NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A., et al.,	:	CIVIL ACTION NO. 15-2077 (MLC)
Plaintiffs,	:	**MEMORANDUM OPINION**
v.	:	
HOSPIRA, INC., et al.,	:	
Defendants.	:	

COOPER, District Judge

This patent infringement action arises from an Abbreviated New Drug Application ("ANDA") submitted by Defendant Hospira, Inc. ("Hospira") for approval from the United States Food and Drug Administration ("FDA") to market generic versions of Plaintiff Helsinn Healthcare S.A.'s ("Helsinn") palonosetron product known as Aloxi®. (See, e.g., dkt. 22; dkt. 33 at 6–10.)[1] Defendants, Hospira and Hospira Worldwide, Inc. ("Worldwide") move to dismiss Helsinn's Amended Complaint for lack of personal jurisdiction under Federal Rule of Civil Procedure ("Rule") 12(b)(2) and for failure to state a claim as to Worldwide under Rule 12(b)(6). (Dkt. 32.)

For the reasons stated below, the Court will deny Defendants' motion to dismiss as asserted under Rule 12(b)(2) and Rule 12(b)(6).

[1] The Court will cite to the documents filed on the Electronic Case Filing System ("ECF") by referring to docket entry numbers by the designation of "dkt." Pincites reference ECF pagination.

BACKGROUND

I. The Parties

Helsinn, a pharmaceutical company incorporated in Switzerland, is one of the assignees of United States Patent No. 7,947,724 ("the '724 patent"), No. 7,947,725 ("the '725 patent"), No. 7,960,424 ("the '424 patent"), No. 8,598,219 ("the '219 patent"), and No. 8,729,094 ("the '094 patent") (collectively, "the Aloxi® patents"). (See dkt. 22 at 2.) Helsinn maintains a principal place of business in Switzerland. (See id. at 6.) Helsinn's distributor, Eisai, Inc., and its research and development company, Helsinn Therapeutics, have their principal places of business in New Jersey. (See dkt. 45 at 10, 23.) Roche Palo Alto LLC ("Roche") is a pharmaceutical company incorporated in Delaware with its principal place of business in California, and is the other assignee of the Aloxi® patents. (See dkt. 22 at 6.) The Aloxi® patents claim various formulations of palonosetron, a compound used to prevent and treat chemotherapy-induced or post-operative nausea and vomiting. (See id. at 5–14.) The FDA Orange Book identifies the aforementioned patents as covering Helsinn's Aloxi® brand palonosetron hydrochloride intravenous solutions. (See id. at 4.)

Hospira, a Delaware corporation having its principal place of business in Illinois, "handles a wide array of corporate functions," including the submission of ANDAs. (See dkt. 33 at 8.) Hospira identifies itself as "the world's leading provider of injectable drugs and infusion technologies." (See id.) Worldwide, Hospira's subsidiary, is also incorporated in Delaware with its principal place of business in Illinois. (See id. at 23.) Worldwide markets, sells, and distributes drugs for Hospira in the United States. (See id. at 8–9.) Worldwide is

registered to do business in New Jersey, and has designated an in-state agent to receive service of process. (See id.)

II. Procedural History

Hospira filed its ANDA seeking FDA approval to manufacture and market generic versions of Aloxi® on April 30, 2014. (See id. at 10.) Hospira's amended ANDA filing included a paragraph IV certification, in which Hospira asserted that the Aloxi® patents were invalid, or in the alternative, would not be infringed by the commercial manufacture, use, or sale of Hospira's generic product. (See id.) Hospira mailed the ANDA notice letter to Roche in California, to Helsinn in Switzerland, and to three law firms in Georgia. (See id.)

Helsinn filed an Amended Complaint naming Hospira and Worldwide in this District on June 30, 2015, alleging that "if Defendant Hospira itself or through its subsidiary, agent and alter ego, Worldwide, commercially manufactures, uses, offers for sale, or sells its proposed generic versions of Helsinn's Aloxi® brand products within the United States, imports its proposed generic versions of Helsinn's Aloxi® brand products into the United States, and/or induces or contributes to such conduct," Hospira will infringe the '724, '725, '424, '219, and '094 patents. (See generally dkt. 22.) This motion followed. (See dkt. 32.)

The Court now resolves Defendants' motion to dismiss without oral argument pursuant to Local Civil Rule 78.1(b).

DISCUSSION

I. Legal Standards

A. Motion to Dismiss: Rule 12(b)(2)

Rule 12(b)(2) permits a party to move to dismiss a complaint for lack of personal jurisdiction. See Fed.R.Civ.P. 12(b)(2). When the Court resolves the issue of personal jurisdiction "based on affidavits and other written materials in the absence of an evidentiary hearing, a plaintiff need only . . . make a prima facie showing that defendants are subject to personal jurisdiction." Elecs. for Imaging, Inc. v. Coyle, 340 F.3d 1344, 1349 (Fed. Cir. 2003). The Court "must accept the uncontroverted allegations in the plaintiff's complaint as true and resolve any factual conflicts in the affidavits in the plaintiff's favor." Id. The plaintiff bears the burden of showing the basis for jurisdiction. Graphics Props. Holdings, Inc. v. ASUS Computer Int'l, 70 F.Supp.3d 654, 659 (D.N.J. 2014). The plaintiff satisfies this burden by "establishing with reasonable particularity sufficient contacts between the defendant and the forum state." Mellon Bank (East) PSFS, Nat'l Ass'n v. Farino, 960 F.2d 1217, 1223 (3d Cir. 1992).

Determining "whether jurisdiction exists over an out-of-state defendant involves two inquiries: whether a forum state's long-arm statute permits service of process and whether assertion of personal jurisdiction violates due process." See Autogenomics, Inc. v. Oxford Gene Tech. Ltd., 566 F.3d 1012, 1017 (Fed. Cir. 2009). New Jersey's long-arm statute extends the exercise of personal jurisdiction to the constitutional limit. See N.J.Ct.R. 4:4-4; see also Otsuka Pharm. Co., Ltd., v. Mylan Inc., 106 F.Supp.3d 456, 462–63 (D.N.J. 2015).

Thus, the two inquiries "collapse into a single inquiry: whether jurisdiction comports with due process." Autogenomics, Inc., 566 F.3d at 1017.

A court may only exercise personal jurisdiction over a defendant if the defendant has "certain minimum contacts with [the State] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." Daimler AG v. Bauman, 134 S.Ct. 746, 754 (2014) (internal quotation omitted). Sufficient jurisdictional contacts may arise under general or specific jurisdiction.

1. General Jurisdiction

General jurisdiction requires that the defendant's contacts be "so continuous and systematic as to render them essentially at home in the forum State." Id. (internal quotation omitted). "[T]he place of incorporation and principal place of business are paradig[m] . . . bases for general jurisdiction." Id. at 760 (internal quotation omitted). However, general jurisdiction may also be established if the corporation's "affiliations with the State are so continuous and systematic as to render [it] essentially at home in the forum State." Id. at 761. The Supreme Court cautioned that finding general jurisdiction based on a corporation's affiliations with the forum state should be limited to exceptional cases, and that such affiliations should be appraised in the context of the "corporation's activities in their entirety, nationwide and worldwide." Id. at 762 n.20.

Daimler did not address the issue of consent-based jurisdiction, and pre-Daimler cases "made clear that a registration statute may suffice to establish jurisdiction, provided that the state's own construction of its statute supports such a broad interpretation." Otsuka, 106 F.Supp.3d at 468; see also Boehringer Ingelheim Pharma GMBH & Co. KG v. Teva Pharms.

USA, Inc., No. 14-7811, U.S. Dist. LEXIS 92921, at *4–5 (D.N.J. July 17, 2015). Thus, while Daimler "fundamentally altered the general jurisdiction analysis" by rejecting the notion that general jurisdiction may be asserted over a corporation that "engages in a substantial, continuous, and systematic course of business in the forum state," a court may still assert jurisdiction over a corporation if it is registered to do business and appointed an agent for service of process in the forum state. See Otsuka, 106 F.Supp.3d at 463–64, 467 (internal quotation and citation omitted).

2. Specific Jurisdiction

Specific jurisdiction requires that the suit "arise[] out of or relate[] to the defendant's [specific] contacts with the forum." See Daimler, 134 S.Ct. at 754. Specific jurisdiction exists if: (1) the defendant purposefully directs activities at the forum's residents; (2) the claim arises out of or relates to those activities; and (3) assertion of personal jurisdiction is reasonable and fair. See Otsuka, 106 F.Supp.3d at 471.

B. Motion to Dismiss: Rule 12(b)(6)

Rule 12(b)(6) permits a defendant to move for dismissal by "challeng[ing] the legal theory of the complaint." Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 988 F.2d 1157, 1160 (Fed. Cir. 1993). The Court must "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." Otsuka Pharm. Co., Ltd. v. Zydus Pharms. USA, No. 14-3168, No. 14-5878, No. 14-7252, 2015 WL 5950091, at *3 (D.N.J. Oct. 13, 2015). To survive a motion to dismiss, the allegations must be well-pleaded and sufficiently demonstrate a plausible entitlement to relief. Ashcroft v.

Iqbal, 556 U.S. 662, 678 (2009). To meet this standard, the plaintiff must show "more than a sheer possibility that a defendant has acted unlawfully"—that is, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Id.; Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). The defendant bears the burden of demonstrating that no plausible claim has been presented. See Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005).

II. Legal Standards Applied Here

A. Motion to Dismiss: Rule 12(b)(2)

1. Parties' Arguments: General Jurisdiction

Defendants first argue that there is no general jurisdiction as to Hospira because: (1) it is incorporated in Delaware and its principal place of business is in Illinois; thus, the "two paradigmatic locations where a corporation is at home" lay outside New Jersey; (2) this case does not fall into the exceptional circumstances set forth by Daimler; (3) it has not consented to jurisdiction "by virtue of . . . prior litigation in New Jersey courts"; (4) it is immaterial to Hospira's jurisdictional inquiry that Worldwide is registered to do business in New Jersey; (5) Hospira does not function as Worldwide's "alter ego," thus the subsidiary's activity cannot be imputed to Hospira; and (6) there is no agency relationship between Hospira and Worldwide. (See dkt. 33 at 15–23.)

Defendants next argue that there is no general jurisdiction as to Worldwide because it: (1) is incorporated in Delaware and has its principal place of business in Illinois; and (2) has not consented to jurisdiction because it is registered to do business in New Jersey; rather,

"these steps are mandatory for any corporation that does business in New Jersey." (See id. at 23.)

Helsinn argues that Worldwide has consented to be subject to general jurisdiction in New Jersey by registering to do business in New Jersey and appointing an agent for service of process in New Jersey. (See dkt. 45 at 13–14.) Helsinn alleges that these contacts are imputable to Worldwide's parent, Hospira, under the single entity test. (See id. at 14–15.) Helsinn states that "it is readily apparent that Hospira and Worldwide are a single entity at least for purposes of selling generic drug products," and points to the following: (1) Hospira's Form 10–K, which identifies Hospira as "a leading provider of injectable drugs . . . and . . . biosimilars all of which it develops, manufactures, markets and distributes," although Hospira identifies Worldwide as its marketer and distributor; (2) the two companies' shared Chief Executive Officer at the time the complaint was filed; and (3) the integration of various aspects of the businesses, i.e., the same address, logo, ticker symbol, legal counsel, and website. (See id. at 15–18.)

2. Parties' Arguments: Specific Jurisdiction

Hospira argues that neither Hospira nor Worldwide are subject to specific jurisdiction in New Jersey. (See dkt. 33 at 25.) Hospira asserts that sending its notice letter to Helsinn in New Jersey was not "purposeful direction of its activities at forum residents," but rather statutorily required as a condition of submitting an ANDA with a paragraph IV certification. (See id.) Moreover, Hospira argues that the lawsuit does not arise out of the notice letter, but rather out of Hospira's ANDA submission, which was prepared in Illinois and submitted in Maryland. (See id. at 26.)

Hospira also denies that the sale and distribution of Hospira products in New Jersey provides a basis for specific jurisdiction. (See id. at 27.) Hospira asserts that the sale and distribution of Hospira products cannot be a basis for specific jurisdiction because: (1) this lawsuit does not arise out of the sale and distribution of Hospira's existing products; (2) Worldwide has not commenced selling or distributing generic palonosetron products because there is no FDA approval; and (3) it would establish "virtually unbounded opportunities for forum–shopping" if the possibility of sale or distribution of a drug product were sufficient to establish specific jurisdiction. (See id. at 27–28.)

Hospira finally argues that even if there is a basis for specific jurisdiction in New Jersey, exercising such jurisdiction would be unfair and unreasonable because: (1) an "efficient resolution of controversies" could be achieved in either this District or the District of Delaware, as both districts are adjudicating palonosetron ANDA actions; and (2) "the forum state's interest in adjudicating this dispute is virtually nonexistent" because "[t]he case arises under federal law . . . not New Jersey law," and none of the parties or the facts underlying the dispute have any connection to New Jersey. (See id. at 28–29.)[2]

[2] Compare Helsinn Healthcare S.A. v. Exela Pharma Scis. LLC, No. 14-1444 (D.Del.); Helsinn Healthcare S.A. v. Hospira, Inc., No. 15-264 (D.Del.); Helsinn Healthcare S.A. v. Fresenius Kabi USA, LLC, No. 15-865, No. 15-918 (D.Del.); Helsinn Healthcare S.A. v. Par Pharm. Cos., No. 15-265 (D.Del.); with Helsinn Healthcare S.A. et al. v. Sagent Pharms., Inc., No. 16-173 (D.N.J.); Helsinn Healthcare S.A. et al. v. Hospira, Inc. et al., No. 15-2077, No. 15-7015, No. 15-7378 (D.N.J.); Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd., No. 15-8132 (D.N.J.); Helsinn Healthcare S.A. et al v. Teva Pharms. USA, Inc., No. 15-8663 (D.N.J.); Helsinn Healthcare S.A. et al. v. Dr. Reddy's Labs. Ltd. et al., No. 12-2867, No. 14-4274, No. 15-8662 (D.N.J.). This list represents those cases currently pending. Others have already been adjudicated. See, e.g., Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd., No. 11-3962, 2016 WL 832089 (D.N.J. Mar. 3, 2016.)

Helsinn first argues that Hospira and Worldwide are subject to specific jurisdiction in New Jersey because the parties have had "sufficient purposeful contacts with New Jersey." (See dkt. 45 at 21.) Helsinn asserts that these sufficient and purposeful contacts with New Jersey include: (1) sending the paragraph IV notice letter to Eisai, Inc. and to a jurisdiction where Helsinn Therapeutics maintains its principal place of business; and (2) designating Worldwide, as Hospira's agent, to "market[], sell[], and distribute[]" drug products for Hospira in New Jersey. (See id. at 21–24.)[3] Helsinn next asserts that the claims relate to Defendants' activities in New Jersey because Hospira's ANDA seeks approval for a product that will be sold by Worldwide to New Jersey residents upon approval. (See id. at 24–25.) Finally, Helsinn notes that the exercise of specific jurisdiction in this case would not be unreasonable or unfair because: (1) "Hospira is no stranger to litigating in this Court"; and (2) this Court has an interest in adjudicating Aloxi® patent cases due to the active cases pending before this Court. (See id. at 27–28.)

3. Analysis

The Court agrees with Helsinn that specific jurisdiction may be asserted over Hospira and Worldwide because of Defendants' suit-related contacts with this District.[4] The Federal

[3] Helsinn additionally notes that it designated Eisai, Inc. as its recipient for any paragraph IV notice letter to put Defendants on notice "that the harm resulting from their technical act of infringement would be directed to Plaintiffs in [New Jersey]." (Dkt. 45 at 22.)

[4] Establishing general jurisdiction under a consent-by-registration theory remains the subject of a circuit split among the courts, and will not be addressed here because the Court finds that specific jurisdiction exists in this case. The Federal Circuit has not spoken as to the continued viability of consent-by-registration. See Takeda GmbH v. Mylan Pharms., Inc., No. 15-3384, 2016 WL 146443, at *3 (D.N.J. Jan. 12, 2016) (discussing circuit split on consent-by-registration theory).

Circuit has squarely addressed this issue in a recent case, Acorda Therapeutics Inc. v. Mylan Pharmaceuticals, Inc., No. 15-1456, No. 15-1460, 2016 WL 1077048 (Fed. Cir. Mar. 18, 2016). The facts in Acorda bear a strong similarity to this action and are discussed below.

The Acorda appeal involved two actions—one brought by Acorda Therapeutics Inc. ("Acorda") and Alkermes Pharma Ireland Ltd. ("Alkermes") and another brought by AstraZeneca AB ("AstraZeneca")—against Mylan Pharmaceuticals ("Mylan") in the District of Delaware. See Acorda Therapeutics, 2016 WL 1077048, at *1. Mylan, a West Virginia corporation with its principal place of business there, filed an ANDA and sent notices to Acorda in New York, Alkermes in Ireland, and AstraZeneca in Delaware and Sweden. See id. at *1–2. The parties had the following contacts with Delaware: (1) Mylan was registered to do business and appointed an agent to accept service in the state; (2) Acorda was incorporated in Delaware; (3) AstraZeneca's U.S. subsidiary is located in Delaware; and (4) both Acorda and AstraZeneca had litigated cases against other generic manufacturers in Delaware. See id. at *2.

The Federal Circuit began its analysis by noting that the minimum-contacts requirement is "retrospective" and "based on past acts." See id. at *3 (noting that defendant must have "purposefully directed" activities at forum, and litigation must result from injuries "aris[ing] out of or relat[ing] to" those activities). The Court noted that this retrospective formula is at odds with the ANDA application process, in which "the economic realities . . . [of] filing [an ANDA] realistically establishes a plan to market." See id. at *4.[5] However, the

[5] The court cited to the following ANDA filing requirements as proof of a filer's commitment to entering the market: (1) showing the bioequivalence of the proposed drug listed in the NDA; (2)

strong connection between an ANDA filing and the marketing activities for which a filer seeks approval led the court to conclude that such activities would "unquestionably" take place in Delaware. See id. at *6. The Court held that:

> As long as the connection to the planned acts is close enough, the subject of such actions readily fits the terms of the minimum-contacts standard. . . . A State's exercise of jurisdiction over a defendant planning such conduct can hardly come as a surprise to the defendant and does nothing to offend traditional notions of fair play and substantial justice.

Id. (internal quotation omitted).

The Acorda Court held that Defendant Mylan had sufficient minimum contacts with Delaware to support a finding of specific jurisdiction because: (1) Mylan was registered to do business and accept service in Delaware; and (2) Mylan had a "network of independent wholesalers and distributors with which it contract[ed] to market the drugs in Delaware." See id. at *7.

The Court is presented here with a similar set of facts. Hospira and Worldwide are not incorporated and do not maintain principal places of business in New Jersey. (See dkt. 33 at 8–9.) At least one of Helsinn's subsidiaries and its distributor maintain their principal places of business in New Jersey. (See dkt. 45 at 10–11, 23.) Both Hospira and Helsinn have litigated Hatch-Waxman cases in this District. (See id. at 26–28.) It is undisputed that

identifying "the facilities and controls used for[] the manufacture, processing, and packing of [its proposed] drug"; and (3) certifying that its facilities comply with the extensive good-manufacturing practices detailed in the FDA regulations. See Acorda Therapeutics, 2016 WL 1077048, at *4.

Hospira has filed a pending ANDA seeking to manufacture and market generic versions of Aloxi®. (See dkt. 33 at 10.)

Under the rationale set forth in Acorda, the Court finds that Hospira's marketing of generic Aloxi® will, at least in some part, take place in New Jersey because Hospira identifies itself as "the world's leading provider of injectable drugs and infusion technologies." (See id. at 8.) Although Hospira argues that it does not sell its drugs directly into the state, it admits that Worldwide has registered to do business in New Jersey and will "market, sell, and distribute" Hospira's palonosetron product in the state. (See id. at 8–9.) These facts lean even more strongly toward a finding of minimum contacts than in Acorda, where the court held that Mylan's "network of independent wholesalers and distributors" alone constitutes a minimum contact with the state. See Acorda Therapeutics, 2016 WL 1077048, at *6. The Court finds that under Acorda's guidance, these facts establish sufficient minimum contacts to find specific jurisdiction over both Hospira and Worldwide with respect to the pending ANDA.

The Court will now turn to the issue of whether asserting specific jurisdiction would be unfair or unreasonable. The Court looks to various factors, including: (1) the burden on the defendants; (2) the forum state's interest in adjudicating the dispute; (3) the plaintiffs' interest in obtaining convenient and effective relief; and (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies. World-Wide Volkswagen v. Woodson, 444 U.S. 286, 292 (1980). The Federal Circuit also looks to "the shared interest of the states in furthering fundamental substantive social policies" as an additional factor. See

Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com de Equip. Medico, 563 F.3d 1285, 1299 (Fed. Cir. 2009).

The Court does not find any unfairness here that would override the minimum contacts that Hospira and Worldwide have with New Jersey. Hospira has litigated Hatch-Waxman lawsuits in this District and has initiated at least two of those actions. (See dkt. 45 at 26.) New Jersey has an interest in adjudicating the parties' dispute because, as previously noted, this Court has adjudicated or is currently adjudicating many similar Hatch-Waxman cases on generic Aloxi® products. (See id. at 27.) See also supra DISCUSSION, Section II.A.2. The Court finds that this only weighs more in favor of judicial economy and efficiency, as the ANDA actions currently pending in this Court involve the same Aloxi® patents as the ones at issue here.

The Court is further persuaded by the policy underlying the Federal Circuit's recent Acorda opinion. Hospira argues that "simply because Hospira's generic drug products are sold in New Jersey . . . is no basis for jurisdiction." (See dkt. 52 at 12.) This argument was rejected by the Federal Circuit in Acorda, which held that ANDA filings establish a substantial connection with a forum state and the ANDA filer because they predict the filer's activities within the state, i.e., the manufacturing or marketing a generic product. See Acorda Therapeutics, 2016 WL 1077048, at *6. The Federal Circuit emphasized the "future real-world market acts" that underlie ANDA filings, and which eventually trigger any ANDA litigation. See id. at *5. In light of these considerations, Defendants have not provided a compelling argument as to why jurisdiction here would be unfair or unreasonable.

B. Motion to Dismiss: Rule 12(b)(6)

1. Parties' Arguments

Hospira argues that the claims asserted against Worldwide should be dismissed for failure to state a claim because: (1) Worldwide did not submit the ANDA; (2) 35 U.S.C. § 271 does not permit an action to proceed on the theory that the defendant induced the submission of an ANDA; and (3) even if § 271 permitted an inducement theory, the inducement claims alleged against Worldwide are boilerplate and do not pass muster under Twombly and Iqbal. (See dkt. 33 at 32–34.)

Helsinn asserts that it has stated a claim against Worldwide because: (1) a party is not required to submit an ANDA to be a proper party in Hatch-Waxman litigation; (2) Worldwide is actively involved in the litigation as Hospira's marketer, distributor, and seller of its ANDA products; and (3) contrary to Defendants' argument, § 271(e) supports an induced infringement action, and in this case, Worldwide "has induced Hospira to commit infringement" by planning to "manufacture, import, market, and sell the [ANDA product]." (See dkt. 45 at 29–30.)

2. Analysis

The Amended Complaint alleges, in its four counts, that: (1) Defendants submitted an ANDA that "seeks FDA approval to market a generic version of Helsinn's Aloxi® brand 0.25 mg/5 mL and 0.075 mg/1.5 mL palonosetron hydrochloride intravenous solutions prior to the expiration" of the Aloxi® patents; (2) Defendants' paragraph IV notice letter allegations that the Aloxi® patents are invalid constitutes infringement of said patents; (3) Worldwide's "active and knowing participation in, contribution to, aiding, abetting, and/or inducement of

the submission" of the ANDA and paragraph IV notice letter constitutes infringement of the Aloxi® patents; and (4) Defendants are jointly and severally liable for any infringement of the Aloxi® patents. (See generally dkt. 22.) The parties dispute as to whether a claim has been asserted against Worldwide for active inducement of the ANDA filing. (See dkt. 33 at 30; dkt. 45 at 28.)

Section 271(b) of the Patent Act provides that: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "To succeed on this theory, a plaintiff must prove that the defendants' actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringement." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363 (Fed. Cir. 2003) (internal quotation omitted). Where an inducement claim is premised on the filing of an ANDA pursuant to § 271(e)(2), the plaintiff cannot rely on alleged acts done in preparation for filing an ANDA, but rather must allege acts to be committed after the ANDA is approved, such as manufacturing, marketing, or selling the infringing products. Forest Labs., Inc. v. Ivax Pharm., Inc., 501 F.3d 1263, 1272 (Fed. Cir. 2007).

Defendants argue that the claims asserted against Worldwide should be dismissed because Worldwide did not submit the ANDA. (See dkt. 33 at 30–31.) However, § 271(e)(2) does not explicitly require Worldwide to sign the ANDA in order for it to be a properly-named defendant. See In re Rosuvastatin Calcium Patent Litig., 703 F.3d 511, 527–28 (Fed. Cir. 2012) (noting that Apotex U.S. could be deemed as having submitted, and thus infringed, patent-in-suit because "it intends to directly benefit from the ANDA"); see also Cephalon, Inc. v. Watson Pharms., Inc., 629 F.Supp.2d 338, 349 (D. Del. 2009) (internal

quotation omitted) ("Parties actively involved in preparing the ANDA are deemed to have submit[ted] the ANDA, regardless of whether they are the named applicant; this is especially true where the parties involved are in the same corporate family."); Wyeth v. Lupin Ltd., 505 F.Supp.2d 303, 305–06 (D. Md. 2007) (finding that U.S. subsidiary and ANDA signer could be liable for infringement because it "is actively involved with filing Lupin's ANDAs with the FDA, and marketing and distributing the approved generic drugs in the United States").[6]

The parties here agree that Worldwide, as Hospira's wholly-owned subsidiary, "market[s], sell[s], and distribute[s] [Hospira] drug products." (See dkt. 33 at 9; dkt. 45 at 11.) If the ANDA is approved, Worldwide will become the generic product's sole marketer, seller, and distributor in the United States. (See id.) Worldwide intends to, and certainly will, benefit from the ANDA if it is approved. See In re Rosuvastatin, 703 F.3d. at 529. Moreover, Helsinn has made allegations that Worldwide acts as Hospira's "subsidiary, agent, and alter ego." (See dkt. 22 at 7, 9, 11–12, 14.) Helsinn has also pleaded that if Hospira, through Worldwide, "commercially manufactures, uses, offers for sale, or sells it proposed generic versions" of Aloxi®, or if Worldwide otherwise induces these acts, Hospira and

[6] Defendant Hospira argued in reply that these cases are distinguishable because the defendants in these cases "actually had filed the ANDA." (See dkt. 52 at 14.) The Court notes that while the facts in In re Rosuvastatin involved a U.S. subsidiary submitting an ANDA on behalf of a foreign corporation, the rationale in the Federal Circuit's decision, i.e., that an entity that does not sign the ANDA but intends to benefit from it is possibly liable for infringement, is nevertheless applicable here because Hospira and Worldwide function together in the "same corporate family," as parent and subsidiary looking to distribute and market their generic Aloxi® product. See Cephalon, 629 F.Supp.2d at 349. Moreover, other courts that have addressed this issue have reached similar conclusions as we do today. See, e.g., id. (noting that even though moving parties, two U.S. subsidiaries, had not literally signed ANDA, their preparatory work and future "involve[ment] in the marketing and distribution of the generic . . . if the ANDA is approved," was sufficient to deem them as having submitted ANDA).

Worldwide will have infringed the Aloxi® patents. (See generally dkt. 22.) These allegations are sufficient "to raise a right to relief above the speculative level." Iqbal, 556 U.S. at 678. Accordingly, we will deny Defendants' motion to dismiss as asserted under Rule 12(b)(6).

CONCLUSION

For the above-stated reasons, the Court will accordingly deny Defendants' motion to dismiss under Rule 12(b)(2) and Rule 12(b)(6). The Court will issue an appropriate order.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: April 5, 2016