UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

APOTEX INC.,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Cause No. 1:16-cv-3145-WTL-MJD**
	)	
ALCON RESEARCH, LTD., et al.,	)	
	)	
Defendants.	)	
	)	
BARR LABORATORIES, INC.,	)	
	)	
Intervenor-Defendant.	)	

ENTRY ON MOTION TO DISMISS

This cause is before the Court on the motion of Intervenor-Defendant Barr Laboratories, Inc., ("Barr") seeking to dismiss this case for lack of subject matter jurisdiction (Dkt. No. 38). The motion is fully briefed, and the Court, being duly advised, **GRANTS** the motion for the reasons set forth below.

I. BACKGROUND

This case arises out of the desire of Plaintiff Apotex, Inc., ("Apotex") to market a generic version of the drug olopatadine, which is currently marketed by the Defendants (collectively referred to herein as "Alcon") under the name Pataday. The parties agree on the following relevant background facts:

> Alcon holds the approved NDA for Pataday® (olopatadine). It has listed two patents in the Orange Book: U.S. Patent No. 6,995,186 (the "'186 patent"), scheduled to expire on May 12, 2024, and U.S. Patent No. 7,402,609 (the "'609 patent"), scheduled to expire on December 19, 2022.
>
> On September 8, 2008, Barr filed the first ANDA to make a generic version of Pataday®. Its ANDA contained a Paragraph IV certification to the '186 and '609 patents. As the first ANDA filer, Barr earned 180-day generic drug exclusivity.

> Barr's ANDA received final approval from the FDA on July 15, 2015. Apotex is a subsequent ANDA filer, meaning it filed its ANDA after Barr filed its ANDA.
>
> Apotex's olopatadine ANDA has received "tentative approval" from the FDA, but the FDA may not approve Apotex's ANDA until Barr's 180-day exclusivity period expires.
>
> In 2009, Alcon sued Barr in this [district], alleging that the generic olopatadine product described in Barr's ANDA would infringe the '186 and '609 patents. *Alcon Research Ltd. v. Barr Labs., Inc.*, No. 1:09-cv-00026-RLY-TAB (S.D. Ind.). After more than four years of litigation, Alcon and Barr settled the case. The court entered a Stipulation of Dismissal on May 9, 2013.
>
> Alcon also sued Apotex in 2009, again in this [district]. *Alcon Research Ltd. v. Apotex Inc.*, No. 1:09-cv-00102-RLY-TAB (S.D. Ind.) (the "Apotex Patent Action"). As in the Barr lawsuit, Alcon alleged that the generic olopatadine product described in Apotex's ANDA would infringe the '186 and '609 patents.

Dkt. No. 39 at 12-13 (citations omitted) (quoted in Dkt. No. 40 at 2-3).

In July 2013, after four years of litigation, Alcon and Apotex settled the Apotex Patent Action and it was dismissed without prejudice. The settlement agreement provided Apotex a license to the '186 and '609 patents. However, despite the license, Apotex could not—and still cannot—launch its generic product because of Barr's right to a 180-day exclusivity period. Pursuant to the Hatch-Waxman Act, the 180-day period will not be triggered until Barr begins marketing its generic product. However, Barr will forfeit its exclusivity period if it fails to begin marketing its generic product within 75 days of:

> **(AA)** In an infringement action brought against [Apotex] with respect to the patent[s] or in a declaratory judgment action brought by [Apotex] with respect to the patent[s], a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
>
> [or]
>
> **(BB)** In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

21 U.S.C.A. § 355(j)(5)(D)(i)(I)(bb). With this provision in mind, the settlement agreement between Apotex and Alcon provided that if Barr failed to launch its generic olopatadine product by July 1, 2016, Apotex had the right to file a declaratory judgment action seeking a declaration that, effective December 29, 2016, Apotex's ANDA Product would not infringe the patents because it would be, as of that date, a licensed product; that Alcon would not oppose the entry of a final judgment to that effect; and that Alcon waived its right to appeal any such judgment.[1] It is that declaratory judgment action that now pends before the Court.

Shortly after filing this lawsuit, the parties filed an Agreed Motion for Court Approval of Consent Judgment Pursuant to Stipulation in which they asked the Court to enter a consent judgment containing the following declarations:

> A. Beginning December 29, 2016, the Patents-In-Suit, namely United States Patent Nos. 6,995,186 and 7,402,609, will not be infringed by Apotex's generic 0.2% olopatadine hydrochloride ophthalmic solution product, as described in Abbreviated New Drug Application No. 90-918, because Apotex's product is licensed as of that date;
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> B. The manufacture, marketing, use, offer for sale, sale and/or importation of the products that are the subject of Apotex's ANDA 90-918 would not, if marketed on or after December 29, 2016, infringe or induce or contribute to the infringement by others of any claims of the Patents-In-Suit; and
>
> C. Defendants Alcon Research, Ltd., Alcon Laboratories, Inc., and Alcon Pharmaceuticals Ltd. (collectively, "Alcon") have waived their right to appeal regarding this matter, thus this order approving the Parties' Consent Judgment is a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) can be taken by Alcon.

Dkt. No. 10-1. Barr then filed a motion to intervene as a party defendant for the purpose of challenging this Court's subject matter jurisdiction over this suit; specifically, whether the case

[1]The Court assumes for purposes of this ruling that the judgment sought in this case would constitute "a final judgment that includes a finding that the patent is invalid or not infringed" pursuant to 21 U.S.C.A. § 355(j)(5)(D)(i)(I)(bb)(BB).

or controversy requirement of Article III is satisfied. Neither Alcon nor Apotex objected to Barr's motion to intervene, and the parties agreed to an expedited briefing schedule for Barr's motion to dismiss. That motion is now ripe for resolution.

II. DISCUSSION

Although Apotex does not cite it in its Amended Complaint, this case is brought pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201(a), which provides: "In 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." The phrase "case of actual controversy . . . 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 reaffirmed the proper standard for determining whether a declaratory judgment action satisfies the Article III case or controversy requirement. Specifically, the Court framed the justiciability inquiry as 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. In addition, the Supreme Court emphasized that Article III requires that the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1290 (Fed. Cir. 2008) (internal citations and quotation marks omitted).

On its face, this case appears to be a paradigmatic example of a case that does not satisfy the case or controversy requirement. It was filed by two parties who do not have "adverse legal interests" and between whom there is no dispute. The parties are not even seeking an advisory opinion; they are simply asking the Court to declare facts that they agree to be true and about

which there can be no dispute—that Alcon has granted Apotex a license to market its generic olopatadine product and that, as a matter of law, a licensed product does not infringe the patents that are the subject of the license. Because that declaration will not resolve any dispute between Apotex and Alcon, and that declaration is the only thing sought in this suit, it appears on the face of the complaint that there is no case or controversy. Indeed, even if Barr had not intervened in this matter, the Court would have been compelled to raise the question of subject matter jurisdiction *sua sponte*. *See DeBartolo v. Healthsouth Corp.*, 569 F.3d 736, 740 (7th Cir. 2009) ("Subject-matter jurisdiction is not an issue that can be brushed aside or satisfied by agreement between the litigants.") (citing *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 514 (2006); *United States v. Tittjung*, 235 F.3d 330, 335 (7th Cir. 2000)).

Apotex advances several reasons why it believes the Court has jurisdiction over this case. First, it argues that it is simply asking the Court to enter a consent judgment agreed upon as part of the settlement of a case—that case being the Apotex Patent Action. While they acknowledge that settlement typically moots a case, they argue that they are entitled to the relief they now seek because "even after settlement 'jurisdiction remains with the district court to enter a consent judgment.'" Dkt. No. 40 at 5 (quoting *Gould v. Control Laser Corp.*, 866 F.2d 1391, 1392 (Fed. Cir. 1989)). That is, of course, true, but it presupposes that the requested consent judgment is for the purposes of resolving an actual dispute by changing the legal relationship between the parties. Indeed, the case cited in *Gould* for that proposition demonstrates that fact:

> The defendants concede that there was a case at the time when the government filed its petition and the defendants their answers; but they insist that the controversy had ceased before the decree was entered. The argument is that, as the government made no proof of facts to overcome the denials of the answers, and stipulated both that there need be no findings of fact and that the decree should not constitute or be considered an adjudication of guilt, it thereby abandoned all charges that the defendants had violated the law; and hence the decree was a nullity. The argument ignores the fact that a suit for an injunction deals primarily, not with past violations,

> but with threatened future ones; and that an injunction may issue to prevent future wrong, although no right has yet been violated.

Swift & Co. v. United States, 276 U.S. 311, 326 (1928). In fact, the majority in *Gould* distinguished that situation from the cases cited by the dissent in which "there was no case or controversy, and no jurisdiction, from the outset" and therefore no jurisdiction to enter judgment. *Gould*, 866 F.2d at 1393 n.4.

So, too, is *S.E.C. v. Randolph*, 736 F.2d 525, 528 (9th Cir. 1984), also cited by Apotex, distinguishable from this case; while it involved a consent decree that was negotiated before suit was filed, the decree, like the one in *Swift*, imposed permanent injunctions against the defendants. In addition, in that case the court noted that the negotiated settlement was contingent on the court entering the proposed decree; "without court approval, the parties might claim the right to withdraw their consent to the agreement." *Id.* In other words, under the terms of the settlement agreement in that case, the dispute between the parties remained unless and until the consent decree was approved by the court. There is no such contingency in this case; the settlement agreement makes that clear on its face. The judgment sought in this case is not sought for the purpose of resolving a dispute; the dispute already has been resolved, and nothing that happens in this case will change the legal obligations of the parties to one another.

Apotex next argues:

> Relatedly, the Southern District of Indiana has jurisdiction to enforce and otherwise interpret the Settlement Agreement because the parties agreed that the federal and state courts of Indiana shall have exclusive jurisdiction in all matters arising under the Agreement [Settlement Agreement, Provision 6.5], and the infringement suit has not been dismissed with prejudice. *See Lynch, Inc. v. SamataMason Inc.*, 279 F.3d 487, 489 (7th Cir. 2002) ("[a] settlement agreement, unless it is embodied in a consent decree or some other judicial order or unless jurisdiction to enforce the agreement is retained (meaning that the suit has not been dismissed with prejudice), is enforced just like any other contract" (emphasis added)).

> The Court need look no further than these simple principles. The Court has subject-matter jurisdiction over the Apotex-Alcon dispute; that dispute resulted in a settlement over which the Court retained jurisdiction; and that settlement permits entry of an agreed judgment.

Dkt. No. 40 at 7.

There are several fundamental problems with this argument. First, this is not the case in which the settlement agreement was reached; if the judge in the Apotex Patent Action had retained jurisdiction to enforce the settlement agreement, any such "enforcing" would occur in that case, not a newly filed case. Second, retaining jurisdiction to enforce a settlement agreement means retaining jurisdiction to resolve disputes over the settlement agreement, but there is no such dispute present here. Third, and most fundamentally, the judge in the Apotex Patent Action did not retain jurisdiction to enforce the settlement agreement.

Apotex misreads the language it quotes from *Lynch, Inc.*, as meaning that *as long as* a case is not dismissed with prejudice when it is settled, the court automatically retains jurisdiction to enforce the settlement. That is incorrect.

> The district judge's "approval" of a settlement, unless that approval is embodied in a judicial order retaining jurisdiction of the case in order to be able to enforce the settlement without a new lawsuit, has no legal significance. There must be a deliberate retention of jurisdiction. An unconditional dismissal terminates federal jurisdiction.

Jessup v. Luther, 277 F.3d 926, 929 (7th Cir. 2002) (citations and internal quotation marks omitted). There was no "deliberate retention of jurisdiction" by the judge in the original Alcon-Apotex case. Rather, the parties filed an unconditional stipulation of dismissal without prejudice that mentioned nothing about retention of jurisdiction. In fact, the stipulation of dismissal does not refer to the settlement agreement at all. The court then entered an "Order of Dismissal" that "granted" the parties' stipulation of dismissal and (mistakenly) dismissed the case with prejudice. Upon the parties' motion, the court corrected the order of dismissal to be without

prejudice. Apotex's suggestion that, because the dismissal was without prejudice, it could continue to seek relief, such as the entry of an agreed judgment, in that case is mistaken. To the contrary, "[a] suit that is voluntarily dismissed under Rule 41(a) generally is treated as if it had never been filed" and therefore "the plaintiff may bring the suit again by filing a new complaint." *Nelson v. Napolitano*, 657 F.3d 586, 587-88 (7th Cir. 2011); *see also Richmond v. Chater*, 94 F.3d 263, 267 (7th Cir. 1996) (filing a new complaint and paying a new filing fee is generally required following dismissal without prejudice); *Adams v. Lever Bros. Co.*, 874 F.2d 393, 395-96 (7th Cir. 1989) (refiling a complaint after a Rule 41(a)(1) dismissal requires a new docket fee and compliance with the statute of limitations).

For the reasons discussed above, the fact that there was once a dispute between the parties is not sufficient to show that there is a justiciable claim between them now. Their dispute was fully resolved by the settlement agreement between them that led to the unconditional dismissal of the Apotex Patent Litigation. That settlement agreement was not contingent on the court entering an agreed judgment, the court did not retain jurisdiction over the settlement agreement, and the parties are not seeking the entry of an injunction or any other type of prospective relief by means of the judgment they are asking this Court to enter.

Apotex also argues that precedent specifically dealing with subject matter jurisdiction in ANDA cases support a finding that there is a justiciable dispute in this case. In particular, Apotex relies on the Federal Circuit's finding of jurisdiction in *Caraco Pharm. Labs., Ltd.*, 527 F.3d 1278. *Caraco*, like this case, involved a generic drug manufacturer (Caraco) that filed an ANDA for a drug for which there were two listed patents and for which another company held first-filer status and therefore was entitled to a 180-day exclusivity period. The patent holder (Forest) sued Caraco for infringement of one of the patents but not the other ("the '941 patent").

After Caraco filed a declaratory judgment action seeking a declaration that the '941 patent was not infringed by the drug described in its ANDA, Forest unilaterally granted Caraco an irrevocable covenant not to sue Caraco for infringement of the '941 patent. Forest then moved to dismiss Caraco's declaratory judgment action on the ground that there was no longer a case or controversy between the parties regarding the '941 patent. The district court granted the motion, but the Federal Circuit reversed.

Applying the "all-the-circumstances" test established by the Supreme Court in *MedImmune*, the court found that Caraco had alleged a judicially cognizable injury-in-fact—the fact that it was unable to obtain FDA approval for its non-infringing generic product because Forest had listed the '941 patent in the Orange Book. *Caraco*, 527 F.3d at 1292 (citing *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1345 (Fed. Cir. 2007) (explaining that an NDA holder's use of an Orange Book-listed patent to exclude a generic drug maker from the market creates "the exact type of uncertainty of legal rights that the ANDA declaratory judgment action . . . was enacted to prevent")). The court further found that the injury was "fairly traceable to the complained-of conduct" of Forest because Forest's listing of the patent was the but-for cause of Caraco's inability to market the drug: "Simply put, if Forest had not listed its . . . patents in the FDA's Orange Book as valid patents covering the drug described in its NDA . . ., then [the exclusivity provision of the Hatch-Waxman Act] would not independently delay Caraco's ANDA from being approved by the FDA." 527 F.3d at 1292. Finally, the court held that Caraco's injury was redressible by a favorable judgment in its declaratory judgment suit because a judgment that its product would not infringe on the '941 patent "would clear the path to FDA approval that Forest's actions would otherwise deny Caraco" by enabling Caraco to

activate the first-filers exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(II). *Id.* at 1293. The court also determined that Caraco's suit was ripe.

Turning to mootness, the court considered whether Forest's unilateral covenant not to sue rendered the dispute between the parties moot. The court found that "Caraco's declaratory judgment action presents an Article III controversy as to whether the drug described in Caraco's ANDA infringes Forest's Orange-Book listed '941 patent." Caraco alleged that it did; Forest "notably, despite giving Caraco this covenant not to sue, . . . refused to concede that the '941 patent was invalid or not infringed by the drug described in Caraco's ANDA." *Id.* at 1289. Forest's covenant not to sue removed the threat of an infringement suit, but it did not eliminate the controversy between the parties because Caraco was still "claiming that it [was] being excluded from the drug market by Forest's '941 patent even though the generic drug described in its ANDA may not infringe the '941 patent." *Id.* at 1294. The Federal Circuit ruled that the suit was not moot because "even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes 'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Id.* at 1297 (quoting *MedImmune*, 127 S. Ct. at 771).

There is a critical difference between the situation in *Caraco* and the situation in this case. In *Caraco*, there was an actual dispute between the parties—whether Caraco's generic product infringed on the '941 patent. That dispute remained unchanged by Forest's covenant not to sue. In this case, there is no longer a dispute between the parties as to whether Apotex's generic product infringes Alcon's patents. That dispute was definitively resolved by the settlement agreement. Unlike Caraco, Apotex does not dispute that but for its license its generic

product would infringe Alcon's patents, and Alcon does not dispute that the license eliminates the infringement. The parties in this case have not had adverse legal interests since they entered into the settlement agreement in the Apotex Patent Litigation, and this new declaratory judgment action does not present any controversy to be resolved. Viewed another way, a judgment in favor of the plaintiff in *Caraco* would have provided it relief that Forest had actively worked to avoid—the ability of Caraco to trigger the first filer's exclusivity period—while in this case Alcon is not seeking to avoid the relief sought by Apotex in this case.

This fact also distinguishes this case from *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356 (Fed. Cir. 2015). In that case, the court held that a case or controversy was present in a case seeking declaratory judgment of non-infringement even though there was and could be no dispute that the patent was not infringed because the patent holder had disclaimed the patent. The court found that "[t]he stakes over which the parties are vigorously fighting are concrete and substantial: the amount of revenue there will be from sales of [the generic drug], and who will get what portions of it, during a period of at least six months." *Id.* at 1361. Apotex wanted a judgment of non-infringement in order to speed its entry into the market; the patent holder wanted to avoid that judgment in order to delay Apotex's ability to compete with it in the market. Under those circumstances, the court found that the requisite "substantial controversy, between parties having adverse legal interests" existed.

Those circumstances are not present here. Again, unlike in this case, a judgment in that case would have provided Apotex with relief that the patent holder was trying to avoid; indeed, the patent holder had moved to dismiss the case for lack of jurisdiction in order to avoid that result. In this case, the parties negotiated an agreement pursuant to which Alcon agreed to license its patents to Apotex. It is not seeking to keep Apotex out of the market.

Unlike the plaintiffs in *Caraco* and *Daiichi Sankyo*, in this case Apotex had the opportunity to litigate its dispute with Alcon over the issue of whether its generic product would infringe Alcon's patents. It litigated that dispute to its conclusion and negotiated a settlement that was not contingent on the entry of a judgment of non-infringement. By entering into that settlement agreement, it eliminated the adversity between itself and Alcon and eliminated the case or controversy that could be addressed by the court. It now asks this Court to declare the legal import of a contract between two private parties, something that Article III does not permit this Court to do. *Cf. Local No. 93, Int'l Ass'n of Firefighters, AFL-CIO C.L.C. v. City of Cleveland*, 478 U.S. 501, 525 (1986) ("To be sure, a federal court is more than 'a recorder of contracts' from whom parties can purchase injunctions; it is 'an organ of government constituted to make judicial decisions.'") (quoting 1B J. Moore, J. Lucas, & T. Currier, Moore's Federal Practice ¶ 0.409[5], p. 331 (1984)); *see also Flast v. Cohen*, 392 U.S. 83, 100 (1968) (noting the general rule that "federal courts will not entertain friendly suits . . . or those which are feigned or collusive in nature") (citations omitted). "Accordingly, a consent decree must spring from and serve to resolve a dispute within the court's subject-matter jurisdiction." *Local No. 93*, 478 U.S. at 525. Because there is no such dispute in this case, subject matter jurisdiction is lacking.

III. CONCLUSION

For the reasons set forth above, the Court finds that it does not have jurisdiction to hear this case because it does not present a case or controversy as required by Article III. Accordingly, Barr's motion to dismiss is **GRANTED** and this case is **DISMISSED** for lack of subject matter jurisdiction.

SO ORDERED: 2/27/17

Hon. William T. Lawrence, Judge
United States District Court
Southern District of Indiana

Copies to all counsel of record via electronic notification