

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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SENJU PHARMACEUTICAL CO.,  
LTD.,  
BAUSCH & LOMB, INC. and BAUSCH  
& LOMB PHARMA HOLDINGS CORP.,

Plaintiffs,

v.

METRICS, INC., COASTAL  
PHARMACEUTICALS, INC., MAYNE  
PHARMA GROUP LIMITED, and  
MAYNE PHARMA (USA), INC.,

Defendants.

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HONORABLE JEROME B. SIMANDLE

Civil Action  
No. 14-3962 (JBS/KMW)

**OPINION**

APPEARANCES:

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**SIMANDLE, Chief Judge:**

## I. INTRODUCTION

This is a patent infringement action brought by Plaintiffs Senju Pharmaceutical Company, Bausch & Lomb, Inc., and its subsidiary, Bauch & Lomb Pharma Holdings Corp. Plaintiffs hold the rights to three patents for novel formulations of bromfenac, an active ingredient in Prolensa®, a drug that is used to treat patients who have undergone cataract surgery. Plaintiffs filed this case on June 20, 2014, alleging that Defendants infringed upon their patents by submitting Abbreviated New Drug Applications ("ANDAs") seeking FDA approval for the manufacture and sale of a bromfenac ophthalmic solution intended to be a generic of Prolensa®, in violation of 35 U.S.C. § 271(e)(2). The case was initially brought against four defendants: Metrics, Inc. ("Metrics"), Coastal Pharmaceuticals, Inc. ("Coastal"), Mayne Pharma Group Limited, and Mayne Pharma (USA), Inc. Only Metrics and Mayne Pharma Group Limited remain in this action.

Six days after plaintiffs filed their Complaint, Defendants filed for inter partes review of two of Plaintiff's patents before the Patent Trial and Appeal Board ("PTAB").

Presently before the Court is Defendants' motion to dismiss the Complaint for lack of personal jurisdiction, and Plaintiffs' motion to enjoin Defendants from proceeding in the parallel

inter partes review process before the PTAB. The Court heard oral argument on both claims and accepted supplemental briefing.

For the reasons that follow, the Court finds that it lacks general jurisdiction over Mayne Pharma Group Limited but will permit limited discovery as to specific jurisdiction. The Court finds that it has jurisdiction over Metrics and will deny Defendants' motion to dismiss with respect to Metrics. The Court will also deny Plaintiffs' motion to enjoin inter partes review before the PTAB.

## **II. BACKGROUND**

### **A. Plaintiffs' patents and Defendants' ANDA application**

Plaintiffs hold all substantial rights to three patents for novel formulations of bromfenac, an active ingredient in the ophthalmic drug Prolensa®, which is approved by the FDA for treatment of post-operative inflammation and reduction of pain in patients who have undergone cataract surgery. The patents are issued by the United States Patent and Trademark Office ("USTPO") under United States Patent Nos. 8,129,431 ("the '431 patent"), 8,669,290 ("the '290 patent"), and 8,754,131 ("the '131 patent").

On March 13, 2014, Defendant Metrics sent a letter to Plaintiffs stating that it had submitted an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration

("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 355(j), for the manufacture and sale of a bromfenac ophthalmic solution intended to be a generic of Prolensa®.

(Compl. [Docket Item 1] ¶ 20; Pls.' Mot. to Enjoin, Ex. 9.) The ANDA included a certification under § 355(j)(2)(A)(vii)(IV), known as a Paragraph IV Certification, claiming that Plaintiffs' '431 and '290 patents were "invalid or will not be infringed by the manufacture, use, or sale" of the new drug being submitted for FDA approval.

Plaintiffs then commenced this action for infringement on June 20, 2014, seeking an injunction to prevent the manufacture, use, import, and sale of defendants' generic, a judgment of infringement on the three patents, and declaratory relief.

(Compl. at 10-11.)

**B. Defendants' motion to dismiss for lack of personal jurisdiction**

Defendant Mayne Pharma Group Limited is a corporation based in Australia; while Metrics, Coastal, and Mayne Pharma (USA), Inc. are subsidiaries of Mayne Pharma Group Limited (Compl. ¶¶ 4-7.)

Defendants moved to dismiss this case for lack of personal jurisdiction, arguing that the Court lacked jurisdiction over all Defendants. [Docket Item 30.] Following oral argument and upon agreement by both parties, the Court entered an Order

dismissing Coastal from this action. Mayne Pharma (USA), Inc. was later also dismissed as a defendant in this case.<sup>1</sup>

The remaining Defendants are Metrics, Inc. and Mayne Pharma Group Limited, the parent company.

Metrics, a wholly-owned subsidiary of Mayne Pharma Group Limited, is a corporation organized under the laws of North Carolina. (Compl. ¶ 4.) Metrics directly manufactures, markets, and sells generic drug products throughout the United States, including New Jersey. (Compl. ¶ 10.) According to Defendants, direct sales of products to New Jersey represented 4% of Metrics' overall U.S. product and service sales for the latest fiscal year. (First Cross Decl. [Docket Item 30-1] ¶ 15.) Although Metrics has no offices, facilities, or other real property in New Jersey, the company is registered to do business in New Jersey and employs one individual in the state who is

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<sup>1</sup> The parties agreed during oral argument that Coastal was an assumed name of Metrics and was not a separate entity nor incorporated in any state. The Court dismissed Coastal from the case with the understanding that any judgment against Metrics would be equally binding as to Coastal. (Oct. 6, 2014 Order [Docket Item 62].) Also during oral argument, Defendants asserted that they did not represent Mayne Pharma (USA), Inc. and had accepted service on their behalf in error. (Oct. 3, 2014 Oral Arg. Tr. [Docket Item 63] 41-43.) The Court allowed Plaintiffs to re-serve the Complaint on the correct party and enlarged the time for service to 30 days beyond the period otherwise required by Federal Rule of Civil Procedure 4(m). No service was made within that time frame, and the Court subsequently dismissed Mayne Pharma (USA), Inc. from this action. (March 17, 2015 Order [Docket Item 81].)

solely associated with the business division of the company.  
(First Cross Decl. ¶ 8-14.)

Plaintiffs served Metrics with the Complaint pursuant to New Jersey Court Rule 4:4-4(a)(6), which provides for *in personam* jurisdiction over a corporate defendant by personal service within the state upon an authorized agent of the corporation. N.J. Ct. R. 4:4-4(a)(6). Defendant's registered agent in New Jersey, Corporation Trust Company, accepted service in West Trenton, New Jersey. (See Executed Summons [Docket Item 8].)

Plaintiffs argue that service upon a registered agent in the state established this Court's personal jurisdiction over Metrics. Defendants argue that service upon a registered agent did not automatically establish jurisdiction, and that Metrics' contacts as a whole are insufficient for either general or specific jurisdiction.

Defendant Mayne Pharma Group Limited, the parent company of Metrics, is an Australian corporation that manufactures, markets, and sells generic drug products around the world. (Compl. ¶ 6.) Defendant has no physical presence in New Jersey, nor does it have any employees in the state. Plaintiffs allege that Defendant's two corporate predecessors, Mayne Pharma Limited and Mayne Pharma Pty Ltd, have previously used a New Jersey address for professional licensure as a pharmaceutical

manufacturer in 2006 and 2007. Plaintiffs attached business certificates to their opposition brief which showed that Mayne Pharma Limited and Mayne Pharma Pty Ltd previously had licenses associated with a Paramus, New Jersey address from approximately 2002 to 2007. (Pls.' Opp. Exs. 23, 24.)

In addition, Plaintiffs allege that three other corporate predecessors and subsidiaries of Defendant, namely Mayne Pharma Limited, F.H. Faulding & Co., and Mayne Pharma International Pty Ltd, filed 11 patent infringement actions in New Jersey over the course of 14 years. (Pls.' Opp. [Docket Item 50] 4, 7, 9; Pls.' Opp. Exs. 11-21.) Specifically, Plaintiffs allege that corporate predecessor F.H. Faulding & Co. previously filed two lawsuits in the District of New Jersey in 2000 and 2001 (Pls.' Opp. 7; id. Ex. 11, 12); subsidiary Mayne Pharma International Pty Ltd previously filed seven lawsuits in this district in the years 2008-2010 (Pls.' Opp. Exs. 13-19); and Mayne Pharma Limited, whose connection to Defendant is disputed, filed two counterclaims in this district in 2007. (Pls.' Opp. Exs. 20, 21.)<sup>2</sup> None of the suits involve the patents at issue in this case.

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<sup>2</sup> Defendants do not appear to dispute that Mayne Pharma International Pty Ltd is a subsidiary, but they do dispute that Mayne Pharma Limited and F.H. Faulding & Co. are corporate predecessors. (See Defs.' Reply 13-16.)

Finally, Plaintiffs note that Defendants' active pharmaceutical ingredient supplier, Johnson-Matthey, is based out of West Deptford, New Jersey. Defendants acknowledge that Johnson-Matthey supplies the active ingredient in the product that is the subject of this suit, but argue that the ingredients in this case were actually manufactured and shipped from Massachusetts. (Def. Supp. Letter of Oct. 17, 2014 [Docket Item 68]; Pls.' Supp. Letter of Oct. 15, 2014 [Docket Item 66], at \*3; Pls.' Opp. 11; Def. Reply 12.)

**C. Plaintiffs' motion to enjoin Defendants from participating in inter partes review**

On March 13, 2014, Defendant Metrics sent a letter to Plaintiff Bausch & Lomb Inc. advising Plaintiff that Metrics had recently submitted an ANDA with the FDA with a Paragraph IV certification to Plaintiffs' '431 patent. Metrics stated that it expected ANDA filing acceptance shortly. (Pl. Mot. to Enjoin, Ex. 9 [Docket Item 10].)

Plaintiffs filed this patent infringement action on June 20, 2014. [Docket Item 1.] On June 26th, Defendants filed two petitions for inter partes review ("IPR") before the Patent Trial and Appeal Board ("PTAB") seeking a ruling on the validity of Plaintiff's '290 and '431 patents.<sup>3</sup> One day later, on June

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<sup>3</sup> Inter partes review allows a party other than the patentee to challenge the validity of a patent by bringing an action before

27th, Defendant Metrics provided a Notice Letter to Plaintiffs advising Plaintiffs that it had filed an ANDA for Prolensa®. The letter informed Plaintiffs that the ANDA included Paragraph IV Certifications to two of Plaintiffs' patents: the '431 patent and the '290 patent.

While Defendants' IPR petitions were pending, Plaintiffs moved for an injunction in this Court to prevent Defendants from participating in the inter partes review process. Plaintiffs argued that the "first-filed" rule requires this Court to decide the issue of infringement. Plaintiffs also argue that when defendants filed their ANDA, they "filed a civil action," under § 35 U.S.C. § 315(a)(1), which therefore prohibits them from filing a subsequent petition for inter partes review.

Defendants opposed Plaintiffs' motion, arguing that Plaintiffs' reading of § 315(a)(1) was not supported by the language of the statute; and that the Court lacks authority to entertain plaintiffs' motion because it lacks personal jurisdiction.

On February 19, 2015, PTAB granted Defendants' petition for inter parties review of the '290 and '431 patents. (Feb. 20, 2015 Letter [Docket Item 74].)

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the PTAB, an administrative body of the U.S. Patent and Trademark Office which decides issues of patentability.

### III. DEFENDANTS' MOTION TO DISMISS

#### A. Legal Standard

On a motion to dismiss for lack of personal jurisdiction under Federal Rule of Civil Procedure 12(b)(2), the plaintiff bears the burden of establishing "with reasonable particularity sufficient contacts between the defendant and the forum state." Provident Nat'l Bank v. Cal. Fed. Sav. & Loan Ass'n, 819 F.2d 434, 437 (3d Cir. 1987); see also AFTG-LG, LLC v Nuvoton Tech. Corp., 689 F.3d 1358, 1360-61 (Fed. Cir. 2012) (discussing the plaintiff's prima facie burden). Because a Rule 12(b)(6) motion "is inherently a matter which requires resolution of factual issues outside the pleadings," the jurisdictional allegations may be supported with sworn affidavits or other documents. Metcalf v. Renaissance Marine, Inc., 566 F.3d 324, 330 (3d Cir. 2009). The Court must "accept the uncontroverted allegations in the plaintiff's complaint as true and resolve any factual conflicts in the affidavits [and other written materials] in the plaintiff's favor." Elecs. for Imaging, Inc. v. Coyle, 340 F.3d 1344, 1349 (Fed. Cir. 2003) (citations omitted).

Jurisdictional discovery may be permitted when the existing record is 'inadequate' to support personal jurisdiction and a party demonstrates that it can supplement its jurisdictional allegations through discovery. Jurisdictional discovery should

be sustained when factual allegations suggest the possible existence of requisite contacts between the defendant and the forum state with "reasonable particularity." Mellon Bank, 960 F.2d at 1223.

#### **B. Personal jurisdiction generally<sup>4</sup>**

In order to determine whether personal jurisdiction exists over a non-resident defendant, in this case, Metrics and Mayne Pharma Group Limited, the Court must determine whether jurisdiction lies under both the state long arm statute and the Due Process Clause of the Constitution. Commissariat A L'Energie Atomique v. Chi Mei Optoelectronics Corp., 395 F.3d 1315, 1319 (Fed. Cir. 2005). New Jersey's long-arm jurisdiction statute permits the exercise of jurisdiction to the full extent allowed under the Due Process Clause. Imo Indus., Inc. v. Kiekert AG, 155 F.3d 254, 259 (3d Cir. 1998); DeJames v. Magnificence Carriers, Inc., 654 F.2d 280, 284 (3d Cir. 1981). Thus, the two

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<sup>4</sup> Because the jurisdictional issue arises in the context of a patent infringement action under the Hatch-Waxman Act, Federal Circuit law governs the dispute, rather than the law of the regional circuit. See Nuance Commc'ns, Inc. v. Abby Software House, 626 F.3d 1222, 1230 (Fed. Cir. 2010); Breckenridge Pharmaceutical v. Metabolite Laboratories, Inc., 444 F.3d 1356, 1362 (Fed. Cir. 2006); Elecs. For Imaging, Inc. v. Coyle, 340 F.3d 1344, 1348 (Fed. Cir. 2003); Pro Sports Inc. v. West, 639 F. Supp. 2d 475, 480 (D.N.J. 2009) (applying Federal Circuit law to decide question of personal jurisdiction in patent case). The Court will, however, refer to decisions in other circuits where there is an absence of Federal Circuit authority.

jurisdictional inquiries in this case collapse into one: whether the exercise of jurisdiction comports with due process.

Autogenomics, Inc. v. Oxford Gene Tech. Ltd., 566 F.3d 1012, 1017 (Fed. Cir. 2009); Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc., 148 F. 3d 1355, 1358 (Fed. Cir. 1998).

In order for the exercise of jurisdiction to satisfy due process, there must be "minimum contacts" between a non-resident defendant and the forum state such that "maintenance of the suit does not offend traditional notions of fair play and substantial justice." J. McIntyre Machinery, Ltd. V. Nicastro, 131 S. Ct. 2780, 2787 (2011) (quoting Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945)). Consistent with these principles, a court may exercise personal jurisdiction over a defendant under two theories: general jurisdiction and specific jurisdiction. General jurisdiction may be asserted over a foreign corporation even when the cause of action has no relation to those contacts if the defendant's contacts with the forum are so "continuous and systematic" as to render them essentially "at home" in the forum state. Daimler AG v. Bauman, 134 S. Ct. 746, 754 (2014); Goodyear Dunlop Tires Operations, S.A. v. Brown, 131 S. Ct. 2846, 2851 (2011); Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 414 (1984). If an out-of-state defendant's contacts with the forum are insufficiently substantial to establish general jurisdiction, a court may still assert

personal jurisdiction under the theory of specific jurisdiction if the suit "aris[es] out of or relate[s] to the defendant's contacts with the forum." Helicopteros, 466 U.S. at 414, n.8. Here, the inquiry is whether the defendant has "purposefully directed" his activities at residents in the forum state, Burger King Corp. v. Rudzewicz, 471 U.S. 462, 472 (1985), or whether there was "some act by which the defendant purposefully avail[ed] itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws." Hanson v. Denckla, 357 U.S. 235, 253 (1958).

**C. Metrics is subject to this Court's jurisdiction because it accepted service of process in this state**

New Jersey Court Rule 4:4-4(a)(6) allows for *in personam* jurisdiction over a corporate defendant by personal service within the state upon an authorized agent of the corporation.<sup>5</sup>

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<sup>5</sup> Rule 4:4-4(a) states that the "primary method of obtaining *in personam* jurisdiction over a defendant in this State is by causing the summons and complaint to be personally served within this State" in one of several ways. Under 4(a)(6), jurisdiction may be obtained over a corporation

. . . by serving a copy of the summons and complaint in the manner prescribed by paragraph (a)(1) of this rule on any officer, director, trustee or managing or general agent, or any person authorized by appointment or by law to receive service of process on behalf of the corporation, or on a person at the registered office of the corporation in charge thereof, or, if service cannot be made on any of those persons, then on a person at the principal place of business of the corporation in this State in charge thereof, or if there is no place of

Plaintiffs served Metrics, which is registered do business in New Jersey, in the state under Rule 4:4-4(a)(6) via its registered agent in West Trenton, New Jersey. Defendants contend that in-state service upon a registered agent is insufficient without also showing that Metrics has "continuous and systematic" contacts with New Jersey. (Defs.' Reply 10-12; Supp. Letter of Oct. 9, 2014 [Docket Item 65].) Plaintiffs argue that acceptance of service by a registered agent in a state where Metrics is registered to do business conclusively establishes personal jurisdiction over Metrics. (Pls.' Opp. 5-7; Sur-reply 2-4; Supp. Letter of Oct. 15, 2014.) The Court agrees with Plaintiffs that by accepting service in the state through a registered agent in the state, that company has consented to be sued in that forum.

The Supreme Court has long recognized that jurisdiction may be established over a defendant who has consented to suit in the state. A party may consent to personal jurisdiction where such jurisdiction might otherwise not exist in a number of ways. In Insurance Corp. of Ireland v. Campagnie des Bauxies de Guinee, 456 U.S. 694 (1982), for example, the Court noted that a party

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business in this State, then on any employee of the corporation within this State acting in the discharge of his or her duties, provided, however, that a foreign corporation may be served only as herein prescribed subject to due process of law  
N.J. Ct. R. 4:4(a)(6).

may waive the requirements of personal jurisdiction through a variety of "legal arrangements [that] have been taken to represent express or implied consent to personal jurisdiction of the court." 456 U.S. at 704. The Court went on to note that one such arrangement may include "state procedures which find constructive consent to the personal jurisdiction of the state court in the voluntary use of certain state procedures." Id.

The Court has also previously suggested that a defendant consents to suit when it agrees to accept service of process in the forum. In Pa. Fire Ins. Co. v. Gold Issue Mining and Milling Co., 243 U.S. 93, 94 (1917), the Court, through Justice Holmes, found that a corporation had consented to personal jurisdiction by complying with a state statute that required it to consent to service in the state as a condition of doing business in that state. Since the defendant had complied with the statute and appointed an agent for service, the Court reasoned that it could rationally be held to consent to service of process in lawsuits filed against the defendant doing business in the state. 243 U.S. at 95.

Similarly, in Perkins v. Benguet Consol. Min. Co., 342 U.S. 437 (1952), the Supreme Court noted:

Today if an authorized representative of a foreign corporation be physically present in the state of the forum and be there engaged in activities appropriate to accepting service or receiving notice on its behalf, we recognize that there is no unfairness in subjecting that

corporation to the jurisdiction of the courts of that state through such service of process upon that representative.

Id. at 444-445. The principle of establishing jurisdiction by in-state service was emphasized more recently in the plurality opinion in Burnham v. Super. Court of California, 495 U.S. 604 (1990). In Burnham, the Court held that personal service upon a defendant who was within a forum state was enough to establish personal jurisdiction, regardless of whether the defendant had sufficient minimum contacts to satisfy due process. The Court explained that the long-standing in-state service rule does not require an independent inquiry into whether "traditional notions of fair play and substantial justice" were observed, because "a doctrine that dates back to the adoption of the Fourteenth Amendment and is still generally observed unquestionably meets that standard." 495 U.S. at 622. Citing a string of cases, including, importantly, some applying the in-state service rule to foreign corporate defendants accepting service by agent, the Court explicitly stated that the in-state service rule "remains the practice of, not only a substantial number of the States, but as far as we are aware all the States and the Federal Government." 495 U.S. at 615-16; id. at 616. Four justices in Burnham who did not join the plurality opinion wrote separately to emphasize that they agreed that personal jurisdiction is obtained over one who is served within the state, thus upholding

the doctrine of "transient jurisdiction," and they thus joined in the unanimous affirmation of the lower court's holding that personal service in California upon a New Jersey resident who was transient in California comported with due process for California to exercise personal jurisdiction even absent minimum contacts with the forum. 495 U.S. at 628-29 (Brennan, J.) Similarly, Justice White and Justice Stevens also wrote separately to affirm the judgment and to agree that in-state service of even a transient defendant suffices to confer personal jurisdiction. 450 U.S. at 628, 640.

Contrary to Defendants' contention, Daimler AG v. Bauman, 134 S. Ct. 746 (2014), did not disturb the consent-by-in-state service rule described in Burnham. Daimler did not discuss in-state service and there was no indication in Daimler that the defendant had registered to do business in the state or been served with process there. In fact, the Court's citation to Perkins v. Benguet Consol. Mining Co., for the "textbook case of general jurisdiction appropriately exercised over a foreign corporation that *has not consented to suit* in the forum," suggests that the Daimler Court was deciding a case where no in-state service had occurred. Daimler, 134 S. Ct. at 755-56 (quoting Goodyear Dunlop Tires Operations, S.A. v. Brown, 131 S. Ct. 2846, 2856 (2011))(emphasis added). The two other general jurisdictional cases examined by Daimler similarly concerned

defendants who were not authorized to do business in the forum state and had not consented to suit. See Goodyear, 131 S. Ct. at 2852 (stating that defendants were not registered to do business in North Carolina); Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 411 (1984) (noting that defendant had never been authorized to do business in Texas and never had an agent for service of process in Texas). The Court therefore does not find Daimler instructive in the present situation, which principally concerns establishing jurisdiction through consent to service. See, e.g., Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc., 2015 WL 186833, at \*12 (D. Del. Jan. 14, 2015) (holding that Daimler did not eliminate consent as a basis for establishing general jurisdiction over a corporation which has appointed an agent for service of process in the state).<sup>6</sup>

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<sup>6</sup> Moreover, Daimler's decision to limit general jurisdiction over a foreign corporation to the few places where a corporation's contacts were so continuous as to make it "at home" in that state was animated by the concern that to subject a corporation to jurisdiction in every state in which it does substantial business would give it little assurance of being able to predict where its conduct will render it liable to suit. Daimler AG v. Bauman, 134 S. Ct. 746, 761-62 (2014). The same due process concerns are absent in this case where the defendant has voluntarily complied with a state registration statute and accepted service of process in the forum state. Such conduct has long been interpreted as constituting consent to general jurisdiction in the state, and, particularly where, as here, the state statute explicitly establishes *in personam* jurisdiction in this manner, the corporation can have little uncertainty as to the judicial consequences of his actions.

Neither party has pointed to relevant case law in the Federal Circuit on the specific question of whether in-state service by a registered agent establishes personal jurisdiction, and the Federal Circuit has yet to address this question. See Acorda Therapeutics, 2015 WL 186833, at \*9. There is, however, ample support in the Third Circuit and New Jersey law for the principle that acceptance of service by a defendant registered to do business in the state establishes personal jurisdiction. See, e.g., Bane v. Netlink, Inc., 925 F.2d 637, 640 (3d Cir. 1991) (Pennsylvania statute establishing jurisdiction over any foreign corporation that registers to do business in the state “carries with it consent to be sued in Pennsylvania courts” and observing that “[c]onsent is a traditional basis for assertion of jurisdiction long upheld as constitutional.”); Sadler v. Hallsmith SYSCO Food Serv., 2009 WL 1096309 (D.N.J. Apr. 21, 2009) (finding that defendant consented to being sued in New Jersey by conceding that it was registered to do business in New Jersey and had a registered agent in the state for service of process); Allied-Signal Inc. v. Purex Ind., Inc., 576 A.2d 942 (N.J. Super. Ct. App. Div. 1990) (holding that foreign defendant corporation was subject to suit in New Jersey because an agent was served in-state even though agent was registered for process in unrelated litigation, and noting that “[w]hile due process merely requires that a nonresident defendant

'reasonably anticipate' being sued in the forum state, . . . presence of an individual defendant in the forum state accompanied by service, confers *in personam* jurisdiction." (citation omitted); Litton Indus. Sys., Inc. v. Kennedy Van Saun Corp., 283 A.2d 551, 556 (N.J. Super. Ct. Law Div. 1971) (concluding that designation of an agent for service of process under N.J.S.A. 14A:4-1 amounted to consent by defendant to be sued in New Jersey); Randolph Labs v. Specialties Dev. Corp., 623 F. Supp. 897, 898-99 (D.N.J. 1945) (finding that corporation's designation of an agent in New Jersey for service of process constituted consent to be sued in the state).

The Court also notes that the Restatement (Second) Conflict of Laws, which views are occasionally adopted by New Jersey courts on issues the courts have not yet considered, provides the same rule for establishing personal jurisdiction over a foreign corporation:

By authorizing an agent or public official to accept service of process in actions brought against it, the corporation consents to the exercise by the state of judicial jurisdiction over it as to all causes of action to which the authority of the agent or official extends. This consent is effective even though no other basis exists for the exercise of jurisdiction over the corporation.

Id., §§ 44 cmt. a; see H. John Homan Co., Inc. v. Wilkes-Barre Iron and Wire Works, Inc., 558 A.2d 42, 45 (N.J. Super. Ct. App. Div. 1989) ("New Jersey typically gives substantial weight to

the Restatement view, particularly in respect of issues it has not yet addressed.”).

The Court is not persuaded by the New Jersey cases cited by Defendants because none include the key facts which establish jurisdiction in this case: personal service upon an agent appointed to accept service on behalf of a corporation registered to do business in New Jersey. See, e.g., Citibank, N.A. v. Estate of Simpson, 676 A.2d 172, 176 (N.J. Super. Ct. App. Div. 1996) (no indication that partner was authorized to accept service on behalf of partnership in New Jersey); JWQ Cabinetry, Inc. v. Granada Wood & Cabinets, Inc., 2014 WL 2050267, at \*3 (D.N.J. May 19, 2014) (no indication that defendant registered to do business in New Jersey or accepted service of process in New Jersey through registered agent); Atkinson & Mullen Travel Inc. v. New York Apple Tours Inc., 1998 WL 750355, at \*2 (D.N.J. Sept. 16, 1998) (no indication that defendant accepted service of process in New Jersey).

Notably, one case cited by Defendants, Nehemiah v. Athletics Congress of U.S.A., 765 F.2d 42, 46-47 (3d Cir. 1985), was cited by the Supreme Court in Burnham as one of the few opinions that have “erroneously” found the practice of in-state service of process unconstitutional. Id. at 615.

In holding that Metrics is subject to personal jurisdiction in New Jersey, the Court makes a distinction between registering

to do business in the state and accepting service in the state by an authorized agent, as was the case here. Although it may also be correct that registering to do business alone (particularly where registration also requires the entity to appoint an agent in the state for service of process) may be sufficient as a basis for personal jurisdiction,<sup>7</sup> the decision to

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<sup>7</sup> At least four federal circuit courts have held that compliance with registration statutes may be a basis for establishing personal jurisdiction. See, e.g., King v. Am. Family Mut. Ins. Co., 632 F.3d 570, 576, 578 (9th Cir. 2011); Bane v. Netlink, Inc., 925 F.2d 637, 640 (3d Cir. 1991); Knowlton v. Allied Van Lines Inc., 900 F.2d 1196, 1199-1200 (8th Cir. 1990); Holloway v. Wright & Morrissey, Inc., 739 F.2d 695, 697 (1st Cir. 1984); Novartis Pharmaceuticals v. Mylan, 2015 WL 1246285, at \*3 (D. Del. Mar. 16, 2015); Forest Laboratories, Inc. v. Amneal Pharmaceuticals LLC, 2015 WL 880599, at \*10 (D. Del. Feb. 26, 2015); Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc., 2015 WL 186833, at \*12 (D. Del. Jan. 14, 2015) (“[W]hen courts have clearly held that compliance with a state's registration statute confers general jurisdiction, corporations have the requisite notice to enable them to structure their conduct so as to be assured where they will, and will not, be subject to suit.”). Two circuits have held that a state registration requirement cannot be the basis for finding consent to general jurisdiction. See Wilson v. Humphreys (Cayman) Ltd., 916 F.2d 1239, 1245 (7th Cir. 1990); Ratliff v. Cooper Labs, Inc., 444 F.2d 745, 748 (4th Cir. 1971) (“The principles of due process require a firmer foundation than mere compliance with state domestication statutes”); see also AstraZeneca AB v. Mylan Pharmaceuticals, Inc., 2014 WL 5778016, at \*4 (D.N.J. Nov. 5, 2014).

This Court recently held that, in an ANDA case, registration to do business in New Jersey, even absent service upon a corporate agent in New Jersey, suffices to confer personal jurisdiction where the corporate defendant was also availing itself of the privilege of doing business in New Jersey, including bringing current lawsuits on pharmaceutical patent disputes in this Court. Otsuka Pharmaceuticals Co., Ltd. v. Mylan, Inc., Civ. No. 14-4508, 2015 WL 13-5764, at \*12 (D.N.J. Mar. 23, 2015).

exercise jurisdiction over Metrics is based upon the fact that Metrics not only registered to do business in New Jersey but, under New Jersey Court Rule 4:4-4(a)(6), accepted service of process through its registered agent in the state.

Accordingly, Defendants' motion to dismiss will be denied with respect to Metrics.

**D. Mayne Pharma Group Limited - general and specific jurisdiction**

Defendants argue that Mayne Pharma Group Limited's contacts in New Jersey are insufficient to establish either general or specific jurisdiction, as it is an Australian company which has no property in New Jersey and does not directly sell its products to New Jersey. (Def. Reply at 11.) Plaintiffs argue that the litigation that Defendant's corporate predecessors and subsidiaries have engaged in in this state, and the fact that its corporate predecessors previously had a New Jersey mailing address, confers jurisdiction. Plaintiffs also argue that Defendants have contracted with a New-Jersey based company, Johnson-Matthey, to manufacture the pharmaceutical ingredient at issue in this litigation. The parties' briefs do not make clear whether Johnson-Matthey has a contract with Metrics or Mayne Pharma Group Limited.

The Court begins with the question of whether it may assert general jurisdiction over Mayne Pharma Group Limited, and holds

that Defendant's contacts with New Jersey fall below the threshold of business activity that is required to render Defendant "at home" in this state. In reaching this conclusion, the Court follows the guidance of Daimler AG v. Bauman, 134 S. Ct. 746 (2014), which finds that general jurisdiction is proper over a foreign corporation "only when the corporation's affiliations with the State in which suit is brought are so constant and pervasive 'as to render [it] essentially at home in the forum State.'" 134 S. Ct. 746, 751 (2014) (quoting Goodyear Dunlop Tires Operations, S.A. v. Brown, 131 S. Ct. 2846, 2851 (2011)).

Daimler involved a dispute over whether a California court could exercise general jurisdiction over a German car manufacturer, DaimlerChrysler Aktiengesellschaft, for the actions of its subsidiary, Mercedes-Benz Argentina, in Argentina during Argentina's "Dirty War" twenty years ago. The plaintiffs in that case argued that an agency relationship existed between Daimler and another one of its subsidiaries, Mercedes-Benz USA ("MBUSA"), and attempted to attribute the activities of MBUSA in California to Daimler. Id. at 751-52. MBUSA was incorporated in Delaware and had its principal place of business in New Jersey but had several corporate facilities in California and distributed cars to California. MBUSA was the largest supplier of luxury vehicles to the California market, and annual sales of

Daimler vehicles in California amounted to 2.4% of Daimler's global sales, or about \$4.6 billion. Id. at 752.

The Supreme Court held that even assuming MBUSA's contacts could be attributed to Daimler, the contacts would be insufficient to subject Daimler to general jurisdiction in California. Id. at 760. The Court followed the general jurisdiction inquiry in Goodyear Dunlop Tires Operations, S.A. v. Brown, 131 S. Ct. 2846, noted above, and explained it was not enough that a corporation engage in "substantial, continuous, and systematic" business in a state. Merely engaging in "continuous and systematic" in-state activities would invite corporations to be subject to suit in every state in which they did substantial business. Id. at 761. In all but the most "exceptional case," a corporation is "at home" in only two places: its place of incorporation and its principal place of business. Id. at 760-61 & n.19. Thus, the Court found that MBUSA's sales in California, although sizable, would not render Daimler subject to suit there on claims "by foreign plaintiffs having nothing to do with anything that occurred or had its principal impact in California." Id. at 762.

Mayne Pharma Group Limited's activities in New Jersey are minimal and fall below the threshold for establishing general jurisdiction. Defendant's primary place of business is Melbourne, Australia. Defendant has no offices, facilities, or

real property in New Jersey, so far as the record discloses at present. Even though Plaintiffs asserts that Mayne Pharma Australia is "engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world," Defendants state, and Plaintiffs does not here deny, that Mayne Pharma Group Limited does not sell products or services directly in the state. (Pls.' Opp. 9; First Cross Decl. ¶ 5, 15.) Unlike Metrics, Mayne Pharma Group Limited is not registered to do business in the state and does not have an agent appointed to accept service in the state. There is no allegation that Defendant has any employees, agents, or bank accounts in New Jersey, or that it solicits business or advertises in the state.

Plaintiffs allege that Mayne Pharma Group Limited's corporate predecessors or subsidiaries previously had an office in New Jersey and previously litigated 11 patent cases in 14 years in this state. Given the high threshold of business activity that is required under Daimler, the Court is not convinced that general jurisdiction may be established solely on Defendant's corporate predecessors' past activity when Defendant has no *current* business activity New Jersey, particularly when Defendant's only past connections are limited to the activity of corporate predecessors and subsidiaries involving products that have nothing whatsoever to do with the ANDA product in this

case. See AstraZeneca AB v. Mylan Pharmaceuticals, Inc., 2014 WL 5778016, at \*4 (Nov. 5, 2014) (declining to find that defendant was subject to general jurisdiction in the state despite its extensive litigation history in the district and observing that "familiarity with the court system of Delaware is insufficient to render a defendant at home here, as envisioned by Daimler." )<sup>8</sup>

Nor does the fact that Defendants potentially have an in-state supplier change the Court's analysis. The fact that Defendants have a contract with one New-Jersey based company to manufacture a part of its product does not make Defendant's activity in the state "constant" and "pervasive" to so as to render it at home in New Jersey for purposes of general jurisdiction. See Daimler, 134 S. Ct. at 760-62 (finding court lacked general jurisdiction in the state even though defendant had multiple in-state facilities, distributed products for sale

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<sup>8</sup> Contrary to Plaintiffs' contention, the fact that Defendant's related entities litigated in this forum does not by itself establish general jurisdiction. See, e.g., In re Rosuvastatin Calcium Patent Litig., 2009 WL 4800702, at \*6 (D. Del. Dec. 11, 2009) ("Filing a counterclaim and defending a lawsuit, and consensually participating in other cases, is not enough to serve as a basis for a finding of a general presence in Delaware for all cases . . . ."); Merlino v. Harrah's Entm't, Inc., 2006 WL 401847, at \*3 (E.D. Penn. Feb. 17, 2006) (unpublished) ("Filing even nineteen lawsuits, without more, cannot constitute continuous and systematic activity so as to establish general jurisdiction."); Jones v. Blige, 2006 WL 1329247, at \*5 (E.D. Mich. May 16, 2006) (unpublished) (general jurisdiction was not established by the defendant's status as a plaintiff in three unrelated lawsuits); Travelers Cas. & Sur. Co. v. Interclaim (Bermuda) Ltd., 304 F. Supp. 2d 1018, 1025 (N.D. Ill. 2004).

in the state, and sold over 10% of its U.S. products in the state); Goodyear, 131 S. Ct. at 2852 (finding court lacked general jurisdiction where defendant's products were distributed to forum state by an affiliate but defendant had no office, employees, or bank accounts in the state, was not registered to do business in the state, did not solicit business or advertise in the state, and did not themselves sell products in the state); Fisher v. Teva PFC SRL, 212 Fed. App'x 72, 75-77 (3d Cir. 2006) (finding defendant did not have continuous presence in the forum where defendant had distribution contract with New Jersey distributor, shipped products to New Jersey customers, its employees visited New Jersey several times a year, it briefly retained an individual as a New Jersey employee, and it was owned for a time by parent company based in New Jersey).<sup>9</sup>

Having decided that Mayne Pharma Group Limited is not subject to general jurisdiction in New Jersey, the Court turns briefly to the question of specific jurisdiction. Plaintiffs did

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<sup>9</sup> The fact that Metrics is a subsidiary of Mayne Pharma Group Limited change this determination, since Plaintiffs do not allege - and the record does not suggest - that Mayne Pharma Group Limited exercises "unusual hegemony" over Metrics such that Metrics' contacts with New Jersey should be imputed to Mayne Pharma Group Limited. See Pfundstein v. Omnicom Group Inc., 666 A.2d 1013, 1016-17 (N.J. Super. Ct. App. Div. 1995) (declining to impute contacts of subsidiaries to defendant parent company for purposes of establishing jurisdiction over parent and noting that forum contacts of a subsidiary will not be imputed to the parent without a showing of something more than mere ownership).

not assert in their initial briefs that the Court has specific jurisdiction over Mayne Pharma Group Limited. Rather, they argued that Defendant's forum-connected activity as a whole creates "continuous and systematic" contacts with New Jersey. (Pl. Opp. 8-12; Pl. Sur-Reply 4-7.)

As explained above, specific jurisdiction may be established over a defendant where the defendant has "purposefully directed" its activities at residents of the state, and the litigation arises out of those forum related activities. Burger King Corp. v. Rudzewicz, 471 U.S. 462, 472 (1985); World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980). In the context of patent litigation, a plaintiff must establish that (1) the defendant purposefully directed its activities at residents of the forum, (2) the claim arises out of or relates to those activities, and (3) assertion of personal jurisdiction is reasonable and fair. Avocent Huntsville Corp. v. Aten Intern. Co., 552 F.3d 1324, 1332 (Fed. Cir. 2008).

Here, the infringement suits filed by Defendant's corporate predecessors and subsidiaries have nothing to do with the product that is the subject of the ANDA litigation in this case, nor do they concern any of the same Plaintiffs. Defendants moreover assert that the ANDA product was developed, manufactured, and tested out-of-state. Similarly, the ANDA application for Defendant's generic bromfenac ophthalmic

solution was prepared and filed out-of-state. (First Cross Decl. ¶ 13.)

Plaintiffs argued that Defendants have a contract with the West Depford-based company, Johnson-Matthey, to supply the active pharmaceutical ingredient in Defendant's bromfenac ophthalmic solution. Plaintiffs do not make clear whether Johnson-Matthey's contract is with Metrics or Mayne Pharma Group Limited,<sup>10</sup> and neither party has sufficiently addressed the question of whether the existence of a contract with an in-state supplier to manufacture part of the ANDA product that is the subject of this suit would be sufficient establish specific jurisdiction in this case. Since injunctive relief against infringing activity is part of the remedy that Plaintiffs seek, it is plausible that an out-of-state defendant that has arranged with an in-state manufacturer to produce the infringing product is deemed to commit an act of infringement in this state and to thus subject itself to jurisdiction for purposes of injunctive relief.

Because the record raises a possibility that Mayne Pharma Group Limited has the requisite contacts with New Jersey

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<sup>10</sup> Although Plaintiffs assert in their supplemental letters that Metrics, Inc. has a contract with Johnson-Matthey, their initial briefs state only that "Defendants" have a contract with Johnson-Matthey and it is unclear whether the connection is with Metrics or Mayne Pharma Group Limited.

specific to the cause of action in this case, the Court will grant Plaintiff's request for jurisdictional discovery relevant to the question of whether Mayne Pharma Group Limited has a connection to Johnson-Matthey with regard to production or distribution of bromfenac, and if so, the nature and extent of such connection. As the Court has explained, as the parties did not clarify in their initial briefs whether Johnson-Matthey has a connection with Mayne Pharma Group Limited or Metrics, the Court cannot at this time rule out the possibility of exerting specific jurisdiction over Mayne Pharma Group Limited through its potential connection with Johnson-Matthey. If, as Plaintiffs' subsequent submissions to the Court suggest (see Pl. Oct. 15, 2014 Letter [Docket Item 66]; Pl. Oct. 20, 2014 Letter [Docket Item 69]), the parties agree that Johnson-Matthey's only connection to Defendants is through Metrics, Inc., the parties are invited to voluntarily dismiss Mayne Pharma Group Limited from this case for lack of personal jurisdiction.

The Court will exert personal jurisdiction over Mayne Pharma Group Limited to the extent necessary to require it to provide this limited specific-jurisdiction related discovery. The period for this discovery shall be 30 days. Within 7 days thereafter, Plaintiff may file a supplemental brief to demonstrate specific jurisdiction, and supplemental opposition

will be due 7 days thereafter. This inquiry will thus remain open pending briefing.

#### **IV. MOTION TO ENJOIN INTER PARTES REVIEW**

Shortly after they filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") which included a Paragraph IV Certification claiming that Plaintiffs' patents were "invalid or will not be infringed by Defendants' drug, Defendants filed petitions for inter partes review ("IPR") before the Patent Trial and Appeal Board ("PTAB") to review the validity of Plaintiffs' '290 and '431 patents. Plaintiffs seek to enjoin Defendants from participating in the IPR proceeding under the novel argument that 35 U.S.C. § 325(a)(1), which governs the filing of IPR petitions, bars Defendants from seeking IPR because they already filed a "civil action" challenging the validity of the patent through the filing of a Paragraph IV Certification with the FDA. Plaintiffs argue that an injunction is also warranted under the "first-filed" rule to prevent duplicative judicial effort and the risk of inconsistent judgments.<sup>11</sup>

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<sup>11</sup> Plaintiffs seek an injunction under the All Writs Act. (Pl. Mot. to Enjoin 5.) The All Writs Act provides a federal court with those writs necessary to the preservation or exercise of its subject matter jurisdiction. Pa. Bureau of Corr. v. U.S. Marshals Serv., 474 U.S. 34, 40 (1985). Unlike a "traditional" injunction, which is issued as an interim or permanent remedy for certain breaches of common law, statutory, or constitutional

On February 19, 2015, the PTAB granted Defendants' petition for inter partes review of the '290 and '431 patents.

#### **A. Inter Partes Review**

Inter partes review, created in 2011 under the Leahy-Smith America Invents Act ("AIA"), allows a party other than the patentee to bring a proceeding before the Patent Trial and Appeal Board to challenge the validity of a patent. 35 U.S.C. § 311. The current system of inter partes review replaces the old system of inter partes reexamination. Unlike the inter partes reexamination process, inter partes review is more akin to an adjudicative proceeding. H.R. Rep. No. 112-98, 46 (2011), *reprinted in* 2011 U.S.C.C.A.N. 67, 77 (the AIA "converts inter partes reexamination from an examinational to an adjudicative proceeding.").

35 U.S.C. § 315(a) provides for the filing of inter partes review in relation to other proceedings. Section 315(a)(1) states:

An inter partes review may not be instituted if, before the date on which the petition for such a review is

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rights, the All Writs Act may properly be invoked to enjoin almost any conduct "which, left unchecked, would have had the practical effect of diminishing the court's power to bring the litigation to a natural conclusion." ITT Comty. Dev. Corp. v. Barton, 569 F.2d 1351, 1359 (5th Cir. 1978). Although the Act "empowers federal courts to fashion extraordinary remedies when the need arises, it does not authorize them to issue ad hoc writs whenever compliance with statutory procedures appears inconvenient or less appropriate." Pa. Bureau of Corr., 474 U.S. at 43.

filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

**B. The Court will decline to enjoin Defendants from proceeding before the PTAB**

The Court first holds that 35 U.S.C. § 315(a) does not bar Defendants from seeking inter partes review before the PTAB because Defendants did not file a "civil action" by filing a Paragraph IV Certification. The term "civil action" has traditionally been defined as a judicial proceeding of some kind. See BP Am. Prod. Co. v. Burton, 549 U.S. 84, 91 n.3 (2006) ("These primary definitions have not changed in substance since 1966. Black's (8<sup>th</sup> ed. 2004) now defines 'action' as '[a] civil or criminal judicial proceeding'); United States v. El-Ghazali, 142 Fed. App'x 44, 46-47 (3d Cir. 2005) (collecting dictionary definitions which define "action" as, among other things, a "judicial proceeding," "a proceeding instituted by one party against another," "proceedings in courts of law," "a judicial proceeding whose purpose is to obtain relief at the hands of the court," and "a legal process or suit."). A Paragraph IV Certification is merely an administrative application to the FDA certifying that the patent in question is invalid or is not infringed by the generic product; it is not part of any judicial proceeding. The certification is not filed before an adjudicative body, nor does it seek a ruling on the application

by a decisionmaker. There can be no real question that a Paragraph IV Certification does not constitute a "civil action" within the plain meaning of that term.<sup>12</sup>

The few opinions that have considered the precise argument Plaintiffs make here have easily and soundly rejected Plaintiffs' interpretation of a "civil action." As noted above, the PTAB has now granted Defendants' petition for inter partes review. In doing so, it specifically rejected Plaintiffs' argument that 35 U.S.C. § 325(a)(1) bars Defendants from filing a petition for review. See Metrics, Inc. v. Senju Pharmaceutical Co., Ltd., PTAB No. IPR2014-01041, slip op. at 8-9 (PTAB Feb. 19, 2015) ("When [35 U.S.C. § 325(a)(1)] refers to filing a civil action, it refers to filing a complaint with a court to commence a civil action" (citing Baldwin Cnty. v. Welcome Ctr. v. Brown, 466 U.S. 147, 149 (1984))); Metrics, Inc. v. Senju Pharmaceutical

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<sup>12</sup> Nor does Plaintiff's argument appear to be supported by language within the AIA. "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." In Re Price, 370 F.3d 362, 369 (2004) (quoting Robinson v. Shell Oil Co., 519 U.S. 337, 341 (1997)). Here, in another part of the AIA, the statute treats a "civil action" as distinct from a Paragraph IV notification that is required as part of an ANDA, which further suggests that Congress intended a "civil action" to mean something other than an ANDA petition. See 35 U.S.C. § 257(c)(1)(2)(A) ("Paragraph (1) shall not apply to an allegation pled with particularity in a *civil action*, or set forth with particularity in a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) . . . .").

Co., Ltd., PTAB No. IPR2014-01043, slip op. at 8-9 (PTAB Feb. 19, 2015) (stating same). In at least two other opinions, the PTAB has held that the filing of a "civil action" in § 325(a)(1) refers to "filing a complaint with a court to commence a civil action," and does not include the filing of a Paragraph IV certification with the FDA. See Noven Pharmaceuticals, Inc. v. Novartis AG and LTS Lohmann Therapie-Systeme AG, PTAB No. IPR2014-00549, slip op. at 6-7 (PTAB Oct. 14, 2014) (holding that petitioner's filing of a Paragraph IV Certification "did not involve filing of a complaint with a court" and thus did not bar petitioner from instituting a petition under § 315(a)); Noven Pharmaceuticals, Inc. v. Novartis AG and LTS Lohmann Therapie-Systeme AG., PTAB No. IPR2014-00550, slip op. at 6-7 (PTAB Oct. 14, 2014) (holding same and citing Ariosa Diagnostics v. Isis Innovation Ltd, PTAB No. IPR2012-00022, slip op. at 4 (PTAB Feb. 12, 2013)).

Plaintiffs do not dispute that the PTAB's interpretation of a statute governing inter partes review is entitled to deference, and the Court finds the PTAB's rulings instructive here. (See Pl. Feb. 26, 2015 Letter [Docket Item 77]); Southeastern Comty. Coll. v. Davis, 442 U.S. 397, 411 (1979) (noting that "an agency's interpretation of the statute under which it operates is entitled to some deference," although court must honor the "clear meaning of a statute"); Eli Lilly & Co. v.

Bd. of Regents of Univ. of Wash., 334 F.3d 1264, 1267 (Fed. Cir. 2003).

Nor is the Court persuaded that the statutory framework of the Hatch-Waxman Act would be undermined if this Court allowed inter partes review before the PTAB to proceed in parallel with this case. Plaintiffs argue that by filing an ANDA, Defendants “intiate[d] district court litigation” and therefore should not be permitted to then seek review of the same patent by filing for IPR in another forum. (Pl. Mot. to Enjoin 9.) As already explained above, Defendants did not initiate litigation by merely filing an ANDA with the FDA. The civil action before this Court did not begin until Plaintiffs filed their Complaint on June 20, 2014. [Docket Item 1.] Had Defendants wanted to initiate litigation, they were free to file a declaratory judgment action of non-infringement under 35 U.S.C. § 271(e)(5) after filing their ANDA, and doing so would have precluded Defendants, under 35 U.S.C. § 315(a), from seeking inter partes review.

The Court does not find that an injunction is warranted under the “first-filed” rule. The “first-filed” rule applies when two lawsuits involving the same issues and parties are filed in different courts. In such a situation, the first-filed rule counsels deference to the earlier-filed suit. E.E.O.C. v. Univ. of Penn., 850 F.2d 969, 971 (3d Cir. 1988) (quoting

Crosley Corp. v. Hazeltine Corp., 122 F.2d 925, 929 (3d Cir. 1941)). The purpose of the first-filed rule is to "encourage[] sound judicial administration and promote[] comity among federal courts of equal rank." E.E.O.C. v. Univ. of Penn., 850 F.2d at 917 (emphasis added). "Courts have consistently recognized that the first-filed rule "is not a rigid or inflexible rule to be mechanically applied." Id. at 976 (citation omitted). "District courts have always had discretion to retain jurisdiction given appropriate circumstances justifying departure from the first-filed rule;" and in exercising its discretion, a district court "must act with regard to what is right and equitable under the circumstances and the law, and directed by the reason and conscience of the judge to a just result." Id. at 972, 977 (internal quotations and citation omitted).

The Court is not convinced that the "first-filed" rule applies. The "first-filed" rule "promotes comity among federal courts of equal rank." E.E.O.C. v. Univ. of Penn., 850 F.2d at 971. Consistent with that principle, the rule is frequently used by one district court to enjoin the prosecution of proceedings involving the same parties and the same issues "already before another *district court.*" Id.; see also Honeywell Intern. Inc. v. Int'l Union, United Auto., Aerospace and Agr. Implement Workers of Am., 502 Fed. Appx. 201, 205 (3d Cir. 2012) (first-filed rule applies "when two lawsuits involving the same issues and parties

are pending in *separate federal district courts.*"); Cataneser v. Unilever, 774 F.Supp.2d 684 (D.N.J. 2011); Abushalieh v. Am. Eagle Exp., 716 F.Supp. 2d 361 (D.N.J. 2010); One World Botanicals Ltd. v. Gulf Coast Nutritionals, Inc., 987 F. Supp. 317 (D.N.J. 1997). Plaintiffs have cited to no case in which a district court applied the "first-filed" rule to enjoin a party from proceeding before the PTAB, and the Court can find no precedent for doing so.

The Court is also not convinced that inter partes review would result in duplicative judicial effort, which the first-filed rule is intended to prevent. Patents are reviewed in IPR proceedings under a different standard of proof than in federal district court. Before the courts, a patent is presumed valid and the party asserting invalidity must prove the facts by clear and convincing evidence. 35 U.S.C. § 282 ("The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.") By contrast, for a patent reviewed under the IPR process, the petitioner need only prove invalidity of a patent by a preponderance of the evidence. 35 U.S.C. § 316(e). Thus, at least one Federal Circuit court ruling has noted that "precise duplication of effort does not occur because the PTO and the courts employ different standards of proof when considering validity." Ethicon v. Quigg, 849 F.2d 1422 (Fed. Cir. 1988).

The Court finally notes that although Plaintiffs cast this injunction as one against Defendants, in reality it operates as an injunction against the IPR process itself. When the PTAB exercises its power to institute inter partes review, that decision is final. 35 U.S.C. § 314(d) ("The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable."); In re Bd. of Trustees of Univ. of Ill., 564 Fed. App'x 1021, 1021 (Fed. Cir. 2014) (holding that statutory scheme precludes the court from hearing an appeal from the decision to institute IPR); In re Dominon Dealer Solutions, LLC, 749 F.3d 1379, 1381 (Fed. Cir. 2014) (same). To issue an injunction against Defendants now would have the direct consequence of preventing the PTAB from reviewing the case after a decision has already been made to institute review, and would undermine the PTAB's final decision-making authority. Whether, in an extraordinary case, a federal court may exercise injunctive authority against the PTAB in aid of the federal court's jurisdiction or to enforce a federal court judgment need not be addressed in the present circumstances.

Accordingly, the Court will deny Plaintiff's motion to enjoin.

**V. CONCLUSION**

For the foregoing reasons, the Court will deny Defendants' motion to dismiss for lack of personal jurisdiction with respect to Metrics, Inc. The Court will also deny Defendants' motion with respect to Mayne Pharma Group Limited without prejudice to Defendants' right to renew the motion following jurisdictional discovery and supplemental briefing.

Jurisdictional discovery will be permitted on the question of whether Mayne Pharma Group Limited has a connection to Johnson-Matthey with regard to production or distribution of bromfenac and if so, the nature and extent of such a connection. The period for this discovery shall be 30 days. Within 7 days thereafter, the parties may file supplemental briefs on the question of whether this Court has specific jurisdiction over Mayne Pharma Group Limited.

Plaintiffs' motion to enjoin proceedings before the PTAB will be denied. An accompanying Order will be entered.

March 31, 2015  
Date

s/ Jerome B. Simandle  
JEROME B. SIMANDLE  
Chief U.S. District Judge