UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No.: 0:22-cv-61192-WPD

SCILEX PHARMACEUTICALS INC., ITOCHU CHEMICAL FRONTIER CORPORATION, AND OISHI KOSEIDO CO., LTD.,

Plaintiffs,

v.

AVEVA DRUG DELIVERY SYSTEMS, INC., APOTEX CORP., AND APOTEX INC.,

Defendants.

**ORDER ON DEFENDANT APOTEX INC.'S MOTION TO DISMISS**

**THIS CAUSE** comes before the Court on Defendant Apotex, Inc.'s Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(2), 12(b)(6), and 12(b)(1). [DE 37]. The Court has considered the Motion, Plaintiffs Scilex Pharmaceuticals Inc. ("Scilex"), ITOCHU CHEMICAL FRONTIER Corporation ("Itochu"), and Oishi Koseido Co., Ltd. ("Oishi") (collectively "Plaintiffs")'s Amended Response in Opposition [DE 53 (redacted); DE 55 (sealed)], Defendant Apotex, Inc.'s Amended Reply [DE 56 (redacted); DE 59 (sealed)], arguments by counsel at the hearing on December 9, 2022, and is otherwise fully advised in the premises.

## I. Background

Plaintiffs Scilex, Itochu, and Oishi filed this action against Defendants Aveva Drug Delivery Systems, Inc. ("Aveva"), Apotex Corp., and Apotex, Inc. (collectively, "Defendants") on June, 22, 2022. *See* [DE 1]. This action arises from Aveva's notification to Plaintiffs by Notice Letter dated May 10, 2022, that it had filed an Abbreviated New Drug Application

("ANDA") No. 217221, seeking approval of a generic version of Scilex's topical lidocaine patch, ZTlido®, before expiration of U.S. Patent Nos. 9,283,174 ("the '174 patent"), 9,925,264 ("the '264 patent"), and 9,931,403 ("the '403 patent") (collectively "Asserted Patents"). [DE 1 ¶ 1, 21].

According to the allegations of the Complaint, Scilex is the holder of approved New Drug Application ("NDA") No. 207962 for Ztlido®. [DE 1] at ¶31. Ztlido® is indicated for the relief of pain associated with post-herpetic neuralgia (PHN) in adults. ¶30. Ztlido® is manufactured for Scilex and is sold in the United States pursuant to NDA No. 207962. ¶31.

The '174 patent, titled "Non-Aqueous Patch," was issued on March 15, 2016. ¶32; *see* [DE 1] at Exh. A. The '174 patent is assigned to Itochu and Oishi. ¶33. Scilex is the exclusive licensee of the '174 patent. ¶34. The '264 patent, titled "Non-Aqueous Patch," was issued on March 27, 2018. ¶36; *see* [DE 1] at Exh. B. The '264 patent is assigned to Itochu and Oishi. ¶37. Scilex is the exclusive licensee of the '264 patent. ¶38. The '403 patent, titled "Non-Aqueous Patch," was issued on April 3, 2018. ¶40; *see* [DE 1] at Exh. C. The '403 patent is assigned to Itochu and Oishi. ¶41. Scilex is the exclusive licensee of the '403 patent. ¶42.

The Complaint asserts six (6) separate counts: Count I, for Infringement of the '174 Patent Under 35 U.S.C. § 271(e)(2); Count II, for Infringement of the '264 Patent Under 35 U.S.C. § 271(e)(2); Count III, for Infringement of the '403 Patent Under 35 U.S.C. § 271(e)(2)); Count IV, for Declaratory Judgment of Patent Infringement of the '174 Patent Under 35 U.S.C. § 271 (a); Count V, for Declaratory Judgment of Patent Infringement of the '264 Patent Under 35 U.S.C. § 271 (b), and/or (c); and Count VI, for Declaratory Judgment of Patent Infringement of the '403 Patent Under 35 U.S.C. § 271 (a). *See* [DE 1].

Defendants Aveva and Apotex, Corp. have filed an Answer, Separate Defenses, and Counterclaims to the Complaint. *See* [DE 12]. Plaintiffs filed an Answer to Defendants' Counterclaims. *See* [DE 24]. Defendant Apotex, Inc. has filed the instant omnibus motion to dismiss, asserting several grounds for dismissal. *See* [DE 37].

## II. Discussion

In its Motion to Dismiss, Defendant Apotex, Inc. argues several grounds for dismissal. First, Apotex, Inc. seeks dismissal pursuant to Rule 12(b)(2) for lack of personal jurisdiction. Second, Apotex, Inc. seeks dismissal pursuant to Rule 12(b)(6) of Counts I–III, the claims for patent infringement under 35 U.S.C. § 271(e)(2), because Apotex, Inc. did not submit Aveva's ANDA. Third, Apotex, Inc. seeks dismissal pursuant to Rules 12(b)(6) and 12(b)(1) of Counts IV-VI, the claims for declaratory judgment under § 271(a), (b), and (c), because Apotex, Inc. did not submit the ANDA under § 271(e)(2) and/or because there is no immediacy to the controversy on claims for future infringement dependent on future events. The Court will address the arguments, in turn.

### *a. Whether Apotex, Inc. should be dismissed from this action pursuant to Rule 12(b)(2) for lack of personal jurisdiction*

First, Apotex, Inc. seeks dismissal pursuant to Rule 12(b)(2) for lack of personal jurisdiction.

#### 1. Standard of Review

Under Federal Rule of Civil Procedure 12(b)(2), "[a] court must dismiss an action against a defendant over which it has no personal jurisdiction." *Verizon Trademark Servs., LLC v. Producers, Inc.*, 810 F. Supp. 2d 1321, 1323–24 (M.D. Fla. 2011).

Both the state long-arm statute and the Due Process Clause of the Fourteenth Amendment must be satisfied in order for a federal court to have personal jurisdiction over a nonresident

defendant. *Posner v. Essex Ins. Co.*, 178 F.3d 1209, 1214 (11th Cir. 1999). First, the Court must determine whether the Florida long-arm statute provides a sufficient basis for personal jurisdiction. *Sculptchair, Inc. v. Century Arts, Ltd.*, 94 F.3d 623, 626 (11th Cir. 1996). After deeming jurisdiction appropriate under Florida law, the Court must then ascertain whether "sufficient minimum contacts exist between the defendant[] and the forum state so as to satisfy 'traditional notions of fair play and substantial justice' under the Due Process Clause of the Fourteenth Amendment." *Id.* (internal quotation and citation omitted). For patent cases, the due process elements are governed by Federal Circuit law. *See see Acorda Therapeutics Inc. v. Mylan Pharms. Inc.,* 817 F.3d 755, 759 (Fed. Cir. 2016).

The burden is on the plaintiff to allege a *prima facie* case; the plaintiff must do so by affidavit only if the challenging defendant provides his own affidavits in support. *Posner*, 178 F.3d at 1214. To the extent not contradicted by the defendant's affidavits, the court should accept the facts alleged in the complaint as true. *Id.* In the event of a conflict, all reasonable inferences should be made in favor of the plaintiff. *See Landia Int'l, Inc. v. Ah Koy*, 690 F. Supp. 2d 1317, 1327 (S.D. Fla. 2010).

When a federal court uses a state long-arm statute, because the extent of the statute is governed by state law, the federal court is required to construe it as would the state's supreme court." *Diamond Crystal Brands, Inc. v. Food Movers Int'l, Inc.*, 593 F.3d 1249, 1258 (11th Cir. 2010) (quoting *Lockard v. Equifax, Inc*., 163 F.3d 1259, 1265 (11th Cir.1998)). The Eleventh Circuit has noted that the statute should be strictly construed. *See Oriental Imports and Exports, Inc. v. Maduro & Curiel's Bank,* 701 F.2d 889, 891 (11th Cir.1983) (internal citations omitted).

Florida's long-arm statute provides for two theories of jurisdiction: (1) specific jurisdiction, if the suit that arises out of or is related to a defendant's contacts with Florida in one

of a number of enumerated ways, Fla. Stat. § 48.193(1)(a); or (2) general jurisdiction, if the defendant engages in "substantial and not isolated activity" in Florida, *id.* § 48.193(2). *Carmouche v. Tamborlee Mgmt., Inc.*, 789 F.3d 1201, 1203–04 (11th Cir. 2015).

2. Analysis

"Specific jurisdiction arises out of a party's activities in the forum that are related to the cause of action alleged in the complaint." *Consol. Dev. Corp. v. Sherritt, Inc.*, 216 F.3d 1286, 1291 (11th Cir. 2000).[1] Under Florida's long-arm statute, specific jurisdiction would require that Apotex Inc. "commit[ed] a tortious act within this state," like patent infringement. *Atmos Nation*, 2016 WL 10514795, at *2.

This Court explained the framework for patent infringement cases arising from ANDA filings in *Reckitt Benckiser Inc. v. Watson Lab'ys, Inc.-Fla.*:

> The Hatch-Waxman Act was established to provide a framework for drug approval and resolution of patent rights in regards to generic versions of patented drugs. The Federal Food, Drug and Cosmetic Act ("FFDCA") requires that NDA holders submit the patent number and expiration date of any patents for which it believes a claim of infringement could be made if an unlicensed person engaged in the manufacture, use, or sale of it. This information is published in the "Orange Book." The FFDCA authorizes a pharmaceutical company to file an Abbreviated New Drug Application ("ANDA"), which the FDA will approve if it is shown that the product has the same active ingredient as, and is bioequivalent to, a product that the FDA has already approved. If an ANDA seeks approval to market a generic before the expiration date in the Orange Book, it must certify that the proposed product would not infringe those products and/or that the patents are invalid or unenforceable (referred to as "Paragraph IV Certifications"). 21 U.S.C. § 355(j)(2)(A)(vii). It is only by filing such a certification that the filer can obtain FDA approval to market a generic version of a listed drug before the expiration of an Orange-Book patent. The first ANDA applicant that files a Paragraph IV certification gains a 180-day period of market exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). For those applications filed after December 8, 2003, the filer's marketing of the generic is the trigger for the exclusivity period (prior to that date, it was based on either the date of the marketing or the date of a final court decision finding the Orange Book patent invalid or infringed).

[1] In this case, Plaintiffs argue there is specific personal jurisdiction, not general personal jurisdiction, as to Apotex, Inc.

> A notice letter must then be sent to the patent holder with a detailed basis for why the patent is invalid, unenforceable, or would not be infringed. 21 U.S.C. § 355(j)(2)(B)(iv)(II). The mere filing of a Paragraph IV certification constitutes an act of patent infringement, entitling the Orange Book-listed-patent holder to initiate an infringement suit. 35 U.S.C. § 271(e)(2). If the patent owner sues the ANDA applicant within 45 days of receiving the notice letter, then the FDA is prohibited from approving the ANDA for 30 months or until the infringement action is over, absent a court order shortening the time period.

*Reckitt Benckiser Inc. v. Watson Lab'ys, Inc.-Fla.*, No. 09-60609-CIV-WPD, 2009 WL 10667836, at *1–2 (S.D. Fla. Oct. 13, 2009).

The Federal Circuit has defined the scope of a § 271(e)(2) ANDA case. If a defendant both participates in the preparation of an ANDA *and* intends to benefit directly from that ANDA, a patent owner may be allowed to maintain a § 271(e)(2) claim against that defendant. *See In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 528-29 (Fed. Cir. 2012); *see also Novartis Pharms. Corp. v. Handa Neuroscience, LLC*, No. CV 21-645-LPS, 2022 WL 610771, at *4 (D. Del. Mar. 1, 2022) ("An entity, however, need not sign, prepare, or file an NDA to be a 'submitter.' Rather, an entity may also 'submit' an NDA if it participates in the preparation of the NDA and stands to benefit from the FDA's approval of the application.") (citations omitted); *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009) ("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."); *Helsinn Healthcare S.A. v. Hospira, Inc.*, No. CV 15-2077 (MLC), 2016 WL 1338601, at *7 (D.N.J. Apr. 5, 2016) ("ANDA filings establish a substantial connection with a forum state and the ANDA filer because they predict the filer's activities within the state, i.e., the manufacturing or marketing a generic product.").

Here, Apotex, Inc. argues that all the claims in this case are based on Aveva's ANDA and Aveva's May 10, 2022 Notice Letter. Apotex, Inc. thus contends that, although filing an ANDA for the purpose of distribution in a forum state is sufficient to establish specific personal jurisdiction, *see Acorda Therapeutics Inc. v. Mylan Pharms. Inc.,* 817 F.3d 755, 762-63 (Fed. Cir. 2016), there is no personal jurisdiction over Apotex, Inc. in this action. Apotex, Inc. contends that the allegations of the Complaint confirm that Plaintiffs received the Notice Letter from Aveva, not Apotex Inc. *See* [DE 1] at ¶ 1 ("Aveva Drug Delivery Systems, Inc. notified [Plaintiffs] that it had submitted this ANDA by a letter dated May 10, 2022 (the 'Notice Letter')."). Accordingly, Apotex, Inc. argues that Plaintiffs knew—or should have known—that Apotex Inc. is an improper and unnecessary party to this ANDA case.

Apotex, Inc. contends that Plaintiffs attempt to circumvent their purported deficiency – that Aveva, not Apotex, Inc., filed the ANDA and sent Plaintiffs the Notice Letter – by indiscriminately lumping together Aveva, Apotex Corp., and Apotex, Inc. with a mere label "Aveva Defendants" and repeatedly alleging in the Complaint that the Aveva Defendants acted in "concert." However, Apotex, Inc. argues, these allegations violate Rule 8 and are too conclusory to be entitled to an assumption of truth. In support, Apotex, Inc. cites to *In re Zantac (Ranitidine) Prod. Liab. Litig.*, No. 20-MD-2924, 2020 WL 6907056, at *5 (S.D. Fla. Nov. 24, 2020) (similar lumping of defendants determined to me insufficient to plead a *prima facie* case). Furthermore, Apotex, Inc. submits that, even if Plaintiffs were permitted to amend, they could not allege facts sufficient to establish specific personal jurisdiction over Apotex, Inc. In support, Apotex, Inc. relies on the facts contained in the Fahner Declaration that it submitted in support of its motion. *See* [DE 37-1]. The Fahner Declaration avers, in part, that: Aveva prepared and filed its ANDA -- Apotex Inc. did not; Apotex Inc. and Aveva did not act in concert to prepare or file

Aveva's ANDA; Apotex Inc. will not manufacture, use, offer for sale, sell, market, distribute or import Aveva's ANDA Product; and that Apotex Inc. will not benefit financially from the approval of Aveva's ANDA Product. ¶¶16, 17, 21, 23. The Fahner Declaration also disputes any claims that Aveva or Apotex Corp. are agents of Apotex, Inc., averring that Aveva, Apotex Corp., and Apotex Inc. have no direct corporate relationship, Aveva and Apotex Corp. are not subsidiaries of Apotex Inc., and the three companies are not operated as a single integrated business nor are they "vertically integrated" companies. ¶¶2-7. Apotex cite favorably to *Noble House, LLC v. Underwriters at Lloyd's, London*, CASE NO. 20-62080-civ-AHS, 2021 WL 896219, at *7 (S.D. Fla. Mar. 3, 2021) (finding no specific jurisdiction under an agency theory where companies "share[d] the same corporate parent, [but were] entirely distinct entities that operate[d] separately").

In response, Plaintiffs argue that the Complaint establishes a *prima facie* case for specific personal jurisdiction by asserting that Apotex Inc. submitted ANDA No. 217221 because it participated in the preparation and submission of the ANDA in Florida. The Court disagrees that the Complaint alone alleges sufficient facts to establish that Apotex, Inc. was actively involved in the preparation of the ANDA. The Complaint's allegations with regard to the preparation of the ANDA use "[u]pon information and belief" language and generically group "the Aveva Defendants," without alleging sufficient facts regarding Apotex, Inc.'s role.

However, the Court rejects Apotex, Inc.'s argument that, if Plaintiffs were permitted to amend, they could not allege facts sufficient to establish specific personal jurisdiction over Apotex, Inc. Importantly, Plaintiffs point to numerous instances in the ANDA documents, which have been produced in this litigation, which Plaintiffs contend unquestionably demonstrate that Apotex Inc. is subject to specific personal jurisdiction under § 48.193(1)(a) Fla. Stat. for causes

of action arising from "[c]ommitting a tortious act within this state[,]"as an ANDA "submitter" under § 271(e)(2). These would be sufficient at this stage of the litigation, which requires all conflicts in evidence to be resolved by reasonable inferences in favor of Plaintiffs, to show that Apotex Inc. led the development of the ANDA product and was actively involved in preparing the ANDA that was filed in Florida by, *inter alia,* developing the formulation and manufacturing process, sponsoring the clinical studies supporting the ANDA, and corresponding with the FDA regarding the ANDA product over a three-year period under the premise that Apotex, Inc. intended to submit an ANDA for a lidocaine topical patch. The evidence of significant effort and investment by Apotex Inc. in this ANDA product would also support an allegation, if pled, that Apotex, Inc. would benefit from the FDA's approval of the application.

Accordingly, the Court determines that Plaintiffs, if permitted to amend, could allege sufficient facts in their complaint to establish a *prima facie* case of specific personal jurisdiction over Apotex, Inc. For the reasons explained, *infra* in sections b and c, Counts I through III are being dismissed as to Apotex, Inc., without prejudice, with leave to replead; Counts IV- VI are being dismissed as to all Defendants, without leave to replead at the present time. Therefore, the Court will grant Apotex, Inc.'s motion to dismiss for lack of personal jurisdiction, without prejudice to Plaintiffs filing an amended complaint in accordance with this Order which sets forth sufficient factual allegations regarding specific personal jurisdiction over Apotex, Inc., as discussed above.

*b. Whether the Court should dismiss as to Apotex Inc. Counts I–III, the claims for patent infringement under 35 U.S.C. § 271(e)(2), under Rule 12(b)(6)*

Second, Apotex, Inc. seeks dismissal pursuant to Rule 12(b)(6) of Counts I–III, the claims for patent infringement under 35 U.S.C. § 271(e)(2), because Apotex, Inc. did not submit Aveva's ANDA.

1. Standard of Review

Rule 8(a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). Under Rule 12(b)(6), a motion to dismiss should be granted only if the plaintiff is unable to articulate "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (abrogating *Conley*, 355 U.S. at 41). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 556). The allegations of the claim must be taken as true and must be read to include any theory on which the plaintiff may recover. *See Linder v. Portocarrero*, 963 F. 2d 332, 334-36 (11th Cir. 1992) (citing *Robertson v. Johnston*, 376 F. 2d 43 (5th Cir. 1967)).

However, the court need not take allegations as true if they are merely "threadbare recitals of a cause of action's elements, supported by mere conclusory statements." *Iqbal*, 129 S. Ct. at 1949. In sum, "a district court weighing a motion to dismiss asks 'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Twombly*, 550 U.S. at n. 8 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *overruled on other grounds, Davis v. Scherer*, 468 U.S. 183 (1984)).

2. Analysis

Pursuant to Section 271(e)(2) states that "[i]t shall be an act of infringement to submit" an ANDA. Liability under this section attaches to an ANDA '"submitter" who participates in the preparation of the ANDA and intends to directly benefit from the ANDA. *In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 528-29 (Fed. Cir. 2012)

Apotex, Inc. argues that Plaintiffs' § 271(e)(2) claims (Counts I-III) should be dismissed under Rule 12(b)(6) as to Apotex, Inc. because the Complaint fails to allege on its face that Apotex Inc. submitted the ANDA. Apotex, Inc. contends that the only allegations referencing the preparation of the ANDA and the benefit from the ANDA are the conclusory allegations regarding the lumped "Aveva Defendants." Apotex, Inc. therefore asserts that, because "there is no specific, express allegation that [Apotex Inc.] played any role in the preparation of the ANDA," let alone an allegation that Apotex Inc. was "actively involved," Apotex Inc. should be dismissed. *See Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, No. CV 18-73-LPS, 2019 WL 581618, at *6 (D. Del. Feb. 13, 2019) ("Here, the group allegations, which are pled 'on information and belief,' are inadequate because they do not include a plausible allegation that INC will have a role in the commercial manufacture, use, or sale of Alembic's proposed ANDA Product."); *Galderma Lab'ys, L.P. v. Teva Pharms. USA, Inc*., 290 F. Supp. 3d 599, 618 (N.D. Tex. 2017) ("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®.").

The Court agrees with Apotex, Inc. that, as pled, Counts I-III fail to state a claim because Plaintiffs fail to allege sufficient facts to establish that the Defendant Apotex, Inc. was actively involved in the preparation of the ANDA and that it will benefit from the FDA's approval thereof, apart from the Complaint's lumping of the "Aveva Defendants" using "information and belief" language. Accordingly, Counts I-III shall be dismissed without prejudice, with leave to amend.

*c. Whether the Court should dismiss Counts IV-VI, the claims for declaratory judgment under § 271(a), (b), and (c), under Rules 12(b)(6) and 12(b)(1)*

Third, Apotex, Inc. seeks dismissal pursuant to Rules 12(b)(6) and 12(b)(1) of Counts IV-VI, the claims for declaratory judgment under § 271(a), (b), and (c), because Apotex, Inc. did not submit the ANDA under § 271(e)(2) and/or because there is no sufficient immediacy to the controversy on claims for future infringement dependent on future events.

1. Standard of Review[2]

Federal courts are courts of limited jurisdiction. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). A motion to dismiss for lack of subject matter jurisdiction brought pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure may present either a facial or a factual challenge to the complaint. *See McElmurray v. Consol. Gov't*, 501 F.3d 1244, 1251 (11th Cir. 2007). In a facial challenge, a court is required only to determine if the plaintiff has "sufficiently alleged a basis for subject matter jurisdiction, and the allegations in [the] complaint are taken as true for purposes of the motion." *Id.* at 1251.

2. Analysis

In deciding a motion to dismiss a claim pled pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, the court must consider "whether the facts alleged, under all circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270 (1941). Further, "the decision to entertain a declaratory judgment is discretionary." *Hackett & Assoc., Inc. v. GE Capital Info. Tech. Sols., Inc*., 744 F. Supp. 2d 1305, 1310 (S.D. Fla. 2010).

[2] The standard of review for a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) is set forth in Section, *supra* b.

Here, Apotex, Inc. argues that there is no actual controversy regarding Plaintiffs' claims in Counts IV-VI regarding future infringement under § 271(a), (b), and (c). Having carefully considered the parties' arguments as to this issue, the Court agrees with Apotex, Inc. that there is not "sufficient immediacy" to the controversy because the alleged future infringement depends on two future events: FDA approval of the ANDA and the decision to market the ANDA Product. While not all courts are in agreement as to this issue, courts routinely dismiss § 271(a), (b), and (c) claims for future infringement because there is "simply no sufficient immediacy to the controversy" and the claims appear "inconsistent with Congressional intent," as plaintiffs have an express statutory remedy designed to provide full relief. *See, e.g., United Therapeutics Corp. v. Sandoz, Inc.,* C.A. Nos. 12-CV-1617, 13-CV-316, 2014 WL 12975194, at *5 (D.N.J. Mar. 31, 2014) (finding declaratory judgment claims "speculative because the FDA has not approved the ANDA product" and because the court "may rule in [plaintiff's] favor"); *In re Rosuvastatin Calcium Pat. Litig.*, No. CIV, 07-805-JJF-LPS, 2008 WL 5046424, at *12 (D. Del. Nov. 24, 2008) (dismissing declaratory judgment claims for no sufficiently immediate controversy, permitting the § 271(a) action inconsistent with Congressional intent, and redundancy of relief); *Eisai Co. v. Mut. Pharm. Co.*, C.A. No. 06-3613 (HAA), 2007 WL 4556958, at *18 (D.N.J. Dec. 20, 2007) ("At least until the ANDA is approved, however, the controversy is not sufficiently immediate."). As one court explained in dismissing the declaratory judgment claim:

> There is not at present a controversy of "sufficient immediacy" between AstraZeneca and the Moving Defendants to permit a declaratory judgment to be awarded under § 271(a). The filing of these lawsuits triggered the automatic 30–month stay of FDA approval of each of Defendants' ANDAs. The Defendants cannot manufacture, import, market, or sell their proposed generic drug in the United States without FDA approval, but FDA approval cannot come until the earlier of the expiration of the stay or the conclusion of this litigation. Absent further order of the Court, the stay will remain in place until June 2010; trial in

> this action is not scheduled to occur until February 2010. Hence, today—in November 2008—there is simply no sufficient immediacy to the controversy AstraZeneca seeks to press in its Count II.

*In re Rosuvastatin Calcium Pat. Litig.*, No. CIV, 07-805-JJF-LPS, 2008 WL 5046424, at *12 (D. Del. Nov. 24, 2008). The Court agrees with the reasoning of these opinions and, therefore, will dismiss the declaratory judgment claims in Counts IV-VI, without prejudice.

## III. Conclusion

1. The Motion [DE 37] is **GRANTED IN PART AND DENIED IN PART**;
2. The Complaint [DE 1] is hereby **DISMISSED WITHOUT PREJUDICE** as to Apotex, Inc. with leave to amend, in accordance with this Order;
3. Counts IV-VI are **DISMISSED** as to all Defendants, without leave to amend unless and until the controversy becomes sufficiently immediate;
4. The deadline to file an Amended Complaint is **December 27, 2022**.
5. Apotex, Inc.'s Motion for Temporary Stay of Discovery with Respect to Apotex, Inc. [DE 63], which seeks a temporary stay of discovery pending the Court's ruling on Apotex, Inc.'s Motion to Dismiss[3], is **DENIED AS MOOT**.

**DONE AND ORDERED** in Chambers at Fort Lauderdale, Broward County, Florida, this 13th day of December, 2022.

WILLIAM P. DIMITROULEAS
United States District Judge

Copies furnished to:
Counsel of Record

[3] Apotex, Inc.'s Motion for Temporary Stay of Discovery with Respect to Apotex, Inc. [DE 63] was ripe for only five (5) days prior to the Court ruling on Apotex, Inc.'s Motion to Dismiss. *See* [DE's 67, 70].