271(e)(2) as requiring a challenged ANDA to contain a Paragraph IV certification in order to invoke jurisdiction and state a claim for patent infringement under that section. *See id.* at *37. For example, the *Eisai* court cited *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1131 (Fed. Cir. 1995), in which the Federal Circuit stated, "[i]nclusion of a paragraph IV certification in an ANDA, however, is deemed an act of infringement." The Federal Circuit also explained that "the Hatch-Waxman Act gives a drug patent owner the right to bring an action for infringement *upon the filing of a paragraph IV certification*." *Id.* at 1135 (emphasis added). The *Eisai* court held that it did not have jurisdiction over the plaintiffs' infringement claims because the subject ANDA did not include a Paragraph IV certification on the asserted patent.[4] *See Eisai*, 2007 U.S. Dist. LEXIS 93585 at *42 (emphasis added).

In *Abbott Labs. v. Zenith Labs., Inc.,* the plaintiff brought a patent infringement claim under § 271(e)(2), but the challenged ANDA did not contain a Paragraph IV certification relating to the asserted patent because it was not listed in the Orange Book. The court stated:

> This Court disagrees with Plaintiff that the plain language of § 271(e)(2)(A) suggests that an infringement action can be brought against an ANDA applicant, who files an ANDA to obtain FDA approval to manufacture or sell a new, often generic, drug, where the non-generic form of the drug is the subject of a patent, *but the ANDA applicant has no notice of the patent because the patent holder did not list the patent, in its NDA*, as one which claims the non-generic form of the drug.

[4] Similarly, the Federal Circuit has held that when the ANDA applicant seeks approval for an indication different from the method of use claimed in an asserted Orange Book-listed patent, the plaintiff may not bring an infringement claim under § 271(e)(2). *Warner-Lambert Co. v. Apotex Corp*, 316 F.3d 1348, 1362 (Fed. Cir. 2003).

Abbott Labs., 1995 U.S. Dist. LEXIS 3256 at **27-28 (emphasis added). The court dismissed the action, stating "this Court concludes that Plaintiff cannot state a claim for patent infringement under § 271(e)(2)(A), based on Defendant's failure to address an unlisted patent in its ANDA application." *Id.* at *34.

Subsequent to the court's dismissal of the complaint, the plaintiff listed the asserted patent in the Orange Book as covering its NDA product. *See Abbott Labs.*, 934 F. Supp. at 932. Plaintiff then asserted a new infringement claim under § 271(e)(2) based on the now late-listed patent. The court ***again*** dismissed the claim because, despite Orange Book listing of the patent, the defendant's ANDA ***still*** did not contain a Paragraph IV certification with respect to the newly Orange Book listed patent.[5] *Id.* at 933, 936. The court held that "Plaintiff does not have a cause of action for patent infringement before Defendant brings the drug to market" because "the procedure for bringing a patent infringement action pursuant to 35 U.S.C. § 271(e)(2)(A) [was] not initiated." *Id.* at 936.

Recently, another district court declined jurisdiction where the Paragraph IV certification was directed to claims different from the asserted claims. *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 09-2445, 2010 U.S. Dist. LEXIS 32569, at *31 (D.N.J. Mar. 31, 2010). In *Novo Nordisk*, the court explained, "[t]he filing of Paragraph IV Certifications as to claims that are not in issue in an infringement action simply cannot constitute an act of infringement upon which the Court may base jurisdiction when the claims for which they are filed have no relation to the infringement action." *Id.* Accordingly, the Court found that it lacked subject matter jurisdiction

[5] The defendant was not required to make a certification regarding the patent because the asserted patent was late-listed in the Orange Book after the 30-day post-issuance window. *See Abbott Labs.*, 934 F. Supp. at 934.

over the § 271(e)(2) infringement claims and granted the Defendant's motion to dismiss. *Id.* at **31, 40.

The law is clear that Plaintiffs cannot invoke subject matter jurisdiction for an infringement action under § 271(e)(2) where the asserted patents were late-listed in the Orange Book and Sandoz's ANDA does not contain a Paragraph IV certification with respect to the Late-Listed Patents.

B. Counts I And III Of The Complaint Must Be Dismissed Under FRCP 12(b)(1) Because The Court Lacks Subject Matter Jurisdiction

In response to a FRCP 12(b)(1) motion seeking dismissal for lack of subject matter jurisdiction, plaintiffs bear the burden of proving that subject matter jurisdiction exists. *Samsung Elecs. Co. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008). For a factual challenge to the complaint, "[t]he Court's inquiry under Rule 12(b)(1) is limited to the allegations in the [complaint], the documents referenced in or attached to the [complaint], and matters in the public record." *Pfizer Inc. v. Ranbaxy Labs., Ltd.*, 525 F. Supp. 2d 680, 684 (D. Del. 2007).

Plaintiffs' Complaint alleges a claim for patent infringement under § 271(e)(2), which states that it is an act of infringement to submit an ANDA seeking approval to engage in the commercial manufacture, use, or sale of a drug 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). This particular section of the Patent Act is considered to "create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004). As explained in Section III.A above, the law is well-settled that a plaintiff cannot invoke subject matter jurisdiction for an infringement action under 35 U.S.C. § 271(e)(2)

where the asserted patents were late-listed in the Orange Book and the defendant's ANDA does not contain a Paragraph IV certification with respect to those late-listed patents.

Here, the Complaint fails to allege any facts that support subject matter jurisdiction for infringement under § 271(e)(2).[6] The Complaint alleges that Sandoz filed an ANDA containing a Paragraph IV certification with the FDA ***only*** as to the '604 and '590 patents at issue ***in the stayed Existing Action***. (Complaint, ¶ 24.) The Complaint does ***not*** allege that Sandoz filed a Paragraph IV certification as to the Late-Listed Patents. In fact, the Complaint concedes that Sandoz's Paragraph IV certification was submitted ***before*** the Late-Listed Patents even issued.[7] (Complaint, ¶ 28.)

Further, the Complaint fails to include any allegations regarding whether Plaintiff Cephalon timely provided information on the Late-Listed Patents to the FDA for listing in the Orange Book. Instead, the allegations in the Complaint suggest that because Sandoz filed a Paragraph IV certification as to the patents asserted ***in the Existing Action***, that somehow suffices to confer jurisdiction as to the Late-Listed Patents. (Complaint, ¶¶ 21-25, 34-35, 44-45.) It does not. Allegations in the Complaint concerning Paragraph IV certifications for other patents (*i.e.*, those asserted in the Existing Action) are completely irrelevant and immaterial to asserted claims related to the Late-Listed Patents and whether this Court has subject matter jurisdiction under § 271(e)(2).

Plaintiffs' Complaint is devoid of any facts sufficient to establish that Sandoz has filed an ANDA with the required patent certification as to the Late-Listed Patents. Thus, Counts I and III

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[6] Counts I and III of the Complaint seek judgment for infringement under 35 U.S.C. § 271(e)(2)(A). (Complaint, ¶¶ 33-35, 43-45.)

[7] Sandoz's ANDA No. 200676, including the Paragraph IV certification, was filed with the FDA more than one year prior to the issuance of the Late-Listed Patents in January, 2011.

of plaintiffs' Complaint alleging infringement under § 271(e)(2) must be dismissed pursuant to FRCP 12(b)(1) for lack of subject matter jurisdiction.

C. Plaintiffs' Claims of Infringement Under 35 U.S.C. § 271(e)(2) Must Also Be Dismissed Under FRCP 12(b)(6)

"To withstand a FRCP 12(b)(6) motion, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Max v. Republican Comm. of Lancaster County*, 587 F.3d 198, 200 (3d Cir. 2009) (citing *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)). This "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do," and further requires factual allegations that "raise a right to relief above the speculative level." *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (interpreting FRCP 8(a)).

On facts strikingly similar to those in this case, district courts have dismissed complaints for failure to state a cause of action for failure to allege the required Paragraph IV certification. In *Eisai Co. v. Mutual Pharm. Co.*, the asserted patent was late-listed in the Orange Book, *i.e.*, the patent information was not submitted to the FDA within 30 days of issuance of the patent. 2007 U.S. Dist. LEXIS 93585 at *18. The court noted that the defendant was correct in not filing a Paragraph IV certification because of the late listing of the asserted patent: "[T]hus if an ANDA contains a correct patent certification at the time of filing, and a patent is *untimely* added to the Orange Book for the drug in question after the ANDA has been filed, the ANDA application need not update its ANDA to certify against the newly and untimely-listed patent." *Id.* at *42 (emphasis in original text). In *Eisai*, the court held that to establish an act of infringement pursuant to § 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.* Accordingly, the court granted defendant's motion to dismiss under FRCP 12(b)(6).

In *Abbott Labs. v. Zenith Labs., Inc.*, the court dismissed a patent infringement action brought under § 271(e)(2) for failure to state a cause of action for which relief may be granted. 934 F. Supp. at 936. The court held that plaintiff did not have a cause of action for patent infringement before defendant brought its generic drug to the market because the procedure for bringing an infringement action pursuant to § 271(e)(2) had not been initiated. *Id.* In reaching its holding, the court relied on the following facts: (1) the asserted patent was not listed in the Orange Book when the defendant filed its ANDA; (2) when the plaintiff did submit information regarding the asserted patent, it was not submitted in a timely manner to the FDA (*i.e.*, within 30-days of issuance); and (3) defendant had not, nor was it required to, amend its ANDA and include a Paragraph IV certification as to the asserted patent. *Id.* at 935-936.

Here the relevant facts are nearly identical to those in *Eisai* and *Abbott Labs.* Plaintiffs admit in their Complaint that the Late-Listed Patents were not even issued at the time Sandoz filed its ANDA. (Complaint, ¶ 28.) The Complaint fails to allege that Sandoz has provided a Paragraph IV certification of the Late-Listed Patents, or that Sandoz is required to provide such a certification. In fact, during a meet and confer, counsel for Plaintiffs admitted that the Late-Listed Patents, which issued on January 4, 2011, were not submitted to the FDA within 30-days after their issuance. (*See* attached Declaration of David H. Dolkas, counsel for Sandoz, ¶ 3.) Under these facts, there is no cause of action nor a claim for relief for patent infringement under § 271(e)(2), and the Court should dismiss Counts I and III of the Plaintiffs' Complaint under FRCP 12(b)(6).

D. Counts II And IV Of The Complaint For Declaratory Judgment Of Infringement Under 35 U.S.C. § 271(a), (b), or (c) Should Also Be Dismissed

The Declaratory Judgment Act empowers the Court to adjudicate "a case of actual controversy within its jurisdiction . . . ." 28 U.S.C. § 2201(a). A declaratory judgment plaintiff

is required to satisfy Article III, which includes standing and ripeness, by proving that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). The declaratory judgment plaintiff bears the burden of proof. *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 272 (1941). Even if, *arguendo,* this Court has subject matter jurisdiction over Plaintiffs' claims for declaratory relief, it retains the discretion pursuant to the Declaratory Judgment Act to decline declaratory judgment jurisdiction. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995). Here, because Plaintiffs cannot avail themselves of § 271(e)(2), they cannot establish the substantial controversy of sufficient immediacy and reality required for a declaratory judgment action.[8] Thus, the Court should dismiss Counts II and IV of the Complaint pursuant to FRCP 12(b)(1). Alternatively, this Court should decline to exercise declaratory judgment jurisdiction because to do so would undermine the safe harbor exemption under § 271(e)(1).

In *Eisai, supra,* the district court also dismissed plaintiff's claim for declaratory relief based on the lack of subject matter jurisdiction because the alleged injury was not sufficiently real and immediate. *Eisai*, 2007 U.S. Dist. LEXIS 93585 at **51-74. The court stated that "the irregularities that prevent Eisai from maintaining a § 271(e)(2) action also doom its declaratory judgment claim." *Id.* at **58-59. "[I]n the absence of this jurisdictional hook [§ 271(e)(2)],

[8] This Court's ruling in *Cephalon, Inc. et al. v. Watson Pharms., Inc. et al.*, Civil Action No. 08-330-SLR (D. Del.) is inapposite and does not provide a basis for the exercise of declaratory judgment jurisdiction in this case. (*See* April 29, 2009 Memorandum Opinion in C.A. No. 08-330-SLR, D.I. 138, p. 19.) In *Watson*, the asserted patents were listed in the Orange Book ***before*** defendants filed their ANDA and Watson's ANDA included a Paragraph IV certification to the asserted patents. *Id.* at pp. 2, 5.

jurisdiction is lacking" for plaintiff's declaratory judgment claim of infringement under § 271(a). *Id.* at *73. First, the court expressly found that any of defendant's potentially infringing activities under § 271(a) were exempted by the Hatch-Waxman's safe-harbor provision of § 271(e)(1). *Id.* Second, the court rejected plaintiff's allegations of future potential infringement as insufficient, finding that a controversy will only materialize if the FDA approves the accused drug and if the generic defendant decided to market the drug. *Id.* at **60-64.

Similarly, in *Abbott Labs v. Zenith Labs, supra,* the court granted defendant's motion to dismiss a claim of infringement under § 271(e)(2) and a claim for a declaratory judgment of infringement under § 271(a). The court reasoned that because § 271(e)(2) could not be invoked, the "safe haven provided by § 271(e)(1) remains in force until Defendant begins to market it generic [drug]." *Abbott Labs.*, 934 F. Supp. at 939. The court also declined to exercise jurisdiction over plaintiff's declaratory judgment claim (even if a justiciable controversy existed) because it would undermine Congress' policy in enacting the safe-harbor exemption under § 271(e)(1). *Id.* at 938-39. The court relied on *Intermedics Inc. v. Ventritex Co.*, 991 F.2d 808 (Fed. Cir. 1993), wherein the Federal Circuit stated, "to permit [defendant] to be protected from direct suit for infringement and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical." *Abbott Labs.*, 934 F. Supp. at 939. The court also found plaintiff's allegations of (i) the defendant taking action directed to the making, using or selling of its generic drug, and (ii) the defendant seeking approval from the FDA to market its generic drug "insufficient to state a controversy as required by 28 U.S.C. § 2201." *Id.* at 937-38.

In *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 05-590-GMS, 2006 WL 2375035, at *3 (D. Del. Aug. 16, 2006), the Court concluded that at the time of filing, the complaint did not present an actual controversy to support declaratory judgment jurisdiction because: (1) the FDA

had not approved defendant's product and patent owner could not predict when, or if, the FDA would approve the product; (2) the product could change based on the FDA's determination in approving the ANDA product; and (3) the complaint did not allege that defendant distributed sales literature, prepared to solicit orders, or engaged in any sales or marketing activity with regard to its glucose monitoring product. *Id.* Judge Sleet emphasized that "the absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate." *Id.*

Here, Counts II and IV of the Complaint fails to allege any facts that support declaratory judgment jurisdiction for infringement under § 271(a)–(c). First, Plaintiffs cannot establish jurisdiction under § 271(e)(2) because Sandoz's ANDA does not include a Paragraph IV patent certification regarding the Late-Listed Patents. Without this jurisdictional "hook," Plaintiffs' allegations concerning preparations and development of a generic product (Complaint, ¶¶ 30, 31, 39, and 49), filing an ANDA and engaging in litigation (Complaint, ¶¶ 31, 32, 40, and 50) are exempt under the Hatch-Waxman's safe-harbor provision of § 271(e)(1). *See Eisai,* 2007 U.S. Dist. LEXIS 93585 at **58-59; *Abbott Labs*., 934 F. Supp. at 939.

Second, the Complaint fails to allege that Sandoz is either making, using, selling, offering to sell or importing a generic drug product within the United States that infringe the Late-Listed Patents. In fact, Sandoz does not have FDA approval of its generic product, a fact Judge Sleet found "*is evidence that the dispute between the parties is neither real nor immediate.*" *See Abbott Diabetes Care*, 2006 WL 2375035 at *3 (emphasis added). As this Court recognized in its Order staying the Existing Action, Sandoz: (i) had not received FDA approval to launch its ANDA product; and (ii) Sandoz could not launch its ANDA product until after the 30-month stay in the Existing Action ends in July 2012. (D.I. 114, p. 4.) These circumstances have not changed.

Further, the Complaint alleges either speculative future acts that do not support any current acts of infringement (*e.g.*, preparation or intention) or acts that are expressly exempt from infringement under the "safe-harbor" provision of § 271(e)(1) – *e.g.*, development of a generic product for an ANDA filing, filing an ANDA, and continuing to seek approval of an ANDA. For example:

> 30. Defendant has made, and continues to make ***substantial preparation*** in the United States to manufacture, offer to sell, sell, and/or import the Sandoz Generic Product prior to patent expiry.
>
> 31. Defendant's actions, including but not limited to, ***the development of the Sandoz Generic Product and the filing of an ANDA with a Paragraph IV certification,*** indicate a refusal to change course of their action in the face of acts by Plaintiffs.
>
> 32. Defendant ***continues to seek approval of ANDA No. 200676 from the FDA and intends*** to continue in the commercial manufacture, marketing and sale of fentanyl citrate buccal tablets.

(Complaint, ¶¶ 30-32) (emphasis added).

35 U.S.C. § 271(e)(1) states: "It shall not be an act of infringement to make, use, offer to sell, or sell within 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 . . . ." Sandoz's development of a generic product and submission of information to the FDA for approval of its ANDA falls within the "safe harbor" and cannot provide the basis for infringement under 35 U.S.C. § 271(a)–(c). *See, e.g., Abbott Labs.*, 934 F. Supp. at 938-39. The Complaint is devoid of any facts to establish a controversy of sufficient immediacy and reality to support declaratory judgment jurisdiction and should be dismissed.

Accordingly, because Plaintiffs cannot establish an actual case or controversy under 28 U.S.C. § 2201(a), this Court should dismiss Counts II and IV of Plaintiffs' Complaint pursuant to FRCP 12(b)(1).

IV. CONCLUSION

For the foregoing reasons, Sandoz respectfully requests that this Court dismiss Counts I-IV of Plaintiffs' Complaint under FRCP 12(b)(1) for lack of subject matter jurisdiction and/or under FRCP 12(b)(6) for failure to state a claim upon which relief can be granted.

Dated: October 25, 2011

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CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on October 25, 2011, I caused to be electronically filed a copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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