NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD., Plaintiffs,	:	**Civil Action No. 20-10172 (JXN) (MAH)** (Consolidated with Civil Action Nos. 20-14833 and 20-14890)
v.	:	**OPINION**
CIPLA LTD., AUROBINDO PHARMA LLC, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC, Defendants.	:	

NEALS, District Judge:

THIS MATTER comes before the Court on a motion by Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, "Plaintiffs" or "Teva") to dismiss Counts V and XI of the Complaint and Counts V and XI of Defendant Cipla Ltd.'s ("Cipla's") Answer, Defenses, and Counterclaims as to U.S. Patent No. 10,086,156 for lack of subject-matter jurisdiction, ECF No. 195, to which Cipla filed opposition, ECF No. 209, and Teva replied, ECF No. 211. The Court reviewed the parties' written and oral arguments. For the reasons stated herein, Teva's motion [ECF No. 195] is **GRANTED**.

I. BACKGROUND

This case involves a declaratory judgment claim by Cipla against the patent holder and New Drug Application ("NDA") filer Teva. The FDA approved Teva's Qvar® inhalers for maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. Compl. ¶ 15. Originally, the dispute between the parties involved seven patents. On or about June 24, 2020, Cipla sent Teva a notice letter stating that it had filed an Abbreviated New Drug

Application ("ANDA") containing a Paragraph IV certification stating that all six of the then-Orange-Book listed patents—including, as relevant here, U.S. Patent Nos. 10,022,509 (the "'509 Patent") and 10,022,510 (the "'510 Patent"), and the 10,086,156 ("'156 Patent")—were invalid or would not be infringed. ECF No. 7, ¶ 15 (Counterclaims). On about September 8, 2020, Cipla sent Teva another notice letter stating that it had filed a Paragraph IV certification for a seventh, newly listed patent, U.S. Patent No. 10,695,512 (the "'512 Patent"). *See* Teva's Br. at 3 (citing ECF No. 8, ¶ 15 (Counterclaims)).

On August 7, 2020, and October 23, 2020, Teva filed two complaints against Cipla, one for each of the two sets of patents identified in its notice letters. ECF No. 1, Civil Action No. 20-14890. On January 8, 2021, the Court consolidated both of Teva's cases against Cipla into this action, along with a third case, between Teva and Aurobindo, another generic applicant that had filed a Paragraph IV certification for each of the seven the Orange-Book listed patents. ECF No. 40.

On May 13, 2021, Teva granted Cipla and Aurobindo covenants not to sue for the '509 and '510 Patents; and on June 6, 2021, the Court entered a stipulation and order dismissing the parties' claims and defenses as to those patents. ECF No. 91. The Court entered a similar stipulation and order between Teva and Aurobindo. ECF No. 183. Similarly, on May 19, 2022, Teva granted Cipla and Aurobindo covenants not to sue on the '512 Patent; and on May 31, 2022, and June 6, 2022, the Court entered stipulations and orders entering judgment on Teva's claims and dismissing Cipla's counterclaims. ECF Nos. 150, 173.

On August 31, 2022, Teva informed Defendants that it intended to provide them with covenants not to sue as to the '156 Patent; and on September 7, 2022, Teva further informed the Court of this development at the pretrial conference. Teva and Aurobindo stipulated to dismiss

Teva's claims as to the '156 Patent three days later. ECF No. 173. Teva and Cipla, however, were unable to agree on the language of an order resolving the parties' claims and counterclaims. As a result, Teva filed the instant motion to dismiss the parties' claims and counterclaims regarding the '156 Patent.

II. LEGAL STANDARD

Federal Rules of Civil Procedure requires the Court to dismiss a claim if it "determines at any time that it lacks subject-matter jurisdiction." A Rule 12(h)(3) motion is "analytically identical" to a Rule 12(b)(1) motion. *Berkshire Fashions, Inc. v. M.V. Hakusan II*, 954 F.2d 874, 880 n.3 (3d Cir. 1992). "The distinction between a Rule 12(h)(3) motion and a Rule 12(b)(1) motion is simply that the former may be asserted at any time and need not be responsive to any pleading of the other party." *Id.* Where a motion presents a factual attack on the Court's subject-matter jurisdiction, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

III. DISCUSSION

The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction." 28 U.S.C. § 2201(a) (2000); *EMC Corp. v. Norand Corp.,* 89 F.3d 807, 810 (Fed. Cir. 1996) (overruled in part on other grounds, *MedImmune, Inc. v. Genentech, Inc.,* 549 U.S. 118 (2007)). Plaintiffs bear the burden of proving the existence of an actual controversy by a preponderance of the evidence with regard to their declaratory judgment complaint. *Shell Oil Co. v. Amoco Corp.,* 970 F.2d 885, 887 (Fed. Cir. 1992).

Following the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), the Federal Circuit has acknowledged that the "reasonable apprehension of suit test is

no longer a necessary criterion for declaratory judgment jurisdiction." Instead, jurisdiction over a declaratory judgment 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 conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune,* 549 U.S at 127 (citations omitted).

Against that legal backdrop, Teva argues that its covenant not to sue eliminates any continuing case or controversy about the '156 Patent. Teva's Br. at 6. In support of its argument, Teva cites to *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008). In *Janssen*, the patents listed in the Orange Book were U.S. Patent No. 4,804,663 ("the '663 patent"), which expired in 2008, and U.S. Patent Nos. 5,453,425 and 5,616,587 ("the '425 and '587 patents"), which both expired in 2014. The first ANDA filer (Teva) was entitled to launch upon the expiration of the '663 patent. The NDA holder (Janssen) sued the second ANDA filer (Apotex) for infringement of the '663 patent. *Id.* at 1358. Apotex then asserted declaratory judgment counterclaims over the later expiring '425 and '587 patents. *Id.* Thereafter, Janssen provided Apotex with a covenant-not-to-sue with respect to the '425 and '587 patents and requested that Apotex withdraw its counterclaims, which Apotex refused. *Id.* at 1358-59. Janssen subsequently moved to dismiss Apotex's counterclaims for lack of subject matter jurisdiction. *Id.* at 1359. The district court granted Janssen's motion and held that there was no declaratory judgment jurisdiction because Apotex stipulated to the validity, infringement, and enforceability of the '663 patent. *Id.* at 1360. The court noted that "[e]ven if Apotex successfully invalidates the '425 and '527 patents, it cannot obtain FDA approval until the expiration of the '663 patent

because of its stipulations with respect to that patent." *Id.* at 1361. The Federal Circuit affirmed the decision.

In response, Cipla contends that Teva's covenant not to sue Cipla does not eliminate subject matter jurisdiction with respect to the '156 patent because a continuing case or controversy exists with respect to this patent. Cipla's Br. at 8. Cipla further contends that *Janssen* is distinguishable. In support of its argument, Cipla contends that "[i]n *Janssen*, the ANDA filer seeking the declaratory judgment ***had stipulated to validity and infringement*** of one of the Orange-Book-listed patents." *Id.* at 9. Cipla argues that *Janssen* is distinguishable because "Cipla has not stipulated to infringement or validity of any of the Orange-Book-listed patents, nor has Cipla agreed to be bound by the outcome of a separate litigation on any of the Orange-Book-listed patents." *Id.* at 10. According to Cipla, it "has not taken any action that would preclude it from obtaining relief as to all of the Orange Book-listed patents so as to trigger forfeiture of the first filers' 180-day exclusivity period." *Id.* The Court disagrees.

The instant matter is analogous to *Janssen*. Like Apotex, Cipla asserted declaratory judgment counterclaims over patents listed in the Orange Book that were not asserted by Teva in its Complaint. Once all the relevant patents listed in Orange Book were included in this litigation, Teva granted Cipla covenants not to sue for the '509 and '510 Patents; and on June 6, 2021, the Court entered a stipulation and order dismissing the parties' claims and defenses as to those patents. *See* ECF No. 91. These stipulations leave Cipla in the same situation as Apotex. Like Apotex, Cipla cannot trigger the first applicant's exclusivity based on ***pending litigation*** because they agreed to dismiss those patents from this case. In other words, a ruling in favor of Cipla on the '156 Patent cannot trigger the first applicant's exclusivity because it would need to obtain

findings as to the ’509 and ’510 Patents also, which are not subject to this litigation or any other pending litigation.

The Court’s conclusion is consistent with the fundamental jurisdictional rule that “a litigant may not use a declaratory-judgment action to obtain piecemeal adjudication of defenses that *would not finally and conclusively resolve* the underlying controversy. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 n. 7 (2007). As noted in Teva’s reply brief, “courts have uniformly held, in both Hatch-Waxman and other cases, that a party cannot invoke declaratory-judgment jurisdiction unless the requested judgment would resolve the entire case or controversy based on presently “pending” litigation.” Teva’s Reply Br. at 3 (citing *AbbVie Inc. v. MedImmune Ltd.*, 881 F.3d 1334, 1336-38 (Fed. Cir. 2018) (no subject-matter jurisdiction where judgment on patent would not resolve the parties’ dispute without additional, future litigation regarding contractual obligations)). In *Abbvie*, the court noted that “[w]e have occasionally permitted an exception to the rule against piecemeal adjudication in circumstances where ***litigation is also pending that would resolve the remaining questions***.” *AbbVie Inc.*, 881 F.3d at 1338 (emphasis added).

That exception does not apply here because Cipla has no pending litigation on the ’509 and ’510 Patents. As noted above, the parties previously dismissed their claims as to those patents by stipulation. Thus, Cipla cannot obtain a favorable finding on those patents based on ***presently pending litigation***. Thus, the Court’s conclusion is consistent with the fundamental jurisdictional rule stated in *MedImmune, Inc*.

Another case from the Federal Circuit that addresses the scope of declaratory judgment jurisdiction is *Caraco Pharm. Lab'ys, Ltd. v. Forest Lab’ys, Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008). In *Caraco*, the patents listed in the Orange Book were U.S. Patent No. RE34,712 (“the ’712 patent”), which expired in 2012, and U.S. Patent No. 6,916,941 (“the ’941 patent”), which

expires in 2023. The first ANDA filer (Ivax) was entitled to launch upon the expiration of the '712 patent. The NDA holder (Forest) sued the second ANDA filer (Caraco) for infringement of the '712 patent. *Id.* at 1288. Caraco then brought a declaratory judgment action over the later-expiring '941 patent. *Id.* Thereafter, Forest unilaterally granted Caraco an irrevocable covenant not to sue for infringement of the '941 patent but refused to concede that the '941 patent was invalid or not infringed by the drug described in Caraco's ANDA. *Id.* at 1289-90. Forest moved to dismiss Caraco's counterclaim on the grounds that it had been rendered moot when Forest unilaterally granted Caraco a covenant not to sue for infringement of the '941 patent. In holding that the district court had jurisdiction over the declaratory judgment action, the Federal Circuit explained that "[i]n claiming that it has been denied the right to sell non-infringing generic drugs, Caraco has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy." *Id.* at 1294. In *Caraco*, Forest's grant of a covenant not to sue on the '941 Patent did not extinguish the controversy as to that patent because Caraco had ***pending claims*** to the two patents listed in the Orange Book, which, if successful, would trigger the first ANDA filer's forfeiture. *Id.* at 1286-90. In *Dey Pharma, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1164 (Fed. Cir. 2012), the Federal Circuit emphasized that the *Caraco* court held that subject-matter jurisdiction existed only because litigation was "***also pending that could eliminate the other barriers***." (Emphasis added).

Here, it is undisputed that there is no "litigation pending" regarding the '509 or '510 Patents. Accordingly, in the Court's view, the instant case is analogous to *Janssen.* Following *Janssen*, the Court concludes that no subject matter jurisdiction exists for Cipla's declaratory judgment action.

IV. CONCLUSION

For the foregoing reasons, Teva's motion to dismiss [ECF No. 195] is **GRANTED**, and Counts V and XI of the Complaint (ECF No. 1) and Counts V and XI of Cipla's Answer, Defenses, and Counterclaims (ECF No. 7) are hereby **DISMISSED**. An appropriate Form of Order accompanies this Opinion.

s/ Julien Xavier Neals
DATED: November 11, 2022 **JULIEN XAVIER NEALS**
United States District Judge