IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

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| GALDERMA LABORATORIES, L.P., GALDERMA S.A., and NESTLÉ SKIN HEALTH S.A., | § | |
| Plaintiffs, | § | |
| v. | § | Civil Action No. 3:17-cv-01076-M |
| TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS INDUSTRIES LTD., | § | |
| Defendants. | § | |

**MEMORANDUM OPINION AND ORDER**

Before the Court are (1) a Rule 12(b)(3) motion to dismiss for improper venue [ECF #21], filed by Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") [ECF #21]; and (2) a Rule 12(b)(6) motion to dismiss for failure to state a claim [ECF #25], filed by Defendant Teva Pharmaceutical Industries Ltd. ("Teva Israel"). For the following reasons, both Motions are GRANTED.

**Background**

Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Nestlé Skin Health S.A. bring this civil action under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), asserting infringement of U.S. Patent Nos. 8,815,816 (the "'816 Patent"); 9,089,587 (the "'587 Patent"); 9,233,117 ("the "'117 Patent"); 9,233,118 (the "'118 Patent"); and U.S. Patent Nos. 8,362,069 (the "'069 Patent"). The patents-in-suit relate to compositions, methods, and regimens for the treatment of rosacea, using ivermectin, an anti-

parasitic medication used to treat infections caused by roundworms, threadworms, and other parasites.

The patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Soolantra® (ivermectin) Cream 1% ("Soolantra®"), a topical prescription drug that contains ivermectin for the treatment of inflammatory lesions of rosacea. Plaintiff Galderma Laboratories, L.P. is the owner and exclusive beneficial holder of the rights to market Soolantra® under the FDA approval of New Drug Application ("NDA") No. 206255, approved December 19, 2014. When a party files an NDA, the FDA requires the applicant to submit certain information regarding any patent that claims the drug, or a method of using the drug, that is the subject of the NDA. *See* 21 C.F.R. §314.53. Upon approval of the NDA, the FDA lists the drug in the Orange Book, along with all official and proprietary names of the drug; and, when the NDA holder submits patent information for the drug in accordance with 21 C.F.R. § 314.53, the patent information is also included in the Orange Book.

A generic drug manufacturer may obtain FDA approval of a generic drug through the Abbreviated New Drug Application ("ANDA") process, if the generic drug is a bioequivalent of a drug previously granted NDA approval. The ANDA process permits a generic drug manufacturer to bypass the costly clinical trials and lengthy delays associated with the NDA process. As part of the ANDA process, the applicant must make a patent certification with respect to each patent that claims the listed drug or a use of such drug for which the applicant is seeking approval. *See* 21 C.F.R. §314.94(a)(12)(i)(A). Specifically, with respect to each patent, the ANDA applicant must certify that:

(1) the NDA holder submitted no patent to the FDA; or

(2) any patent submitted has expired; or

(3) the date the applicable patent expires; or

(4) that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the abbreviated application is submitted.

*See* 21 C.F.R. §314.94(a)(12)(i)(A); 21 U.S.C. §355(j)(2)(A)(I)-(IV). If the ANDA applicant certifies that a patent is invalid, unenforceable, or will not be infringed (a "paragraph IV certification"), it must notify the NDA holder of its assertion. 21 C.F.R. §314.95. The NDA holder then has 45 days to file suit against the ANDA applicant for patent infringement. 35 U.S.C. §271(e)(2)(A).

Generally, patent infringement occurs when an infringer makes, uses, offers for sale, sells, or imports an invention into the United States. Under Section 271(e)(2)(A) of the Hatch-Waxman Act, however, the submission of an ANDA application with a paragraph IV certification constitutes an artificial act of infringement, which can form the basis of a claim for injunctive relief to prevent the approval, sale, or use of the generic drug until after the NDA holder's patent expires. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-405 (2012) ("The patent statute treats [the filing of a paragraph IV certification] as itself an act of infringement, which gives the brand an immediate right to sue."). An NDA holder's timely-filed lawsuit automatically stays the ANDA process for a period of thirty months. *See* 21 C.F.R. §314.107(b)(3)(i)(A). If the NDA holder fails to bring suit within 45 days, the ANDA applicant may file a declaratory judgment action to adjudicate its paragraph IV challenge. See 21 C.F.R. §355(j)(5)(C)(i)(II).

In this lawsuit, Plaintiffs allege that Teva USA submitted ANDA No. 210019 to the FDA seeking, approval to engage in the commercial manufacture, use, and sale of a generic ivermectin

cream 1% prior to the expiration of the patents-in-suit. Plaintiffs seek declaratory relief that Defendants have and will infringe the patents-in-suit by filing the ANDA and by making or selling their accused generic creams. Plaintiffs also seek an order that the effective date of any FDA approval of the ANDA shall not be earlier than the expiration of the patents-in-suit, and other injunctive relief. Defendants generally contend the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of their accused generic ivermectin creams.

Teva USA has filed a motion to dismiss under Rule 12(b)(3) [ECF #21], arguing venue is not proper in this district under the patent venue statute, because Teva USA (1) is incorporated in Delaware, (2) has not committed any acts of infringement in the Northern District of Texas, and (3) does not maintain a regular and established place of business in this district.[1] Teva Israel has filed a Rule 12(b)(6) motion to dismiss on the ground that Plaintiffs' First Amended Complaint ("FAC"), which is the live pleading in this action, fails to plead sufficient facts to state a plausible case that Teva Israel is responsible for the alleged infringement, because the only alleged act of infringement is the submission of the ANDA, and Teva Israel had no role in submitting the ANDA.

With respect to Teva USA's Rule 12(b)(3) motion, the Federal Circuit issued a precedential opinion on the patent venue statute, *In re Cray, Inc.*, 871 F.3d 1355 (Fed. Cir. 2017), after the venue motion was fully-briefed. Because the *Cray* holding clarifies the venue analysis, which is particularly fact-specific, the Court allowed Plaintiffs to conduct limited venue-related discovery. Both parties filed additional evidence on the venue issue, and the Court

[1] Originally, the Rule 12(b)(3) motion to dismiss was a joint motion by Teva USA and Actavis Laboratories UT, Inc. ("Actavis). Plaintiffs dismissed their claims against Actavis on November 2, 2017. *See* Notice of Dismissal [ECF #52]. Accordingly, the Court considers the motion with respect to Teva USA only.

held oral argument on Defendants' motions on November 6, 2017. The issues have been fully briefed and argued, and the motions are ripe for determination.

**Rule 12(b)(3) Motion to Dismiss for Improper Venue**

**Legal Standards**

Teva USA brings its motion to dismiss for improper venue under Fed. R. Civ. P. 12(b)(3). Courts are divided on which party bears the burden of proof on a motion to dismiss for improper venue. The Fifth Circuit has not ruled on which party bears the burden on a Rule 12(b)(3) motion. However, most district courts within this circuit have imposed the burden of proving that venue is proper on the plaintiff once a defendant has objected to the plaintiff's chosen forum. *See, e.g., Broadway Nat'l Bank v. Plano Encryption Techns., LLC*, 173 F. Supp. 3d 469, 473 & n.2 (W.D. Tex. 2016); *Graham v. Dyncorp Intern., Inc.*, 973 F. Supp. 2d 698, 700 (S.D. Tex. 2013); *Asevedo v. NBC Universal Media, LLC*, 921 F. Supp. 2d 573, 589 (E.D. La 2013); *Praetorian Specialty Ins. Co. v. Auguillard Const. Co., Inc.*, 829 F. Supp. 2d. 456, 470 (W.D. La. 2010); *EnviroGLAS Products, Inc. v. EnviroGLAS Products, LLC*, 705 F. Supp. 2d. 560, 566 (N.D. Tex. 2010); *ATEN Intern. Co. Ltd. v. Emine Techn. Co., Ltd*., 261 F.R.D. 112, 120 (E.D. Tex. 2009). This Court, in particular, has consistently held that the plaintiff bears the burden of sustaining venue in the district in which the suit was brought. *See Nuttall v. Juarez*, 984 F. Supp. 2d 637, 642 & n.3 (N.D. Tex. 2013) (Lynn, J.); *Emelike v. L–3 Communications Corp*., 2013 WL 1890289, at *1 (N.D. Tex. May 7, 2013) (Lynn, J.); *Tracfone Wireless, Inc. v. Stone*, 2008 WL 648942, at *3 (N.D. Tex. Feb. 26, 2008) (Lynn, J.); *Nayani v. Horseshoe Entm't*, 2007 WL 1062561, at *2 (N.D. Tex. Apr. 10, 2007) (Lynn, J.).

In ruling on Teva USA's Rule 12(b)(3) motion, the Court initially accepts as true all of the well-pleaded allegations in the FAC and resolves any factual conflicts in Plaintiffs' favor.

*Nuttall*, 984 F. Supp. 2d at 642 (citing *Braspetro Oil Servs. Co. v. Modec (USA), Inc.*, 240 F. App'x 612, 615 (5th Cir. 2007)). However, the Court may consider evidence in the record beyond the facts alleged in the FAC and its attachments, including affidavits or evidence submitted by Teva USA in support of its motion to dismiss, or by Plaintiffs in response to the motion. *Ginter ex rel. Ballard v. Belcher, Prendergast & Laporte*, 536 F.3d 439, 449 (5th Cir. 2008). Where the defendant submits affidavits or evidence controverting specific facts alleged in the complaint, the Court is no longer required to accept those controverted facts as true; rather, the Court may make factual findings in the context of a Rule 12(b)(3) venue challenge based upon an evidentiary hearing. *See id*. (citing *Murphy v. Schneider Nat'l, Inc*., 362 F.3d 1133, 1138-40 (9th Cir. 2004) (holding that affidavits and other evidence submitted in response to a Rule 12(b)(3) motion are viewed in the light most favorable to the non-movant only in the absence of factual findings made by the district court based on an evidentiary hearing); *see also Kranos IP Corp. v. Riddell, Inc.*, 2017 WL 3704762, at *2 (E.D. Tex. Aug. 8, 2017) (observing that the court assumes venue allegations are true only to the extent such facts are not contradicted by other evidence). In this case, the Court held an evidentiary hearing on November 6, 2017, and both sides submitted evidence in support of their venue arguments. As set forth herein, the Court made factual findings with respect to certain venue-related allegations, but only to the extent the allegations were contradicted by the evidence in the record.

If venue is improper, the Court has broad discretion to dismiss the case or, in the interest of justice, transfer the case to any district where venue is proper. 28 U.S.C. § 1406(a); *Caldwell v. Palmetto State Savs. Bank of S.C.*, 811 F.2d 916, 919 (5th Cir. 1987).

## Analysis

Venue in a patent infringement action is governed by a special patent venue statute, which provides that a patent infringement case may be brought in the judicial district where (1) the defendant resides, or (2) where the defendant has committed acts of infringement and has a regular and established place of business. 28 U.S.C. §1400(b). The Supreme Court recently clarified that, for purposes of the patent venue statute, a domestic corporation "resides" only in its state of incorporation. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1519 (2017). Because Teva USA is a Delaware corporation, venue is proper in this district only if Teva USA (a) has committed acts of infringement in this district ***and*** (b) has a regular and established place of business in this district. 28 U.S.C. §1400(b).

## Acts of Infringement

Teva USA contends that venue is improper in the Northern District of Texas because the alleged act of infringement—the ANDA submission—did not occur in this district. Rather, the ANDA was prepared in New Jersey at Teva USA's offices and electronically submitted in Maryland at the FDA. Def. App., Jungreis Decl. at 2, ¶8. Plaintiffs respond that venue is proper in this district because, under the Hatch-Waxman Act, an act of infringement also occurs wherever an ANDA filer intends to market the accused product, and in this case, Defendants allegedly intend to market the accused generic drug in the Northern District of Texas. Plaintiffs further contend that Teva USA committed an act of infringement in this district when it sent the paragraph IV certification to Plaintiffs, who are located in the district.

It is undisputed that, under the Hatch-Waxman Act, filing an ANDA containing a Paragraph IV certification, such as Teva USA did with respect to Soolantra®, constitutes an act of infringement. 35 U.S.C. § 271(e)(2) ("It shall be an act of infringement to submit an [ANDA]

for a drug claimed in a patent … if the purpose of such a submission is to obtain approval … to engage in the commercial manufacture, use, or sale of a drug … claimed in a patent … before the expiration of such patent."). It is an open question, however, as to whether an act of infringement also occurs wherever an ANDA filer intends to market the accused product. The only court decision directly addressing the issue is the District of Delaware's recent opinion in *Bristol-Myers Squibb Company v. Mylan Pharmaceuticals Inc.*, which held:

> an applicant's submission of an ANDA, *in conjunction with other acts the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval*, plus steps already taken by the applicant indicating its intent to market the ANDA product in [a particular] District, must all be considered for venue purposes, and can be sufficient to demonstrate that the ANDA-filing Defendant "has committed" "acts of infringement" in [the particular] District.

2017 WL 3980155, at *13 (D. Del. Sept. 11, 2017) (emphasis added).

In arriving at its decision, the Delaware court observed that the choice of verb tense in the patent venue statute—"has committed"—is problematic in the context of the Hatch-Waxman Act, where the infringement analysis is focused on whether infringement will occur in the future, and not on past or present acts. *Id.*, at *6. Because Hatch-Waxman Act litigation is forward-looking in nature, the court concluded "an ANDA filer's future, intended acts must be included as part of the 'acts of infringement' analysis for purposes of determining if venue is proper." *Id.*, at *9. The Delaware court relied heavily on the Federal Circuit's decision in *Acorda Therapeutics, Inc. v. Mylan Pharm., Inc.*, 817 F.3d 755 (Fed. Cir. 2016), which held that an ANDA filer's planned future conduct that would be purposefully directed at the state satisfies the minimum contacts standard for personal jurisdiction. *Acorda*, 817 F.3d at 762-63. The Delaware court concluded that the defendant's submission of the ANDA, the future acts the defendant intended to take upon ANDA approval, plus steps already taken by the applicant indicating its

intent to market the ANDA product in the district, were sufficient to show that the defendant "has committed" acts of infringement in the district. *Bristol-Myers Squibb*, 2017 WL 3980155, at *13.

Plaintiffs urge the Court to adopt the Delaware court's reasoning and find that an act of infringement has occurred in the Northern District of Texas because Teva USA filed an ANDA and intends to market a generic version of Soolantra® in this district. Plaintiffs' argument closely follows the framework of the Delaware court's decision, pointing out the forward-looking nature of ANDA litigation and drawing heavily from the Federal Circuit's *Acorda* decision on specific personal jurisdiction.

While the Delaware court's opinion is very thorough, there are several issues with the decision that counsel this Court away from adopting the holding that an act of infringement occurs in any district where the ANDA filer intends to market the ANDA product after it receives FDA approval. "First, and most prominently," as the opinion itself concedes, is that the plain language of the patent venue statute provides that venue is proper "where the defendant ***has committed*** acts of infringement." *Bristol-Myers Squibb*, 2017 WL 3980155, at *12 (emphasis added). In the Hatch-Waxman Act context, because the generic drug is not yet being marketed, the only act of infringement that actually has occurred is the filing of the ANDA. The Delaware court discerned an irreconcilable conflict between what the court characterized as the backward-looking nature of the patent venue statute and the forward-looking nature of Hatch-Waxman Act litigation. To give the Hatch-Waxman Act full effect, the Delaware court determined that the acts of infringement an ANDA filer has committed must include all of the acts that would constitute ordinary patent infringement if, upon FDA approval, the generic drug product is launched into the market. This rationale is inconsistent with the plain language of the statute, which does not

identify any artificial act of infringement other than the ANDA submission. The Federal Circuit recently struck down a patent venue test crafted by a district court because the test was "not sufficiently tethered" to the statutory language. *In re Cray*, 871 F.3d at 1362. The Federal Circuit's conclusion echoes the Supreme Court's instruction that Section 1400(b) "is [not] to be given a 'liberal' construction." *See Schnell v. Peter Eckrich & Sons, Inc*., 365 U.S. 260, 264 (1961). In the sense of the *Cray* analysis, the Delaware court's approach to venue in ANDA cases is a liberal interpretation of the venue statute and, thus, inconsistent with the Federal Circuit's guidance.

Plaintiffs insist that their interpretation is not only consistent with the statute, it is required to give effect to the second part of Section 271(e)(2), which requires that the submission of an ANDA will be an act of infringement if the purpose of the submission is to obtain approval to engage in the commercial manufacture, use, or sale of a patented drug before the expiration of the patent. 35 U.S.C. § 271(e)(2). This Court disagrees. The Hatch-Waxman Act provides that the submission of an ANDA constitutes an act of infringement for purposes of bringing a lawsuit. The statute itself recognizes the forward-looking nature of the litigation and identifies the ANDA submission as an artificial act of infringement on which a lawsuit can be based. The commencement of a lawsuit effectuates the purpose of the Hatch-Waxman Act; it is not necessary to recognize additional speculative acts of infringement to give the statute effect.

The *Bristol-Myers Squibb* decision borrowed heavily from *Acorda*, but *Acorda* is a personal jurisdiction decision, not a venue decision. *In re Cray*, the most recent pronouncement from the Federal Circuit on the application of the patent venue statute, warns courts to "be careful not to conflate showings that may be sufficient for other purposes, e.g., personal jurisdiction or the general venue statute, with the necessary showing to establish proper venue in

patent cases." *In re Cray, Inc.*, 871 F.3d at 1361. This language provides a clear admonition to courts to avoid importing personal jurisdiction standards into a venue analysis. This Court declines to find that an act of infringement occurs wherever an ANDA filer intends to market the accused product.

In determining proper venue in a Hatch-Waxman Act case, it is appropriate to look to the forum where the ANDA submission itself was prepared and submitted. *See, e.g., Abbott Labs. v. Roxane Labs., Inc.*, 2013 WL 2322770, at *19 (D. Del. May 28, 2013). In the context of examining the relative convenience of proper venues under 28 U.S.C. § 1404(a) in Hatch-Waxman Act cases, other courts have recognized that the act of infringement arises out of the preparation and submission of the ANDA. *See Pfizer Inc. v. Synthon Holding, B.V.*, 386 F. Supp. 2d 666, 675-76 (M.D.N.C. 2005); *see also Pfizer Inc. v. Apotex, Inc.*, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009) ("location of the preparation and submission of the ANDA" is "the location of the injury" for venue purposes in Hatch-Waxman Act cases). Preparation of the ANDA submission involves the compilation of information from multiple sources and completion of various FDA-required forms. *See* Abbreviated New Drug Application (ANDA) Forms and Submission Requirements,https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm120955.htm (updated Oct. 19, 2017). Among the information that must be included in the ANDA submission is: scientific data regarding the quality, safety, and efficacy of the proposed generic drug and the FDA-approved drug listed in the Orange Book, as well as data supporting the bioequivalence of the generic drug to the approved drug; patent information for the approved drug; information regarding the applicant's manufacturing facilities; and information pertaining to the proposed labeling and packaging for the generic drug. *See id.*

Submission of the actual ANDA is accomplished electronically. *See id.* ("The FDA no longer accepts paper ANDA submissions. All ANDA submissions MUST be in eCTD format.").

Plaintiffs argue the Court should ignore Teva USA's ANDA preparation because Section 271(e)(1) provides that "it shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs." 35 U.S.C. §271(e)(1). The Supreme Court has recognized that this "safe harbor" includes preclinical research studies performed in connection with the development of a generic drug pertaining to the drug's safety and efficacy, the results of which would be relevant to, and possibly included with, an ANDA submission for the approval of a generic drug. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202, 206-07 (2005). In this case, the Court is not relying on research or activities other than the preparation and actual submission of the ANDA itself. Here, there is no evidence—much less an allegation—that Teva USA prepared or submitted ANDA No. 210019 in or from the Northern District of Texas. The Court thus determines that venue is not proper in this district because no act of infringement occurred here.

Plaintiffs also argue that Teva USA committed an act of infringement in this District when it submitted the ANDA which included a paragraph IV challenge to Plaintiffs' patents, because Plaintiffs are residents of the Northern District. But Plaintiffs cite no authority for their assertion that the location of the patent holder is relevant to the patent venue analysis, and the patent venue statute does not provide for venue based on the plaintiff's residence. 28 U.S.C. §1400(b) (providing that patent infringement case may be brought in the judicial district where (1) the *defendant* resides, or (2) where the *defendant* has committed acts of infringement and has a regular and established place of business). Rather, the statue makes the submission of an

ANDA an act of infringement. In this case, there is no dispute that the ANDA submission occurred outside this district. The Court therefore determines that Plaintiffs have failed to carry their burden to establish that an act of infringement occurred in this district. For this reason, the Court GRANTS Teva USA's Rule 12(b)(3) motion to dismiss.

**Regular and Established Place of Business**

As an additional or alternative basis for granting the motion to dismiss for improper venue, the Court considers whether Teva USA has a regular and established place of business in the Northern District, as required by the second prong of Section 1400(b) in order for venue to be proper in this district. As the Federal Circuit recently clarified, Section 1400(b)'s "regular and established place of business" clause imposes three requirements: "(1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant. *In re Cray*, 871 F.3d at 1360. "If any statutory requirement is not satisfied, venue is improper under § 1400(b)." *Id*.

With respect to the first requirement, "[t]he statute requires a 'place,' *i.e.*, '[a] building or part of a building set apart for any purpose' or 'quarters of any kind' from which business is conducted." *Id*. at *5. Significantly, "[t]he statute [ ] cannot be read to refer merely to a virtual space or to electronic communications from one person to another." *Id*. "While the 'place' need not be a 'fixed physical presence in the sense of a formal office or store,' there must still be a physical, geographical location in the district from which the business of the defendant is carried out." *Id*., at *5 (quoting *In re Cordis Corp*., 769 F.2d 733, 737 (Fed. Cir. 1985)).

Regarding the second requirement, regularity means that the business "operates in a 'steady[,] uniform[,] orderly[, and] methodical' manner. In other words, sporadic activity cannot create venue." *Id*. (citation omitted). The "established" limitation means "that the place of

business is not transient. It directs that the place in question must be 'settle[d] certainly, or fix[ed] permanently.'" *Id.* at *6 (citation omitted). "Accordingly, while a business can certainly move its location, it must for a meaningful time period be stable, established." *Id.*

The third requirement—that "the regular and established place of business" must be "the place of the defendant"—means that it cannot be solely a place of the defendant's employee, such as an employee's home, if that employee works from home. *Id*. "Employees change jobs. Thus, the defendant must establish or ratify the place of business. It is not enough that the employee does so on his or her own." *Id*. According to the Federal Circuit,

> Relevant considerations include whether the defendant owns or leases the place, or exercises other attributes of possession or control over the place . . . Another consideration might be whether the defendant conditioned employment on an employee's continued residence in the district or the storing of materials at a place in the district so that they can be distributed or sold from that place . . . . Marketing or advertisements also may be relevant, but only to the extent they indicate that the defendant itself holds out a place for its business.

*Id*. "[I]f an employee can move his or her home out of the district at his or her own instigation, without the approval of the defendant, that would cut against the employee's home being considered a place of business of the defendant." *Id*.

Plaintiffs contend that Teva USA has a regular and established place of business in the Northern District because it has dozens of employees who live and work in the district. Specifically, Plaintiffs point to evidence that [redacted]

[redacted] Plaintiffs maintain that Teva USA, which is the only entity licensed to distribute Teva-branded drugs in the state of Texas, exercises significant control over [redacted] These employees distribute the promotional materials to Teva USA customers throughout the district.

Plaintiffs argue that the business activities performed by the sales representatives on behalf of Teva USA closely resemble, and even exceed, the activities performed by sales representatives in *In re Cordis*, 769 F.2d 733 (Fed. Cir. 1985), which found venue was proper in Minnesota based on the presence and activities of the defendant's employees in the district. The defendant, Cordis, a Florida medical products company, did not own or lease any real property in Minnesota, but it did employ two sales representatives exclusively, and it compensated those sales representatives with salaries, commissions, reimbursements, and other benefits. *In re Cordis*, 769 F.2d at 734. The Cordis sales representatives stored Cordis medical products at their homes, and hospitals that wanted to purchase Cordis products could contact the sales representatives directly to obtain the Cordis products. *Id.* at 735. The sales representatives also provided doctors and hospitals with Cordis product literature, which the salespeople stored at their homes. Cordis hired a secretarial service in the district to answer the sales representatives' calls and receive mail addressed to Cordis. *Id.* Based on these facts, the Federal Circuit determined that the employees' homes constituted "a place of the defendant," as required by Section 1400(b).

Plaintiffs' argument ignores the fact that none of the sales representatives identified in the record are Teva USA employees. Rather, the record establishes that the sales representatives are employed by a separate, but related, entity—Teva Sales & Marketing, Inc. ("TSM"). *See* B. Scoll Depo., Pl. Supp. App. at 301, 305. [redacted] There is no evidence in the record, nor even a contention, that TSM and Teva USA are not separate corporate entities.

A subsidiary's presence in the district cannot be imputed to the parent for venue purposes so long as the two entities maintain formal corporate separateness. *Symbology Innovations v. Lego Sys., Inc.*, 2017 WL 4324841, at *10 (E.D. Va. Sept. 28, 2017). This is true even if the parent corporation controls the subsidiary's operations and the companies share a unitary business purpose. *Soverain IP, LLC v. AT&T, Inc.*, 2017 WL 5126158, at *1 (E.D. Tex. Oct. 31, 2017). Plaintiffs cannot rely on the presence of TSM sales representatives in the district to establish a physical presence of Teva USA, unless the Court ignores the corporate formalities of TSM and Teva USA. *See, e.g., Post Consumer Brands, LLC v. General Mills, Inc.*, 2017 WL 4865936, at *3 (E.D. Mo. Oct. 27, 2017) ("[E]xcept where corporate formalities are ignored and an alter ego relationship exists, the presence of a corporate relative in the district does not establish venue" under the patent venue statute.). In this case, Plaintiffs have not shown that TSM and Teva USA do not maintain formal corporate separateness.

At the November 6 hearing, for the first time, Plaintiffs suggested the Court could impute the presence of TSM's employees to Teva USA under an alter ego theory or an agency theory. However, Plaintiffs did not plead either of these theories, and the Court declines to consider whether either type of relationship may exist in this case in the absence of any specific allegations of alter ego or agency.

[redacted] Plaintiffs argue that it is a disputed fact question as to whether Teva USA actually employs sales representatives in the United States. In support of their argument, Plaintiffs point to declarations from [redacted] and a recent job posting stating that Teva USA is recruiting sales representatives in the Northern District of Texas. Plaintiffs further contend Teva USA has judicially admitted in two different lawsuits filed in the Northern District of Illinois that it employs sales representatives in the United States.

The Court determines proper venue from the facts as they existed at time the Plaintiffs' Original Complaint was filed. *Nutrition Physiology Corp. v. Enviros Ltd.*, 87 F. Supp. 2d 648, 652 (N.D. Tex. 2000). Contrary to Plaintiffs' assertions, the evidence does not raise a fact question as to whether Teva USA employed any sales representatives in the Northern District of Texas in April 2017, when this lawsuit was filed. [redacted], and evidence about a different entity's employment practices does not raise a fact issue as to whether Teva USA employs sales representatives in the Northern District of Texas in 2017. [redacted]

[redacted] knowledge of Teva USA's employment practices ends in December 2013 and is too temporally attenuated to raise a fact issue as to Teva USA's current practices.

In a similar way, Teva USA's alleged judicial admissions also do not raise a fact question as to whether Teva USA employed any sales representatives in the Northern District of Texas in April 2017. In *Keen v. Teva USA*, 1:16-cv-09964, N.D. Ill., the plaintiff, Janice Keen, sued TSM and Teva USA for employment discrimination under the Americans with Disabilities Act and Title VII. *See* Ans., Pl. Supp. App. at 255-61. In the answer filed in *Keen*, TSM and Teva USA admitted the following allegations:

> Defendant, TEVA Sales and Marketing, Inc., . . . during *2015-2016* issued Plaintiff, Janice Keen, IRS W-2 forms stating her employer was Defendant, Teva Sales and Marketing, Inc.
>
> During *2013 and 2014*, at the Illinois Department of Human Rights (IDHR), Defendant TEVA Pharmaceuticals USA, Inc., . . . claimed it was Plaintiff's employer notwithstanding no W-2 confirmation.
>
> During the entire time Plaintiff was employed by Defendant TEVA, Plaintiff worked in the Chicago Metropolitan area as a Territory Sales Specialist and later an Executive Sales Specialist.

*Id.*, ¶¶ 3, 4, 8 (emphasis added). Contrary to Plaintiffs' argument, the Keen answer supports Teva USA's assertion that the sales representatives engaged in marketing Teva-branded drugs are currently employed by TSM. In *Stavropoulos v. Teva Pharmaceuticals USA, Inc*., 1:17-cv-04588, N.D. Ill., the plaintiff, Tara Stavropoulos, sued Teva USA for pregnancy discrimination.

In its answer, Teva USA admitted that it employed Stavropoulos as a sales representative in the Rockford, Illinois sales territory from May 2010 through April 11, 2016. *Id.* at 275, ¶¶8, 10-11. Although Stravopoulos's employment is closer in time to the relevant date for determining venue in this case, it is still too far removed to raise a fact issue as to whether Teva USA employed any sales representatives in the Northern District of Texas in 2017.

Plaintiffs also rely on job postings from June and July 2017 that purportedly advertise for sales representative positions with Teva USA. *See* Pl. App. at 159-163. Although the banner at the top of the job listing includes Teva USA's logo, the postings themselves do not specify that the successful candidate would be employed by Teva USA. In fact, the first posting advertising for a respiratory sales specialist in Dallas, Texas, states that the job opportunity is with "Teva Respiratory, LLC, a member of the Teva Pharmaceuticals family." *Id.* at 159. The other job postings are silent as to the specific entity that is recruiting candidates. The Court concludes that this evidence does not raise a fact issue as to whether Teva USA employs sales representatives anywhere in the United States, let alone the Northern District of Texas.

Having reviewed all the evidence, the Court finds that only two of the employees identified by Defendants as living and working in the district actually work for Teva USA: [redacted]

There is no evidence that either of these two employees keep any inventory at their homes or distribute Teva-branded drugs directly to Defendants' customers. There is also no evidence that Teva USA conditioned [redacted] employment on their continued residence in the district. To the contrary, [redacted]

[redacted]. Nothing in the record indicates that Teva USA owned, leased, or rented any portion of [redacted] homes; nor is there any evidence that Teva USA played a part in these employees' selection of their homes in the Northern District of Texas. Teva USA did not hold out these employees' homes as the company's places of business, and no home addresses or personal phone numbers of the employees were listed in any directory or listing for Teva USA. The Court thus determines that neither [redacted] presence in the district warrants a finding that Teva USA has a regular and established place of business in this district. *See Regents of the University of Minnesota v. Gilead Sciences, Inc.*, 2017 WL 4773150 (D. Minn. Oct. 20, 2017) (finding that the location of a sales force in the district actually weighed against a finding that the defendant's physical presence in the district was "regular and established" because the physical location of that sales force was not permanently fixed; defendants' employees were not required to live in the district; defendant did not condition its offers of employment on residence in the district; defendant did not own, lease, or rent any portion of the employees' homes, nor did it play a part in the employees' selection of the employees' homes).

Plaintiff also argue the facts that Teva USA has a network of authorized distributors throughout the district and derives economic benefit from sales efforts in the district on its behalf weigh in favor of finding that Teva USA has a regular and established place of business here. However, the fact that Teva USA may derive revenue from sales activities in the district does not establish a physical place in the district, as required by the patent venue statute. *See Symbology*, 2017 WL 4324841 (finding that revenue derived from the forum has no bearing on whether §1400(b)'s requirements are met); *Cao Lighting, Inc. v. Light Efficient Design and Electrical*

*Wholesale Supply Co., Inc.*, 2017 WL 4556717 (D. Idaho Oct. 11, 2017) (finding fact that defendant received income from sales in the district has little significance in light of the three general requirements the Federal Circuit laid out in *Cray*). That Teva USA has distributors in the district also does not help Plaintiffs, unless Plaintiffs can also show that the distributors work out of a physical location owned or controlled by Teva USA. *Cao Lighting*, 2017 WL 4556717 (finding no regular or established place of business for purposes of the patent venue statute where defendant had 17 distributors in the state that were obligated to stock the defendant's products and display its marketing materials, but the physical locations were the locations of the distributors, not of the defendant). To the extent the evidence in the record addresses this issue, [redacted]

The Court determines that Plaintiffs have failed to carry their burden to show Teva USA has a regular and established place of business in the Northern District. Accordingly, for this additional reason, the Court GRANTS Teva USA's Rule 12(b)(3) motion to dismiss.

**Transfer**

Having found that venue is not proper in this district, Plaintiffs request that the Court transfer rather than dismiss the claims against Teva USA. It is well-established that when a court finds venue improper, it may, in the interest of justice, transfer the case to any district or division in which the case could have been brought. 28 U.S.C. §1406(a) ("The district court of a district in which is filed a case laying venue in the wrong division or district shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought."). Because Teva USA is a Delaware corporation, venue properly lies in Delaware

under the first prong of the patent venue statute. 28 U.S.C. §1400(b) (providing that venue for patent infringement actions properly lies in the district where the defendant "resides"); *TC Heartland*, 137 S. Ct. at 1521 (holding that, as to domestic corporate defendants, "residence," under the first prong of §1400(b), refers solely to the state in which the defendant is incorporated). This case could have been brought in the District of Delaware and could be transferred to Delaware, in the interest of justice. *See Gilead Sciences,* 2017 WL 4773150 (transferring patent case to the district in which the defendant was incorporated after finding the defendants did not have a regular and established place of business in the district where the case was originally brought).

Plaintiffs argue that the interests of justice weigh in favor of transfer over dismissal in this case because dismissal could result in lifting the thirty-month stay and the approval of the ANDA. Teva USA opposes transfer and prefers dismissal. Teva USA further objects to the Court severing the claims against it and transferring only those claims while retaining the claims against Teva Israel. The Court is inclined to transfer the claims against Teva USA, in the interest of justice to avoid interfering with the statutorily-mandated thirty-month stay. To avoid duplicative litigation, the Court could transfer the remaining claims under 28 U.S.C. §1404(a) "to any district or division to which all parties have consented." The parties, including Teva Israel, are therefore directed to confer and advise the Court by no later than November 30, 2017, whether they consent to transfer the case to Delaware.

**Rule 12(b)(6) Motion to Dismiss for Failure to State a Claim**

Teva Israel has filed a separate motion to dismiss under Rule 12(b)(6) [ECF #25] on the ground that the FAC admits it was Teva USA that submitted the ANDA, and the facts pled are not sufficient to state a plausible case that Teva Israel is responsible for that act.

## Legal Standards

Fed. R. Civ. P. 8(a)(2) requires a pleading to contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). The purpose of this requirement is to give the defendant fair notice of what the claim is and the grounds upon which it rests. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Detailed factual allegations are not required, but the pleading must present more than "an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To survive a Fed. R. Civ. P. 12(b)(6) motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id*. at 556. A pleading that offers only "labels and conclusions" or "a formulaic recitation" of the elements of a cause of action will not suffice. *Id*. at 555.

## Analysis

Teva Israel argues that Plaintiffs fail to state a claim against it because Teva Israel was not the entity that submitted the ANDA application. As discussed, the Hatch-Waxman Act makes it "an act of infringement to submit" an ANDA on a drug covered by valid and infringed patents found in the Orange Book listing for a drug. 35 U.S.C. § 271(e)(2). An entity submits an ANDA if it participates in the preparation of the ANDA and intends to benefit directly from the ANDA by selling the ANDA product upon approval. *In re Rousvastatin Calcium Patent Litig*., 703 F.3d 511, 528-29 (Fed. Cir. 2012). An entity can be an ANDA submitter without signing the ANDA. "Parties 'actively involved' in preparing the ANDA are deemed to have 'submit[ted]' the ANDA, regardless of whether they are the named applicant; this is especially true where the

parties involved are in the same corporate family." *Cephalon, Inc. v. Watson Pharm., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009) (quoting *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 306-07 (D. Md. 2007)).

Plaintiffs allege in the FAC [ECF #15]:

> *Teva USA* filed ANDA No. 210019 on December 30, 2016. ¶50 (emphasis added).
>
> On or about March 10, 2017, *Teva USA* sent the Paragraph IV Certification to GLP in Fort Worth, Texas and to GSA. Through the Paragraph IV Certification, Teva USA first notified Plaintiffs that Teva USA had filed the ANDA with the FDA relating to the Accused Product, and that the ANDA includes a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) that, in Teva USA's opinion, the claims of the '816 Patent, '587 Patent, '117 Patent, and '118 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of the Accused Product. ¶51 (emphasis added).

The FAC contains no other allegations pertaining to the submission of the ANDA. Thus, all of Plaintiffs' allegations state that Teva USA was the entity that committed that act of infringement.

However, the FAC also contains the following allegations pertinent to Teva Israel's involvement in the alleged infringement:

> Teva USA is a wholly-owned subsidiary of Teva Israel, and acts at the direction of, under the control of, and for the benefit of Teva Israel. ¶7.
>
> Teva Israel [and] Teva USA . . . *collectively file* ANDAs, including the ANDA at issue here, for the purpose of collectively manufacturing, importing, offering for sale, selling, and distributing generic pharmaceutical products throughout the United States, including this district; maintain a broad distribution network within this district; and enjoy substantial income from sales of generic pharmaceutical products in this district. ¶10 (emphasis added).
>
> Teva USA conducts business in the United States as a representative of Teva's global brand and an agent of Teva Israel. According to Teva Israel's website, 1 out of every 6 generic prescriptions in the United States is filled with a Teva-branded product. Teva Israel

> maintains that it has over 7,500 employees at more than 30 locations in the United States, its territories, and Canada. ¶18.
>
> Teva Israel [and] Teva USA . . . work in active concert with respect to the development, manufacturing, regulatory approval, importation, marketing, sale, and distribution of generic pharmaceutical products, including the generic pharmaceutical product described in ANDA No. 210019, throughout the United States, including this district. *Teva Israel works in active concert with its subsidiaries, including Teva USA and Actavis, in the submission of ANDAs for approval of its generic pharmaceutical products in the United States*. ¶45 (emphasis added).
>
> Teva Israel files a single annual report—Form 20-F—to the United States Securities and Exchange Commission for itself and its subsidiaries, including Teva USA and Actavis. ¶46.
>
> Defendants share common directors, officers, and facilities, and operate as agents of each other. In prior litigation, Teva USA has stipulated that all documents, witnesses, and information held by Teva Israel are within the custody and control of Teva USA, and that Teva USA would accept service of case documents on behalf of Teva Israel. . . . ¶47.
>
> *Teva Israel* [and] Teva USA . . . *were involved in the submission of the ANDA seeking FDA approval to engage in the commercial manufacture, use, and sale of a generic version of Accused Product* prior to the expiration of the Asserted Patents. ¶48 (emphasis added).
>
> *Teva Israel* and] Teva USA . . . *intend to continue collectively seeking approval of the ANDA from the FDA and engage in the commercial manufacture, marketing, and sale of the Accused Product* (including commercial marketing and sale of the Accused Product in the State of Texas and this district), in the event that the FDA approves the ANDA. ¶55 (emphasis added).

The key inquiry for the Court is whether the FAC sufficiently alleges that Teva Israel was "actively involved" in preparing the ANDA, as "[p]arties 'actively involved' in preparing the ANDA are deemed to have 'submit[ted]' the ANDA." *Cephalon*, 629 F. Supp. 2d at 349. "Active involvement" includes "marketing and distributing the approved generic drugs in the United States." *Id.* Plaintiffs argue that they have sufficiently alleged that Teva Israel will be

involved in the marketing and distribution of the generic version of Soolantra®, if the ANDA is approved.

In *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, a district court in Delaware denied a Rule 12(b)(6) motion finding that the plaintiff's allegations were sufficient to raise related corporate entities' active involvement in the preparation of an ANDA above the speculative level. However, the allegations deemed sufficient in *Cephalon* were more specific than Plaintiffs' allegations in this case. For example, the *Cephalon* complaint alleged that the related entities each took part in Generic Division operations and further alleged that each related entity contributed employees to the various teams responsible for preparing the ANDA, and employees of each related entity prepared and executed ANDA-related documents. There are no similar allegations in the FAC as to Teva Israel's involvement in preparing the ANDA. To the contrary, the FAC specifically alleges that Teva USA filed ANDA No. 210019, and Teva USA sent the Paragraph IV Certification. First Am. Compl. at ¶¶50, 51.

The plaintiff in *Cephalon* further alleged that each related entity will be involved in the marketing and distribution of the accused generic drug if the ANDA is approved. Plaintiffs here make a similar allegation, but the allegation is a collective allegation against all the defendants. There are no specific facts alleged that Teva Israel will be involved in marketing the Accused Product. The *Cephalon* complaint survived dismissal because it contained more than the bare-bones assertions made in the FAC that Teva Israel, together with Teva USA, was involved in the submission of the ANDA. *Id.* at ¶48. Additionally, the court in *Cephalon* found that all the allegations together were sufficient to withstand dismissal. The case does not stand for the proposition that an allegation that a parent company will be involved in post-approval marketing

and distribution, with no other facts, is sufficient to plausibly state that the parent company was actively involved in the submission of an ANDA by a subsidiary of the parent company.

Two decisions from the Eastern District of Texas denied Rule 12(b)(6) motions on thinner allegations. First, in *Warner Chilcott Company, LLC v. Mylan Pharmaceuticals, Inc.*, 2017 WL 603309 (E.D. Tex. Jan. 19, 2017), the court determined that the plaintiffs adequately stated a claim that each related Defendant entity submitted the ANDA at issue based on allegations that:

> [T]he Mylan entities "prepared ANDA No. 207826," that Mylan, Inc., Mylan Pharmaceuticals, and Mylan Laboratories are "agents of each other" or "work in active concert either directly or through one or more of their wholly owned subsidiaries" to develop, manufacture, and sell generic drug products through the United States, and that Mylan Laboratories "manufactured the Generic Product relied upon in ANDA No. 207826 . . . ."

*Warner Chilcott*, 2017 WL 603309, at *4. The court did not indicate that the complaint included any specific factual allegations beyond what was set forth in the opinion. The *Warner Chilcott* decision demands far less than was required in *Cephalon*, and likely less than the federal pleading standards require.

The other Eastern District of Texas case Plaintiffs point to is *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, 2016 WL 1572193 (E.D. Tex. Apr. 19, 2016). In *Allergan*, the defendants argued that the complaint failed to state a claim against the corporate parent entity because the parent did not prepare and submit the ANDA. However, the complaint alleged:

> [Subsidiary] and [parent] are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the drug at issue in this case . . . [and parent] markets and sells the drugs manufactured by [subsidiary]. [I]f the ANDA is approved [parent] will become the generic product's marketer, seller, and distributor in the United States, and that [parent] would benefit from the ANDA's approval. . . . [Parent] has worked in

> concert with [subsidiary] with respect to the regulatory approval of the drugs at issue in this case.

*Id.* at *5. The Eastern District court found the allegations sufficient to state a claim.

Despite the holdings of the two Eastern District of Texas decisions that generic, factually unsubstantiated allegations are sufficient to state a claim, the Court comes to a different conclusion here. Plaintiffs' allegations do not distinguish Teva Israel's conduct from Teva USA's conduct; nor are the allegations supported by any specific factual assertions that make the allegation more than a bare-bones conclusion. Additionally, it appears that Plaintiffs may simply have copied what they perceive to be "magic words" regarding active involvement from other decisions without demonstrating how those allegations can support a claim against Teva Israel in this case.

Plaintiffs also assert that their allegations are sufficient to state a claim for inducement against Teva Israel because Plaintiffs have alleged that the Defendants, collectively, will be engaged in post-approval marketing and distribution of a generic version of Soolantra®. Regardless of the particular theory asserted, Plaintiffs' allegations against Teva Israel fail because they are not specific to Teva Israel. Rather, the FAC lumps together all of the Defendants. To survive dismissal, Plaintiffs must specifically allege facts that would support an inference that Teva Israel will be engaged in post-approval marketing and distribution of a generic version of Soolantra®. Plaintiffs indicate that they could allege additional facts about Teva Israel's ownership of the ANDAs and the revenues generated by those ANDAs, which may support the necessary inference.

Plaintiffs request leave to file an amended complaint setting forth more specific allegations, if the Court grants the Rule 12(b)(6) motion. This is a reasonable request, and the Court thus exercises its discretion to give Plaintiffs one last opportunity to cure the deficiencies

identified herein. If all the parties do not consent to transfer this case to Delaware, Plaintiffs may file an amended complaint against Teva Israel only **on or before December 15, 2017**.

**Motion for Leave to File Supplemental Complaint**

Also pending before the Court is Plaintiffs' opposed motion [ECF #47] for leave to file a First Supplemental Complaint and serve Supplemental Infringement Contentions, which seeks to add a related patent, U.S. Patent No. 9,782,425 (the "'425 Patent") that did not exist when Plaintiffs filed their Original Complaint and FAC. The claims of the '425 Patent allegedly cover generic versions of Soolantra®, and the Supplemental Complaint alleges infringement of the '425 Patent based on the same accused product. Defendants oppose Plaintiffs' Motion on the ground that the Motion is futile, because their Motions to Dismiss the First Amended Complaint should be granted. The Court defers to the Delaware court consideration of Plaintiffs' request to file a supplemental complaint to assert the '425 Patent against Teva USA. If all the parties do not consent to transfer this case to Delaware, Plaintiffs may include allegations against Teva Israel pertaining to the '425 Patent in their amended complaint to be filed **on or before December 15, 2017**.

**Conclusion**

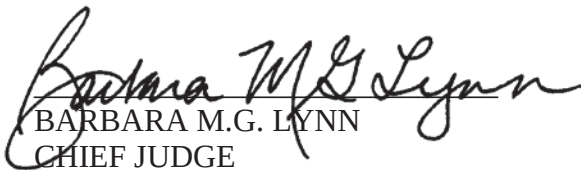
The Court determines that venue is not proper in this district as to Teva Pharmaceuticals USA, Inc. under 28 U.S.C. §1400(b) because Teva Pharmaceuticals USA, Inc. did not commit any act of infringement in this district, nor does Teva Pharmaceuticals USA, Inc. have a regular and established place of business in this district. Accordingly, the Court GRANTS Teva Pharmaceuticals USA, Inc.'s Rule 12(b)(3) Motion to Dismiss [ECF #21]. The parties, including Teva Israel, are directed to confer and advise the Court by **no later than November 30, 2017**, whether they consent to transfer the entire case to Delaware.

The Court further determines that the allegations in Plaintiffs' First Amended Complaint are not sufficient to state a claim that Teva Pharmaceutical Industries Ltd. was actively involved in Teva USA's submission of the ANDA at issue. Therefore, the Court also GRANTS Defendant Teva Pharmaceutical Industries Ltd.'s Motion to Dismiss for failure to state a claim [ECF #25]. Plaintiffs' claims against Teva Pharmaceutical Industries Ltd. are DISMISSED without prejudice. If all the parties do not consent to transfer this case to Delaware, Plaintiffs may file an amended complaint against Teva Israel only **on or before December 15, 2017**.

Finally, the Court GRANTS in part Plaintiffs' Motion for Leave to File a First Supplemental Complaint and to serve Supplemental Infringement Contentions [ECF #47]. If all the parties do not consent to transfer this case to Delaware, Plaintiffs may include allegations against Teva Israel pertaining to the '425 Patent in their amended complaint to be filed on or before December 15, 2017.

SO ORDERED.

November 17, 2017.



BARBARA M.G. LYNN
CHIEF JUDGE