

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN  
MANUFACTURING, LTD.,  
Plaintiffs;

v.

HOSPIRA, INC.,  
Defendant.

Civil Action No. 15-839-RGA

MEMORANDUM OPINION

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August 5, 2016

*Richard G. Andrews*  
**ANDREWS, U.S. DISTRICT JUDGE:**

Presently before the Court is Defendant's Motion to Dismiss Count I of the Amended Complaint. (D.I. 15). The issues have been fully briefed. (D.I. 16, 17, 19). The Court heard oral argument on February 17, 2016. (D.I. 24). For the reasons stated herein, Defendant's motion to dismiss is **DENIED**.

## **I. BACKGROUND**

Plaintiffs filed this patent infringement action pursuant to 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("BPCIA"), as well as 35 U.S.C. § 271(a). (D.I. 1). Plaintiffs allege that Defendant's biosimilar product will infringe U.S. Patent No. 5,856,298, and that Defendant's manufacturing process infringes U.S. Patent No. 5,756,349. (D.I. 11 ¶¶ 86-106). Plaintiffs, in Count I of an amended complaint, also seek a declaratory judgment that Defendant's refusal to give notice of commercial marketing violates 42 U.S.C. § 262(l)(8)(A). (*Id.* ¶¶ 76-85). In Count I, Plaintiffs also seek "injunctive relief requiring [Defendant] to provide [Plaintiffs] with legally effective notice of commercial marketing . . . ." (*Id.* ¶ 85). Defendant's motion to dismiss only concerns Count I, and is based on both Rules 12(b)(1) and 12(b)(6).

## **II. LEGAL STANDARD**

Rule 8(a) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). When reviewing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept the complaint's factual allegations as true, but may disregard any legal conclusions. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Bell Atl. Corp. v. Twombly*, 550

U.S. 544, 555-56 (2007) (“Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact).”). There must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint’s factual content “allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (“Where a complaint pleads facts that are merely consistent with a defendant’s liability, it stops short of the line between possibility and plausibility of entitlement to relief.” (quotation marks omitted)).

There are two ways a party may attack a complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1). *Constitution Pty. of Pa. v. Aichele*, 757 F.3d 347, 357-58 (3d Cir. 2014). “A challenge to a complaint for failure to allege subject matter jurisdiction is known as a ‘facial’ challenge, and must not be confused with a ‘factual’ challenge contending that the court in fact lacks subject matter jurisdiction, no matter what the complaint alleges . . . .” *NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 341 n.7 (3d Cir. 2001). In reviewing a facial challenge under Rule 12(b)(1), the court must accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Id.* at 341. “[T]he court must only consider the allegations of the complaint and documents referenced therein and attached thereto . . . .” *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000).

### **III. ANALYSIS**

Count I of the Amended Complaint pertains to 42 U.S.C. § 262(l)(8)(A). That subsection of the BPCIA provides that a “subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the

biological product licensed under subsection (k).” 42 U.S.C. § 262(l)(8)(A).<sup>1</sup> The Federal Circuit has held that “a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product.” *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1358 (Fed. Cir. 2015), *petition for cert. filed*, 84 U.S.L.W. 3455 (U.S. Feb. 16, 2016) (No. 15-1039).

Defendant moves pursuant to Rules 12(b)(1) and 12(b)(6), contending that Plaintiffs may not privately enforce (8)(A). Defendant argues, under both bases for its motion, that Congress did not intend to create a private right of action, and where there is no intent, “a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute.” *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001).

Both bases for Defendant’s motion implicate the same analysis, and—since Defendant’s challenge to subject matter jurisdiction is facial<sup>2</sup>—the same standard. If Plaintiffs cannot privately enforce (8)(A), Count I fails to state a claim upon which relief can be granted, and must be dismissed pursuant to Rule 12(b)(6). Similarly, absent a “private, federal cause of action for the [alleged] violation, [a complaint] does not state a claim ‘arising under the Constitution, laws, or treaties of the United States,’” and therefore must be dismissed pursuant to Rule 12(b)(1). *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 817 (1986) (quoting 28 U.S.C. § 1331); *see also Smith v. Indus. Valley Title Ins. Co.*, 957 F.2d 90, 93 (3d Cir. 1992). Thus, the only relevant question is whether Plaintiffs’ (8)(A) claim may proceed.

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<sup>1</sup> Subsequent citations to subsections of § 262(l) will omit the “§ 262(l).”

<sup>2</sup> Defendant has not answered the complaint. Therefore, its attack on subject matter jurisdiction is a facial one. *See Mortensen v. First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 891-92, 892 n.17 (3d Cir. 1977).

While this motion was pending, the Federal Circuit decided *Amgen Inc. v. Apotex Inc.*, — F.3d—, 2016 WL 3606770 (Fed. Cir. July 5, 2016). In that case, the district court had concluded that “Apotex [did] not intend to comply with § 262(l)(8)(A),” and issued an injunction requiring that, if the FDA approved Apotex’s application, Apotex “provide Amgen with at least 180 days notice before the date of the first commercial marketing of the biological product approved by the FDA.” *Amgen, Inc. v. Apotex Inc.*, No. 15-61631-CIV-COHN/SELTZER, slip op. at 8-9 (S.D. Fla. Dec. 9, 2015) (order granting preliminary injunction). The Federal Circuit affirmed, concluding that “an applicant must provide a reference product sponsor with 180 days’ post-licensure notice before commercial marketing begins, regardless of whether the applicant provided the (2)(A) notice of FDA review.” *Apotex*, 2016 WL 3606770, at \*10. The Federal Circuit explicitly acknowledged that this mandatory requirement was “enforceable by injunction.” *Id.* at \*6.

As Defendant correctly points out, the Federal Circuit did not squarely address whether (8)(A) creates a private right of action. Indeed, “Apotex [did] not assert[] that (8)(A) create[d] no privately enforceable right.” *Id.* at \*8. Instead, the court rejected Apotex’s contention that paragraph (9) of § 262(l) provided the exclusive remedy for violations of (8)(A). In so holding, the court reasoned “that the federal courts’ ‘equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command,’ whether ‘in so many words, or by a necessary and inescapable inference.’” *Id.* at \*8 (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946)). Since Apotex appealed the grant of Amgen’s motion for preliminary injunction, the Federal Circuit did not directly address the propriety of Amgen’s request for a “Declaratory Judgment that Apotex’s Notice of Commercial Marketing Violates 42 U.S.C. §

262(l)(8)(A).” Complaint at 15, *Amgen, Inc. v. Apotex Inc.*, No. 15-61631-CIV-COHN/SELTZER (S.D. Fla. Dec. 9, 2015).

The rationale underpinning *Apotex* applies with equal force to the declaratory judgment claim at issue here. “Actions for declaratory judgments are neither legal nor equitable, and courts have therefore had to look to the kind of action that would have been brought had Congress not provided the declaratory judgment remedy.” *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 284 (1988). In the context of analyzing the right to a jury trial, the Third Circuit articulated the following standard:

If the declaratory judgment action does not fit into one of the existing equitable patterns but is essentially an inverted law suit—an action brought by one who would have been a defendant at common law—then the parties have a right to a jury. But if the action is the counterpart of a suit in equity, there is no such right.

*AstenJohnson, Inc. v. Columbia Cas. Co.*, 562 F.3d 213, 223 (3d Cir. 2009) (quoting *Owens-Illinois, Inc. v. Lake Shore Land Co.*, 610 F.2d 1185, 1189 (3d Cir. 1979)). Where, as here, “[a] declaratory judgment action seek[s] . . . injunctive relief, [it] is clearly equitable in nature . . . .” *In re Stambaugh*, 532 B.R. 572, 578 (M.D. Pa. 2015). Plaintiffs do not seek any monetary damages for a violation of (8)(A). Rather, Plaintiffs explicitly request “a declaration of its rights under the statute and injunctive relief requiring [Defendant] to provide [Plaintiffs] with legally effective notice of commercial marketing.” (D.I. 11 ¶ 85). Absent the availability of declaratory relief, Plaintiffs would simply seek an injunction.

“The Declaratory Judgments Act was not devised to deprive courts of their equity powers or of their freedom to withhold relief upon established equitable principles.” *Great Lakes Dredge & Dock Co. v. Huffman*, 319 U.S. 293, 300 (1943). Rather, “the express purpose of the Federal Declaratory Judgment Act was to provide a milder alternative to the injunction remedy.” *Alli v. Decker*, 650 F.3d 1007, 1014 (3d Cir. 2011) (alteration and quotation marks omitted)

(quoting *Steffel v. Thompson*, 415 U.S. 452, 467 (1974)). The Federal Circuit has already recognized the availability of injunctive relief for violations of (8)(A). If presented with the question raised by Defendant's motion, it would make sense to come to the same conclusion regarding the availability of declaratory relief.

#### **IV. CONCLUSION**

For the reasons set forth above, Defendant's motion to dismiss (D.I. 15) is **DENIED**. An appropriate order will be entered.