UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

TORRENT PHARMACEUTICALS LIMITED and TORRENT PHARMA INC., Plaintiffs,	)	
v.	)	**No. 16 C 2988**
DAIICHI SANKYO, INC. and DAIICHI SANKYO CO., LTD., Defendants.	)	**Judge Rebecca R. Pallmeyer**
MYLAN PHARMACEUTICALS INC., Intervenor-Defendant.	)	
ALEMBIC PHARMACEUTICAS LIMITED Plaintiff,	)	
v.	)	**No. 16 C 3956**
DAIICHI SANKYO CO., LTD., Defendant.	)	**Judge Rebecca R. Pallmeyer**
MYLAN PHARMACEUTICALS INC., Intervenor-Defendant.	)	
AUROBINDO PHARMACEUTICALS, LIMITED and AUROBINDO PHARMA, INC. Plaintiffs,	)	
v.	)	**No. 16 C 4876**
DAIICHI SANKYO, INC. and DAIICHI SANKYO CO., LTD., Defendants.	)	**Judge Rebecca R. Pallmeyer**
MYLAN PHARMACEUTICALS INC., Intervenor-Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs, three manufacturers of generic drugs, are seeking a declaratory judgment, which they believe would give them the green light to produce a generic form of Defendants' popular blood pressure medicine, Benicar® (olmesartan medoxomil), at the earliest possible date. As explained here, however, this court lacks jurisdiction over Defendants. Accordingly,

the case is dismissed without prejudice.

INTRODUCTION

Defendant Daiichi Sankyo Co., Ltd. ("DS Japan"), a Japanese pharmaceutical company, owns certain patents, including United States Patent No. 6,878,703 ("the '703 patent"), concerning the pharmaceutical drug product Benicar®. Defendant Daiichi Sankyo, Inc. ("DS USA"), DS Japan's United States subsidiary, is incorporated in Delaware and has its principal place of business in New Jersey. DS USA markets and sells Benicar® throughout the United States and holds the United States New Drug Application ("NDA") for the drug.[1] Plaintiffs Torrent Pharmaceuticals Limited and Torrent Pharma Inc. ("Torrent"), Alembic Pharmaceuticals Limited ("Alembic"), and Aurobindo Pharmaceuticals Limited and Aurobindo Pharma Inc. ("Aurobindo") are all seeking approval from the United States Food and Drug Administration ("FDA") to market and sell their own generic versions of Benicar®. Each has brought separate suits in this district seeking a declaratory judgment that their applications for FDA approval, as well as the sale and marketing following such approval, would not infringe the '703 patent.[2] Without such a judgment, Plaintiffs insist that Intervenor-Defendant Mylan Laboratories Limited ("Mylan") will have the exclusive right to market a generic version of Benicar® for a 180-day period beginning October 25, 2016. Under federal law, Mylan is entitled to this exclusivity period because it was the first generic manufacturer to challenge the '703 patent. Plaintiffs assert that a declaratory judgment of non-infringement in this case would result in Mylan's forfeiting the exclusivity period. Unless this court enters the judgment they seek, Plaintiffs contend, they will be deprived of sales revenue for the 180-day period, and the public will be deprived of the benefits of a competitive market for generic versions of Benicar®.

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[1] The court refers to DS Japan and DS USA collectively as "Daiichi."

[2] Torrent's case, No. 16 C 2988, was assigned to this court, and the court granted Alembic's [27] and Aurobindo's [46] motions to reassign their cases—No. 16 C 3956 and No. 16 C 4876, respectively—with Torrent's related case. Except where otherwise noted in this opinion, docket references are to the docket in *Torrent Pharm. Ltd. v. Daiichi Sankyo, Inc.*, 16 C 2988.

Plaintiffs have filed motions for summary judgment ([41], *Alembic Pharm. Ltd. v. Daiichi Sankyo Co.*, 16 C 3956 [16], *Aurobindo Pharm. Ltd. v. Daiichi Sankyo Inc.*, 16 C 4876 [17]), contending that Plaintiffs' products, as a matter of law, could not infringe the '703 patent because Defendants have already disclaimed the patent. Mylan has filed a motion for judgment on the pleadings [54], arguing that the court lacks subject matter jurisdiction. Mylan insists the declaratory judgment Plaintiffs seek would not redress their asserted injuries because it would not cause Mylan to forfeit its exclusivity period as Plaintiffs contend. In addition, Mylan argues that there is no case or controversy regarding infringement of the '703 patent because Daiichi has already disclaimed it. Defendants, for their part, contend that the court lacks personal jurisdiction over them and should therefore dismiss Plaintiffs' complaints in their entirety. For the reasons discussed below, the court agrees with Defendants and grants their motions to dismiss ([30], *Alembic*, No. 16 C 3956 [43], *Aurobindo*, No. 16 C 4876 [29]) for lack of personal jurisdiction.

BACKGROUND

Benicar® is drug approved by the FDA for the treatment of hypertension. *See* http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm215245.htm (last visited July 20, 2016). To obtain FDA approval to market and sell Benicar®, Defendants listed two patents in the FDA's published list of *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"). (Pl. Torrent's Compl. For Decl. J. (hereinafter "Torrent Compl.") [1] at 28.); *see* 21 U.S.C. § 355(b)(1) (requiring applicants to list patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug"). United States Patent No. 5,616,599 ("the '599 patent) covers the drug's active ingredient, olmesartan medoxomil, while the '703 patent covers methods of treatment. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1358 (Fed. Cir. 2015). The '703 patent remains listed in the Orange Book though Daiichi disclaimed every term

of the patent on July 11, 2006. (*Id.* ¶¶ 24, 29.)[3] With the '703 patent disclaimed, approved generic manufacturers would ordinarily be able to begin marketing a version of the drug when the '599 patent expired on April 25, 2016. Defendants, however, qualify for a six-month extension of their market exclusivity for the drug because they submitted certain data concerning the drug's effects on children. *See* 21 U.S.C. § 355a(b)(1)(B)(i); *Apotex*, 781 F.3d at 1358. As a result, FDA cannot approve any generic version of Benicar® until October 25, 2016, six months after the expiration of the '599 patent. (Torrent Compl. ¶ 32.)

Drug manufacturers who seek FDA approval to market and sell generic versions of previously-approved drugs may do so by submitting abbreviated new drug applications ("ANDAs"). *See* 21 U.S.C. § 355(j). Plaintiffs have submitted ANDAs with respect to their own generic versions of Benicar®. In doing so, they certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)[4] that the '703 patent will not be infringed by the manufacture, use, or sale of their generic products. Though each Plaintiff filed an ANDA containing such a "Paragraph IV" certification concerning the '703 patent, Intervenor-Defendant Mylan was the first generic manufacturer to do so. As a result, Mylan is presumptively entitled to a 180-day period, beginning once it enters

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[3] Defendants disclaimed the '703 patent, pursuant to 35 U.S.C. § 253, after receiving notice of Mylan's challenge to the patent's validity. (*See* Alembic Compl. ¶ 61.) Though Defendants requested that FDA delist the patent from the Orange Book, FDA must continue to list the patent because the first generic applicant's exclusivity period depends upon the patent's continued listing in the Orange Book. (*Id.* ¶¶ 61–62); *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1315–18 (D.C. Cir. 2010).

[4] Under 21 U.S.C. § 355(j)(2)(A)(vii), every ANDA must contain, among other information, a certification with respect to each patent which claims the drug at issue or claims a use for that drug

> (I) that such patent information has not been filed,
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> (II) that such patent has expired,
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> (III) of the date on which such patent will expire, or
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> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

in the market, in which it is the only generic manufacturer that can market and sell the drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv).[5] Plaintiffs point out, however, that the first ANDA filer's 180-day exclusivity may be forfeited under certain conditions. (Torrent Compl. ¶ 26.) They assert that if the FDA grants tentative approval for another ANDA filer and that filer obtains a non-appealable court judgment of non-infringement, the first ANDA filer would be required to market the drug within 75 days of the court judgment or else forfeit the exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(l)(bb)(AA).[6] Each Plaintiff claims that a declaratory judgment of non-infringement in this case, as long as it is entered (or, if appealed, affirmed) at least 75 days before October 25, 2016, would trigger forfeiture of Mylan's 180-day exclusivity period. (Torrent Compl. ¶ 46; Pl. Aurobindo's Compl. for Decl. J. [1] ¶ 44, *Aurobindo*, No. 16 C 4876 (hereinafter "Aurobindo Compl."); Pl. Alembic's Compl. for Decl. J. of Patent Non-infringement of U.S. Patent No. 6,878,703 [1] ¶ 94, *Alembic*, No. 16 C 3956 (hereinafter "Alembic Compl.").)

In an earlier lawsuit in this district, another manufacturer of a generic version of Benicar® sought the same declaratory judgment of non-infringement of patent '703 that Plaintiffs seek here. *See Apotex, Inc. v. Daiichi Sankyo, Inc.*, No. 12 C 9295, 2014 WL 114127, at *1 (N.D. Ill Jan. 9, 2014). In that case, the district court initially concluded that the case did not present a case or controversy and dismissed it for lack of subject-matter jurisdiction. *Id.* at *4. The Federal Circuit reversed that decision on appeal, finding that the parties' dispute over the plaintiff's ability to sell the patented drug involved sufficiently concrete and substantial stakes. *See Apotex*, 781 F.3d at 1361–62. On remand, the district court granted the generic manufacturer's motion for summary judgment of non-infringement. *Apotex, Inc. v. Daiichi*

[5] The 180-day exclusivity period provides "an incentive for generic pharmaceutical companies to challenge suspect Orange Book listed patents . . . ." *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008)

[6] A favorable judgment in the district court, from which Defendants fail to appeal, or which is affirmed by the Federal Circuit, would trigger the 75-day requirement. The possibility of a petition to the Supreme Court for a writ of certiorari does not render the decision "appealable" under the statute. *See* 21 U.S.C. § 355(j)(5)(D)(i)(l)(bb)(AA).

Sankyo, Inc., No. 12 C 9295, 2016 WL 98572, at *4 (N.D. Ill. Jan. 8, 2016). The court ruled that non-infringement follows as a matter of law from the fact that the '703 patent had been formally disclaimed. *Id.* Defendants have appealed that ruling, and the case is now pending again before the Federal Circuit. Plaintiffs suggest that for the same reason the court entered summary judgment in *Apotex*, this court should grant summary judgment in their favor in this case. (*See, e.g.*, Pl. Torrent's Br. in Supp. of its Mot. for Summ. J. of Noninfringement of U.S. Patent 6,878,703 [41] at 1.) In the alternative, they argue that the district court's decision in *Apotex* requires summary judgment in this case on collateral estoppel grounds. (*Id.*)

Defendants—respectively, a Japanese company and a company incorporated in Delaware with a primary place of business in New Jersey—object that the court lacks personal jurisdiction over them and argue for dismissal of Plaintiffs' complaints in their entirety without consideration of the merits. Plaintiffs respond that Defendants consented to, or waived their right to object to, personal jurisdiction in this court by failing to contest jurisdiction in the factually and legally similar *Apotex* litigation. And even apart from any waiver or consent, Plaintiffs contend, Defendants' contacts with the United States are sufficient to confer personal jurisdiction over them anywhere in the United States. In particular, they note that DS Japan has purposefully availed itself of the benefits of the United States patent laws by prosecuting and obtaining the '703 patent, engaging in licensing activities for the '703 patent, and allowing the patent to be listed in the FDA's Orange Book. (Pls.' Jt. Br. in Opp. of Defs.' Mot to Dismiss (hereinafter "Pls.' Jt Br.") [68] at 5–6.) DS USA, they point out, also benefits from the '703 patent's listing in the Orange Book and has employees in Illinois, sells products in Illinois, is registered to do business in Illinois, and has an appointed agent in Illinois. (*Id.* at 11–12.) The court will address Plaintiffs' personal jurisdiction arguments in turn.

DISCUSSION

Because the issue of personal jurisdiction in this declaratory judgment action is intimately related to patent law, the court applies the law of the Federal Circuit to determine

whether personal jurisdiction exists. *See Silent Drive, Inc. v. Strong Indus., Inc.*, 326 F.3d 1194, 1201 (Fed. Cir. 2003). In the absence of an evidentiary hearing, which neither party has requested in this case, a plaintiff bears the burden of making a prima facie showing that the court has personal jurisdiction over the defendants. *Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com de Equip. Medico*, 563 F.3d 1285, 1292 (Fed. Cir. 2009). When deciding whether Plaintiffs have met that burden, the court accepts the uncontroverted allegations in their complaints as true and resolves any factual conflicts in their favor. *Id.* Before discussing the merits of Plaintiffs' contention that Defendants' contacts with the United States allow this court to exercise personal jurisdiction over them, the court turns to Plaintiffs' argument that Defendants have waived a personal jurisdiction defense in this case.

I. Waiver

Plaintiffs assert that Defendants waived their right to challenge personal jurisdiction in this case by failing to raise the issue in the *Apotex* litigation. The *Apotex* suit, Plaintiffs note, was brought in this district and involved the same patent, the same undisputed material facts, and the same legal issues of infringement. (Pls.' Jt. Br. at 8.) Plaintiffs argue that it would be inequitable to allow Defendants, who have "enjoyed the full benefits of access to this District," to avoid litigating the same legal issues in the forum to which they previously consented. (*Id.*)

Plaintiffs' waiver theory is not the law. By failing to object to jurisdiction in a case brought by one plaintiff in 2012, Defendants did not waive their right to contest personal jurisdiction in 2016 in a separate—though similar—case brought by different plaintiffs. "A party's consent to jurisdiction in one case . . . extends to that case alone." *Klinghoffer v. S.N.C. Achille Lauro Ed Altri-Gestione Motonave Achille Lauro in Amministrazione Straordinaria*, 937 F.2d 44, 50 n.5 (2d Cir. 1991). In the cases on which Plaintiffs rely, courts have recognized that a defendant may consent—or waive the right to object—to personal jurisdiction in a district when the defendant itself has brought suit involving the same transaction in that district as a *plaintiff*. *See Gen. Contracting & Trading Co., LLC v. Interpole, Inc.*, 940 F.2d 20, 23 (1st Cir.

1991); *Neuralstem, Inc. v. StemCells, Inc.*, 573 F. Supp. 2d 888, 898 (D. Md. 2008). In such circumstances, where a defendant has previously brought suit in the forum, it is fair to conclude that the defendant has "purposefully availed itself of the privileges and benefits of [the] forum." *Neuralstem*, 573 F. Supp. 2d at 898. And it does appear inequitable to allow a party to "enjoy the full benefits of access to a state's courts *qua* plaintiff, while nonetheless retaining immunity from the courts' authority *qua* defendant" concerning claims asserted by the party it was suing. *Gen. Contracting & Trading*, 940 F.2d at 23.

But where a party itself has not instituted an action in the district and has merely failed to contest jurisdiction in some prior case, equity does not require the party to adhere to that position in a later case. It is quite possible that a party may decide to waive a personal jurisdiction defense based on the the circumstances of one case but make a different decision in a later case based on changed circumstances or other strategic considerations.

Permitting Defendants to assert a jurisdictional defense is particularly appropriate in this case because the Supreme Court's personal jurisdiction jurisprudence has developed significantly between the filing of the *Apotex* suit and now. In 2014, the Supreme Court issued its decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). Departing from the "expansive views" of general jurisdiction held by some lower courts, *id.* at 763, the Court in *Daimler* ruled that general jurisdiction must be limited to those situations in which a defendant's contacts with the forum are so continuous and systematic that the defendant is "essentially at home" in the forum state. The paradigmatic bases for general jurisdiction over a corporation, the Court observed, are the place of incorporation or the principal place of business. *Id.* at 754. Following *Daimler*, lower courts have recognized that it is now "incredibly difficult to establish general jurisdiction in a forum other than" the place where a defendant is incorporated or has its principal place of business. *Monkton Ins. Servs., Ltd. v. Ritter*, 768 F.3d 429, 432 (5th Cir. 2014); *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 627 (2d Cir. 2016). The *Apotex* case was filed in 2012, well before *Daimler*. Defendants therefore plausibly assert that their failure to

contest personal jurisdiction in *Apotex* was based on a good-faith position that general jurisdiction may have been present in that case—a position now foreclosed in this case by *Daimler*. (*See* Defs.' Reply in Supp. of Mots. to Dismiss Pl.'s Compls. [83] at 10.) In any event, whatever Defendants' reasons for failing to contest personal jurisdiction in *Apotex*, Plaintiffs cite no case in which a court found that a party consented to jurisdiction in one case by failing to raise that defense in a separate case brought by a different plaintiff. Defendants' waiver of personal jurisdiction in that case does not carry over to this one.[7]

II. Specific Jurisdiction

In most cases, the law of the state in which a district court sits will determine the bounds of that court's jurisdiction. *See* FED. R. CIV. P. 4(k)(1)(A) (service of process establishes jurisdiction over a defendant "who is subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located"). In addition to any jurisdictional limitations imposed by state law, the "Due Process Clause of the Fourteenth Amendment [also] constrains a State's authority to bind a nonresident defendant to a judgment of its courts." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). In Illinois, because the state's long-arm statute allows the exercise of jurisdiction on any basis permitted by the United States Constitution, "the state statutory and federal constitutional requirements merge." *uBID, Inc. v. GoDaddy Grp., Inc.*, 623 F.3d 421, 425 (7th Cir. 2010); *see* 735 Ill. Comp. State. 5/2-209(c). The Due Process Clause permits courts to exercise either general ("all-purpose") jurisdiction or specific ("conduct-linked") jurisdiction. *Daimler*, 134 S. Ct. at 751. Where a defendant is "essentially at home" in a

[7] Plaintiffs also argue that Defendants waived personal jurisdiction in this case by agreeing to the form of the judgment entered in *Apotex* after Judge Coleman granted summary judgment. (*Id.*) In support of this claim, they cite to an unpublished Federal Circuit opinion. *See Aeration Sols., Inc. v. Dickman*, 85 F. App'x 772, 774 (Fed. Cir. 2004) ("[T]he defendants also waived personal jurisdiction concerns by consenting to an injunction in this jurisdiction."). In that case, however, the court ruled simply that by signing a stipulated injunction order, without reserving the right to challenge jurisdiction, a defendant waives its right to raise a personal jurisdiction defense *later in that same case*. *Id.* at *3. *Aeration* suggests nothing about the potential waiver effect of a defendant's agreement to the language of a judgment before another court in a different case.

forum—for example, in the state in which a corporation is incorporated—a court in that forum may exercise general jurisdiction over the defendant "on any and all claims." *Id.* at 760. Plaintiffs concede that Defendants are not subject to general jurisdiction in this case. (Pls.' Jt. Br. at 3.) In situations like this, where a defendant is not essentially at home in the forum and thus not subject to general jurisdiction, a court may still exercise *specific* jurisdiction if the defendant has sufficient minimum contacts with the forum and the suit arises out of or relates to such contacts. *Daimler*, 134 S. Ct. at 749. In the typical case, therefore, the specific personal jurisdiction analysis focuses on the relationship among the defendant, the forum state, and the conduct at issue in the litigation. *Walden*, 134 S. Ct. at 1121.

In addition, in some cases, where a defendant is not subject to jurisdiction in any state's courts and the plaintiff's claim arises under federal law, any federal district court may properly exercise jurisdiction under the so-called federal long-arm statute. *See* FED. R. CIV. P. 4(k)(2). As is the case when jurisdiction is grounded in Rule 4(k)(1)(a), the court's exercise of jurisdiction in a Rule 4(k)(2) case must still comport with the Constitution's due process requirements. *Id.* In such a case, in determining whether the exercise of specific jurisdiction is constitutionally proper, the court considers the entire United States as the forum and asks whether the defendant had sufficient minimum contacts with the country as a whole. *Synthes*, 563 F.3d at 1295.

Plaintiffs assert that the court may properly exercise jurisdiction over DS USA under Rule 4(k)(1)(a) (and thus under the Illinois long-arm statute) and over DS Japan under Rule 4(k)(2). For that to be true, the court would have to find that DS USA had sufficient contacts with Illinois, that DS Japan had sufficient contacts with the United States, and that Plaintiffs' claims arise from or relate to those contacts. In making such a determination, the Federal Circuit applies a three-factor test, asking whether "(1) the defendant purposefully directed its activities at residents of the forum; (2) the claim arises out of or relates to the defendant's activities with the forum; and (3) assertion of personal jurisdiction is reasonable and fair." *Id.* at

1291.

Before analyzing Defendant's forum-based activities, however, the court must determine which of Defendants' activities are relevant to the jurisdictional analysis in this case. As the Federal Circuit has explained, in "the ordinary patent infringement suit," the patentee plaintiff asserts a claim against a defendant who has engaged in some act of "making, using, offering to sell, selling, or importing products or services" that allegedly infringed the plaintiff's patent. *Avocent Huntsville Corp. v. Aten Int'l Co.*, 552 F.3d 1324, 1332 (Fed. Cir. 2008). In such cases, the jurisdictional inquiry can be focused on the nature and extent of the defendant's allegedly infringing commercialization of the accused products or services within the forum. *Id.* But in the case of a declaratory judgment action where a plaintiff is asserting a claim of non-infringement against the patentee, the defendant's activities that give rise to or are related to the suit are those concerning the *enforcement* or the *defense of the validity* of the patent at issue. *Id.* at 1334. In such cases, therefore, the defendant patentee's commercialization activity in the forum is not relevant to enforcement or defense of the patent. Thus, in declaratory judgment actions against patentees, the Federal Circuit has consistently required the defendant to have engaged in activities related to enforcement or defense of the patent within the forum for the exercise of specific jurisdiction to be proper. *Id.* at 1334–35.

Under a straightforward application of *Avocent* to this declaratory judgment action, it appears that the court lacks jurisdiction over Defendants. Plaintiffs have not alleged that DS USA engaged in any activities relating to enforcement of the '703 patent in Illinois or that DS Japan has engaged in such activities within the United States. Indeed, Defendants assert that DS Japan has never sought to enforce the '703 patent against any alleged infringer. (Decl. of Kevin Takeuchi in Supp. of Defs.' Mot. to Dismiss (hereinafter "Takeuchi Decl.") [31-1] ¶ 11.) Plaintiffs contend that the mere fact that DS Japan filed for and obtained the '703 patent is a sufficient contact with the United States to support jurisdiction. (Pls.' Jt. Br. at 5.) But it would be inconsistent with Federal Circuit precedent to conclude that a foreign patentee could be sued

in any United States District Court merely because it has obtained a United States patent. The Federal Circuit has previously ruled that a foreign patentee cannot be haled into a forum in a declaratory judgment action merely because it has sent a cease-and-desist letter to an alleged infringer within the forum. *Silent Drive, Inc. v. Strong Indus., Inc.*, 326 F.3d 1194, 1202 (Fed. Cir. 2003). "[E]xercis[ing] jurisdiction in such a situation would not comport with fair play and substantial justice." *Id.* (internal quotation marks omitted). If sending a cease-and-desist letter into a forum is insufficient to establish personal jurisdiction, then *a fortiori*, a patentee's having applied for and obtained the patent in the first place cannot be an adequate basis to confer jurisdiction.

Plaintiffs also rely on the fact that DS Japan allegedly "engaged in licensing activities for the '703 patent" (including licensing it to DS USA) and allowed the patent to be listed in the Orange Book. (Pls.' Jt. Br. at 6.) Indeed, the Federal Circuit has recognized that licensing activity can be the basis for specific jurisdiction in a declaratory judgment non-infringement case, but in order for licensing activity to support jurisdiction, the license at issue must be of the sort that "imposes enforcement obligations with a party residing or regularly doing business in the forum." *Avocent*, 552 F.3d at 1334. Plaintiffs' complaints contain no allegations concerning DS Japan's licensing of the '703 patent; Plaintiffs assert only in their joint brief opposing the motion to dismiss that DS Japan has "engaged in licensing activities." (Pls.' Jt. Br. at 6.) Without more specific details about the type of licensing in which DS Japan has engaged, Plaintiffs' allegation is inadequate to confer jurisdiction in an action like this. Notably, DS Japan specifically denies Plaintiffs' claim that it has licensed the '703 patent to DS USA, and Plaintiffs have offered nothing to rebut that denial. (Takeuchi Decl. ¶ 13.) Finally, for the same reason that simply obtaining a patent is inadequate to confer jurisdiction in a case like this, so too is Defendants' mere listing of the patent in the FDA's Orange Book. In short, for declaratory judgment actions for non-infringement like this one, specific personal jurisdiction requires a showing of the patentee's enforcement activities within the forum, and Plaintiffs have alleged no

such activities.

Plaintiffs insist that it would be misguided to rely on *Avocent* in this case. That precedent, they suggest, is not applicable in a case arising under the Hatch-Waxman Act. (*See* Pls.' Jt. Br. at 10–11.) Because the Hatch-Waxman Act authorizes declaratory judgment suits under certain circumstances for ANDA filers seeking patent certainty, *see* 21 U.S.C. § 355(j)(5)(C)(i)(II), Plaintiffs argue that *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals, Inc.*, 817 F.3d 755 (Fed. Cir. 2016), the Federal Circuit's most recent personal jurisdiction decision in the Hatch-Waxman context, provides the governing standard for this case. (Pls.' Jt. Br. at 11.) In *Acorda*, the defendant was not the patentee, but rather an ANDA filer seeking FDA approval to market and sell its generic drug products. 817 F.3d at 757. In filing its ANDA, the defendant certified under Paragraph IV that doing so would not infringe the patents at issue. 817 F.3d at 757. The holders of the patents brought suit in the District of Delaware for patent infringement, arguing that defendant's Paragraph IV certification constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A). *Id.* Affirming the denial of the defendant's motion to dismiss for lack of personal jurisdiction, the Federal Circuit concluded that though the defendant had yet to begin marketing or selling the drugs at issue in Delaware (or anywhere else in the United States), its plans to market the drugs in Delaware and its conduct in applying for FDA approval to do so were sufficient suit-related contacts with Delaware to warrant the exercise of jurisdiction. *Id.* at 759–60.

Acorda, therefore, was the type of "ordinary patent infringement suit" the Federal Circuit discussed in *Avocent.* In such a case, the court considers the defendants' commercialization activity related to the accused product within the forum as part of the jurisdictional analysis. *Avocent*, 552 F.3d at 1332. The Federal Circuit in *Acorda* simply added the wrinkle that in the Hatch-Waxman context, the court may consider an ANDA filing as an act of alleged infringement in the forum state because of the commercialization activity within the forum state in which the defendant is *likely* to engage following FDA approval. *Acorda*, 817 F.3d at 759–60.

Acorda, therefore, allows a court to look beyond actual commercialization activity within the forum state when a patentee plaintiff brings an infringement suit against an ANDA filer in the Hatch-Waxman context. Nothing in the Federal Circuit's opinion, however, suggests that a court should deviate from the *Avocent* standard in a declaratory judgment action brought against a patentee defendant.

Plaintiffs note that the effect of *Acorda* is that a generic company that files an ANDA may be sued anywhere in the United States, and the exercise of personal jurisdiction over that company will be proper. (Pls.' Jt. Br. at 11.) Where it appears that the generic company would market or sell the product in every state following FDA approval of its ANDA, Plaintiffs' statement about *Acorda*'s effect is probably accurate. But Plaintiffs also insist that this case presents the mirror image of *Acorda*, and that the Federal Circuit's reasoning "applies in equal force in the mirror." (Pls.' Jt. Br. at 12.) In other words, Plaintiffs argue that because, under *Acorda*, a patentee may sue an ANDA filer for patent infringement in any state, an ANDA filer should be able to sue a patentee for a judgment of non-infringement in any state, as well. As the Federal Circuit has noted elsewhere, however, the problem with such a "mirror-image analysis" in the declaratory judgment context is that "it ignores the essential fact that in a declaratory judgment action, the patentee is, after all, the defendant." *Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998). Thus an ANDA-filer defendant may be subject to personal jurisdiction in every state in a patent infringement suit because the activities the court considers for the jurisdictional inquiry—that is, commercial activities—are activities in which the defendant intends to engage in every state. Where the defendant is a *patentee* in a declaratory judgment action, however, the defendant must have engaged in the relevant activities—that is, enforcement activities—in the forum to be subject to jurisdiction there.

As DS Japan asserts that it has not engaged in any enforcement activities relating to the '703 patent (Takeuchi Decl. ¶ 11), the court's reasoning above might suggest that the company

is not subject to personal jurisdiction anywhere in the United States. It would be a troubling result if a foreign holder of a United States patent could dodge suits challenging the validity of its patent in the United States simply by refraining from enforcement activities. But fortunately, the court's reasoning need not lead to such a result. Under 35 U.S.C. § 293, the so-called patent long-arm statute, the United States District Court for the Eastern District of Virginia may exercise personal jurisdiction over every foreign patentee (unless the patentee designates an agent to receive service of process in another jurisdiction). Thus, although neither Defendant has engaged in the type of enforcement activities within Illinois (in DS USA's case) or within the United States (in DS Japan's case) to warrant the exercise of personal jurisdiction in this case, Plaintiffs have other venues available to prosecute their claims.

CONCLUSION

For the reasons stated above, the court grants Defendants' motions to dismiss ([30], *Alembic*, No. 16 C 3956 [43], *Aurobindo*, No. 16 C 4876 [29]) for lack of personal jurisdiction. The court is aware that Mylan has also intervened as a defendant in this case. Plaintiffs, however, have only asserted claims against Daiichi, and the court has concluded that it lacks jurisdiction to hear such claims. Thus the parties are ordered to show cause within 14 days why their cases should not be dismissed in entirety without prejudice.

ENTER:

Dated: July 25, 2016

REBECCA R. PALLMEYER
United States District Judge