IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC.,	§	
	§	
Plaintiff,	§	CASE NO. 2:14-CV-638
	§	**LEAD CASE**
v.	§	
	§	CASE NO. 2:14-CV-188
ACTAVIS, INC. et al.	§	MEMBER CASE
	§	
Defendants,	§	

MEMORANDUM OPINION AND ORDER

Before the Court are Defendants' (Actavis PLC, Actavis, Inc., Watson Laboratories, Inc. and Actavis Pharma, Inc., collectively, "Defendants") Motions to Dismiss for Lack of Personal Jurisdiction (-188 Case, Dkt. No. 24; -638 Case, Dkt. No. 35) and Plaintiff Allergan, Inc.'s Motions for Summary Judgment on Count I and Motions to Dismiss Count II (-188 Case, Dkt. No. 35; -638 Case Dkt. No. 14). Having considered the parties' briefing and the entire record, the Court finds as follows:

- Defendants' motions to dismiss for lack of personal jurisdiction should be, and hereby are **DENIED**;
- Allergan's motions for summary judgment with respect to its declaratory judgment claims should be, and hereby are **GRANTED-IN-PART**; and
- Allergan's motions to dismiss its patent infringement claims should be, and hereby are **GRANTED.**[1]

[1] The instant motions were originally filed in Case No. 2:14-cv-188. The Court later consolidated the above-captioned cases for all purposes. The parties advance identical arguments in both of the above-captioned cases, the parties submitted consolidated briefing, and the Court's order is effective as to each motion and each case.

I. BACKGROUND AND SUMMARY OF THE COURT'S OPINION

A. Statutory Framework

This case involves the Defendants' efforts to obtain FDA approval for, and then bring to market, a generic version of Plaintiff Allergan, Inc.'s FDA approved and patented drug, RESTASIS. To accomplish their goal, Defendants must comply with the statutes and regulations governing the approval of generic drugs, including the Food, Drug and Cosmetic Act ("FDCA"), codified at 21 U.S.C. §§ 301 *et seq.*, and specifically the Hatch Waxman amendments to the FDCA, codified at 21 U.S.C. § 355 and 35 U.S.C. § 271(e). The purpose of the Hatch Waxman framework is "to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (citing *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds)).

1. The ANDA process and "safe harbor."

Under the Hatch Waxman framework, "a pharmaceutical manufacturer seeking approval to market a generic version of a previously approved drug may submit an abbreviated new drug application ('ANDA') to the FDA." *Id.*, at 1325-26 (citing 21 U.S.C. § 355(j) (1994)). An ANDA provides the generic manufacturer with an expedited approval process and dramatically reduces the cost of bringing the generic drug to market, as compared to the approval process required for new "brand-name" drugs. *Id.* Moreover, the Hatch-Waxman "safe harbor" provisions shield the generic manufacturer from liability for patent infringement that might otherwise attach to the development of the generic drug. *See* 35 U.S.C. § 271(e)(1).

The expedited approval process and "safe harbor" from patent infringement are valuable assets to a generic manufacturer. To balance these advantages, generic manufacturers must strictly comply with the statutory and regulatory provisions governing the timing and content of disclosures made to the FDA during the ANDA process. *See, e.g.*, 21 U.S.C. § 355(j)(2)(A)(iv) (concerning the bioequivalence of the proposed generic drug).

2. Infringement under 35 U.S.C. § 271(e)(2) and paragraph IV notice.

Once an ANDA has been submitted to the FDA, the name brand manufacturer/patentee may bring an action for infringement under 35 U.S.C. § 217(e)(2), which provides in pertinent part:

> It shall be an act of infringement to submit--
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(j)] or described in section 505(b)(2) of such Act [21 USCS § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent.

This provision creates a "highly artificial act of infringement," allowing the patentee to assert its rights before the generic manufacturer has actually entered the market by making, using or selling the patented product. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

Further, the Hatch Waxman framework requires the applicant to:

(1) give notice to the name brand manufacturer that it has filed an ANDA targeting the name brand drug;

(2) certify whether its proposed generic drug will infringe any of the patents listed in connection with the name brand drug in the Orange Book; and

(3) state in detail the basis for any belief that the relevant patents are invalid, unenforceable, or not infringed by the proposed generic drug.

21 U.S.C. § 355(j)(2)(B)(i); 21 C.F.R. § 314.95(c)(6). An ANDA applicant has four such certification options: it may certify (I) that the required patent information has not been filed, (II) that the patent has expired, (III) that the patent will expire on a particular date, or (IV) that the patent is invalid, unenforceable or will not be infringed by the drug for which the applicant seeks approval. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). The fourth option, aptly named a "paragraph IV" notice, is at issue in this case.

Such notice triggers a forty-five (45) day count down, during which the patentee may sue the generic manufacturer for infringement. 21 U.S.C. § 355(j)(5)(B)(iii). "If the patentee files suit within that period, the FDA may not approve the ANDA until the expiration of the patent, judicial resolution of the infringement suit, a judicial determination that the patent is invalid or unenforceable, or thirty months from the patentee's receipt of notice, whichever is earliest." *Mylan Pharms.*, 268 F.3d at 1327 (citing 21 U.S.C. § 355(j)(5)(B)). This automatic stay of the ANDA process balances the competing interests of the generic applicant and the patentee, and "enable[s] a court to promptly resolve any dispute concerning infringement and validity." *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

B. Procedural History, Pre-Suit

Allergan manufactures and distributes RESTASIS, an ophthalmic product for the treatment of dry eye. It has done so since the FDA approved Allergan's New Drug Application in December of 2002.

On November 14, 2011 Defendants submitted ANDA No. 203463 to the FDA in order to obtain approval for a generic form of RESTASIS. *See* Dkt No. 14-1.[2] The FDA responded to Defendants' ANDA on August 30, 2013, stating that "We [the FDA] are refusing to receive this

[2] Unless otherwise noted, all docket entries refer to the Lead Case, No. 2:14-cv-638.

ANDA under 21 CFR 314.101(d)(3) . . . " *Id.* at 2-3 (listing the defects in Defendant's ANDA and potential remedial measures Defendants might take). The FDA further clarified that, "[i]f [Defendants] choose to respond to this letter to correct the deficiencies, the response will be considered a new original ANDA." *Id.* at 3 (emphasis in original). Defendants replied in a letter dated October 18, 2013, and submitted various revised or supplemental information to the FDA. *See* Dkt. No. 14-2. Based on the record before the Court, it does not appear that the FDA has responded to Defendants' October 2013 correspondence.

On January 14, 2014, U.S. Patent No. 8,629,111 issued, listing Allergan as the assignee (-188 Case, Dkt. No. 1-2). On the same day, Defendants sent Allergan a letter asserting (among other things) that that the FDA had "received" Defendants' ANDA and that such ANDA contains a paragraph IV notice for the '111 Patent:

> Pursuant to 21 U.S.C. § 3550)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), we advise you that **FDA has received an Abbreviated New Drug Application ("ANDA")** from Watson for Cyc1osporine Ophthalmic Emulsion, 0.05%. The ANDA contains the required bioequivalence data and/or bioequivalence waiver. The ANDA was submitted under 21 U.S.C. § 3550) and **contains a paragraph IV certification requesting approval to engage in the commercial manufacture, use or sale of cyc1osporine ophthalmic emulsion, 0.05%, prior to the expiration of the '111 patent.**

See -188 Case, Dkt. No. 1-3 at 2 (emphasis added). In response, Allergan contacted the FDA in order to determine the status of Defendants' ANDA. Dkt. No. 1-6. Allergan also asked that Defendants withdraw their purported paragraph IV notice. Dkt. No. 1-5.

C. Procedural History before this Court

Allergan filed suit in this Court on March 6, 2014, seeking a declaratory judgment that Defendants' ANDA application cannot trigger infringement under 35 U.S.C. § 271(e)(2), or alternatively, seeking to recover for infringement of the '111 Patent. *See* -188 Case, Dkt. No. 1

at 16, 17. In lieu of answering Allergan's complaint, Defendants' filed a motion to dismiss for lack of personal jurisdiction (-188 Case, Dkt. No. 24). Allergan opposed the motion to dismiss, *see* Dkt. No. 40, filed a motion for summary judgment on its claim for declaratory relief, and simultaneously moved to dismiss its patent infringement claims for lack of subject matter jurisdiction. *See* -188 Case, Dkt. No. 35.

In the interim, the U.S. Patent and Trademark Office issued four additional patents relating to RESTASIS. *See* Dkt. No. 1-2 (U.S. Patent. No. 8,633,162); Dkt. No. 1-3 (U.S. Patent No. 8,642,556); Dkt. No. 1-4 (U.S. Patent. No. 8,648,048); and Dkt. No. 1-5 (U.S. Patent No. 8,685,930). Such patents were listed in the Orange Book as covering RESTASIS, and Defendants sent Allergan a second letter, purporting to constitute a paragraph IV notice regarding the same:

> Pursuant to 21 U.S.C. § 355G)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), we advise you that **FDA has received an Abbreviated New Drug Application ("ANDA")** from Watson for Cyclosporine Ophthalmic Emulsion, 0.05%. The ANDA contains the required bioequivalence data and/or bioequivalence waiver. The ANDA was submitted under 21 U.S.C. § 355G) **and contains a paragraph IV certification requesting approval to engage in the commercial manufacture, use or sale of cyclosporine ophthalmic emulsion, 0.05%, prior to the expiration of the '162, '556, '048, and '930 patents**.

Dkt. No. 1-6 (emphasis added).

Accordingly, and after additional correspondence among Allergan, Defendants, and the FDA, Allergan filed a second complaint against Defendants in this Court. Dkt. No. 1. This second complaint is essentially identical to Allergan's first, and merely expands Allergan's claims for relief to include the recently-issued patents. *Id.* As in the first action, Defendants filed a motion to dismiss for lack of personal jurisdiction (Dkt. No. 35), and Allergan filed a competing

motion for summary judgment on its claim for declaratory relief coupled to a motion to dismiss its patent infringement claims (Dkt. No. 14).

Given that the two cases (No. 2:14-cv-188 and No. 2:14-cv-638) involve the same parties, the same issues, and the same claims for relief, the Court consolidated them for all purposes. Dkt. No. 18 (designating No. 2:14-cv-638 as the lead case). The Court then conducted a hearing on the parties' motions on November 21, 2014. *See* Dkt. No. 93.

II. DEFENDANTS' MOTIONS TO DISMISS

A. Undisputed Facts

Allergan is a Delaware corporation with its principal place of business in Irvine, California. Complaint (Dkt. No. 1), at ¶ 11. Allergan operates a facility in Waco, Texas for the manufacture and distribution of pharmaceutical products, including RESTASIS; Allergan employs roughly six hundred people at its Waco facility. *Id.* at ¶ 21.

Defendants are related companies engaged in the development, manufacture and marketing of pharmaceutical products. *See* Defendants' Motion (-188 Case, Dkt. No. 24), at 3. Defendant Actavis, Inc. is a Nevada corporation with its principal place of business in New Jersey. *Id.* at 4. It is the parent of Watson Laboratories, Inc. ("Watson") and Actavis Pharma, Inc. ("Actavis Pharma"). Watson is a Nevada corporation, and Actavis Pharma is a Delaware corporation; both maintain their principal places of business in New Jersey. *Id.*

Nevertheless, Defendants engage in substantial business in Texas. Allergan asserts that Defendants achieved sales of more than $1 billion in Texas during 2013—with more than $120 million in sales occurring in this District alone. While Defendants dispute the precise numbers offered by Allergan, they do not dispute that they achieved substantial sales in both Texas and this

District in prior years and continue to do so. Defendants have additional and substantial contacts with Texas which involve this litigation, well beyond sales, which are discussed below.

B. Governing Law

A federal court may assert jurisdiction over a non-resident defendant if "(1) the state's long-am statute applies, as interpreted by the state's courts; and (2) if due process is satisfied under the fourteenth amendment to the United States Constitution." *Cycles, Ltd. v. W. J. Digby, Inc.*, 889 F.2d 612, 616 (5th Cir. 1989); *see also Breckenridge Pharm., Inc. v. Metabolite Labs, Inc.*, 444 F.3d 1356, 1361 (Fed. Cir. 2006). "Because the Texas long-arm statute extends to the limits of federal due process, the two-step inquiry collapses into one federal due process analysis." *Johnston v. Multidata Sys. Int'l Corp.*, 523 F.3d 602, 609 (5th Cir. 2008) (internal citations omitted).

In a patent-related case, the Court looks to Federal Circuit law in order to conduct said federal due process analysis. *Deprenyl Animal Health, Inc. v. Univ. of Toronto Innovations Found.*, 297 F.3d 1343 (Fed. Cir. 2002). Where the parties have not conducted discovery, the plaintiff need only make a *prima facie* showing that defendants are subject to personal jurisdiction; and, the pleadings and supporting material are construed in the plaintiff's favor. *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1017 (Fed. Cir. 2009).

There are two, independent bases for the excise of personal jurisdiction over a defendant—general and specific personal jurisdiction. General personal jurisdiction involves situations in which the defendant's contacts with the forum state are "continuous and systematic," permitting the forum to exercise personal jurisdiction over the defendant even if the cause of action does not arise from or relate to activities conducted within the forum state. *Autogenomics,* 566

F.3d at 1017. In contrast, specific personal jurisdiction "must be based on activities that arise out of or relate to the cause of action, and can exist even if the defendant's contacts are not continuous and systematic." *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1017 (Fed. Cir. 2009). "So long as it creates a 'substantial connection' with the forum, even a single act can support jurisdiction." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 n.18 (1985). Moreover, a defendant may be subjected to specific personal jurisdiction based on acts outside the forum state when the defendant knew that the injury would be felt by the plaintiff in the forum state. *Calder v. Jones*, 465 U.S. 783, 790-91 (1984). In this case, the Court is persuaded that Defendants are subject to specific personal jurisdiction within this District. Accordingly, the Court need not reach the issue of general personal jurisdiction.

To establish specific personal jurisdiction, due process requires a plaintiff to prove that: "(1) the defendant purposely 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." *Autogenomics*, 566 F.3d at 1017; s*ee also Breckenridge Pharm., Inc. v. Metabolite Labs., Inc.*, 444 F.3d 1356, 1363 (Fed. Cir. 2006); *Int'l Shoe Co. v. Wash.*, 326 U.S. 310, 316 (1945). The first two factors correspond to the "minimum contacts" prong of the jurisdictional analysis, while the third factor relates to the "fair play and substantial justice" prong of the same. *Autogenomics*, 566 F.3d at 1018-19 (internal citations omitted).

Ultimately, a determination of whether a defendant has sufficient "minimum contacts" to create specific personal jurisdiction "focuses on the relationship among the defendant, the forum, and the litigation." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). "[A] defendant's contacts with the forum State may be intertwined with his transactions or interactions with the plaintiff or

other parties." *Id.* at 1123. However, "a defendant's relationship with a plaintiff or third party, standing alone, is an insufficient basis for jurisdiction." *Id.* (internal citations omitted).

C. Analysis: Specific Personal Jurisdiction and Allergan's Declaratory Judgment Claims

Defendants' motion and briefing substantially ignore Allergan's claim for declaratory judgment, focusing instead on Allergan's claim for patent infringement. *See e.g.* Reply (Dkt. No. 29), at 7-13. However, the Court understands Defendants to be making essentially the same arguments with respect to both Allergan's declaratory judgment and infringement claims: that Allergan is the only link between Defendants and the forum. The Court is not persuaded by these arguments.

1. Defendants have established sufficient minimum contacts to the forum.

The Court agrees with both parties that Defendants' Motion turns on the application of a line of cases beginning with *Calder v. Jones*, 465 U.S. 783, 790-91 (1984). In *Calder*, the Supreme Court held that the California state courts had specific personal jurisdiction over defendants in a libel claim brought by a California resident. *Id.* at 789-90. The defendants had sought to avoid jurisdiction, arguing that the allegedly libelous story was written and edited exclusively in Florida. 465 U.S. at 789. The Court rejected that argument, holding that the defendants' purposeful targeting of a plaintiff in the forum state constituted sufficient minimum contact to subject said defendant to personal jurisdiction in that forum. *Id.* at 789-90.

Earlier this year, the Supreme Court clarified the application of *Calder* in *Walden v. Fiore*, 134 S. Ct. 1115 (2014). In *Walden*, the plaintiffs sued a Georgia police officer—Anthony Walden—in the United States District Court for the District of Nevada, following his seizure of the

plaintiffs' cash at the airport in Atlanta, Georgia. *Id.* at 1119-20. The *Walden* plaintiffs alleged that the defendant violated their Fourth Amendment rights by, among other things, seizing the cash without probable cause and then authoring a false and misleading affidavit to support said seizure. *Id.* at 1120.

In *Walden*, the Supreme Court reiterated that the jurisdictional inquiry is "focused on the relationship among the defendant, the forum and the litigation." *Id.* at 1123 (internal citations and quotations omitted). The Court further warned that where the only basis for an assertion of specific personal jurisdiction was "defendant's relationship with a plaintiff or third party," then such exercise is inconsistent with the requirements of due process. *Id.* Applying these principles, the Court concluded that the Nevada district court could not exercise jurisdiction over a Georgia police officer (Walden) who had "never traveled to, conducted activities within, contacted anyone in, or sent anything or anyone to Nevada." *Walden,* 134 S. Ct. at 1124.

The Court reconciled its *Walden* holding with its prior decision in *Calder*, by explaining that, "the crux of *Calder* was that the reputation-based 'effects' of the alleged libel connected the defendants to California, not just to the plaintiff." *Id.* at 1123-24. Under *Calder*, as now clarified in *Walden*, "[t]he proper question is not where the plaintiff experienced a particular injury or effect but whether the defendant's conduct connects him to the forum in a meaningful way." *Id.* at 1125.

Here, Defendants' contacts with Texas and this litigation fundamentally differ from the situation at issue in *Walden*. As noted above, Allergan first seeks a declaratory judgment that Defendants' ANDA filings are ineffective to trigger a claim for patent infringement action under 36 U.S.C. § 271 (e)(2).

Assuming—as the Court must when evaluating Defendants' motion to dismiss—that Defendants' ANDA filings are premature, Defendants' conduct will cause substantial harm to Allergan *in Texas*. Allergan manufactures RESTASIS in Texas. In addition, it not only sells RESTASIS in Texas (as it does throughout the nation), but also coordinates the nationwide distribution of RESTASIS from Texas. Defendants' conduct will undoubtedly erode Allergan's sales, manufacture and distribution of RESTASIS in Texas. Such erosion will damage Allergan's Texas-based manufacture and distribution of RESTASIS, specifically threating the jobs of at least sixty nine specialized employees who work exclusively on RESTASIS in Texas.

In *Calder*, the plaintiff's reputational harm would not have occurred but for the defendants' publication and circulation of an allegedly libelous magazine article in California. *Calder*, 465 U.S. at 788-789. Similarly, the harm to Allergan in this case is unavoidably connected to Defendants' extensive efforts in Texas to sell a generic version of RESTASIS. Part and parcel of this undertaking is Defendants' solicitation of a license to distribute prescription drugs in Texas, and Defendants' efforts to establish contracts with Texas wholesalers, retailers and state agencies to effect drug sales, including the sale of a generic version of RESTASIS. Allergan's declaratory judgment claim relates to all these activities. Reading *Calder*, in light of *Walden*, this Court concludes that Defendants' contacts with Texas are inextricably linked to the harm (or threatened harm) to Allergan in Texas; this supports the exercise of specific personal jurisdiction in this District. *See Walden*, 134 S. Ct. at 1123 ("To be sure, a defendant's contacts with the forum state may be intertwined with its transactions or interactions with the plaintiff or other parties.").

Further, Allergan is not the only link between the Defendants and Texas. This is certainly not a case where Defendants "never traveled to, conducted activities within, contacted anyone in,

or sent anything or anyone to [the forum]." 134 S. Ct. at 1124. To the contrary, Defendants do not dispute that they conduct extensive business activities in Texas and this District. As discussed above, Defendants sought and now hold a state-issued license to distribute prescription drugs in Texas; they have established contracts with Texas wholesalers, retailers and state agencies as the ways and means to further such sales; and, they have been enormously successful, selling more than $1 billion in drugs in Texas during 2013 alone.[3] Moreover, Texas is the third largest market for RESTASIS and a lucrative target for the sale of Defendants' generic version of the same. Defendants do not deny that they are targeting Texas for the sale of such a generic. Accordingly, this Court is persuaded that it now faces an inherently different context than that which confronted the Supreme Court in *Walden*.

Defendants' inevitable complaint that the Court's approach would subject it to specific jurisdiction in every state is inapposite. Here, Defendants' contacts with the forum state are directly "intertwined with its transactions or interactions with the plaintiff or other parties." *Walden*, 134 S. Cit. at 1123. Furthermore, a manufacturer who (successfully) targets a nationwide consumer base is fundamentally distinct from an individual defendant who is connected to a forum state only by the fact that the injured plaintiff resides there. While the latter connection is random, fortuitous, or attenuated and cannot, alone, support jurisdiction, *Walden*, 134 S. Ct. at 1123, the former connection shows a purposeful direction of activities at residents of this forum. Here, the litigation arises out of or relates to those activities and the exercise of specific personal jurisdiction is justified. *See Burger King*, 471 U.S. at 472.

[3] But for the precise dollar amount of Defendants' sales, Plaintiff's assertions are not challenged. The Court resolves disputed factual allegations in favor of the non-movant.

Defendants attempt to dismiss their efforts to sell a generic form of RESTASIS in Texas as irrelevant. Reply (Dkt. No. 29), at 10-13. They argue primarily that the Defendants' efforts to secure *future* sales of a generic version of RESTASIS cannot constitute a present harm directed at Allergan. *Id.* at 12. In doing so, Defendants are ignoring the basic nature of declaratory judgment claims—to address the threat of future injury. While a "purely subjective or speculative fear of future harm" cannot constitute a case or controversy, it remains a "bedrock rule" that a "real and immediate injury or threat of future injury" is sufficient to grant the courts subject matter jurisdiction. *See Prasco, LLC v. Medics Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008) (emphasis added).

Defendants' submission of a premature paragraph IV certification, coupled with its extensive efforts to bring a generic form of RESTASIS to the market, constitute just such a real and immediate injury (or at the very least threaten imminent injury). The right to the exclusive sale of RESTASIS—including the right to exclude generic version of the drug—is undoubtedly valuable. The Hatch Waxman framework attempts to maintain the value of that exclusivity, "while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Mylan Pharms.*, 268 F.3d at 1326 (Fed. Cir. 2001) (internal citations omitted). Part of that framework involves the submission of a paragraph IV notice, the forty-five day count down for a patent infringement allegation, and the (generally) thirty month stay of FDA approval of the generic. *See infra* at 3-4; *Mylan Pharms.*, 268 F.3d at 1327. A generic manufacturer who prematurely initiates the paragraph IV process has improperly invoked a statutory and regulatory scheme that is specifically designed to terminate a brand name manufacture's exclusive rights. This constitutes a present injury to a brand name manufacturer, such as Allergan. To hold

otherwise would deprive a plaintiff such as Allergan of any remedy against a generic competitor attempting to effectively "jump-start" the paragraph IV and § 271(e)(2) process.

2. It is reasonable and fair to exercise jurisdiction over Defendants in Texas.

Defendants do not squarely challenge the "fairness" of the exercise of specific personal jurisdiction in Texas. With respect to this factor, "the burden of proof is on the defendant, which must 'present a compelling case that the presence of some other considerations would render jurisdiction unreasonable.'" *Breckenridge*, 444 F.3d at 1363. (quoting *Burger King*, 471 U.S. at 477).

As set out above, Defendants have engaged in significant efforts to sell generic drugs in Texas—including a generic form of RESTASIS. This conduct threatens severe harm to Allergan, who has an established and substantial presence in Texas. The harm to Allergan is inextricably linked to Defendants' substantial ties to this forum. Defendants have not carried their burden.

D. The Court need not decide the issue of general personal jurisdiction

As discussed above, the Court is persuaded that the exercise of specific personal jurisdiction is appropriate in this case. Accordingly, the Court need not reach the question of general personal jurisdiction.

E. The Court need not reach Defendants' motion to dismiss Allergan's patent infringement claims.

As discussed in detail below, the Court is persuaded that there is no ripe case or controversy with respect to Allergan's patent infringement claims. Accordingly, the Court will dismiss such claims without prejudice and need not reach the issue of personal jurisdiction at this time.

III. ALLERGAN'S MOTIONS FOR SUMMARY JUDGMENT

Having determined that Defendants' are subject to specific personal jurisdiction in this District, at least with respect to Allergan's declaratory judgment claims, the Court now turns to the merits of Allergan's motions for summary judgment / motions to dismiss.

A. Applicable Law

Fed. R. Civ. P. 56(a) provides that the Court, "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The movant may introduce evidence affirmatively supporting its position, and is entitled to summary judgment if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact." *Epps v. NCNB Nat'l Bank*, 838 F. Supp. 296, 298-99 (N.D. Tex. 1993), affd., 7 F.3d 44 (5th Cir. 1993). "Summary judgment reinforces the purpose of the Rules, to achieve the just, speedy, and inexpensive determination of actions, and, when appropriate, affords a merciful end to litigation that would otherwise be lengthy and expensive." *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1197 (5th Cir. 1986) (footnote omitted).

B. Analysis

In their motions for summary judgment, Allergan contends that there are no live disputes of material fact in this case. Specifically, Allergan argues that:

(1) Defendants' submitted an ANDA for RESTASIS in November 2011;

(2) the FDA responded in August 2013, and refused to receive Defendants' ANDA;

(3) Defendants' ANDA and paragraph IV notices are therefore deficient as a matter of law, and insufficient to trigger either:

a. the procedural framework set out in 21 U.S.C. § 355(j)(5)(B)(iii); or

b. a claim for patent infringement under 35 U.S.C. § 271(e)(2).

Dkt. No. 35. Despite their initial statements, Defendants do not, and cannot, now dispute that the FDA has not officially "**received**" Defendants' ANDA. *See, e.g.*, Dkt. No. 72 at 10-11. Instead, Defendants assert that Allergan is not entitled to relief from this Court. Dkt. No. 56 at 13-20. Accordingly, the ultimate question is: Does this Court have the authority to decide the legal effect of Defendants' ANDA filings and paragraph IV notices?

Having reviewed the parties briefing, the controlling law, and the *particular* facts of this case, the Court is persuaded that it has authority to—and should—grant part of the relief Allergan is seeking. Specifically, the Court is persuaded that Defendants' ANDA filings are insufficient to trigger infringement under § 271(e)(2). However, to the extent Allergan's declaratory judgment claims seek to enforce the substantive requirements of 21 U.S.C. § 355(j)(5)(B)(iii), or to impose some kind of injunction that would bind the FDA, the Court agrees with Defendants that such a request is beyond the scope of the Court's authority.

1. Defendants' incomplete ANDA cannot trigger infringement under 35 U.S.C. § 271(e)(2).

Allergan argues that Defendants' ANDA filings are insufficient to trigger infringement under 35 U.S.C § 271(e)(2). Having reviewed the parties' arguments and the particular facts in the record, the Court agrees.

a. The Court expressly finds that the FDA has not received Defendants' ANDA.

As an initial matter, Allergan's arguments rest on a specific factual allegation: that the FDA has not "received" Defendants' ANDA. In support of that proposition, Allergan has offered into evidence the FDA's official response to the ANDA at issue (No. 203463). Dkt. No. 14-1. In that document, dated August 30, 2013, the FDA states:

> We have given your application a preliminary review, and **we find that it is not sufficiently complete to merit a critical technical review.**
>
> **We are refusing to receive this ANDA** under 21 CFR 314.101(d)(3) for the following reasons:

Dkt. No. 14-1 (emphasis added). The agency then requested six categories of additional information it required from Defendants, and added:

> Thus, **your application will not be received as an abbreviated new drug application within the meaning of Section 505(j) of the Act**. If you choose to respond to this letter to correct the deficiencies, the response will be considered a new original ANDA.

Id. (bold emphasis added; underline in original).

Despite such unequivocal statements from the FDA, Defendants nevertheless sent letters to Allergan stating that:

> Pursuant to 21 U.S.C. § 355G)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), we advise you that **FDA has received an Abbreviated New Drug Application ("ANDA")** from Watson for Cyclosporine Ophthalmic Emulsion, 0.05%.

Dkt. 1-6 (emphasis added). Allergan contends that such statements motivated this entire case. Dkt. No. 60 at 1. Defendants, on the other hand, have refused to squarely address the issue. At certain times, Defendants acknowledge that the FDA has not received their ANDA:

- In a January 22, 2014 press release, defendant Actavis PLC admitted that "[the] FDA notified Actavis' subsidiary [defendant Watson Laboratories, Inc.] that it had refused to receive the ANDA for filing." Dkt. No. 1-7.
- In their briefing, Defendants further admit that they submitted additional data to the agency because "[the] FDA had not yet accepted [Defendants'] ANDA for filing." Dkt. No. 56 at 11.
- Further, at the hearing conducted on November 21, 2014, Defendants' counsel stated that "[w]e accept the fact that FDA has not received our ANDA for filing . . . and has not to this date done that." Dkt. No. 94 at 10.

However, at other times Defendants side-step the issue. For example:

- Defendants deny Allergan's allegations that it made false statements in its notice letters, arguing that Defendants were "up front with Allergan and even disclosed their correspondence with FDA to show the status of the application." Dkt. No. 72 at 11.
- Defendants deny the clear and unambiguous meaning of the FDA's statements, "[w]e are refusing to receive this ANDA under 21 CFR 314.101(d)(3)," and "your application will not be received as an abbreviated new drug application within the meaning of Section 505(j) of the Act [codified, in part, at 21 U.S.C. § 355]." Dkt. No. 14-1.
- Defendants then deny that its notice letters, which unequivocally state that "FDA has received an Abbreviated New Drug Application," contain any false statements or are inconsistent with the FDA's stated position. Dkt. No. 56-1. ("Watson did not make any false statements to the FDA or to Allergan").

- Defendants further deny Allergan's allegation that its notice letters are inconsistent with its own press release. Dkt. No. 56-1 at 2 ("[D]efendants dispute that there was any inconsistency between Watson's paragraph IV notice and its parent's press release.").

The record is clear. The FDA has expressly refused to accept Defendants' ANDA. The Court takes notice of that fact, and in order to resolve any lingering uncertainty, expressly finds that the FDA has not received Defendants' ANDA. While Defendants may sincerely disagree[4] with the FDA, such disagreement does not alter the fact that the FDA has made its decision.[5] The Court is deeply troubled by Defendants', and their counsels', refusal to squarely acknowledge the facts regarding the status of Defendants' ANDA. The Court comes away from Defendants' briefing and oral arguments convinced that Defendants' have engaged in an effort to blur and obscure these facts, when they are quite clear—all for their own defensive purposes. Such conduct reflects poorly on both Defendants and their counsel.

b. Defendants' ANDA filings are insufficient to trigger infringement under 35 U.S.C. § 271(e)(2).

Having established that the FDA has refused to accept Defendants' ANDA, the Court must decide what, if any, effect that fact has on Allergan's claims. Defendants assert that it is completely irrelevant; that the mere transmission of an ANDA to the FDA is sufficient to trigger infringement under 35 U.S.C. § 271(e)(2); and, that the Court is barred from conducting any

[4] *See* Dkt. No. 1-7 ("Actavis disagrees with FDA's refusal to receive its ANDA for filing"); *see also* Dkt. No. 56 at 11, Dkt. No. 56-1 at 2.

[5] The Court need not, and will not, opine as to whether or not Defendants' ANDA complied with the relevant statutes and regulations such that it should have been received by the FDA. As defendants' point out, substantial compliance with the Hatch Waxman statutes is not an issue to be decided in a patent case. Still, the Court has reviewed the evidence in the record—including the findings by the FDA—and is confident that the agency has given Defendants' application full and measured consideration.

inquiry into the sufficiency of the purported ANDA. *See* Dkt. No. 94 at 10-26. Allergan disagrees, and argues that an ANDA cannot trigger infringement under 35 U.S.C. § 271(e)(2) unless and until it is received by the FDA.

The Court is not aware of any controlling cases that specifically address whether receipt of an ANDA by the FDA is required to trigger 35 U.S.C. § 271(e)(2). However, in *SB Phamco P.R., Inc. v. Mut. Pharm. Co.*, the Eastern District of Pennsylvania confronted nearly identical issues to those currently before this Court. 552 F. Supp. 2d 500 (E.D. Pa. April 28, 2008). In both *SB Phamco* and this case:

- the defendants submitted an ANDA, followed by an "amendment" to said ANDA;
- concurrently with (*SB Phamco*) or shortly after (this case) said amendment, the defendants sent the plaintiff a paragraph IV notice letter;
- the FDA refused to receive said ANDA (this case) or had not received the ANDA at the time that the paragraph IV notice was sent (*SB Phamco*); and
- the plaintiffs filed a complaint seeking declaratory judgment that the paragraph IV notices were deficient, or in the alternative seeking relief under 35 U.S.C. § 271(e)(2).

Id. at 504. After reviewing the Hatch Waxman framework, the Court in *SB Phamco* held that the defendants' paragraph IV notice was premature and improper under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95(b). That Court further held that "the term 'submit' in § 271(e)(2) clearly means that an ANDA has been received, not merely delivered." 552 F. Supp. 2d at 511. This Court agrees.

To hold otherwise would invite generic manufacturers to submit incomplete or otherwise deficient applications, in order to secure their position as the first-filed generic. They could then

attempt to remedy any deficiencies through an amendment to their premature application, while claiming priority to the original application for purposes of securing exclusive access to the market and other benefits.

Defendants do not shirk this possibility. In fact, they argue that this strategy is not only permitted, but is compelled by the statute governing the amendment of an ANDA and the service of paragraph IV certifications. Defendants rely on 21 U.S.C. § 355(j)(2)(B)(ii)(II) which provides two periods when the generic may provide paragraph IV notice:

> (I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or
>
> (II) **if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification** contained in the application or in an amendment or supplement to the application.

(emphasis added). Defendants argue that these provisions establish that acceptance by the FDA is irrelevant to their compliance with 35 U.S.C. § 271(e)(2):

> Thus, if the certification is in the original ANDA, subsection I requires that the notice letter be sent after the ANDA "has been filed," i.e., after the FDA has accepted it for filing. **Subsection II, however, requires that if the Paragraph IV certification is made by amendment, the notice must be sent "at the time at which the applicant submits the amendment," regardless of whether the FDA has accepted the ANDA.**

Dkt. No. 56 at 16 (emphasis added). In other words, Defendants argue that an original ANDA must be accepted by the FDA before paragraph IV notices may be sent, potentially triggering litigation under § 271(e)(2); **but** acceptance by the FDA is irrelevant to the triggering of § 271(e)(2) if an ANDA is amended. The Court disagrees. Defendants' reading of the statute is at best strained, if not actually contorted.

35 U.S.C. § 217(e)(2) makes it an act of infringement to:

> submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(j)] or described in section 505(b)(2) of such Act [21 USCS § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent.

This provision protects the property rights of name brand drug manufactures, and stands as a counterbalance to the expedited approval process and "safe harbor" provisions that dramatically decrease the cost of bringing a generic drug to market. *See Medtronic*, 496 U.S. at 676-77 ("These abbreviated drug-application provisions incorporated an important new mechanism designed to guard against infringement of patents relating to pioneer drugs."). In this context, Defendants' argument is clearly flawed. It would essentially eviscerate "the cardinal rule that a statute is to be read as a whole, . . . since the meaning of statutory language, plain or not, depends on context," *King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991). Moreover, the FDA has expressly rejected this interpretation of the relevant statutes in the past:

> FDA has not interpreted this to require or permit applicants who amend their applications before receipt of an acknowledgement letter to provide notice before learning whether their application has been determined to be sufficiently complete to be received. Rather, this provision applies only to amendments made after an ANDA has been received."

Dkt. No. 60-1 at 2. Reading the statute as a whole, the Court finds the FDA's interpretation to be persuasive; 21 U.S.C. § 355(j)(2)(B)(ii)(II) clearly permits that the notice be sent concurrently with the amendment only if the amendment is submitted for an ANDA that has already been received for filing by the FDA.

Accordingly, the Court is persuaded that "submission" of an ANDA under 35 U.S.C. § 271(e)(2) requires said ANDA to be received by the FDA. Mere transmission of an application cannot satisfy the statutory requirements for infringement. Were transmission alone the test, such

a result would unavoidably promote a flood of "hit and run" filings in which glaring deficiencies would be no impediment to gaining the benefits properly reserved for those applicants who now survive the FDA's careful review and obtain its certification as "received." As the Eastern District of Pennsylvania concluded, "[i]t would be illogical for the statutory provisions and federal regulations to carefully construct a safeguard against incomplete ANDAs, only to allow those same potentially insufficient applications to constitute the act of infringement that triggers litigation." *SB Phamco*, 552 F. Supp. 2d at 511. Accordingly, because the FDA has not received Defendants' ANDA, the Court is persuaded that Defendants' ANDA cannot trigger infringement under 35 U.S.C. § 271(e)(2), as a matter of law.

2. The Court declines to determine the proper application of the "count-down" or stay provisions of 21 U.S.C. § 355(j)(5)(B)(iii).

In addition to a declaration that Defendants' ANDA filings cannot trigger infringement under 35 U.S.C. § 271(e)(2), Allergan also seeks a declaration from the Court that:

(1) Defendants' paragraph IV notices do not start the 45-day countdown in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); and

(2) No 30-month stay of Defendants' ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) will begin until Defendants send a valid paragraph IV notice to Allergan following FDA receipt of the ANDA for substantive review.

See Dkt. No. 1 at ¶ 99; Dkt. No. 35 at 20. Defendants respond, arguing that "§ 355(j)(2)(B) cannot be enforced by a private party in a patent infringement action, but must be enforced, if at all, only in the context of an action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§

702-706." *Minnesota Mfg. and Mining v. Barr Labs.*, 289 F.3d 775, 777 (Fed. Cir. 2001) ("*Barr*").

Barr dealt with a substantive challenge to a generic manufacturer's paragraph IV notice under § 355(j)(2)(B). There, the plaintiff (3M) received paragraph IV notices from two separate generic manufactures. 289 F.3d at 778-79. 3M then filed suit against the first such manufacturer (Alphapharm) on January 4, 1999, triggering a stay of Alphapharm's ANDA until thirty months after the date 3M received Alphapharm's paragraph IV notice, or the termination of the infringement suit in favor of Alphapharm, whichever was earlier. *Id.* at 778 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). Thereafter, a second generic manufacturer (Barr) filed an ANDA and sent a paragraph IV notice to 3M. *Id.* As the second-filer, Barr was subject to both the thirty-month stay under 21 U.S.C. § 355(j)(5)(B)(iii)—which would protect 3M—and also to a 180-day stay pursuant to § 355(j)(5)(B)(iv)—which would protect the first-filing generic manufacturer (in that case, Alphapharm). *Id.*

Following receipt of Barr's paragraph IV notice, 3M filed a second lawsuit against Barr. *Id.* Alphapharm intervened in order to protect its potential 180-day exclusivity period. *Id.* However, during discovery 3M became convinced that Barr did not, in fact, infringe its patent. *Id.* at 799. Accordingly, 3M sought to dismiss its case, without prejudice, alleging that Barr had "hoodwinked" it into filing a premature suit by providing substantively deficient paragraph IV notices. *Id.* The district court disagreed and dismissed 3M's claims against Barr, with prejudice. *Id.* Alphapharm and 3M appealed the district court's dismissal of 3M's claims *with prejudice*. They argued that Barr's paragraph IV notices were "ambiguous at best" and therefore failed to

provide the "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed" required by 21 U.S.C. § 355(j)(2)(B). *Id.* at 781-782.

The Federal Circuit rejected 3M and Alphapharm's arguments, concluding that:

> we hold that we need not, indeed cannot, decide this question of compliance with the paragraph IV certification requirements. Under the Hatch-Waxman Amendments we cannot enforce the requirements of paragraph IV certifications in an infringement suit.

Barr, 289 F.3d at 782. The Federal Circuit clarified that there is no private right of action under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and held that the district court erred in deciding the issue of compliance. *Id.* at 783. (citing *Mylan Pharms., Inc. v. Thompson*, 139 F. Supp. 2d 1 (D.D.C. 2001); *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, (Fed. Cir. 2002)).

Allergan contends that *Barr* is inapposite because "the question here is not whether [Defendants'] paragraph IV notices were sufficiently detailed, but whether they could properly be sent at all." Dkt. No. 60 at 6. The Court is not persuaded that this distinction is sufficient to avoid the rule announced in *Barr*—at least with respect to Allergan's request for an order declaring that Defendants' paragraph IV notices would not trigger the 40-day countdown and/or the 30-month stay provided for in § 355(j)(5)(B)(iii). Such an order would go too far, effectively constituting a mandate that compells the FDA to take specific action with respect to Defendants' ANDA. "Such an order would also constitute improper judicial enforcement of the provisions of the Hatch-Waxman Amendments." *Barr*, 289 F.3d at 783, n.4.

3. The Court's order does not prejudice that parties' ability to seek additional relief in the future.

The Court is aware that its grant of partial relief could result in a difficult predicament, should the FDA ultimately reverse its position and issue a stay dating from the original date of Defendants' ANDA submission. Nevertheless, the Court is bound by the Federal Circuit's pronouncement that, in most cases, questions of substantial compliance with the Hatch Waxman requirements must be adjudicated in administrative proceedings before the FDA, and reviewed by the Courts, if at all, under the APA. *See Barr*, 289 F.3d at 782. The Court has considerable faith in that agency's ability to apply and enforce the statutes and regulations governing the ANDA process. The FDA has already issued a definitive ruling in this case when it refused to accept Defendants' ANDA. Moreover, the FDA has refused in the past to reward generic manufacturers attempting to jump-start the stay provisions that protect name brand manufacturers. *See* Dkt. No. 60-1 at 2. The Court is satisfied that the FDA will continue to promptly evaluate the parties' claims and issue appropriate relief. However, nothing in this order should be read to prejudice the parties' ability to pursue whatever review they determine to be necessary and appropriate, including without limitation, an action under the APA.

IV. ALLERGANS' MOTIONS TO DISMISS.

As discussed above, the Court finds that the mere transmission of documents purporting to be an "ANDA" is insufficient to trigger infringement under 35 U.S.C. § 271(e)(2). To the contrary, the statute requires that the FDA receive such an ANDA before a defendant can satisfy the statutorily-defined act of infringement. In this case, the FDA has unequivocally refused to receive Defendants' ANDA. Accordingly, there was no case or controversy under 35 U.S.C. §

271(e)(2) that could have supported Allergan's patent infringement claims at the time the complaint was filed. Such claims are not ripe, and accordingly must be dismissed without prejudice.

V. CONCLUSION

For the reasons stated above, the Court **ORDERS** that:

- Defendants' motions to dismiss for lack of personal jurisdiction (-188 Case, Dkt. No. 24; -638 Case, Dkt. No. 35) are **DENIED**; and
- Allergan's motions for summary judgment and motions to dismiss (-188 Case, Dkt. No. 35, -638 Case Dkt. No. 14) are **GRANTED-IN-PART**, as announced above; and
- Count II of Allergan's complaints are **DISMISSED WITHOUT PREJUDICE**.

All relief not expressly granted herein is **DENIED**. All other pending motions are **DENIED**.