IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SEATTLE CHILDREN'S HOSPITAL, ET AL.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No.: 10-CV-5118
	)	
AKORN, INC.,	)	Judge Robert M. Dow, Jr.,
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

This action relates to Defendant Akorn, Inc.'s efforts to obtain FDA approval to market a generic version of Novartis Pharmaceuticals' Tobramycin Inhalation Solution ("TOBI"). Plaintiffs Seattle Children's Hospital, Novartis Vaccines and Diagnostics, Inc., and Novartis Pharmaceuticals Corporation have moved to dismiss [36] the lawsuit that they brought for (i) lack of subject matter jurisdiction, or (ii) in the alternative, for dismissal without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(2). In turn, Defendant Akorn has moved to amend its answer to include a claim for a declaratory judgment of noninfringement. For the reasons set forth below, the Court grants Defendant's motion to amend [39] and denies Plaintiffs' motion to dismiss [36].

I. Background

A. Statutory Framework

The approval of prescription drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act of

2003 ("MMA"). The Hatch-Waxman Act requires pharmaceutical companies seeking to market new, previously unapproved drugs to file a New Drug Application ("NDA") with the FDA. 21 U.S.C. § 355(a), (b). As part of its NDA, an applicant must provide certain information to the FDA about "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA publishes the patent information in the *Approved Drug Products With Therapeutic Equivalence Evaluations*, which is commonly referred to as the "Orange Book." 21 U.S.C. § 355(j)(7)(A). Drugs approved by the FDA are known as "listed drugs." 21 U.S.C. § 355(j)(2)(A)(i).

In 1984, with the enactment of the Hatch-Waxman Act, Congress created "an expedited approval process known as an Abbreviated New Drug Application (ANDA)" in order "[t]o encourage the development of generic versions of listed drugs." *Janssen Pharmaceutica, N.V. v. Apotex, Inc*., 540 F.3d 1353, 1355-56 (Fed. Cir. 2008); see also 21 U.S.C. § 355(j). The Hatch-Waxman Act allows generic drug companies to rely on the FDA's previous approval of a listed drug if the generic drug company demonstrates in its ANDA that its generic drug product is bioequivalent to the NDA drug. 21 U.S.C. § 355(j)(2)(A). An ANDA applicant also must include a certification to each patent listed in the Orange Book covering the listed drug. 21 U.S.C. § 355(j)(2)(A)(vii). There are four types of patent certifications: (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; and (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. See 21 U.S.C. § 355(j)(2)(A)(vii); *Janssen*, 540

F.3d at 1356.

The timing of ANDA approval by the FDA depends on the types of certifications contained in the ANDA. An ANDA with a Paragraph III certification cannot be approved until the expiration of the last to expire of any patent that is the subject of that certification. 21 U.S.C. § 355(j)(5)(B)(ii). Where an ANDA contains a Paragraph IV certification, the timing of approval depends on two events: (i) whether the holder of the listed patent brings an infringement suit within 45 days of receiving notice of the ANDA filing, and (ii) whether the company seeking approval was the first to file an ANDA with a Paragraph IV certification to the listed patent. 21 U.S.C. § 355(j)(5)(B)(iii).

With respect to the first potential event, the Hatch-Waxman Act provides that the filing of a Paragraph IV certification is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A). If the patentee or NDA holder does not bring suit within 45 days of receiving notice of the Paragraph IV certification, the statute mandates that FDA "shall" approve the ANDA immediately. 21 U.S.C. § 355(j)(5)(B)(iii). If the brand name company does bring suit within 45 days, the FDA may not approve the ANDA for 30 months, unless a court decides that the patent(s)-in-suit are invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii).

With respect to the second potential event, to encourage generic pharmaceutical companies to challenge Orange Book listed patents, the Hatch-Waxman Act grants the first company to submit a Paragraph IV ANDA a 180-day period of generic marketing exclusivity during which time FDA will not approve a later-filed Paragraph IV ANDA based on the same NDA. 21 U.S.C. § 355(j)(5)(B)(iv). Under a prior version of Hatch-Waxman Act, the start of the 180-day exclusivity period was triggered by the earlier of two events: (1) the first-filer's commercial marketing of its generic drug product; or (2) a court decision of non-infringement or

invalidity.[1] *Id.* § 355(j)(5)(B)(iv)(I)-(II) (2000). However, in 2003, Congress enacted the MMA, which amended the Hatch-Waxman provisions governing the commencement of the 180-day exclusivity period. With the 2003 amendment, the exclusivity period now can be triggered only through the first filer's marketing. 21 U.S.C. § 355(j)(5)(B)(iv). Under the new regime, when a subsequent filer obtains a final judgment of invalidity or non-infringement, the first filer must begin marketing within 75 days or forfeit its exclusivity period. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

B. Factual Background

Plaintiff Novartis Pharmaceuticals Corp. ("Novartis") holds NDA No. 50-753 for its brand name Tobramycin Inhalation Solution. Novartis listed the '269 Patent in the Orange Book in connection with NDA No. 50-753. In doing so, Novartis attested to the FDA that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" described in its NDA. See 21 U.S.C. § 355(b)(1), (c)(2). Novartis also invoked the Hatch-Waxman statutory framework to regulate the ability of Abbreviated New Drug Application ("ANDA") applicants to market their generic products. As previously set forth, this statutory framework provides for the creation of several "barriers" to the regulatory approval of such ANDAs.

The second barrier, particularly relevant here, applies only to ANDA filers that are not the first to make a Paragraph IV certification ("subsequent filers") because the Hatch-Waxman

[1] A court decision of non-infringement or invalidity can come in any court action, including one involving a subsequent Paragraph IV ANDA applicant. Consequently, "subsequent Paragraph IV ANDA filers have a strong incentive to generate a triggering event allowing the FDA to approve their subsequent Paragraph IV ANDAs 181 days after the triggering event," while "NDA holders have a strong incentive to prevent a triggering event, because subsequent Paragraph IV ANDAs cannot be approved until the exclusivity period [is triggered and] expires." *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1284 (Fed. Cir. 2008).

Act grants to the first Paragraph IV ANDA filer a 180-day marketing exclusivity period over subsequent filers. Under the statutory framework, the FDA cannot approve the subsequent filer's ANDA until the first filer's 180-day exclusivity period terminates. See *Caraco Pharm. Labs. Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283-84 (Fed. Cir. 2009). "Importantly, the first Paragraph IV ANDA filer is entitled to the 180-day exclusivity period whether or not it establishes that the NDA holder's Orange-Book-listed patents are invalid or not infringed by the drug described in its ANDA; all that is required is that the first Paragraph IV ANDA filer submit a substantially complete ANDA that contains a Paragraph IV certification." *Id.* at 1283.

Here, non-party Teva Pharmaceuticals USA, Inc. ("Teva") is the first filer with respect to Novartis's NDA; Akorn is a subsequent filer.[2] Thus, pursuant to statute, the FDA may not approve Akorn's ANDA until Teva's exclusivity period is removed as a barrier. To date, Teva's exclusivity period has not begun and has not been forfeited. On June 27, 2011, Plaintiffs gave Akorn a covenant not to sue with respect to infringement of the '269 patent by the proposed generic product described in Akorn's abbreviated new drug application ("ANDA"). Plaintiffs submit that the Court no longer has subject matter jurisdiction because such a covenant not to sue moots the entire controversy between the parties in a patent infringement action and therefore the Court should dismiss this action, without prejudice. In the alternative, Plaintiffs request that the Court dismiss this action without prejudice pursuant to Fed. R. Civ. P. 41(a)(2), given the early stage of these proceedings and the alleged lack of prejudice to Akorn. In response, Akorn contends that the only way for it to remove Teva's exclusivity period as a barrier to the approval of Akorn's ANDA, whether through expiration or forfeiture, is to obtain a final judgment that the '269 Patent is invalid or not infringed, thus triggering Teva's 75-day marketing exclusivity

[2] According to Akorn, it notified Plaintiffs of its ANDA on July 1, 2010. Teva notified Plaintiffs of its first-filed ANDA on October 27, 2009. No final judgment has been entered in the still pending lawsuit that ensued between Teva and Plaintiffs based on Teva's ANDA.

period. According to Akorn, if the Court grants Plaintiffs' motion, Akorn will be deprived indefinitely of the legal right to enter the market.

II. Analysis

A. Plaintiffs' Motion to Dismiss for Lack of Subject Matter Jurisdiction

"It is axiomatic that a federal court must assure itself that it possesses jurisdiction over the subject matter of an action before it can proceed to take any action respecting the merits of the action." *Scott Air Force Base Properties, LLC v. County of St. Clair, Ill.*, 548 F.3d 516, 520 (7th Cir. 2008) (citation omitted); see also *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83 (1998) (rejecting the proposition that a court may proceed to the merits question before resolving whether it has Article III jurisdiction); *Cook v. Winfrey,* 141 F.3d 322, 325 (7th Cir. 1998) (holding that the district court erred by dismissing case pursuant to Rule 12(b)(6) without reaching the jurisdictional challenge asserted under Rule 12(b)(1)); *Crawford v. United States*, 796 F.2d 924, 929 (7th Cir. 1986) ("once the district judge has reason to believe that there is a serious jurisdictional issue, he is obliged to resolve it before proceeding to the merits even if the defendant, whether as a matter of indolence or strategy, does not press the issue"). Therefore, the Court begins by addressing Plaintiffs' jurisdictional challenge.

As pointed out by Plaintiffs, a federal court only has subject matter jurisdiction where there is an "actual case or controversy" between the parties. *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477-78 (1990); *N. Carolina v. Rice*, 404 U.S. 244, 246 (1971) ("To be cognizable in a federal court, a suit * * * must be a real and substantial controversy" (internal quotations omitted)). When, in the course of an action, it appears that there is no longer an actual case or controversy because "a party's legally cognizable interest in the litigation ceases to exist," the "case becomes moot" and "must be dismissed for lack of jurisdiction." *Evers v. Astrue*, 536 F.3d

651, 662 (7th Cir. 2008) ("Mootness is a threshold jurisdictional question that insures that the court is faithful to the case or controversy limitation in Article III of the Constitution.") (citations omitted); see also *N. Carolina*, 404 U.S. at 246 ("Mootness is a jurisdictional question because [a federal court] 'is not empowered to decide moot questions or abstract propositions'"); *Holstein v. City of Chicago* 29 F.3d 1145, 1147 (7th Cir. 1994) (a case that becomes moot "must be dismissed for lack of subject matter jurisdiction"). In determining whether an action has become moot—and thus whether the court no longer has subject matter jurisdiction—a court is not limited to the pleadings and may look to "whatever evidence has been submitted on the issue." *St. John's United Church of Christ v. City of Chicago*, 502 F.3d 616, 625 (7th Cir. 2007). A dismissal for lack of subject matter jurisdiction is without prejudice. *Murray v. Conseco, Inc.*, 467 F.3d 602, 605 (7th Cir. 2006) ("A court that lacks subject matter jurisdiction cannot dismiss a case with prejudice.").

Congress has extended federal court jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201, to ANDA Paragraph IV disputes (21 U.S.C. § 355(j)(5)(C)), and has directed federal courts to exercise jurisdiction over such actions "to the extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)). See *Janssen*, 540 F.3d at 1359. The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction * * * any court of the United States * * * may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The phrase "case of actual controversy," as it appears in the Declaratory Judgment Act, "refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

In *MedImmune*, the Supreme Court explained that, in determining whether a justiciable

declaratory judgment action exists, "the question * * * is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 771 (citation omitted). "In applying the all-the-circumstances test * * *, [courts are] guided by the Supreme Court's three-part framework for determining whether an action presents a justiciable Article III controversy." *Caraco*, 527 F.3d at 1291. Pursuant to that framework, an action is justiciable under Article III where (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case has not been rendered moot. *Id.* (citations omitted).

At issue here is whether Akorn has alleged a controversy of sufficient "immediacy and reality" so as to be justiciable under Article III. The immediacy inquiry can be viewed either through the lens of standing (*i.e.*, whether plaintiff alleges an actual or imminent injury caused by the defendant that can be redressed by judicial relief) or through one of the prongs of the ripeness doctrine (*i.e.*, whether withholding court consideration would cause hardship to the parties). See *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 n.6 (Fed. Cir. 2008); *MedImmune*, 549 U.S. at 127. In either case, "the underlying inquiry [is] rooted in the requirement that Article III courts cannot issue advisory opinions." *Prasco*, 537 F.3d at 1338 n.6. Plaintiffs contend that they have granted Akorn a properly executed covenant not to sue, which eliminates any possibility that Akorn may be subject to a claim that it has infringed the '269 patent based on its ANDA and its generic version of TOBI. Plaintiffs maintain that the covenant moots the controversy between Plaintiffs and Akorn, and, as a result, the Court no longer has subject matter jurisdiction over the action.

Akorn admits that the covenant not to sue "resolves the infringement issue," but maintains that it does not resolve the "regulatory issue"—Akorn's efforts to obtain FDA

approval to market a generic version of Novartis' TOBI. Under the framework discussed above, because Akorn is not the first filer in connection with Plaintiffs' NDA, the FDA cannot grant to Akorn the desired approval until Teva's 180-day exclusivity period is exhausted or forfeited. And, also pursuant to the framework, the only way for Akorn to bring about the exhaustion or forfeiture is through a final judgment in Akorn's favor. Akorn's hope is to obtain a decision from this Court that the '269 patent is invalid or is not infringed by Akorn's product, thereby triggering Teva's exclusivity period. Absent such a court ruling (either in this case or other litigation), Akorn will not be able to market its generic drug until 180 days after Teva begins marketing its drug.

The Federal Circuit has recognized, in the context of the Hatch-Waxman Act, that the creation of "an independent barrier to the drug market" by a brand drug company "that deprives [the generic company] of an economic opportunity to compete" satisfies the injury-in-fact and causation requirements of Article III standing. *Caraco*, 527 F.3d at 1285; see also *Prasco*, 537 F.3d at 1339 (holding that a patentee creates an immediate injury or threat of future injury by "creating a barrier to the regulatory approval of a product that is necessary for marketing"). Two Federal Circuit decisions, *Caraco* and *Janssen*, are particularly instructive for determining whether an Article III controversy exists in a declaratory judgment action arising under the Hatch-Waxman Act. *Caraco* holds that the exclusion of non-infringing generic drugs from the market can be a judicially cognizable injury-in-fact. 527 F.3d at 1291-92. Because a company is not free to manufacture or market drugs until it receives FDA approval, under the Hatch-Waxman framework such an injury occurs when the holder of an approved NDA takes action that delays FDA approval of subsequent ANDAs. *Novartis*, 482 F.3d at 1345. In the cases of *Caraco* and *Janssen*, the alleged action taken (giving rise to the injury-in-fact) was the listing of

particular patents in the Orange Book. *Caraco,* 527 F.3d at 1292; *Janssen,* 540 F.3d at 1359-60. The generic drug company's injury (*i.e.*, exclusion from the market) is fairly traceable to the NDA-holder's actions because "but-for" the decision to list a patent in the Orange Book, FDA approval of the generic drug company's ANDA would not have been independently delayed by that patent. 527 F.3d at 1292. When an Orange Book listing creates an "independent barrier" to entering the marketplace that cannot be overcome without a court judgment that the listed patent is invalid or not infringed—as is the case for Paragraph IV filers—the company manufacturing the generic drug has been deprived of an economic opportunity to compete. *Id.* at 1293. A declaratory judgment redresses this alleged injury because it eliminates the potential for the corresponding listed patent to exclude the generic drug from the market. *Caraco,* 527 F.3d at 1293 (holding that a declaratory judgment action as to one of the listed patents would "clear the path to FDA approval that [the NDA holder's] actions would otherwise deny [the generic pharmaceutical]").

Though its facts were slightly different, *Janssen* reaffirms *Caraco's* holding that the injury-in-fact must stem from the actions of the company that listed the patents in the Orange Book, not the inherent framework of the Hatch-Waxman Act. See *Janssen* 540 F.3d at 1360-61. In *Janssen,* a subsequent Paragraph IV filer sought to trigger the first-filer's exclusivity period by obtaining a declaratory judgment. However, while the declaratory judgment action was pending, this subsequent filer stipulated to the validity, infringement, and enforceability of another patent listed in the Orange Book for the same drug. *Id.* As a result of the stipulation, even if the subsequent filer had prevailed in its declaratory judgment action, it could not have launched its generic drug before expiration of the patent covered by the stipulation. Accordingly, unlike in *Caraco,* there was no risk that invalid patents were keeping the

subsequent filer's generic drugs off the market; because of the stipulation, the company could not have marketed its generic drug in any event. *Id.* at 1361. In other words, the subsequent filer's alleged harm—inability to enter the market—was not "fairly traceable" to the listing of the subject patents in the Orange Book. Rather, the stipulation was the cause of the plaintiff's injury.

Plaintiffs argue that in order for there to be a case or controversy, the court judgment that Akorn seeks must directly result in FDA approval of Akorn's ANDA, and that would not necessarily occur here. Plaintiffs are correct that there is always the potential for the first filer to begin commercialization, thereby allowing subsequent filers to gain approval 181 days later and enter the market irrespective of any court judgment. Yet the court in *Caraco* determined that there was a case or controversy because a judgment of noninfringement or invalidity "would eliminate the *potential* for the [listed patent] to exclude Caraco from the drug market." *Caraco*, 527 F.3d at 1293 (emphasis added). A judgment of non-infringement or invalidity in this case likewise would eliminate the potential for the Orange Book-listed '269 Patent to exclude Akorn from the tobramycin inhalation solutions market. See also *Pfizer*, 726 F. Supp. 2d at 930 (quoting *Davis v. Federal Election Com'n*, 554 U.S. 724 (2008)) (noting that a party facing prospective injury has standing to sue where the threatened injury is "real, immediate, and direct."). The fact that a judgment in this litigation will not necessarily or directly result in the approval of Akorn's ANDA does not preclude jurisdiction.

The Court holds that this case presents an actual controversy. Here, as in *Caraco*, a favorable judgment "would eliminate the potential for the ['269 patent] to exclude [Akorn] from the drug market." 527 F.3d at 1293. Unlike the generic drug company in *Janssen*, Akorn has not stipulated to the validity, infringement, or enforceability of any other patent listed in the

Orange Book for TOBI. 540 F.3d at 1360. Given the absence of this factor, *Caraco* controls and Akorn has alleged a potentially cognizable injury.[3]

In their reply brief, Plaintiffs argue that *Caraco* is not controlling because it was decided under the pre-2003 version of the Hatch-Waxman Act and not under the current version.[4] However, *Caraco* specifically addressed the concept that a generic applicant be permitted to seek prompt resolution of these patent issues under the original and amended versions of the Act:

> The discussion [of Congressional intent] here refers to the [amended] provision of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(D*)*, under which the first Paragraph IV ANDA filer can forfeit its 180-day exclusivity period by failing to market its generic drug. Section 355(j)(5)(D) replaced the 180-day exclusivity period triggering provisions that are applicable to this case, *i.e.* 21 U.S.C. § 355(j)(5)(B)(iv) (2000), including the court-judgment trigger * * * Although the legislative discussion here refers to the amended 180-day provisions, *this distinction is inconsequential because under both the original and amended 180-day provisions, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed*. Thus, Senator Kennedy's

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[3] Although vacated for other reasons, the Federal Circuit's language in *Teva Pharms. Usa, Inc. v. Eisa Co., Ltd.* also supports this result. 620 F.3d 1341, 1346-47 (Fed. Cir. 2010) ("Because a company is not free to manufacture or market drugs until it receives FDA approval, under the Hatch-Waxman framework such an injury occurs when the holder of an approved NDA takes action that delays FDA approval of subsequent ANDAs") (reversing dismissal of lawsuit by district court). Although the *Teva* decision was recently vacated by the Supreme Court and remanded to the Federal Circuit with instructions to dismiss the case as moot, the case had become moot not because of a covenant not to sue but because non-party Ranbaxy, the first filer, began marketing its generic drug, thus triggering its 180 day exclusivity period. See *Teva Pharms. Usa, Inc. v. Eisa Co., Ltd.*, 131 S. Ct. 2991 (June 13, 2011) (citing *United States v. Munsingwear, Inc*., 340 U.S. 36 (1950)). In *Teva*, the Federal Circuit reiterated that, under the Hatch-Waxman framework, "a judicially cognizable injury-in-fact * * * occurs when the holder of an approved NDA takes action [i.e., 'listing particular patents in the Orange Book'] that delays FDA approval of subsequent ANDAs." *Teva*, 620 F.3d at 1346-47. The Federal Circuit's decision "turn[ed] on whether a subsequent Paragraph IV filer has a legally cognizable interest in when the first-filer's exclusivity period begins, such that delay in triggering [or forfeiting under the current regime] that period qualifies as 'injury-in-fact' for the purposes of Article III," which the court when on to state a subsequent filer does have pursuant to *Caraco*. See *Teva*, 620 F.3d at 1343 (citing *Caraco*, 527 F.3d 1278).

[4] In their initial brief, Plaintiffs argue that *Caraco* was not controlling for a different reason—namely, that it involved a declaratory judgment and in this case, until Akorn moved to amend its answer to include a claim for declaratory judgment of noninfringement, the infringement claim was brought only affirmatively by Plaintiffs. Plaintiffs now concede that "[t]he same jurisdictional requirement of an 'actual case or controversy' is applicable regardless of whether a patent infringement claim is brought affirmatively by a patentee, or as a declaratory judgment counterclaim."

> remarks concerning the brand name drug company's incentive to delay such court decisions are equally applicable to this case.

Caraco, 527 F.3d at 1285, n.4 (emphasis added). Furthermore, a comparison of the original and amended 180-day provisions demonstrates why a subsequent filer's ability to "seek prompt resolution of these patent issues" remains unchanged. Under both versions of the Act, a 180-day period of exclusivity is available to whomever files the first substantially complete Paragraph IV ANDA ("first filer"). See 21 U.S.C. § 355(j)(5)(B)(iv) (2000); 21 U.S.C. § 355(j)(5)(B)(iv). Under both versions of the Act, this exclusivity period is against subsequent ANDA filers and operates by prohibiting the FDA from approving a subsequent filer's ANDA before or during that exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv) (2000); 21 U.S.C. § 355(j)(5)(B)(iv)(I). Pre-2003, the exclusivity period could only be removed as a barrier to approval of a subsequent ANDA through expiration 180 days after being triggered. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). It could be triggered either through commercialization by the first filer or through a court judgment of invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(B)(iv)(I) and (II) (2000). Post-2003, the exclusivity period can now be removed as a barrier to approval of a subsequent ANDA through expiration as well as forfeiture. 21 U.S.C. § 355(j)(5)(B)(iv) and § 355(j)(5)(D). Post-2003, the exclusivity period is no longer triggered by a court judgment of invalidity or non-infringement; it can only be triggered by a first filer's commercialization. 21 U.S.C. § 355(j)(5)(B)(iv)(I). However, a court judgment remains critical to a subsequent filer such as Akorn because it can now result in forfeiture of the exclusivity period. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). If the first filer does not market within 75 days of such a judgment (and either 75 days has passed since the first filer received approval or 30 months has passed since the first filer applied for approval), then the exclusivity period is forfeited. *Id*. If the first filer does market within 75 days, then the exclusivity period is saved from forfeiture but becomes triggered. *Id*. Thus, a court judgment of

invalidity or non-infringement will cause the exclusivity period to be forfeited 75 days later or expire within 255 days later. Either way, the exclusivity period's days as an obstacle to the approval of subsequent ANDAs become numbered once such a judgment is obtained. Under both versions of the Act, a court judgment of invalidity or non-infringement is the only manner through which a subsequent filer can hasten approval of its Paragraph IV ANDA. All of the other mechanisms are controlled by the first filer or the patentee NDA holder. See 21 U.S.C. § 355(j)(5)(D).

Plaintiffs argue that there is no injury to Akorn and no controversy between Akorn and Plaintiffs over the '269 patent even if Akorn prevailed against Plaintiffs tomorrow, because Akorn has yet to receive "tentative approval" of its ANDA and there is no telling if or when the FDA may approve Akorn's ANDA.[5] In other words, Plaintiffs argue that Akorn's absence of tentative approval from the FDA, not their conduct, precludes jurisdiction. However, this argument appears to conflict with certain rationales behind the 2003 amendments to the Hatch-Waxman Act. The 2003 amendments created a civil action to obtain patent certainty ("CAPC") that could be brought by an ANDA applicant at a time when it likely would not have tentative approval. An ANDA applicant may bring a CAPC when it notifies an NDA holder of its Paragraph IV ANDA and 45 days pass without the NDA holder suing. 21 U.S.C. § 355(j)(5)(C)(i)(II); *Caraco*, 527 F.3d at 1285. The intent of the CAPC was stated as follows:

[5] The FDA grants "tentative" approval when an ANDA meets all of the technical, safety and efficacy requirements for approval, 21 C.F.R § 314.105(d), but must await expiration of an exclusivity granted to another party. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.107(b)(3)(v). According to the FDA's website, "If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product."

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market. In * * * these * * * circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period. *We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes.* The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

Caraco, 527 F.3d at 1285 (quoting 149 Cong. Rec. S15885) (brackets, ellipses, and emphasis in original).

Here, Plaintiffs sued Akorn within the 45-day period. If Plaintiffs had not sued Akorn within 45 days, Akorn could have brought a CAPC against Plaintiffs. 21 U.S.C. § 355(j)(5)(C)(i)(II); 35 U.S.C. § 271 (e)(5). Notably, such a CAPC would have been authorized by statute even though Akorn had not received tentative approval for its ANDA at that time and even if Plaintiffs had not threatened suit. The case law and the expression of congressional intent recognized above, as well as the realities and time commitments associated with complex litigation, support Akorn's attempt to pursue tentative approval of its ANDA with the FDA while simultaneously seeking "a favorable judgment in this action [to] eliminate the potential for the [listed] patent to exclude [Akorn] from the drug market." See *Caraco*, 527 F.3d at 1293; see also *Pfizer*, 726 F. Supp. 2d at 930 (denying motion to dismiss even though applicant's ANDA had not yet been approved and its Paragraph III certification independently precluded approval at the time it filed its claims).

Notwithstanding Plaintiffs' unilateral covenant not to sue, the case or controversy between the parties here endures because of the continued listing of the '269 Patent in the FDA's Orange Book in connection with NDA No. 50-753 for Novartis' TOBI drug product, which bears

on Akorn's efforts to obtain FDA approval to market a generic version of Novartis' TOBI. In these circumstances, guidance from the Federal Circuit, admittedly decided under the pre-2003 version of the Hatch-Waxman Act, suggests that Akorn may pursue a court judgment in order to advance the regulatory issues surrounding Akorn's efforts to obtain FDA approval to market a generic version of Novartis' TOBI in light of Akorn's status as a subsequent filer.

B. Voluntary Dismissal

Plaintiffs alternatively ask the Court to dismiss this case without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(2). Rule 41(a)(2) permits a court to exercise its discretion to dismiss an action at the request of the plaintiff. A dismissal under Rule 41(a)(2) is "without prejudice" unless the court specifically directs otherwise. Whether to dismiss an action pursuant to Rule 41(a)(2) is committed to the court's discretion. *Kunz v. DeFelice*, 538 F.3d 667, 677-678 (7th Cir. 2008). In considering whether dismissal should be granted, courts in the Seventh Circuit look at four non-dispositive factors as guidelines for exercising their discretion: "(1) the defendant's effort and expense in preparing for trial; (2) excessive delay and lack of diligence on the plaintiff's part in prosecuting the action; (3) insufficient explanation for the need to take a dismissal; and (4) the defendant's filing of a motion for summary judgment." *Heartland Rec. Vehicles, LLC v. Forest River, Inc.*, 2010 WL 497327, at *9 (N.D. Ind. Feb. 4, 2010) (citing *Tyco Labs., Inc. v. Koppers Co.*, 627 F.2d 54, 56 (7th Cir. 1980)).

In the present case, the factors cited by Plaintiffs do not favor dismissal. The first factor, "the defendant's effort and expense in preparing for trial," weighs against dismissal because Akorn has already sustained significant effort and expense in that Akorn has already prepared, filed, and served a dispositive motion in this case. The parties also have extensively briefed the instant motions. The second factor also weighs against dismissal. At a minimum, the grant of a

unilateral covenant not to sue, in light of cases such as *Caraco* and *Janssen*, brings Plaintiffs' motives into question. See *Caraco*, 527 F.3d at 1284 (noting that "NDA holders have a strong incentive to prevent a triggering event, because subsequent Paragraph IV ANDAs cannot be approved until the exclusivity period [is triggered and] expires."). The third factor, "insufficient explanation for the need to take a dismissal," weighs against dismissal because Plaintiffs have not offered any such explanation beyond their argument that the covenant divests the Court of jurisdiction, an argument which has been rejected. The fourth factor, "the defendant's filing of a motion for summary judgment," weighs against dismissal as Akorn has in fact filed such a motion. For all of these reasons, the Court declines to exercise its discretion to dismiss this action pursuant to Rule 41(a)(2).

C. Defendant's Motion for Leave to Amend Answer

Because the Court finds that an actual case or controversy exists, the Court grants Akorn leave to file an amended answer to assert a claim for declaratory judgment of noninfringement.

III. Conclusion

For these reasons, the Court grants Defendant's motion to amend its answer to include a claim for a declaratory judgment of noninfringement [39] and denies Plaintiffs' motion to dismiss [36].

Dated: December 20, 2011

Robert M. Dow, Jr.
United States District Judge