

licensed to Lilly, and covers Lilly's anti-cancer drug pemetrexed. The '209 patent is owned by Lilly and is directed to methods of administering pemetrexed with folic acid and vitamin B₁₂. Lilly sells the patented drug and its associated method of administration under the trade name ALIMTA[®].

Nang Kuang is a Taiwanese generic drug manufacturer seeking approval from the FDA to market generic versions of ALIMTA[®]. CANDAs, a Texas limited liability company, entered into an agreement with Nang Kuang whereby Nang Kuang agreed to exclusively manufacture and supply the ANDA Product to CANDAs, and CANDAs agreed to assist Nang Kuang with the U.S. litigation arising from Nang Kuang's submission of the ANDA, and find marketing partners to market, sell and distributed the ANDA Product if the ANDA application is approved by the FDA. As of this date, the FDA has not approved the ANDA, and neither Nang Kuang nor CANDAs has commercially manufactured, used, sold or offered for sale in, or imported into, the United States any ANDA Product. On August 25, 2014, Nang Kuang and CANDAs jointly provided a notice of certification to the required parties pursuant to 21 C.F.R. § 314.95(a) ("Notice Letter"), including Lilly's Indianapolis-based General Counsel and its Indianapolis trial counsel. The submission of the Notice Letter triggered the forty-five day period in which Lilly had to file the instant Hatch-Waxman action to challenge the ANDA and seek an order that the effective date of any approval of Nang Kuang's ANDA be not earlier than the expiration date of Plaintiffs' patents.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(2) requires dismissal of a claim where personal jurisdiction is lacking. When "[a] defendant moves to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction, the plaintiff bears the burden of demonstrating the existence of jurisdiction." *Purdue Research Found. v. Sanofi-Synthelabo, S.A.*,

338 F.3d 773, 782 (7th Cir. 2003) (citations omitted). When a district court rules on a defendant's motion to dismiss based on the submission of written materials, the plaintiff "need only make out a *prima facie* case of personal jurisdiction" and "is entitled to the resolution in its favor of all disputes concerning relevant facts presented in the record." *Id.* (internal quotation marks and citations omitted).

Federal Circuit law governs personal jurisdiction issues in patent infringement cases. *See Hildebrand v. Steck Mfg. Co.*, 279 F.3d 1351, 1354 (Fed. Cir. 2002). A district court may properly exercise personal jurisdiction over a non-resident defendant if a two-step analysis is undertaken and satisfied. First, the party resisting the exercise of jurisdiction must be amenable to service of process under the state's long-arm statute; second, the exercise of personal jurisdiction must comport with the due process clause of the Constitution. *Id.* Because Indiana's long-arm statute, Indiana Rule of Trial Procedure 4.4(A), "expand[s] personal jurisdiction to the full extent permitted by the Due Process Clause," *LinkAmerica Corp. v. Cox*, 857 N.E.2d 961, 966 (Ind. 2006), the sole question before the Court is whether due process would be offended if the Court were to exercise personal jurisdiction over the Defendants.

III. DISCUSSION

The Court previously provided extensive discussion on the issue of general and specific jurisdiction in the context of ANDA litigation in its Entry denying Plaintiffs' motion for jurisdictional discovery; thus it need not be repeated in detail here. *See* [Filing No. 54](#). Plaintiffs argue, *inter alia*, that this Court has specific jurisdiction over the Defendants. The Federal Circuit applies a three-prong test to determine if specific jurisdiction exists over a defendant: (1) whether the defendant purposefully directed activities at residents of the forum; (2) whether the claim arises out of or relates to those activities; and (3) whether exercising personal jurisdiction is reasonable

and fair. *Nuance Commc'ns, Inc. v. Abbyy Software House*, 626 F.3d 1222, 1231 (Fed. Cir. 2010). In Hatch-Waxman infringement cases decided since the Supreme Court's decision in *Daimler AG v. Bauman*, 134 S.Ct. 746 (2014), district courts have consistently found that these requirements for the exercise of personal jurisdiction over defendants filing ANDAs are satisfied.

Defendants improperly focus on the act of completing the ANDA and the possible future distribution of the ANDA Product as the basis for the Court's jurisdictional analysis, arguing that neither of these acts occurred in or are directed toward Indiana. However, what is relevant is the fact that Defendants sent the Notice Letter to Plaintiffs in Indiana, and the Court agrees with Plaintiffs and other courts that this is sufficient to establish specific jurisdiction over the Defendants. *See Eli Lilly & Co. v. Mylan Pharm., Inc.*, No. 1:14-CV-00389-SEB-TA, 2015 WL 1125032, at *6 (S.D. Ind. Mar. 12, 2015) ("Defendants purposefully directed their activities at Indiana by sending a Paragraph IV certification notice letter to Lilly in Indiana, which act they knew would trigger the forty-five-day period within which Plaintiffs were empowered to file suit under the Hatch–Waxman framework."); *AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 559 (D. Del. 2014) *motion to certify appeal granted sub nom. Astrazeneca AB v. Aurobindo Pharma Ltd.*, No. CV 14-664-GMS, 2014 WL 7533913 (D. Del. Dec. 17, 2014) ("The court is convinced that the act of filing an ANDA and the paragraph IV notification provide sufficient minimum contacts with the state of Delaware under a specific jurisdiction analysis.")

Likewise, in this case, Defendants' actions in filing the ANDA and sending the Notice Letter was the act that gave rise to this action in this district. The Defendants' actions were purposefully directed toward a resident of this forum—Lilly—and the instant claim arises out of those activities, as it is Lilly that was required to file this action to protect its intellectual property rights, and it is Lilly that would be injured if Defendants' ANDA Products infringe on the

Plaintiffs' patents. Because Lilly's state of incorporation is Indiana, the Court considers Indiana to be the place of the injury that Plaintiffs allege arose by the filing of the ANDA. *See Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572 (D. Del. 2015) (“[I]t seems logical to conclude that the state of incorporation is at least one place in which a corporation whose patents are artificially infringed by an ANDA filing is injured.”). Accordingly, the Court concludes that the Defendants' act of filing an ANDA and directing a Paragraph IV certification to Indiana provide sufficient minimum contacts with this district to satisfy the requirements of an exercise of specific jurisdiction over Nang Kuang and CANDA.¹

IV. CONCLUSION

For the reasons set forth above, the Court finds that it has personal jurisdiction over Defendants Nang Kuang and CANDA based upon their actions directed toward Plaintiff Lilly in Indiana. Therefore, Defendants' Motion to Dismiss ([Filing No. 11](#)) is **DENIED**.

SO ORDERED.

Date: 8/24/2015



TANYA WALTON PRATT, JUDGE
United States District Court
Southern District of Indiana

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¹ Because the Court finds that there is sufficient basis for the exercise of specific jurisdiction over Defendants, there is no need to address the parties' arguments regarding general jurisdiction or jurisdiction arising under Federal Rule of Civil Procedure 4(k)(2). Likewise, Defendants' arguments for dismissal under Rule 12(b)(7) are moot.

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