

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

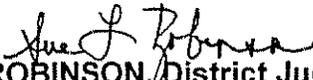
CEPHALON, INC.,)	
and CIMA LABS, INC.)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 08-330-SLR
)	
WATSON PHARMACEUTICALS, INC.,)	
WATSON LABORATORIES, INC.,)	
and WATSON PHARMA, INC.,)	
)	
Defendants.)	

William J. Marsden, Jr., Esquire, Douglas E. McCann, Esquire, and Kyle Wagner Compton, Esquire, of Fish & Richardson P.C., Wilmington, Delaware. Counsel for Plaintiffs. Of Counsel: Duane-David Hough, Esquire, and Michael Siem, Esquire, of Fish & Richardson P.C., New York, New York, and Jonathan E. Singer, Esquire, of Fish & Richardson P.C., Minneapolis, Minnesota.

Frederick L. Cottrell, III, Esquire, and Steven J. Fineman, Esquire of Richards, Layton & Finger P.A., Wilmington, Delaware. Counsel for Defendants. Of Counsel: Barry S. White, Esquire, James K. Stronski, Esquire, John G. Taylor, Esquire, H. Sarah Park, Esquire, and Jonathan R. Wise, Esquire, of Frommer Lawrence & Haug LLP, New York, New York.

MEMORANDUM OPINION

Dated: April 3, 2009
Wilmington, Delaware


ROBINSON, District Judge

I. INTRODUCTION

On June 2, 2008, plaintiffs Cephalon, Inc. ("Cephalon"), and CIMA LABS, Inc. ("CIMA"), brought this suit against defendants Watson Pharmaceuticals, Inc. ("Pharmaceuticals"), and Watson Laboratories, Inc. ("Laboratories"), for infringement and declaratory judgment of infringement of United States Patent Nos. 6,200,604 B1 ("the '604 patent") and 6,974,590 B2 ("the '590 patent"). (D.I. 1) On January 16, 2009, plaintiffs amended their complaint to, *inter alia*, add Watson Pharma, Inc. ("Pharma") as a defendant. (D.I. 75). The suit concerns defendants' filing of Abbreviated New Drug Application No. 79-075 ("the ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Cephalon's FENTORA® brand fentanyl citrate buccal tablets. (*Id.*)

The defendants have filed motions to dismiss. Laboratories moves to dismiss (D.I. 15) pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(2), arguing that it is not subject to personal jurisdiction in Delaware. (D.I. 17) Pharmaceuticals moves to dismiss (D.I. 12) pursuant to Rules 12(b)(6) and (7), arguing principally that plaintiffs (a) have failed to state a claim against it because it did not file the ANDA or, in the alternative, (b) have failed (assuming no personal jurisdiction over Laboratories) to join an indispensable party. (D.I. 14) Pharma moves to dismiss (D.I. 95) on essentially the same grounds cited by Pharmaceuticals. (D.I. 96) Defendants also together move to dismiss (D.I. 95) plaintiffs' declaratory judgment counts (counts III and VI) in the amended complaint pursuant to Rules 12(b)(1) and (6), arguing principally that (a) the court lacks subject matter jurisdiction over those counts because defendants' potential

future actions do not create a real or immediate controversy.¹ (D.I. 96)

For the reasons that follow, the court denies the motions.

II. BACKGROUND

A. The Parties and Patents-in-Suit

CIMA, a Delaware corporation with its principal place of business in Brooklyn Park, Minnesota, owns the '590 and '604 patents.² (D.I. 75 at ¶¶ 2, 47, 48) Cephalon, a Delaware corporation with its principal place of business in Frazer, Pennsylvania, holds the approved New Drug Application ("NDA") No. 21-947 for FENTORA®-brand fentanyl citrate buccal tablets. (*Id.* at ¶¶ 1, 49) In conjunction with NDA No. 21-947, Cephalon listed with the FDA the '590 and '604 patents, which cover methods of using FENTORA®³ (*Id.*) Cephalon is the sole licensee of the '590 and '604 patents in the United States and markets and distributes FENTORA® nationwide, including in the District of Delaware. (*Id.* at ¶¶ 19, 49) FENTORA® is used to treat breakthrough pain in adult cancer patients who are regularly using other opioid pain medicines to relieve

¹Pharmaceuticals and Laboratories also moved to dismiss, pursuant to Rule 12(b)(6), counts III and VI of the original complaint on the ground that those counts alleged direct infringement, whereas plaintiffs' asserted patents claim methods of administration, rather than products. (See D.I. 14; D.I. 17) In the amended complaint, plaintiffs corrected counts III and VI to allege indirect infringement (see D.I. 75), thus making moot Pharmaceuticals' and Laboratories' original arguments for dismissal of those counts.

²The '604 patent, titled "Sublingual Buccal Effervescent," issued on March 13, 2001. (D.I. 75 at ¶ 47) The '590 patent, also titled "Sublingual Buccal Effervescent," issued on December 13, 2005. (*Id.* at ¶ 48)

³The '590 and '604 patents appear in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for FENTORA®. (D.I. 75 at ¶ 49)

cancer pain. (*Id.* at ¶ 18)

Pharmaceuticals and Laboratories are Nevada corporations with their principal places of business in California. (*Id.* at ¶¶ 3, 4) Pharma is a Delaware corporation with its principal place of business in New Jersey. (*Id.* at ¶ 6) Laboratories and Pharma are wholly-owned subsidiaries of Pharmaceuticals, and each subsidiary has at least some officers and directors in common with Pharmaceuticals. (*Id.* at ¶¶ 5, 7)

Pharmaceuticals, both directly and through its subsidiaries, is engaged in the development, marketing, sale, and distribution of brand and generic pharmaceutical products throughout the United States, including Delaware. (*Id.* at ¶¶ 8, 20)

Pharmaceuticals organizes its operations not by corporation, but by division – Generic, Brand, and Distribution.⁴ (*Id.* at ¶ 21) The Generic Division, which is responsible for developing and submitting ANDAs, relies on contributions from Pharmaceuticals, Laboratories, and Pharma; the Generic Division's president is a Pharmaceuticals employee, and the Generic Division's products are manufactured by Laboratories and marketed and sold by Pharma.⁵ (*Id.* at ¶¶ 26-30) Also, the

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⁴Pharmaceuticals reports financial results to investors by reference to these divisions, not by reference to the individual subsidiaries (D.I. 75 at ¶ 22) Similarly, employees from Pharmaceuticals, Laboratories, and Pharma often identify themselves as employees of Pharmaceuticals or one of its operating divisions and not as employees of the corporation employing them. (*Id.* at ¶ 38)

⁵In addition, Pharmaceuticals' Board of Directors ("the Board"), along with the Board-created Regulatory Compliance Committee, has oversight responsibilities for, *inter alia*, the Generic Division's development, preparation, and submission of ANDAs incident to the manufacture, marketing, and sale of generic products. (D.I. 75 at ¶¶ 23-25)

Redacted, *i.e.*, those that would normally require ANDAs, Redacted
(*Id.* at ¶ 31; see also *id.* at ¶¶ 32, 34)

B. The Preparation and Filing of the ANDA

The Redacted chose FENTORA® for development as a generic product, after which a fentanyl buccal project management team began regular meetings – meetings that included Pharmaceuticals' and Laboratories' employees – to plan the development of generic fentanyl citrate buccal tablets and the submission of the ANDA. (*Id.* at ¶¶ 33-35) Redacted

(*Id.* at ¶ 37)

(*Id.* at ¶ 36)

(*Id.* at ¶ 39)

(*Id.* at ¶ 40)

On Redacted, the ANDA was filed seeking FDA approval for the commercial manufacture, use, and sale throughout the United States of generic fentanyl tablets

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⁶ (See *id.* at ¶ 50; D.I. 97 at ex. 13)

Filed in connection with the ANDA was a Paragraph IV Patent Certification asserting that the '604 and '590 patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the proposed generic fentanyl citrate buccal tablets. (See *id.* at ¶ 51)

On or about April 21 and 22, 2008, plaintiffs received letters (the "Paragraph IV letters") notifying them of the filing of the ANDA and the allegations in the Paragraph IV Patent Certification. (*Id.* at ¶¶ 51-52) The Paragraph IV letters were on Pharmaceuticals' letterhead but referred to both Pharmaceuticals and Laboratories in relation to the ANDA. (*Id.* at ¶¶ 42, 45, 51, 54) Likewise, the Paragraph IV letters were signed by Ernest Lenge, Ph.D., identified as "Executive Director, Regulatory Affairs, Watson Laboratories, Inc.," but instruct plaintiffs to direct ANDA-related information requests to Redacted

C. Laboratories' Contacts with Delaware

Laboratories has transacted business, including contracting with, and/or

⁶ Redacted
(D.I. 75 at ¶ 50) If the ANDA is approved, Pharma and Pharmaceuticals will be involved in the manufacture, marketing, and sale of the generic products. (*Id.* at ¶ 64)

⁷

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purchasing goods or services with, companies located in Delaware, including

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(D.I. 79 at ex. 10, p. 8; *id.* at ex. 11) Laboratories first entered into a contract with Redacted on March 4, 1999, to purchase Redacted (*id.* at ex. 13) Laboratories and Redacted later amended this contract on three different occasions. July 17, 2000 (*id.* at ex. 14), December 24, 2003 (*id.* at ex. 15), and December 16, 2005 (*id.* at ex. 27).

Laboratories and Redacted also entered into an additional contract on March 10, 2003, to purchase Redacted ⁶ (*id.* at ex. 16) Between 2000 and 2008, Laboratories purchased more than \$115 million worth of products from Redacted Delaware facility. (*id.* at ex. 12) The Redacted executive responsible for this supplier relationship with Laboratories is located in Redacted Delaware, and the parties have met multiple times in Redacted (*id.* at ex. 19)

Laboratories' dealings with other Delaware companies have included the following:

- Between fiscal years 2002 and 2008, Laboratories purchased from Redacted \$15 million of Redacted manufactured in Redacted Delaware. (*id.* at ex. 20) Redacted is an approved manufacturer. (*id.* at ex. 22)
- Between 2004 and 2008, Laboratories obtained from Redacted facility products and services worth more than \$1.5 million. (*id.* at ex. 24-26)
- Between 2005 and 2008, Laboratories has licensed software and obtained

⁶This contract is nominally between Pharmaceuticals and Redacted (see D.I. 79 at ex. 16), but it was signed by the same person who signed the December 24, 2003 amendment on behalf of Laboratories (see *id.* at 15).

services worth approximately \$575,000 from Redacted, a Delaware corporation headquartered in Redacted (*Id.* at ex. 28-30)

- Between 2004 (at the latest) and 2008, Laboratories purchased goods from Redacted a Delaware entity, headquartered in Redacted (*Id.* at ex. 22, 31-33) Redacted, is an "approved manufacturer." (*Id.* at ex. 22)
- Between 2004 and 2008, Laboratories purchased from Redacted goods and services valued at more than \$400,000. (*Id.* at ex. 11) Redacted is a Delaware entity headquartered in Redacted, Delaware. (*Id.* at ex. 38-40)
- Pursuant to a contract in effect from April 16, 2003 through March 31, 2005, Laboratories received consulting services from Redacted Redacted a Delaware corporation headquartered in Redacted Delaware (*Id.* at ex. 34-36)
- Laboratories solicited Redacted to participate in a supplier evaluation program. (*Id.* at ex. 37) Redacted is an "approved manufacturer" and is located in Delaware. (*Id.* at ex. 22, 37)

Laboratories sells products in Delaware (and elsewhere in the United States)

through Pharma pursuant to a Redacted⁹ (D.I. 17 at ex. 2 D) Redacted

¹⁰ (*Id.* at

⁹The Redacted does not appear to be the product of arm's-length negotiations.

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¹⁰Also, from July 1, 2005, to June 30, 2006, Pharma was party to a contract with the Delaware Department of Health and Social Services ("DHSS") whereby Pharma agreed to pay rebates to DHSS for oxytrol. (D.I. 79 at ex 54)

ex. 2.D; D.I. 79 at ex. 45-46)

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Sales data from IMS Health, Inc., an organization that provides pharmaceutical sales data, estimates revenues of roughly \$22.2 million from Laboratories' products sold in Delaware from October 2006 through October 2008. (*Id.* at ex. 68)

III. STANDARDS OF REVIEW

In reviewing a motion filed under Rule 12(b)(1), the court must first identify whether the motion presents a facial or factual challenge to the court's subject matter jurisdiction. See *Samsung Elecs. Co., Ltd. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008). Where the movant presents a facial challenge, the court must accept all factual allegations in the complaint as true and may only consider the complaint and documents referenced therein or attached thereto. *Id.* (citing *Gould*

¹¹It appears from the evidence that, at no time relevant here, has Pharma had more than a handful employees residing or working in Delaware. (D.I. 79 at ex. 46, 55-57)

Elecs., Inc., v. United States, 220 F.3d 169, 176 (3d Cir. 2000)). Where the movant presents a factual challenge, the court need not confine its consideration to the allegations of the complaint nor accept those allegations as true. *Mortensen v. First Fed. Sav. & Loan*, 549 F.2d 884, 891 (3d Cir. 1977). Rather, the court may consider evidence outside the pleadings, including affidavits, depositions, and testimony, "to resolve any factual issues bearing on jurisdiction."¹² *Samsung*, 541 F. Supp. 2d at 648 (citing *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997)). "[P]laintiff bears the burden of proving that [subject matter] jurisdiction exists." *Id.*

In reviewing a motion filed under Rule 12(b)(2), the court must accept all of a plaintiffs' allegations as true and construe disputed facts in the plaintiff's favor. *Pinker v. Roche Holding Ltd*, 292 F.3d 361, 368 (3d Cir. 2002) (quoting *Carteret Sav. Bank, FA v. Shushan*, 954 F.2d 141, 142 n.1 (3d Cir. 1992)). A plaintiff still, however, bears "the burden of demonstrating the facts that establish personal jurisdiction."¹³ *Id.* (citing *Mellon Bank (East) PSFS Nat'l Ass'n v. Farino*, 960 F.2d 1217, 1223 (3d Cir. 1992)).

In reviewing a motion filed under Rule 12(b)(6), the court must accept all factual

¹²Although 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." See 2 James W. Moore, Moore's Federal Practice § 12.30[1] (3d ed. 1997). 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).

¹³"[C]ourts are to assist the plaintiff [in meeting its burden] by allowing jurisdictional discovery unless the plaintiff's claim is 'clearly frivolous.'" *Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003).

allegations in a complaint as true and take them in the light most favorable to plaintiff.¹⁴ See *Erickson v. Pardus*, 551 U.S. 89, 127 S.Ct. 2197, 2200 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). 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, 127 S.Ct. 1955, 1964 (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 1964-65 (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.* at 1959.

Finally, in reviewing a motion filed under 12(b)(7), the court must accept the allegations in the complaint as true and may consider evidence outside the pleadings. *E.g.*, *Davis Companies v. Emerald Casino, Inc.*, 268 F.3d 477, 479 n.2, 480 n.4 (7th Cir. 2001); *Cafesjian v. Armenian Assembly of Am., Inc.*, Civ. No. A. 07-2079, 2008 WL 906194, *4 (D. Minn. Mar. 31, 2008); *Colon v. Blades*, 570 F. Supp. 2d 204, 209 (D.P.R. 2008). "The movant has the burden of showing why the absent party should be joined." *Colon*, 570 F. Supp. 2d at 209; see also *Rotec Indus., Inc. v. Aecon Group*,

¹⁴"Generally, in ruling on a motion to dismiss, a district court relies on the complaint, attached exhibits, and matters of public record." *Sands v. McCormick*, 502 F.3d 263, 268 (3d Cir. 2007) (citing *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)).

Inc., 436 F. Supp. 2d 931, 933 (N.D. Ill. 2006).

IV. DISCUSSION

A. Personal Jurisdiction Over Laboratories

To establish personal jurisdiction, plaintiff must show, by a preponderance of the evidence, that (1) "there is a statutory basis for jurisdiction under the forum state's long arm statute"¹⁵ and (2) "the exercise of jurisdiction comports with the defendant's right to due process." *L'Athene, Inc. v. EarthSpring LLC*, 570 F. Supp. 2d 588, 590 (D. Del. 2008) (citing *Time Share Vacation Club v. Atlantic Resorts, Ltd.*, 735 F.2d 61, 66 (3d Cir. 1984); *Reach & Assocs. P.C. v. Dencer*, 269 F. Supp. 2d 497, 502 (D. Del. 2003)).

Pursuant to the Delaware long arm statute, 10 *Del.C.* § 3104, a court may exercise personal jurisdiction over a defendant where the defendant or its agent, as provided in subsection (c)(1), "[t]ransacts any business or performs any character of work or service in the State" or, as provided in subsection (c)(4), "[c]auses tortious injury¹⁶ . . . [and] regularly does or solicits business [in the State], engages in any other persistent course of conduct in the State or derives substantial revenue from services,

¹⁵The court applies the Delaware long arm statute consistent with Delaware state courts' interpretations. *Intel Corp. v. Broadcom Corp.*, 167 F. Supp. 2d 692, 700 (D. Del. 2001); see also *LSI Indus. Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1371 (Fed. Cir. 2000). Delaware state courts interpret the long arm statute as "confer[ring] jurisdiction to the maximum extent possible under the Due Process Clause." *Hercules Inc. v. Leu Trust & Banking (Bahamas) Ltd.*, 611 A.2d 476, 480-81 (Del. 1992); *LaNuova D & B S.p.A. v. Bowe Co., Inc.*, 513 A.2d 764, 768 (D. Del. 1986); see also *Boone v. Oy Partek Ab*, 724 A.2d 1150, 1156-57 (Del. Super. 1997, *aff'd*, 707 A.2d 765 (Del. 1998). As this district has before acknowledged, Delaware courts "liberally interpret the [long arm] statute in favor of exercising jurisdiction." *Jeffreys v. Exten*, 784 F. Supp. 146, 151 (D. Del. 1992).

¹⁶Patent infringement is a tortious act for purposes of the Delaware long-arm statute. *Merck & Co., Inc. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 373 (D. Del. 2002).

or things used or consumed in the State." 10 *Del.C.* § 3104(c). The long arm statute lists the subsection (c)(4) activities in the disjunctive, and the defendant need only engage in one for that subsection to apply. *Power Intergrations, Inc. v. BCD Semiconductor Corp.*, 547 F. Supp. 2d 365, 374 (D. Del. 2008) (citing *LaNuova*, 513 A.2d at 769)

If defendant is found to be within the reach of the long arm statute, the court then must analyze whether the exercise of personal jurisdiction comports with due process. *Shoemaker v. McConnel*, 556 F. Supp. 2d 351, 354 (D. Del. 2008). The exercise of personal jurisdiction comports with due process where "the defendant's conduct is such that it should 'reasonably anticipate being haled into court there.'" *L'Athene*, 570 F. Supp. 2d at 591 (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)). Personal jurisdiction may be either specific or general. *Vikoma Int'l, Ltd. v. Oil Stop, Inc.*, 1993 WL 14647, at *2 (D. Del. Jan. 14, 1993). For the court to exercise specific personal jurisdiction consistent with due process, plaintiff's cause of action must have arisen from the defendant's activities in the forum state. *Id.* (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985); *Woodson*, 444 U.S. at 297) For the court to exercise general personal jurisdiction consistent with due process, plaintiff's cause of action can be unrelated to the defendant's activities in the forum state so long as the defendant has "continuous and systematic contacts with the forum state." *Applied Biosystems, Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1470 (D. Del. 1991); *Vikoma*, 1993 WL 14647, at *2. Subsection (c)(1) of the long arm statute requires a showing of specific jurisdiction. See *G & G LLC v. White*, 535 F. Supp. 2d

452, 461 (D. Del. 2008). In contrast, subsection (c)(4) of the long arm statute requires a showing of general jurisdiction, that is, a showing that defendant or its agent, through more than minimum contacts, is "generally present" in the forum state. See *id.*; *Shoemaker*, 556 F. Supp. 2d at 355.

Relevant here, there are two theories under which a defendant company may be subject to personal jurisdiction in Delaware by virtue of the court's personal jurisdiction over the defendant company's affiliate: the "alter ego theory" and the "agency theory." *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 559 (D. Del. 1998). "Under the alter ego theory, a court may attribute the actions of a subsidiary to its parent and ignore corporate boundaries if the court finds that the subsidiary is a mere "alter ego" of the parent." *Id.* This theory properly applies where plaintiff shows "some fraud, injustice, or inequity in the use of the corporate form," including a showing that the two corporations did not observe corporate formalities. *Id.*

"Under the agency theory, the court may attribute the actions of a subsidiary company to its parent where the subsidiary acts on the parent's behalf or at the parent's direction." *Id.* at 560. This theory does not treat the parent and subsidiary as one entity, but rather attributes specific acts to the parent because of the parent's authorization of those acts. *Id.*; see also *Applied Biosystems*, 772 F. Supp. at 1464 (under the agency theory, "only the precise conduct shown to be instigated by the parent is attributed to the parent"). The agency theory may be applied not only to parents and subsidiaries, but also to companies that are "two arms of the same business group," operate in concert with each other, and enter into agreements with

each other that are nearer than arm's length. See *Wesley-Jessen Corp. v. Pilkington Visioncare, Inc.*, 863 F. Supp. 186, 188-89 (D. Del. 1993).

In the case at bar, plaintiffs argue that the acts of Pharma, which is a Delaware corporation selling products in Delaware, should be attributed to Laboratories for purposes of establishing personal jurisdiction. The court concludes that Pharma's acts are not attributable to Laboratories under the alter ego theory because plaintiffs have not shown that Laboratories and Pharma have engaged in fraud or failed to maintain their corporate formalities; collaborating on the parent company's business operations and dealing at nearer than arm's length is neither fraud nor a disregard for the corporate form. The court does conclude, however, that Pharma's sales activities in Delaware are attributable to Laboratories under the agency theory because: (1) Pharma, pursuant to the nearer-than-arm's-length ^{Redacted}, was the sales agent for Laboratories' products in the United States, including Delaware; and (2) Pharma and Laboratories operated in concert with each other with respect to drug sales. The question, then, is whether Pharma's sales activities in Delaware and Laboratories' dealings with businesses in Delaware are, taken together, sufficient to establish personal jurisdiction over Laboratories.

The court concludes that they are sufficient to establish general personal jurisdiction. Laboratories' activities in Delaware are not sufficient to establish specific personal jurisdiction because they do not relate to the patent infringement action brought against Laboratories and so do not satisfy subsection (c)(1) of Delaware's long arm statute. See *C.R. Bard*, 997 F. Supp. at 559 (citing *Applied Biosystems*, 772 F. Supp. at 1466) ("Section 3104(c)(1) provides for specific jurisdiction over a party, where

that party's actions are linked to the cause of action.") (internal quotation marks omitted). The same activities are sufficient, however, to establish general personal jurisdiction because they show that Laboratories "regularly does or solicits business" in Delaware or engages in a "persistent course of conduct" in Delaware and so satisfy subsection (c)(4) of Delaware's long arm statute. Thus, plaintiffs have shown a basis under Delaware's long arm statute for jurisdiction over Laboratories.

The court also finds that the exercise of general personal jurisdiction over Laboratories comports with due process. Laboratories' activities in Delaware are "continuous and systematic." Over the last eight years, approximately, Laboratories has transacted business in Delaware with multiple suppliers, some of which are "approved manufacturer[s]" with which future transactions are reasonably foreseeable.¹⁷ During that same time period, Laboratories has, through Pharma, sold products in Delaware through the efforts of sales personnel assigned to cover Delaware. There is nothing unintended or haphazard about these efforts to sell products in Delaware, and nothing in the record suggests these efforts have ceased. Indeed, these activities, taken together, are of the sort that typically support the exercise of general personal jurisdiction. See *Kloth v. S. Christian Univ.*, 494 F. Supp. 2d 273, 280 (D. Del. 2007)

¹⁷The Supreme Court held in *Helicopteros Nacionales de Colombia, S.A. v. Hall*, that purchases and related trips, even if occurring at regular intervals, are not sufficient to support the exercise of general personal jurisdiction where the purchases are not central to the conduct of its business. See 466 U.S. 408, 417-18 (1984). Assuming that Laboratories' purchases are not central to the conduct of its business, the instant case is still distinguishable from *Helicopteros* because, whereas the *Helicopteros* defendant's contacts with the forum state consisted primarily of purchases and related training, Laboratories, through Pharma, has employees assigned to cover the forum state and has generated revenue from sales in the forum state.

(exercise of general personal jurisdiction typically requires that defendant be engaged in longstanding business in forum state, including, *inter alia*, shipping products and maintaining offices there). Thus, Laboratories can reasonably expect to be "haled into court" in Delaware, and its motion to dismiss is denied.

B. Pharmaceuticals' and Pharma's Liability Under § 271(e)(2)

"It shall be an act of infringement to submit" an ANDA to the FDA 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); see also *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 305 (D.Md. 2007). 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. *Id.* at 306-07; see also *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 492-94 (E.D.Va. 2005). "Active involvement" includes "marketing and distributing the approved generic drugs in the United States." *Wyeth*, 505 F. Supp. 2d at 306; see also *Aventis*, 403 F. Supp. 2d at 492-93.

Pharmaceuticals and Pharma move to dismiss counts I and IV on the grounds that they did not "submit" the ANDA. Accepting plaintiffs' allegations as true, however, the court concludes that Pharmaceuticals and Pharma did "submit" the ANDA.¹⁸ As described above, each took part in Generic Division operations and contributed employees to the various teams responsible for preparing the ANDA, and employees of

¹⁸Laboratories does not dispute that it "submit[ted]" the ANDA.

each prepared and executed ANDA-related documents. Moreover, each will be involved in the marketing and distribution of the generic fentanyl buccal tablets if the ANDA is approved. These allegations are sufficient to raise Pharmaceuticals' and Pharma's active involvement in the preparation of the ANDA above the speculative level. Accordingly, with respect to counts I and IV, Pharmaceuticals' and Pharma's motions to dismiss are denied.

C. Pharmaceuticals' and Pharma's Liability Under § 271(b)

"Pursuant to 35 U.S.C. § 271(b), 'whoever actively induces infringement of a patent shall be liable as an infringer.'" *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 321 F. Supp. 2d 612, 615 (D. Del. 2004). To support a count of active inducement, a plaintiff must allege that the accused infringer "knowingly aided and abetted another's direct infringement," *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999), and committed an act that constitutes inducement, *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1559 (Fed. Cir. 1994). Where an inducement claim is premised on the filing of an ANDA pursuant to § 271(e)(2), 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. *Pfizer*, 321 F. Supp. 2d at 616; *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007).

As noted above, plaintiffs here have alleged that Pharmaceuticals and Pharma will be involved in the marketing and distribution of the generic fentanyl buccal tablets if the ANDA is approved. These allegations are sufficient to raise Pharmaceuticals' and

Pharma's active inducement above the speculative level. Accordingly, with respect to counts II and V, Pharmaceuticals' and Pharma's motions to dismiss are denied.

D. Declaratory Judgment Act Jurisdiction

"The Declaratory Judgment Act requires an actual controversy between the parties before a federal court may exercise jurisdiction." *Id.* (internal quotation marks omitted). A plaintiff bringing an action for declaratory judgment must prove, by a preponderance of the evidence, that an actual controversy exists. *See id.* (citing *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 (Fed. Cir. 1992)). An actual controversy exists where "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) (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). "[T]he phrase 'case of actual controversy' in the [Declaratory Judgment] Act refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." *MedImmune*, 549 U.S. at 127 (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937)). Consequently, the analysis of whether "a case of actual controversy" exists is essentially an analysis of whether Article III standing exists. *See generally id.*; *see also, e.g., Sandisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007), *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 901 (Fed. Cir. 2008).

For Article III standing to exist, a plaintiff must show "injury in fact, connection between the challenged conduct and the injury, and redressability of the injury by the

requested remedy." *Allergan, Inc v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003) (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998)). Relevant here, while claims under 35 U.S.C. § 271(e)(2) are, "by [their] very nature, speculative to a certain degree, . . . a section 271(e)(2) induced infringement claim . . . is not sufficiently so to contravene the case or controversy requirement." *Allergan*, 324 F.3d at 1331-32. Thus, claims for induced infringement predicated on § 271(e)(2), "filed prior to the occurrence of direct infringement, do[] not violate the case or controversy requirement of Article III," *id.* at 1332, or, by logical extension, the case or controversy requirement of the Declaratory Judgment Act.

Applying the foregoing, it is clear that plaintiffs' counts III and VI, seeking declaratory judgment of infringement of the patents-in-suit under §§ 271(b) or (c), are proper so long as plaintiffs can show the existence of real and immediate controversy. The court concludes, under the totality of the circumstances, that such a controversy exists. Defendants have filed the ANDA and have declared their intent to manufacture, market, and sell potentially infringing products in the event that the FDA approves the ANDA. (See D.I. 14 at ex. 2, ¶ 20) In the context of a § 271(e)(2) infringement action, where the court is engaged in a forward-looking analysis of what defendants will do upon ANDA approval, defendants' declared intent is sufficient to make the controversy real and immediate. Accordingly, defendants' joint motion to dismiss counts III and VI is denied.¹⁹

¹⁹While the court finds that there is a sufficiently real and immediate controversy to allow it to exercise jurisdiction over these declaratory judgment counts, it is not entirely clear to the court why these counts have been included. Plaintiffs should be prepared to discuss these counts during the next proceeding with the court.

V. CONCLUSION

For the aforementioned reasons, the court denies defendants' motions to dismiss. An appropriate order shall issue.

