

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>ROXANE LABORATORIES, INC.,</b>	:	
	:	<b>Case No. 2:16-cv-00179</b>
<b>Plaintiff,</b>	:	
	:	<b>JUDGE ALGENON L. MARBLEY</b>
v.	:	
	:	<b>Magistrate Judge Kemp</b>
<b>VANDA PHARMACEUTICALS, INC.,</b>	:	
	:	
<b>Defendant.</b>	:	

**OPINION & ORDER**

This declaratory judgment action is before the Court for a ruling on Defendant Vanda Pharmaceuticals, Inc.’s (“Vanda”) motion to dismiss for lack of personal jurisdiction, or in the alternative, to transfer venue. (Doc. 15.) Vanda, a Delaware corporation with its principal place of business in Washington D.C., argues that this case cannot or should not proceed in an Ohio district court. The Court agrees. For the reasons set forth below, Vanda’s motion to dismiss is **GRANTED**.

**I. FACTUAL AND PROCEDURAL BACKGROUND**

Roxane is a generic drug company incorporated in Nevada<sup>1</sup> with its principal place of business in Ohio (Compl. ¶ 2), and Vanda is a corporation incorporated in Delaware, with its principal place of business in Washington, D.C. (*Id.* ¶ 3; Mot. to Dismiss (Doc. 15) at 3.)

Vanda is a small pharmaceutical company that sells two products: Hetlioz® (tasimelton); and Fanapt® (iloperidone), a drug approved by the Food and Drug Administration (“FDA”) to

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<sup>1</sup> While Roxane pleads in its Complaint that it is incorporated in Nevada, (Compl. ¶ 2), in its Memorandum in Opposition to Vanda’s Motion to Dismiss (Doc. 19), it claims that Roxane is a Delaware corporation. (Doc. 19 at 7.)

treat schizophrenia. (Doc. 15 at 1–2.<sup>2</sup>) Patheon is a Canadian company and manufactures Fanapt® in Canada. (Declaration of Mihael Polymeropoulos, M.D. (“Polymeropoulos Decl.”) ¶ 4.) Hetlioz®, which is not the subject of this lawsuit, is “manufacture[d], test[ed], quality control[led], and package[d]” in Ohio by Patheon Pharmaceuticals, Inc. (“Patheon”), under contract with Vanda. (Compl. ¶ 6; *see also* Polymeropoulos Decl. ¶ 4.)

Vanda owns New Drug Application (“NDA”) 0221292 for iloperidone, which—as stated above—it markets under the name Fanapt®. (Compl. ¶ 19; Doc. 15 at 3.) It also owns by assignment a total of nine patents related to iloperidone: the ’610, ’432, ’776, ’638, ’742, ’254, ’255, ’256 and ’121 patents. (Compl. ¶¶ 18–19; Doc. 15 at 3.) As the owner of NDA 0221292, Vanda was required by federal law to list all of these patents in an FDA publication called *Approved Drug Products with Therapeutic Equivalence Evaluations*, otherwise known as the “Orange Book,” (*see* Reply in Support of Mot. to Dismiss (Doc 22) at 6 (citing 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53), which it did. (*See* Compl. ¶ 7.)

Pharmaceutical companies seeking to manufacture the generic form of a drug (like Roxane) file an Abbreviated New Drug Application (“ANDA”) with the FDA. (*See* Doc. 19 at 2.) An ANDA applicant must certify to the FDA either that there are no Orange Book patents listed for the drug, that the Orange Book listed patents have expired, or that the Orange Book listed patents are invalid or will not be infringed by the proposed generic form of the product. (*Id.* at 2 n.1 (citing 35 U.S.C. § 355(j)(2)(A)(vii).) If the ANDA applicant certifies that the Orange Book patents are invalid or not infringed, then the applicant must provide notice to the patentee. (*Id.* (citing 35 U.S.C. § 355(j)(2)(B)(ii).) The notice triggers a 45-day statutory period

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<sup>2</sup> On a motion to dismiss under Rule 12(b)(2), the Court must construe the pleadings in the light most favorable to the plaintiff, but may also accept as true undisputed factual assertions made by the defendant that are consistent with the plaintiff’s representations. *Kerry Steel, Inc. v. Paragon Indus., Inc.*, 106 F.3d 147, 153 (6th Cir. 1997). Thus, where the Court cites facts from Vanda’s papers, they are facts not disputed by Roxane.

during which the patentee has the first opportunity to initiate patent infringement litigation. (Compl. ¶ 24.) If the patentee fails to bring suit against the ANDA applicant in that time period, federal law “provid[e]s for a civil action to obtain patent certainty and allow[s] ANDA filers to obtain a declaratory judgment with respect to patents listed in the Orange Book.” (*Id.* ¶ 25.)

Roxane is one of several pharmaceutical companies seeking approval from the FDA to make, use, sell or import generic iloperidone. (*Id.* ¶ 7; Doc. 15 at 3.) As such, it filed an ANDA (ANDA 205480) and provided Vanda with notice of the application. (Compl. ¶ 23.) Because Vanda did not initiate patent infringement litigation within the requisite 45-day period, Roxane brought a declaratory judgment action in this Court, seeking a declaration that seven of Vanda’s iloperidone-related patents (patent numbers ’776, ’638, ’742, ’254, ’255, ’256 and ’121, or the “Patents-in-suit”) are either invalid or not infringed. (Compl. ¶¶ 1, 35–88, Prayer for Relief.)

Vanda moved to dismiss, citing this Court’s lack of personal jurisdiction over it, as Vanda is “incorporated in Delaware, headquartered in Washington, D.C., and has no office, manufacturing plant, or corporate presence of any kind in Ohio.” (Doc. 15 at 3; *see also* Polymeropoulos Decl. ¶ 2.) Roxane opposed Vanda’s motion. (Doc. 19.) The crux of Roxane’s opposition is that Vanda has listed the Patents-in-suit in the Orange Book in connection with NDA 0221292 for iloperidone tablets, injuring Roxane by “injecting uncertainty into the legal status of Roxane’s ANDA, subjecting Roxane to a continuing threat of litigation initiated by Vanda, and restraining Roxane’s free exploitation of its generic iloperidone product.” (Compl. ¶ 7.) According to Roxane, because Vanda has previously initiated litigation against Roxane over “ANDA 205480 based on other patents listed in the Orange Book in connection with NDA 022192,” Vanda “knew or reasonably should have known that it would be sued in this District by

listing the Patents-in-suit in the Orange Book and thereby injuring Roxane.”<sup>3</sup> (*Id.*) As additional bases for jurisdiction, Roxane cites: (1) Vanda’s systematic and continuous advertising and sales of its pharmaceutical products in this judicial district; (2) Vanda’s systematic and continuous business activities in Ohio, as evidenced by its contract with Patheon to manufacture, test, quality control and package Hetlioz® in Ohio; and (3) Vanda’s “patent enforcement activities directed at Roxane in the State of Ohio.” (*Id.* ¶¶ 6–9.)

Vanda’s motion is now fully briefed and ripe for review by this Court.

## II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(2) permits a defendant to move for dismissal of a complaint for lack of personal jurisdiction. Fed. R. Civ. P. 12(b)(2). Roxane, the “party seeking assertion of *in personam* jurisdiction, bears the burden of showing that such jurisdiction exists.” *CompuServe Inc. v. Patterson*, 89 F.3d 1257, 1262 (6th Cir. 1996). Where, as here, a district court determines that it can rule on a Rule 12(b)(2) motion based on the parties’ written submissions alone, the plaintiff “need only make a prima facie showing of jurisdiction.” *Bird v. Parsons*, 289 F.3d 865, 871 (6th Cir. 2002). Roxane can make this showing by “establishing with reasonable particularity sufficient contacts between [Vanda] and the forum state to support jurisdiction.” *Neogen Corp. v. Neo Gen Screening, Inc.*, 282 F.3d 883, 887 (6th Cir. 2002) (internal quotation marks and citation omitted). Roxane may not, however, rest on its pleadings to answer Vanda’s affidavits, but must set forth (by affidavit or otherwise) specific facts showing that the Court has jurisdiction. *Serras v. First Tenn. Bank Nat’l Ass’n*, 875 F.2d 1212, 1214 (6th

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<sup>3</sup> Vanda has sued Roxane and four other generic-drug companies that have filed ANDAs to make iloperidone in the United States District Court for the District of Delaware. (Doc. 15 at 3; *see also* Declaration of Eric Stone (“Stone Decl.”) ¶ 2.) All of the cases are pending before the same judge. (Doc. 15 at 3.) A trial between Vanda and Roxane regarding the ’610 patent took place earlier this year, and a trial about patent ’432 is scheduled for the spring of 2017. (*Id.* at 4.) Because of these similar, pending cases, Vanda has moved for the transfer of this action to Delaware if the Court does not dismiss it. (*Id.* at 12–14.)

Cir. 1989). The Court must construe the pleadings and affidavits in the light most favorable to Roxane, *CompuServe*, 89 F.3d at 1263; however, it may also accept as true undisputed factual assertions made by Vanda that are consistent with Roxane's representations. *Kerry Steel*, 106 F.3d at 153.

### III. LAW AND ANALYSIS

Courts apply Federal Circuit law to "personal jurisdiction inquiries over out-of-state patentees as declaratory judgment defendants." *Hildebrand v. Steck Mfg. Co., Inc.*, 279 F.3d 1351, 1354 (Fed. Cir. 2002); *see also Big Lots Stores, Inc. v. Sorenson Research & Dev. Tr.*, No. 2:08-cv-00506, 2009 WL 4547599, at \*2 (S.D. Ohio Dec. 2, 2009). In cases like this one, where a court's subject-matter jurisdiction over a case stems from the existence of a federal question, personal jurisdiction exists if: (1) a defendant is amenable to process in the forum state; and (2) the court's exercise of personal jurisdiction over the defendant complies with the precepts of federal due process. *LSI Indus. Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1371 (Fed. Cir. 2000); *Bird*, 289 F.3d at 871.

Personal jurisdiction comes in two "flavors": general and specific. *Kerry Steel*, 106 F.3d at 149. General jurisdiction, or "all-purpose jurisdiction," depends on a showing that the defendant has contacts with a state that are "so 'continuous and systematic' as to render [the defendant] essentially at home in the forum State." *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945)). Such continuous and systematic contacts empower a court to entertain claims *unrelated* to the foreign defendant's contacts with the forum state. *Id.* By contrast, specific jurisdiction, or "case-linked jurisdiction," depends on an affiliation "between the forum and the underlying

controversy, principally, an activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation." *Id.*

As stated above, Roxane alleges four bases for this Court's personal jurisdiction over Vanda: (1) Vanda's listing of the Patents-in-suit in the Orange Book; (2) Vanda's systematic and continuous advertising and sales of its pharmaceutical products in this judicial district; (3) Vanda's systematic and continuous business activities in Ohio, as evidenced by its contract with Patheon to manufacture, test, quality control and package Hetlioz® in Ohio; and (4) Vanda's "patent enforcement activities directed at Roxane in the State of Ohio." (*See* Compl. ¶¶ 6–9.) Roxane's Complaint does not clearly invoke this Court's general or specific personal jurisdiction over Vanda. Accordingly, the Court will address both "flavors" of jurisdiction.

**A. The Court Does Not Have General Jurisdiction over Vanda.**

Despite the lack of clarity in Roxane's Complaint, the Court agrees with Vanda that Roxane's allegations of Vanda's "systematic, purposeful, and continuous business activities" in Ohio, including its contractor Patheon's manufacture and testing of Hetlioz® and the sales of its products "throughout the United States and Ohio" (Compl. ¶¶ 6, 9), "speak in the vernacular of general jurisdiction." (Doc. 15 at 6.)

As a threshold matter, the Court acknowledges the "robust arguments" reflected in federal case law about whether Ohio's long-arm statute permits the exercise of general jurisdiction over non-resident defendants, as noted by the parties. (*See* Doc. 15 at 6–7; Doc. 19 at 14–16.) But Federal Circuit law, the applicable law in patent-related jurisdictional inquiries, recognizes a basis for general jurisdiction in Ohio. *See LSI Indus.*, 232 F.3d at 1373–75; *Delta Sys. Inc. v. Indak Mfg. Corp.*, 4 F. App'x 857, 860–61 (Fed. Cir. 2001).

While personal jurisdiction under Ohio’s long-arm statute must be specific, *see Capitol Specialty Ins. Corp. v. Splash Dogs, LLC*, 801 F. Supp. 2d 657, 665 (S.D. Ohio 2011), the Federal Circuit has ruled that a defendant is amenable to service in Ohio under *either* the state long-arm statute *or* by fulfilling “the requirements outlined by the Ohio Supreme Court in *Perkins v. Benguet Consolidated Mining Co.*, 158 Ohio St. 145, 107 N.E.2d 203 (Ohio 1952).” *LSI Indus.*, 232 F.3d at 1371. Under *Perkins*, “when an out-of-state defendant conducts continuous and systematic business in Ohio, it is ‘doing business’ in Ohio and amenable to process there, even if the cause of action did not arise from activity in Ohio.” *Id.* at 1373. Essentially, the Ohio Supreme Court adopted a federal due process standard for establishing general jurisdiction. *See id.* The enactment of Ohio’s long-arm statute in 1965 did not “supplant the viability of *Perkins*,” as the long-arm statute “does not limit personal jurisdiction in Ohio to causes of action arising from conduct it covers.” *Id.*

With that being said, this Court does not have general jurisdiction over Vanda. First, the Supreme Court’s *Goodyear* decision “made clear that only a limited set of affiliations with a forum will render a defendant amenable to all-purpose jurisdiction there.” *Daimler AG v. Bauman*, 134 S. Ct. 746, 760 (2014). For a corporation, “the place of incorporation and principal place of business are paradigm bases for general jurisdiction.” *Goodyear*, 564 U.S. at 924. While these are not the *only* fora in which a defendant may be subject to general jurisdiction, “these bases afford plaintiffs recourse to at least one clear and certain forum in which a corporate defendant may be sued on any and all claims.” *Daimler*, 134 S. Ct. at 760. Neither Vanda’s state of incorporation nor its principal place of business is Ohio. (Compl. ¶ 3; Doc. 15 at 3.)

Second, in *Perkins*, which Roxane contends provides a basis for this Court’s general jurisdiction over Vanda (*see* Doc. 19 at 5), general jurisdiction was appropriate where Benguet, a

company incorporated under the laws of the Philippines, operated out of Ohio during the Japanese occupation of the Philippines in World War II. *Perkins v. Benguet Consol. Mining Co.*, 342 U.S. 437, 448 (1952). Benguet’s president moved to Ohio and kept an office in the state, where he maintained the company’s files and oversaw the company’s activities. *Id.* The Supreme Court held that “the Ohio courts could exercise general jurisdiction over Benguet without offending due process,” *Daimler*, 134 S. Ct. at 756 (citing *Perkins*, 342 U.S. at 44), because “Ohio was the corporation’s principal, if temporary, place of business.” *Id.* (citing *Keeton v. Hustler Magazine*, 465 U.S. 770, 780 n.11 (1984)). Here, unlike Benguet in *Perkins*, Vanda has *no* corporate presence of any kind in Ohio. (Doc. 15 at 3.) Vanda is incorporated in Delaware, headquartered in Washington D.C., and maintains no offices or manufacturing plants in Ohio. (*Id.*; *see also* Polymeropoulos Decl. ¶ 2.) None of Vanda’s directors or officers resides in Ohio. (Polymeropoulos Decl. ¶ 2.)

Finally, the Supreme Court’s recent decision in *Daimler AG v. Bauman* makes clear that this Court lacks general jurisdiction over Vanda under these circumstances. 134 S. Ct. 746 (2014). In *Daimler*, the Court considered whether it could “entertain a claim brought by foreign plaintiffs against a foreign defendant [(Daimler)] based on events occurring entirely outside the United States.” *Id.* at 751. Jurisdiction was predicated, however, on the California contacts of a Daimler subsidiary, Mercedes-Benz USA, LLC (“MBUSA”), which was incorporated in Delaware with its principal place of business in New Jersey. *Id.* Plaintiffs argued that MBUSA should be considered Daimler’s agent for jurisdictional purposes. *Id.* at 752. MBUSA’s contacts with California, which plaintiffs argued were sufficient to support general jurisdiction, were as follows: (1) its existence as Daimler’s exclusive importer and distributor of automobiles in the United States, and its importation and distribution of automobiles to independent dealerships

throughout the nation; (2) MBUSA’s multiple California-based facilities, including a “regional office in Costa Mesa, a Vehicle Preparation Center in Carson, and a Classic Center in Irvine”; and (3) MBUSA’s status as the largest supplier of luxury vehicles to the California market. *Id.* Specifically, MBUSA’s California sales accounted for 2.4 percent of Daimler’s worldwide sales. *Id.*

The *Daimler* Court held that MBUSA’s contacts with California were too “slim” to render it “at home” in California and to impute those contacts to Daimler. *Id.* at 760. By arguing for general jurisdiction largely on the basis of MBUSA’s substantial sales in California, plaintiffs sought to have the Court “approve the exercise of general jurisdiction in every State in which [Daimler] engage[d] in a substantial, continuous, and systematic course of business”—a formulation the Court held to be “unacceptably grasping.” *Id.* at 761. Indeed, if the Court had approved that formulation, “the same global reach would presumably be available in every other State in which MBUSA’s sales [were] sizable.” *Id.* “Such exorbitant exercises of all-purpose jurisdiction would scarcely permit out-of-state defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit.” *Id.* at 761–62 (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (internal quotation marks omitted)).

So too here. Roxane argues that this Court has general jurisdiction over Vanda due to Patheon’s manufacture, testing, quality control and packaging of Hetlioz® and its sales of both Hetlioz® and Fanapt® in Ohio.<sup>4</sup> (Compl. ¶¶ 6, 8.) But Roxane does not allege that Patheon is an agent or alter ego of Vanda or otherwise show why Patheon’s contacts with Ohio should be imputed to Vanda. And, although Roxane makes much of Vanda’s “continuous and systematic”

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<sup>4</sup> Although, as Vanda points out (Doc. 22 at 1 n.1), in its Opposition to Vanda’s Motion to Dismiss, Roxane appears to abandon Vanda’s sales as a basis for general jurisdiction and focus solely on Vanda’s contract with Patheon to manufacture Hetlioz® in Ohio. (See Doc. 19 at 17–18.)

sales of its products in Ohio (*see* Compl. ¶ 6), Vanda’s sales are not sufficient to render it “at home” in Ohio. As the *Daimler* Court noted, basing an argument for general jurisdiction on a corporation’s large volume of sales in a particular state would allow for the “exorbitant” exercise of general jurisdiction by courts in *all* states where that corporation had sizeable sales. *Daimler*, 134 S. Ct. at 761.

Roxane takes issue with Vanda’s reliance on *Daimler*, claiming that it does not “overrule the proper application of long-established tests for the exercise of general jurisdiction,” (Doc. 19 at 18) and that “[g]eneral personal jurisdiction is still available when the defendant’s contacts with the forum State are continuous and systematic.” (*Id.*) Roxane is correct that *Daimler* does not wholly alter the general jurisdiction analysis. It refines the analysis and clarifies *Goodyear*. *Daimler* establishes that, for general jurisdiction to exist, contacts with the forum state must be *so* continuous and systematic as to render the foreign corporation *at home* in the forum state. *Daimler*, 134 S. Ct. at 761. (“Accordingly, the inquiry under *Goodyear* is not whether a foreign corporation’s in-forum contacts can be said to be in some sense continuous and systematic, it is whether that corporation’s affiliations with the State are so continuous and systematic as to render it essentially at home in the forum State.”) (Internal quotation marks and citations omitted). The pre-*Daimler* cases Roxane relies on are beside the point. *Daimler* is the most recent iteration of the doctrine of general personal jurisdiction from the nation’s highest court. As such, this Court will follow it.

#### **B. The Court Does Not Have Specific Jurisdiction Over Vanda.**

Roxane asserts that this Court has specific personal jurisdiction over Vanda under both

Ohio's long-arm statute and due process. (Doc. 19 at 5.) Because "[t]he Ohio long-arm statute does not grant Ohio courts jurisdiction to the limits of the due process clause," the Court must consider both. *Hildebrand*, 279 F.3d at 1354.

In declaratory judgments against patent holders, "only those activities of the patentee that relate to the enforcement or defense of the patent can give rise to specific personal jurisdiction." *Radio Sys. Corp. v. Accession, Inc.*, 638 F.3d 785, 789 (Fed. Cir. 2011) (emphasis added); *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1019–20 (Fed. Cir. 2009). Thus, for purposes of analyzing specific jurisdiction, Court will consider only Vanda's alleged patent enforcement activity; that is: (1) its listing of the Patents-in-suit in the Orange Book; and (2) the alleged May 28, 2015 phone call between the CEOs of Roxane and Vanda. (See Compl. ¶¶ 7–8.) These contacts do not give rise to specific jurisdiction under either the state long-arm statute or the Due Process Clause.

### **1. The Court Does Not Have Jurisdiction Under Ohio's Long-Arm Statute.**

In its Complaint, Roxane broadly alleges that this Court has personal jurisdiction over Vanda "pursuant to Ohio Revised Code Sections 2307.382(A) and (B)." (*Id.* ¶ 5.) Yet, in responding to Vanda's motion to dismiss, Roxane addresses the applicability of only a single subsection of the Ohio long-arm statute: Section 2307.382(A)(6). (Doc. 19 at 6–7, 13–14.) Under this subsection, a court may exercise personal jurisdiction where a cause of action arises from the defendant "[c]ausing tortious injury in this state to any person by an act outside this state committed with the purpose of injuring persons, when he might reasonably have expected that some person would be injured thereby in this state." O.R.C. § 2307.382(A)(6). As is clear from the statutory language, for subsection (A)(6) to apply: (1) the out-of-state act must be committed with the *purpose* of inflicting an injury; and (2) the injury must be reasonably

expected to occur. *Coleman v. Parra*, 163 F. Supp. 2d 876, 889 (S.D. Ohio 2000) (citing *Clark v. Connor*, 695 N.E.2d 751 (Ohio 1998)).

The tortious injury Roxane complains of is Vanda's listing of the Patents-in-suit in the Orange Book. (Compl. ¶ 7.) According to Roxane, Vanda's listing of the Patents-in-suit in the Orange Book caused injury to Roxane by "*inter alia*, injecting uncertainty into the legal status of Roxane's ANDA, subjecting Roxane to a continuing threat of litigation initiated by Vanda, and restraining Roxane's free exploitation of its generic iloperidone product." (*Id.*) Roxane argues that it was foreseeable that the listing of the Patents-in-suit would inflict injury in Ohio because that is where Roxane holds its principal place of business. (*Id.*)

Roxane's argument has several fatal flaws. First, Roxane failed to plead that Vanda listed the Patents-in-suit with the purpose of injuring Roxane—a key requirement for the applicability of subsection (A)(6). *See* O.R.C. § 2307.382(A)(6); *Coleman*, 163 F. Supp. 2d at 889. Even if Roxane had addressed the purpose requirement, however, Roxane has provided no legal support for the notion that listing the Patents-in-suit in the Orange Book is tortious. Quite the contrary, by notifying the FDA that the Patents-in-suit should be listed in the Orange Book, Vanda was complying with federal law. (*See* Doc. 22 at 6; *see also* Doc. 19 at 2 n.1.)

For these reasons, this Court does not have specific jurisdiction over Vanda under subsection (A)(6) of the Ohio long-arm statute.

## **2. The Exercise of Specific Jurisdiction by this Court Does Not Comport with the Precepts of Federal Due Process.**

A court may exercise specific personal jurisdiction over a nonresident defendant consistent with the Due Process Clause when the defendant has "certain minimum contacts with the forum such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal

quotation marks and citations omitted). This standard has been articulated as a three-prong inquiry: (1) whether the defendant “purposely directed its activities at residents of the forum”; (2) whether the lawsuit arises out of or relates to those activities; and (3) whether the exercise of personal jurisdiction is fair and reasonable. *Autogenomics*, 566 F.3d at 1018. “The first two factors correspond with the ‘minimum contacts’ prong of the *International Shoe* analysis, and the third factor corresponds with the ‘fair play and substantial justice’ prong of the analysis.” *Id.* (quoting *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1360 (Fed. Cir. 2001)). None of these factors is present here.

With regard to the first factor, the Supreme Court “has repeatedly cautioned that it is essential in each case that there be some act by which the defendant purposely avails itself of the privilege of conducting activities within the forum state, thus invoking the benefits and protections of its laws.” *Avocent Huntsville Corp. v. Aten Int’l Co., Ltd.*, 552 F.3d 1324, 1329 (Fed. Cir. 2008) (quoting *Hanson v. Denckla*, 357 U.S. 235, 253 (1958)) (internal quotation marks omitted). This purposeful availment requirement ensures that a defendant “will not be haled into a jurisdiction solely as a result of random, fortuitous, or attenuated contacts.” *Id.* (quoting *Burger King Corp.*, 471 U.S. at 475). Considering only patent enforcement-related activities, as is required in declaratory judgment lawsuits against patent holders, *Radio Sys. Corp.*, 638 F.3d at 789, it is clear that Vanda has not taken *any* action with respect to the Patents-in-suit—much less action that is directed specifically at Ohio and its residents. This lawsuit is about the Patents-in-suit—none of which Vanda has attempted to enforce against Roxane. Roxane does not dispute that the only patent litigation initiated by Vanda against it pertains to the ’432 and ’610 patents. (*See* Doc. 19 at 2–3.) Indeed, Roxane admits that Vanda “selectively

su[ed] Roxane on only two” of the nine iloperidone-related patents listed in the Orange Book”—neither of which is a patent at issue in this lawsuit. (*Id.* at 3.)

But, Roxane argues that it is precisely this *inaction* that was purposely directed at Ohio. Roxane claims that by listing the Patents-in-suit in the Orange Book and deciding selectively to sue Roxane over only certain patents, Vanda injected uncertainty into the legal status of Roxane’s ANDA, thereby injuring Roxane. (Compl. ¶ 7; *see also* Doc. 19 at 3.) In essence, Roxane argues that because Vanda: (1) knows Roxane is a generic drug company seeking to manufacture and sell generic iloperidone; (2) knows that Roxane’s principal place of business is in Ohio; and (3) has sued Roxane before, its listing of the Patents-in-suit in the Orange Book and keeping Roxane in “limbo” by not suing on them was an “action” purposely directed at Ohio.

This argument is problematic for two reasons. First, Roxane points to no case law supporting its claim that listing a patent in the Orange Book constitutes conduct directed at or purposeful avilment of the jurisdiction of a particular state (or is patent enforcement activity at all, for that matter). The cases Roxane cites to support its argument that listing the Patents-in-suit in the Orange Book caused a foreseeable injury to Roxane in Ohio stand for the proposition that doing so creates an injury-in-fact and a justiciable controversy under Article III—neither mentions personal jurisdiction. (*See* Doc. 19 at 7–9 (discussing *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1130 (Fed. Cir. 2007) and *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008); *see also* Doc. 22 at 6–7.)

Second, as Vanda correctly notes, the “Orange Book is a national publication; there is no Ohio-specific Orange Book.” (Doc. 15 at 10.) Vanda’s listing of the Patents-in-suit in the Orange Book put the FDA and *all* of the generic drug manufacturers in the United States on notice that Vanda owns those patents. It may have been *foreseeable* that generic drug companies

in Ohio, like Roxane, would be injured by that listing—but that applies to drug companies in every other state as well. There is no evidence that Vanda’s listing of was *purposefully directed* at Ohio, or any other state.

Nor does the May 28, 2015 phone call between the CEOs of Roxane and Vanda, during which, Roxane alleges “[u]pon information and belief,” the two discussed “ANDA 205480 and litigation related to patents listed in the Orange Book in connection with NDA 022192” constitute an act purposely directed at the forum state for purposes of specific personal jurisdiction. (*See* Compl. ¶ 8.) In Vanda’s motion to dismiss and a supporting declaration, Vanda disputes that the phone call could have possibly been related to the Patents-in-suit, given that it took place “nearly a year before Roxane filed this lawsuit” and that the majority of the Patents-in-suit had not yet issued. (*See* Doc. 15 at 11; Stone Decl. ¶ 7.) Roxane does not rebut Vanda’s arguments. In fact, Roxane seemingly abandons the phone call as a basis for specific jurisdiction altogether—neglecting to address it in its opposition to Vanda’s motion. (*See* Doc. 22 at 1 n.1; Doc. 19 at 6–9, 10–12.)

Even so, however, under well-settled Federal Circuit precedent, multiple communications about or threats of litigation are insufficient to establish specific personal jurisdiction, even if they are specifically directed at the forum state. *See, e.g., Avocent*, 552 F.3d at 1333–34; *Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1359–60 (Fed. Cir. 1998).

Because Roxane cannot establish that Vanda has sufficient contacts with Ohio, it goes without saying that the exercise of specific personal jurisdiction by this Court would not be fair and reasonable under these circumstances.

#### IV. CONCLUSION

For all of the foregoing reasons, the Court finds that it does not have personal jurisdiction

over Vanda. No additional evidence is needed for the Court to arrive at this determination. Accordingly, the Court **GRANTS** Vanda's motion to dismiss, and **DENIES** Roxane's request to conduct jurisdictional discovery. (*See* Doc. 19.) Because dismissal is warranted, the Court need not consider Vanda's arguments in support of transferring the case to the U.S. District Court for the District of Delaware. This case is hereby **DISMISSED** without prejudice to its filing in the proper court.

**IT IS SO ORDERED.**

s/Algenon L. Marbley  
**ALGENON L. MARBLEY**  
**UNITED STATES DISTRICT JUDGE**

**DATED: December 20, 2016**