NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMGEN INC. & AMGEN MANUFACTURING LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, Defendants.	:	**Civil Action No. 16-1276 (SRC)(CLW)** **OPINION**

CHESLER, District Judge

This matter comes before the Court upon Defendant Sandoz, Inc.'s ("Sandoz") motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(1) or 12(b)(6) [Docket Entry 28]. Plaintiffs Amgen Inc. and Amgen Manufacturing Limited ("Amgen") have opposed the motion [Docket Entry 43]. The Court has considered the parties' submissions and proceeds to rule without oral argument, pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, the Court will grant Sandoz's motion to dismiss.

I. BACKGROUND

a. RELEVANT PROVISIONS OF THE BPCIA

This dispute arises under the Biologics Price Competition & Innovation Act ("BPCIA"), in which Congress created an FDA regulatory process for the approval of biological products that are "biosimilar" to biological reference products approved by the FDA. 42 U.S.C. § 262. Biosimilar products must be "highly similar to the reference product notwithstanding minor differences in clinically inactive components," and there must be no clinically meaningful

differences between biosimilars and reference products in terms of safety, purity, or potency. *Id.* § 262(i). In § 262(k), the BPCIA establishes an abbreviated approval pathway in which biosimilar applicants rely upon the prior licensure and approval status of the relevant reference product sponsor ("RPS") of the biological reference product. *Id.* § 262(k).

In § 262(l), the BPCIA outlines various pre-marketing litigation procedures for biosimilar applications submitted under § 262(k). Primarily of interest in this dispute are the BPCIA's information exchange provisions, which are reviewed here. Under (l)(2)(A), within 20 days after the FDA notifies the § 262(k) applicant that its application has been accepted for review, the § 262(k) applicant shall give notice to the RPS by providing the § 262(k) application to the RPS, along with information about the manufacturing process of the biosimilar product. *Id.* § 262(l)(2)(A). Within 60 days of receiving the § 262(k) applicant's notice, the RPS shall provide an initial list of patents that could reasonably be asserted against the § 262(k) applicant. *Id.* § 262(l)(3)(A). The RPS must also indicate which of these patents, if any, it would be willing to license to the applicant. *Id*. Within 60 days of the § 262(k) applicant's receipt of the RPS's initial list of patents, the § 262(k) applicant shall respond with either (1) detailed contentions explaining why each patent on the RPS's list is invalid, unenforceable, or not infringed by the § 262(k) applicant's product; or (2) a statement that the § 262(k) applicant shall not market its product until before a particular patent expires. *Id.* § 262(l)(3)(B). In its response under § 262(l)(3)(B), the § 262(k) applicant may provide its own list of patents that it believes could be reasonably asserted against it. *Id.* § 262(l)(3)(B)(i). Within 60 days of receiving the § 262(k) applicant's (l)(3)(B) response, the RPS shall reply with detailed contentions regarding the infringement, enforceability, and validity of the patents on its (l)(3)(A) list. *Id.* § 262(l)(3)(C).

Based on the exchanges outlined above, the parties then proceed to identify a set of patents for the first stage of litigation.[1] Under (l)(3)(c), the parties shall negotiate in good faith to identify the patents that will be the subject of an immediate action for patent infringement for the 15 days after the RPS replies to the § 262(k) applicant. *Id.* § 262(l)(4)(A). If the parties agree at this stage, the RPS shall bring suit on those patents within 30 days. *Id.* § 262(l)(6)(A); see 35 U.S.C. § 271(e)(2)(C)(i).

If the parties cannot reach an agreement on the patents to include in the first phase of litigation within the 15 days of negotiation specified by (l)(3)(c), the parties again exchange patent lists to determine the scope of the first phase of patent litigation. *Id.* §§ 262(l)(4)(B), (l)(5)(A). Before the parties exchange lists, the § 262(k) applicant shall notify the RPS of how many patents it will list. *Id.* § 262(l)(5)(A). Within 5 days of providing this number, the parties simultaneously exchange their lists; these lists should include all patents the parties believe should be the subject of immediate litigation. *Id.* § 262(l)(5)(B). The RPS is not permitted to include more patents on its list than the § 262(k) applicant includes, except in a case where the § 262(k) applicant lists no patents; in this situation, the RPS may list one patent. *Id.* Within 30 days of the final patent list exchange under (l)(5)(B), the RPS must sue for patent infringement on those patents that appear on the combined lists. *Id.* § 262(l)(6)(B).

Under § 262(l)(6) of the BPCIA, Congress created a set of remedies available to the RPS in the event that infringement and validity are found; the remedies available are dependent on the RPS's compliance with the pre-litigation procedures outlined above. If a patent was included on

[1] The RPS may supplement its initial (l)(3)(A) list of patents if a relevant patent issues or is exclusively licensed to the RPS, but must do so within 30 days of such an event occurring. *Id.* § 262(l)(7). The § 262(k) applicant shall respond within 30 days, providing detailed invalidity, unenforceability, and/or non-infringement contentions. Patents on a supplemental list under this provision of the BPCIA will be litigated, if at all, in the second phase of litigation. *Id.* This provision of the BPCIA is not in contention in the action currently before this Court.

a list under (l)(4)(A) or (l)(5), and the RPS brought suit on the patent within 30 days of the production of the lists, injunctive relief is available to the RPS. *See* 35 U.S.C. § 271(e)(4)(D). Where a court has made a final decision on infringement and validity, and the exclusivity period for the reference product has not yet expired, injunctive relief is mandatory. *Id.* Furthermore, if the RPS fails to bring suit within 30 days on a patent included on a list under (l)(4)(A) or (l)(5), 35 U.S.C. § 271(e)(6)(B) states that the "sole and exclusive remedy" for an untimely suit is a reasonable royalty. Finally, § 262(l)(9)(B) provides the remedy for a § 262(k) applicant's failure to act under the BPCIA's abbreviated approval pathway:

> If a [§ 262] (k) applicant fails to complete an action required of the [§ 262] (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the [§ 262] (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

Id. § 262(l)(9)(B).

b. BACKGROUND ON *AMGEN V. SANDOZ* LITIGATION RELATED TO PEGFILGRASTIM

Amgen markets Neulasta®, an FDA-approved reference product containing the active ingredient pegfilgrastim. The FDA granted Amgen a biologics license for Neulasta® in 2002, under 42 U.S.C. § 262(a).

Sandoz submitted its abbreviated Biologics License Application to Amgen on October 26, 2015. (Compl. ¶ 12.) The parties proceeded through the (l)(2) and (l)(3)(A) steps of the BPCIA information exchange process, as outlined above. (Compl. ¶¶ 63-65.) In its (l)(3)(A) disclosure, Amgen identified two patents—U.S. Patent Nos. 8,940,878 ("the '878 patent") and 5,824,784 ("the '784 patent")—as the patents Amgen believed could "reasonably be asserted against the Sandoz Pegfilgrastim Product." (Compl. ¶ 65.) On February 2, 2016, Sandoz

provided its (l)(3)(B) "contentions that the '878 and '784 patents are invalid, unenforceable, or will not be infringed" by Sandoz. (Compl. ¶ 66.) In this same letter, Sandoz notified Amgen that it agreed with Amgen that the '878 and '784 patents were the relevant patents to be asserted with respect to Sandoz's biosimilar pegfilgrastim product. (Compl. ¶ 67; Docket Entry 35, Ex. A.) Given that the '878 patent was at the time (and is still currently) the subject of litigation between these parties in the Northern District of California in a patent infringement suit related to Sandoz's proposed filgrastim biosimilar product (*Amgen v. Sandoz*, No. 14-cv-4741-RS), and since Amgen had already provided Sandoz with (l)(3)(C) contentions in that litigation, Sandoz waived its right to receive Amgen's (l)(3)(C) contentions with respect to the '878 patent's validity and infringement for the action related to pegfilgrastim [Docket Entry 35, Ex. A at 3]. Furthermore, Sandoz asserted that since the parties had agreed on the patents that would be the subject of a suit under (l)(6), Sandoz viewed the negotiations under (l)(4) as complete at that time. (*Id.*) Therefore, for Amgen to timely file a patent infringement suit against Sandoz with respect to the pegfilgrastim product, Amgen would need to file its suit within 30 days of Sandoz's letter (by March 4, 2016). (*Id.*)

On March 4, 2016, Amgen filed this action, seeking the following relief relevant to Sandoz's motion to dismiss: (1) a declaration that Sandoz has failed to comply with the requirements of the BPCIA mandatory information-exchange provisions, including (*l*)(4) and (*l*)(5) if necessary; (2) a declaration that Sandoz's failure to comply with the requirements of the BPCIA mandatory information-exchange provisions, including (*l*)(4) and (*l*)(5) if necessary, means that there can be no "immediate patent infringement action" under (*l*)(6); (3) a declaration that Amgen's not filing a patent infringement action by March 4, 2016—before the parties have complied with (l)(4), and (l)(5) if necessary—does not deprive Amgen of the remedies for

infringement available under 35 U.S.C. § 271(e)(4), including lost profits damages and injunctive relief; (4) an order compelling Sandoz to comply with the BPCIA mandatory information-exchange provisions set forth in (*l*)(4) and (*l*)(5) if necessary; and (5) an order compelling Sandoz to compensate Amgen for and awarding damages incurred as a result of Sandoz's actions or inactions [Docket Entry 1].

On April 1, 2016, Sandoz sent a letter to Amgen, proposing that Amgen provide its (l)(3)(c) response to Sandoz by April 4, 2016 per Amgen's interpretation of the BPCIA, and then suggesting that the parties complete the remaining steps to prepare for the first stage of patent litigation under § 262(l) [Docket Entry 35, Ex. B at 2]. In this letter, Sandoz also agreed to "not challenge whether the limiting provisions of 35 U.S.C. § 271(e)(6) apply to this case," so long as Amgen filed a suit under the provisions of (l)(6)(A) within 30 days of Sandoz's assent to the patents subject to suit under (l)(4). (*Id.*) Amgen provided its (l)(3)(C) disclosures to Sandoz on April 2, 2016 [Docket Entry 35, Ex. C at 3]. Sandoz then assented to the patents Amgen had disclosed in its (l)(3)(A) disclosure, and the parties participated in (l)(4) negotiations on April 8 and April 12, 2016 [Docket Entry 35, Ex. E at 3-4; Ex. F]. On April 12, 2016, the parties agreed that provision (l)(4) of the BPCIA had been completed, and that provision (l)(5) was inapplicable to Sandoz's proposed pegfilgrastim product [Docket Entry 35, Ex. F].

Amgen filed a patent infringement suit against Sandoz in the Northern District of California under (l)(6) on May 12, 2016. *Amgen Inc. v. Sandoz Inc.*, No. 3:16-cv-2581-RS (N.D. Cal. May 12, 2016). In the Complaint, Amgen asserted infringement of the '878 and the '784 patents. (*Id.* ¶ 78.)

II. LEGAL STANDARDS

a. CHALLENGES TO SUBJECT MATTER JURISDICTION UNDER RULE 12(B)(1)

Federal Rule of Civil Procedure 12(b)(1) permits the dismissal of a complaint for lack of subject matter jurisdiction at any point during the case. *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Rule 12(b)(1) challenges may be either facial or factual attacks on the Court's subject matter jurisdiction. *Id.*

"A motion to dismiss on the basis of Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction made prior to the filing of the defendant's answer is a facial challenge to the complaint." *Bennett v. City of Atl. City*, 288 F. Supp. 2d 675, 678 (D.N.J. 2003) (citing *Mortensen*, 549 F.2d at 891). A facial challenge asserts that the Complaint does not allege sufficient grounds to establish subject matter jurisdiction or that there is a legal bar to the court hearing the case, such as sovereign immunity. *Id.* at 679-80. When reviewing a facial challenge under Rule 12(b)(1), Rule 12(b)(6)'s standards apply—requiring that the Court must accept all factual allegations in the Complaint as true, and that the Court may only consider the Complaint and documents referenced in or attached to the Complaint. *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000).

When the 12(b)(1) motion is "factual," in that it challenges the facts underpinning the Court's jurisdiction, the Court may "consider and weigh evidence outside the pleading and properly place[] the burden of establishing jurisdiction" on the plaintiff. *U.S. ex rel. Atkinson v. PA. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007). The Court may not place any "presumption of truthfulness" on a plaintiff's allegations in the Complaint when analyzing a factual attack under Rule 12(b)(1). *CNA v. United States*, 535 F.3d 132, 139 (3d Cir. 2008). The plaintiff bears the burden to prove that subject matter jurisdiction exists over a complaint once it

has been challenged. *Mortensen*, 549 F.2d at 891. "Dismissal for lack of subject-matter jurisdiction because of the inadequacy of the federal claim is proper only when the claim is so insubstantial, implausible, foreclosed by prior decisions of [the Supreme Court], or otherwise completely devoid of merit as not to involve a federal controversy." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998) (internal quotation marks omitted).

III. ANALYSIS

Sandoz asserts that Amgen's Complaint fails to present a justiciable "case or controversy." For the following reasons, the Court agrees.

Several of Amgen's requested forms of relief are requests for declaratory judgment, and the Court will examine these first. The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, 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" "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). The party bringing a declaratory judgment action must prove that an actual controversy exists, by a preponderance of the evidence. *See, e.g., Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 (Fed. Cir. 1992). An actual controversy exists where "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." *MedImmune*, 549 U.S. at 127 (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). The Supreme Court has only "required 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 'admi[t] 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.'" *Id.* (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). An "adverse legal interest" requires a dispute as to a legal right, "for example, an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring." *Arris Grp., Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1374 (Fed. Cir. 2011). This inquiry is necessarily fact specific, and the court must consider all of the relevant circumstances. *See MedImmune*, 549 U.S. at 127.

To the extent that Amgen seeks declaratory relief, the Court notes that the burden here rests on Amgen, the party requesting declaratory judgment, "to establish that jurisdiction over its declaratory judgment action existed at, and has continued since, the time the [claim] was filed." *Sierra Applies Scis., Inc. v. Advanced Energy Indus.*, 363 F.3d 1361, 1373 (Fed. Cir. 2004) (citing *Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enters. Holdings, Inc.*, 787 F.2d 572, 575 (Fed. Cir. 1986)). Importantly, "district courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdiction prerequisites." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995). In essence, the Court must determine whether issuing a declaratory judgment will move forward a concrete, fully developed dispute. Amgen has not met its burden to show that this is the case here. Sandoz correctly notes that any declaratory relief the Court grants on this issue would not impact Sandoz's behavior in the dispute currently before this Court, because Sandoz already completed the (l)(4) step of the BPCIA with respect to its pegfilgrastim product, and the parties agreed to waive the (l)(5) step. There is no concrete dispute left for the Court to decide as to the information exchange steps of the BPCIA, based on the facts presented here.

In addition, it would be improper for the Court to grant the other declaratory forms of relief Amgen has requested in this action. Amgen requests declarations as to (1) the consequences of Sandoz's failure to comply with the information exchange provisions; and (2) which remedies should be available to an RPS in Amgen's position. In effect, Amgen asks the Court to rule on what remedies and causes of action would be available to an RPS, should Sandoz or another § 262(k) applicant balk at completing the (l)(4) and (l)(5) steps in the future, on the timeline in which Amgen believes they should be completed. Granting these forms of relief would violate the clear prohibition on the issuance of advisory opinions. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 213 (2000) (citation omitted). Furthermore, Amgen's pleas for guidance from this Court, based on other disputes it has with other litigants in other courts, and for the biopharmaceutical industry at large, highlight the fact that Amgen is requesting advisory opinions. Amgen has not shown that an actual controversy exists between these parties, based on these facts.

Sandoz additionally challenges this Court's subject matter jurisdiction over Amgen's Complaint under the doctrine of mootness. The Court makes no ruling on whether a case or controversy existed between the parties at the time that Amgen filed its Complaint; it need not do so, because the parties' conduct following the filing of this Complaint shows that there is no longer a live controversy on the issues that Amgen raises in its Complaint, and therefore the dispute before this Court is moot as to all requested forms of relief.

It is well settled that Article III of the Constitution requires that any cause of action before a federal court must involve a live case or controversy. *DeFunis v. Odegaard*, 416 U.S. 312, 316 (1974). Mootness occurs "when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *Powell v. McCormack*, 395 U.S. 486, 496

(1969). In other words, "the central question of all mootness problems is whether changes in circumstances that prevailed at the beginning of the litigation have forestalled any occasion for meaningful relief." *Jersey Cent. Power & Light Co. v. State of New Jersey*, 772 F.2d 35, 39 (3d Cir. 1985) (quoting *Int'l Bhd. of Boilermakers v. Kelly*, 815 F.2d 912, 915 (3d Cir. 1987)). The lack of available relief is one indication that there may no longer be "a continuing controversy between parties with cognizable interests in the outcome." *Int'l Bhd. of Boilermakers*, 815 F.2d at 915-16. A Rule 12(b)(1) motion may be used to present a challenge for mootness, which is a factual attack on the jurisdictional facts; on such a motion, the court is permitted to consider evidence outside the pleadings. *See Gould Elecs. Inc. v. United States*, 220 F.3d 160, 176-77 (3d Cir. 2000). As mootness necessarily means there is no continuing controversy between the parties, a finding of mootness removes the case from the subject matter jurisdiction of the Court.

Despite Amgen's assertions to the contrary, there is no longer a live case or controversy between the parties based on the information exchange provisions of the BPCIA. The parties agree that both Amgen and Sandoz have complied with the information exchange provisions of the BPCIA in a timely fashion. The parties further agreed to waive the provisions under (l)(5), since the parties agreed on the patents to be asserted in Amgen's patent infringement suit with respect to Sandoz's pegfilgrastim product. Amgen filed suit in the Northern District of California on May 12, 2016, under (l)(6).

Based on the parties' actions subsequent to the filing of the Complaint, the Court is unable to grant Amgen's requested relief. For example, an order compelling Sandoz to comply with the (*l*)(4) and (*l*)(5) steps in the information exchange process under the BPCIA would be completely pointless now, because Sandoz has already complied, on Amgen's preferred timeline; a declaration that Sandoz failed to comply with these steps similarly would be pointless.

Granting Amgen compensation for damages Sandoz has caused is similarly moot; Amgen already received the relief it wanted in terms of Sandoz's compliance with Amgen's preferred view of the BPCIA information exchange steps. In addition, as noted above, due to the clear prohibition on granting advisory opinions, it would be inappropriate for the Court to grant any other forms of relief Amgen has requested in this action. *Friends of the Earth, Inc*, 528 U.S. at 213 (2000).

Finally, Amgen asserts that this Court retains jurisdiction over this action because Sandoz has failed to show that Sandoz's allegedly wrongful behavior could not reasonably be expected to recur. To this point, Amgen raises the voluntary cessation doctrine: "a defendant cannot automatically moot a case simply by ending its unlawful conduct once sued." *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 727 (2013) (citing *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982)). "[A] defendant claiming that its voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth*, 528 U.S. at 190.

Even if Sandoz did in fact commit a violation of the BPCIA in its initial behavior with respect to the information exchange provisions of the BPCIA, Amgen's argument as to the likelihood of recurrence still fails. The current dispute between these parties cannot recur; the parties have already completed the (l)(4) and (l)(5) information exchanges, and Amgen has brought a timely suit under (l)(6) in the Northern District of California. Amgen attempts to support its argument by citing to ongoing litigation between Sandoz and Amgen subsidiary Immunex (*Immunex Corp. v. Sandoz Inc.*, No. 16-1118 (D.N.J. 2016)), in which Sandoz and Immunex previously disputed how to complete the information exchange process. Again, Amgen's cites to pending cases in other courts indicate that it is seeking expansive relief from

this Court that would in effect amount to an advisory opinion. The Court declines to engage in such a practice.

Currently, the only live controversy between Amgen and Sandoz with respect to pegfilgrastim is the patent infringement suit currently pending in the Northern District of California. For the reasons explained above, the Court will decline to exercise jurisdiction over this dispute.

IV. CONCLUSION

For the foregoing reasons, the Court will grant Sandoz's motion to dismiss. An appropriate Order will be filed herewith.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: July 22, 2016