IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. HOSPIRA, INC., Defendant.	C.A. No. 15-839 (RGA)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

PROCTOR HEYMAN ENERIO LLP

Dominick T. Gattuso (# 3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300

Counsel for Defendant Hospira, Inc.

OF COUNSEL:

WILLKIE FARR & GALLAGHER LLP

Thomas J. Meloro
Michael W. Johnson
787 Seventh Avenue
New York, NY 10019
(212) 728-8000

Dated: November 12, 2015

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Case **Page(s)**

Statutes, Rules and Regulations

I. NATURE AND STATE OF THE PROCEEDINGS

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") initiated this action by filing a complaint against Defendant Hospira, Inc. ("Hospira") on September 18, 2015 (the "Initial Complaint"). (D.I. 1.) The Initial Complaint alleged various causes of action based on the Biologics Price Competition and Innovation Act (the "BPCIA"), 42 U.S.C. § 262, including separate statutory violations of paragraphs (*l*)(8)(A) ("paragraph (8)(A)") and (*l*)(2)(A) ("paragraph (2)(A)") of the BPCIA.

Specifically, Count I of the Initial Complaint sought a declaratory judgment that Hospira's alleged refusal to provide a legally effective notice of commercial marketing violates paragraph (8)(A). Count I also sought injunctive relief requiring Hospira to comply with paragraph (8)(A). Count II of the Initial Complaint sought a declaratory judgment that Hospira failed to provide information in violation of paragraph (2)(A), and further requested "injunctive relief or other equitable relief preventing Hospira from profiting by its deliberate non-compliance with the mandatory provisions of [paragraph (2)(A)]."

On October 13, 2015, Hospira moved to dismiss Counts I and II of the Initial Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) (the "Initial Motion"). (D.I. 8.) In response to the Initial Motion, Amgen filed an amended complaint on November 6, 2015 (the "Amended Complaint"). (D.I. 11.) The main difference between the Initial Complaint and the Amended Complaint is that Amgen has withdrawn the claim alleging a violation of paragraph (2)(A) as previously set forth in Count II of the Initial Complaint.[1] Hospira now moves to dismiss Count I of the Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

[1] Though not directly at issue herein, the Amended Complaint (as did the Initial Complaint) also alleges one count of patent infringement under 35 U.S.C. § 271(e)(2)(C) and two counts of patent infringement under 35 U.S.C. § 271(a).

II. SUMMARY OF THE ARGUMENT

As described in greater detail below, the fatal flaw in claiming that Hospira violated paragraph (8)(A) of the BPCIA is that Amgen seeks to privately enforce statutory provisions despite the fact that Congress did not create a structure for private enforcement of paragraph (8)(A). In determining whether a private right of action exists where Congress has not explicitly created one, congressional intent is determinative. *See, e.g.*, *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Absent congressional 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." *Id.* at 286-87.

Paragraph (8)(A) contains no "rights-creating language" entitling Amgen to bring a private right of action to remedy any purported injury. *See Alexander*, 532 U.S. at 288. To the contrary, Congress expressly set forth that an aggrieved reference product sponsor in those circumstances may sue a subsection (k) applicant for patent infringement under 35 U.S.C. § 271. And that is precisely what Amgen has already done here.[2]

While Hospira looks forward to a trial on the merits with respect to Amgen's infringement claims, Amgen's attempt to carve out a private right of action in contravention of plain statutory text and clear congressional intent is legally meritless, and may be readily foreclosed upon this motion. Accordingly, Count I of the Complaint should be dismissed with prejudice pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

[2] *See supra*, n.1.

III. STATEMENT OF FACTS

A. THE ENACTMENT OF THE BPCIA

In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the BPCIA.[3] The BPCIA established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product (the "reference product"). The purpose of this law was to create a "biosimilar pathway balancing innovation and consumer interests."[4]

The Food and Drug Administration (the "FDA") traditionally approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a).[5] An applicant filing a biologics license application ("BLA") typically provides clinical data to demonstrate the safety and efficacy of the product. By design, the BPCIA allows an applicant to file an abbreviated biologics license application ("aBLA" or "subsection (k) application"), relying in part on the approved license of a reference product, to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product.[6]

To balance innovation and price competition in the BPCIA, Congress provided for a 12-year-exclusivity period for reference products beginning on the date of their initial licensure.[7] Consequently, approval of a subsection (k) application "may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first

---

3 *See* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010).

4 *Id.* at 804.

5 *Id.*

6 42 U.S.C. § 262(k)(2)-(5); *see also* 42 U.S.C. § 262(i).

7 *Amgen Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1351 (Fed. Cir. 2015).

licensed under subsection (a)."[8] This affords the sponsor of an approved reference product (the "reference product sponsor" or "RPS") up to 12 years of exclusivity against biosimilar products, regardless of patent protection.

The BPCIA also established a streamlined patent-dispute-resolution regime by amending Titles 28, 35, and 42 of the United States Code to create an artificial "act of infringement" that allows infringement suits based on a subsection (k) application prior to FDA approval and prior to the marketing of the biosimilar product.[9] This process encourages the subsection (k) applicant and the RPS to narrow the scope of potential litigation early on.

As a first step, the subsection (k) applicant may grant the RPS confidential access to its aBLA no later than 20 days after the FDA accepts the subsection (k) applicant's aBLA for review. *See* 42 U.S.C. § 262(*l*)(1)-(2). Within 60 days of receipt of the aBLA under paragraph (2)(A), the RPS shall provide to the subsection (k) applicant a list of patents for which the RPS believes a claim of patent infringement could reasonably be asserted by the RPS. 42 U.S.C. § 262(*l*)(3)(A)(i). Following that, a subsection (k) applicant may provide the RPS with a list of patents to which the biosimilar applicant believes a claim of patent infringement could reasonably be asserted by the RPS. 42 U.S.C. § 262(*l*)(3)(B)(i). Additionally, the subsection (k) applicant may provide the RPS with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patents identified by the RPS pursuant to paragraph (3)(A) are invalid, unenforceable, or will not be infringed by the commercial marketing of the product described in the aBLA before the date that such patent expires, or a statement that the subsection (k) applicant does not intend to begin commercial marketing of the product

---

8 42 U.S.C. § 262(k)(7).

9 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6).

described in the aBLA before the date that such patent expires. 42 U.S.C. § 262(*l*)(3)(B)(ii). The parties may then agree on a list of patents that would be the subject of an immediate infringement action (*see* 42 U.S.C. § 262(*l*)(4)-(5)). The RPS may then sue the biosimilar applicant within 30 days. 42 U.S.C. § 262(*l*)(6).

Separately, paragraph (8)(A) states that the 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)." *Id.* at § 262(*l*)(8)(A). After receiving this notice and before such date of the first commercial marketing of the product, the RPS may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of the product described in the aBLA until a court decides the issue of patent validity, enforcement, and infringement with respect to patents that are included in the RPS's paragraph (3)(A) or the subsection (k) applicant's paragraph (3)(B) submissions but *not* included in the immediate infringement action.

B. *AMGEN V. SANDOZ*

Amgen has quickly become a prominent player in the world of BPCIA litigation—no doubt due to its interest in preventing competition as to products for which it has had exclusive rights for decades—beginning with its case against Sandoz Inc. ("Sandoz"). Following passage of the BPCIA, Sandoz notified Amgen that it had filed a subsection (k) application referencing Neupogen® ("Neupogen"), the brand name for Amgen's filgrastim product that Amgen has marketed since 1991. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1352-53 (Fed. Cir. 2015). Sandoz disclosed to Amgen that it believed its subsection (k) application would be approved by the FDA in "Q1/2 of 2015" and that it intended to launch its biosimilar product immediately upon FDA approval. *Id.* at 1353. Sandoz subsequently informed Amgen that it had "opted not to provide Amgen with Sandoz's [subsection (k)] application within 20 days of the FDA's

notification of acceptance" and that Amgen was entitled to sue Sandoz based on paragraph (9)(C); in so doing, Sandoz decided against making the disclosure permitted by paragraph (2)(A). *Id.*

In October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims for (1) unfair competition for unlawful business practices under California state law predicated on Sandoz's purported violations of paragraphs (2)(A) and (8)(A) of the BPCIA; (2) conversion for allegedly wrongful use of Amgen's approved license on Neupogen; and (3) infringement of Amgen's relevant patent that claims a method of using filgrastim. *Id.*[10]

The district court dismissed Amgen's unfair competition and conversion claims with prejudice because it concluded, based on its interpretation of the BPCIA, "that Sandoz did not violate the BPCIA or act unlawfully." *Id.* The district court also denied Amgen's motion for a preliminary injunction based on its state law claims, noting that Amgen "has yet to proceed on its remaining claim for patent infringement." *Id.* Amgen then appealed from the final judgment and from the denial of a preliminary injunction to the Federal Circuit. *Id.* at 1354.

On July 21, 2015, the Federal Circuit issued a seminal ruling that bears directly on certain issues presently before the Court. The Federal Circuit held that although the BPCIA says that the biosimilar applicant "shall provide" its application, this does not impose a mandatory requirement, because the BPCIA and the Patent Act "expressly provide the only remedies as those being based

[10] Conspicuously, Amgen did not assert a private right of action under the BPCIA in its litigation against Sandoz. During oral argument before the district court, Amgen's counsel conceded that it was unclear from Amgen's perspective whether or not a private right of action existed under paragraph (8)(A): "when we looked . . . we were saying we think that that's unclear . . . ." Transcript of Oral Argument at 16:3-6, *Amgen, Inc. v. Sandoz, Inc., et al.*, No. C 14-4741 (N.D. Cal. Mar. 13, 2015) (ECF No. 104). It is also worth noting that other parties have begun to assert claims based on a private right of action under this provision of the BPCIA in other recently filed district court cases. *See, e.g., Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd., et al.*, No. 15-cv-10698 (D. Mass. 2015). However, this question remains a matter of first impression for the Court, as the Federal Circuit did not directly address this issue in *Sandoz*.

on a claim of patent infringement." *Id*. at 1355, 1357. The *Sandoz* court reasoned that paragraph (2)(A)'s "'shall' provision . . . cannot be read in isolation" (*id.* at 1355) — noting that "both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." *Id.* at 1356. "Moreover, 35 U.S.C. § 271(e)(4) provides 'the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2).'" *Id.* (emphasis in original). Thus, when "the BPCIA explicitly contemplates that a subsection (k) applicant might fail" to take action required by the statute and "specifically sets forth the consequence for such failure," this indicates that "'shall' . . . does not mean 'must.'" *Id.* at 1355. Otherwise, "mandating compliance [with the "shall" provision] in all circumstances would render [the consequence provisions] superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." *Id*. at 1356.

The Federal Circuit further held that the notice of commercial marketing provision in paragraph (8)(A) is mandatory only when the applicant "completely fails" to participate in the statutory information-exchange procedures:

> We therefore conclude that, where, as here, a subsection (k) applicant *completely fails* to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(8)(A) is mandatory. Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015.

Id. at 1360 (emphasis added).[11] The Federal Circuit reiterated that where the BPCIA's provisions "explicitly contemplate[ ] that a [biosimilar] applicant might fail to comply . . . and further specifies

[11] It is worth noting that the procedural history of *Sandoz* that the Federal Circuit based this part of its holding on is dissimilar to the facts at issue in this case. As the Federal Circuit recognized, Sandoz "did not comply with paragraph (*l*)(2)(A) to begin with. Indeed, the consequence specified in paragraph (*l*)(9)(B) is a declaratory judgment action brought by the RPS based on 'any patent included in the list described in paragraph (3)(A), including

the consequence for such failure," the BPCIA must be construed to allow for noncompliance to avoid rendering those provisions superfluous. *Id.* at 1359. It further held that "paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with [the notice of commercial marketing per paragraph (*l*)(8)(A)] *after the applicant has complied* with paragraph (*l*)(2)(A)." *Id.* (emphasis in the original).[12]

Sandoz thus established that a notice of commercial marketing pursuant to paragraph (8)(A) is not mandatory *unless* the applicant "completely fails" to participate in the BPCIA patent-exchange process. *Id.* at 1360.[13] The BPCIA, as interpreted by the Federal Circuit in *Sandoz*, therefore prevents a situation where the applicant does not disclose its application and launches upon FDA approval without any prior notice to the RPS. *See id.* (noting that "paragraph (*l*)(8)(A) . . . require[s] notice of commercial marketing be given to allow the [RPS] a period of time to assess and act upon its patent rights"). However, even assuming that a notice of commercial marketing is mandatory, there is no evidence of congressional intent that would allow a private enforcement of paragraph (8)(A) to stand. (*See infra*, Section V.B.)

C. HOSPIRA COMPLIED WITH THE PROVISIONS OF § 262(*l*)

Amgen obtained in 1989 a license from the FDA for EPOGEN® (epoetin alfa) ("Epogen"), a biological product that treats anemia due to chronic renal failure. (Am. Compl. at ¶ 24.) Epogen was also approved subsequently to treat patients suffering from cancer and HIV, and to decrease

---

as provided under paragraph (7)." *Sandoz*, 794 F.3d at 1359 (quoting 42 U.S.C. § 262(*l*)(9)(B)). Here, Hospira timely complied with the requirements of paragraph (2)(A).

12 The court concluded that Sandoz's notice of commercial marketing was legally ineffective because it was sent prior to the FDA's approval of its product. *Id.* at 1358.

13 Following the Federal Circuit's decision, Amgen and Sandoz each filed petitions for a rehearing en banc. Both petitions were denied on October 16, 2013. *Sandoz*, 3:14-cv-04741-RS (Fed. Cir. Oct. 16, 2015), ECF No. 162.

the need for blood transfusions in patients during particular surgeries. (Am. Compl. at ¶ 24.) Amgen has marketed and sold Epogen exclusively for 26 years.[14] (Am. Compl. at ¶ 24.)

Hospira is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the drug product ("Epoetin Hospira") described in Hospira's BLA No. 125-545. (Am. Compl. at ¶ 25.) On February 23, 2015, Hospira timely notified Amgen that Hospira's aBLA had been accepted for filing by the FDA. (Am. Compl. at ¶ 40.) On March 3, 2015, Amgen timely received Hospira's complete aBLA. (Am. Compl. at ¶ 43.) Amgen concedes this in its Complaint. (Am. Compl. at ¶ 44.) Hospira's production of its aBLA included 507 native files and over 747,000 additional pages of information concerning Epoetin Hospira and the processes employed to make its product. Hospira also provided notice pursuant to paragraph (8)(A) of its intent to begin commercial marketing of Epoetin Hospira as early as 180 days from the date of the letter. (Am. Compl. at ¶ 62.)

Amgen provided Hospira with its purported paragraph (3)(A) disclosure by identifying three patents for which Amgen believed a claim of patent infringement could reasonably be asserted. (Am. Compl. at ¶ 55.) On June 19, 2015, pursuant to paragraph (3)(B), Hospira provided Amgen with its detailed factual and legal basis for its opinion that the three identified patents were invalid and unenforceable, and/or would not be infringed by the importation, commercial manufacture, offer to sell, sale, and/or use of Epoetin Hospira, or that Hospira does not intend to begin commercial marketing of the biosimilar product prior to patent expiration. (Am. Compl. at ¶ 56.) Amgen provided Hospira with its statement pursuant to paragraph (3)(C) on August 18, 2015. (*Id.*) On August 19, 2015, Hospira accepted Amgen's paragraph (3)(A) list and indicated

[14] According to the Amended Complaint, Amgen also manufactures and supplies epoetin alfa to Ortho Biotech, a division of Johnson and Johnson, for sale in the United States under the trade name PROCRIT®. (Am. Compl. at ¶ 24.)

that Hospira was prepared to proceed to trial on the three listed patents. Hospira's agreement to Amgen's patent list ended the negotiations contemplated under paragraph (4)(A).

IV. LEGAL STANDARD

While the Federal Circuit is the court of appeals for all cases raising claims under patent law, it defers to regional circuit courts on non-patent issues. *See* 28 U.S.C. § 1338(a); *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002); *Research Corp. Techs. Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008). Third Circuit law therefore governs the disposition of this motion.

A. RULE 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of jurisdiction over the subject matter, or if a plaintiff lacks standing to file the claim. *See Brown v. Meredith*, No. 08-171-JJF, 2009 WL 347394, at *1 (D. Del. Feb. 11, 2009). In reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the complaint, and the presumption of truthfulness does not attach to the allegations in the complaint. *See Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Once the Court's subject matter jurisdiction over a complaint is challenged, the plaintiff bears the burden of proving that jurisdiction exists. *Id.*

B. RULE 12(b)(6)

In evaluating a Rule 12(b)(6) motion to dismiss, the Court must accept as true all material allegations of the complaint. *See Sprull v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) ("The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims."). The Court may grant a Rule 12(b)(6) motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to

plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000).

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[A] complaint may be subject to dismissal under Rule 12(b)(6) when an affirmative defense . . . appears on its face." *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994).

V. ARGUMENT

A. CONGRESS MUST CONFER A PRIVATE RIGHT OF ACTION

Congress may authorize an express right of action where it allows private parties to enforce a range of rights and obligations that Congress creates. *See Three Rivers Ctr. for Indep. Living v. Housing Auth. of City of Pittsburgh*, 382 F.3d 412, 420 (3d Cir. 2004). For example, some statutes create personal rights and provide that private parties may bring suit to enforce those personal rights. *See, e.g.*, 42 U.S.C. §§ 2000e-2(a)(1), 2000e-5(f)(1) (Title VII of the Civil Rights Act of 1964). *Cf. Block v. North Dakota*, 461 U.S. 273, 287-88 (1983) (finding no congressional intent in statute or legislative history to exempt states suing the federal government from a statute of limitations condition attached to an immunity waiver); *United States v. King*, 395 U.S. 1, 5 (1969) (refusing to find Declaratory Judgment Act jurisdiction at Court of Claims "absent an express grant of jurisdiction from Congress"); *United States v. Sherwood*, 312 U.S. 584, 590 (1941) ("relinquishment of a sovereign immunity . . . must be strictly interpreted").

A private right of action analysis is generally applied to determine whether a right of action

exists for one private party against another private party alleged to have violated statutory or regulatory law over which an agency or other governmental entity has the power of enforcement. *See O'Neill v. Town of Middletown*, No. Civ. A. 1069-N, 2006 WL 205071, at *16 (Del. Ch. Jan. 18, 2006). In determining whether a private right of action exists where Congress has not explicitly created one, congressional intent is determinative. *See, e.g.*, *Alexander*, 532 U.S. at 286 ("The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy."). Absent congressional 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." *Id.* at 286-87; *see also Northwest Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 94 (1981) ("But unless this congressional intent can be inferred from the language of the statute, the statutory structure, or some other source, the essential predicate for implication of a private remedy simply does not exist."). As emphasized by the Supreme Court, "[t]he courts should not create liability . . . where Congress has elected not to[.]" *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014).

Congress's intent in enacting a statute is always the "focal point" in determining whether courts should infer a private right of action from the statute. *Thompson v. Thompson,* 484 U.S. 174, 179 (1988). While courts may consider the legislative history for clues of congressional intent, *see Univs. Research Ass'n v. Coutu*, 450 U.S. 754, 786 (1981), the analysis must begin with a review of the text and structure of the relevant statute. *See Alexander*, 532 U.S. at 288; *see also Gonzaga Univ. v. Doe*, 536 U.S. 273, 286 (2002) ("where the text and structure of a statute provide no indication that Congress intends to create new individual rights, there is no basis for a private suit, whether under § 1983 or under an implied right of action.").

There is no evidence that Congress intended to create a private right of action to enforce paragraph (8)(A). Indeed, the BPCIA sets forth the explicit consequences for failing to abide by this provision. *See* 35 U.S.C. § 271(e)(4); 42 U.S.C § 262(*l*)(9)(B). Congress could have created a private right of action if that is what it intended. Congress could have, for instance, provided that an RPS may "assert a claim seeking an order requiring" a biosimilar applicant to comply with paragraph (8)(A). Congress did not do so, even though it *did* expressly provide a remedy for statutory violations *elsewhere* in the BPCIA. *See, e.g.*, 42 U.S.C. § 262(*l*)(1)(H) ("The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy ***and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph***.") (emphasis added).

Additionally, the Federal Circuit has observed that the BPCIA contains "certain similarities in its goals and procedures" to 1984's Hatch-Waxman Act ("Hatch-Waxman"). *Sandoz*, 794 F.3d at 1351. For example, in Hatch-Waxman, which addresses small-molecule drugs (as opposed to biologics), Congress specifically provided that a generic drug manufacturer may "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information." 21 U.S.C. § 355(j)(5)(C)(ii)(I). The "counterclaim," therefore, "enables a generic competitor to obtain a judgment directing a brand to 'correct or delete' certain patent information that is blocking the FDA's approval of a generic product." *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012). In other instances, where Congress remained silent or expressly conferred rights of enforcement under different statutory schemes, including the Administrative Procedure Act, courts have refused to find a private right of action under Hatch-Waxman.

The development of this particular section of Hatch-Waxman is particularly instructive. In the original Hatch-Waxman statute, there was no specific private right to compel a brand company to delist a patent in the Orange Book. This exact issue was litigated in the case of *Mylan Pharms, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001). There, the court concluded that no private cause of action existed because there is "nothing in the Hatch-Waxman Amendments to alter the statement in section 337(a) of the FFDCA that 'all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Id.* at 1332 (quoting 21 U.S.C. § 339(a)). In response, Congress amended Hatch-Waxman specifically to allow an ANDA (Abbreviated New Drug Application) applicant to bring a counterclaim to compel a brand company to delist an Orange Book patent. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I) (enacted in 2003 as part of the Medicare Prescription Drug, Improvement, and Modernization Act (also called the Medicare Modernization Act, or, the "MMA") Pub. L. 108–173, 117 Stat. 2066).

The analysis by the Federal Circuit in another Hatch-Waxman case, *3M v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002), provides additional guidance to the Court here. The issue in *3M* was whether or not a private right of action existed to remedy an alleged violation of paragraph (j)(2)(B)(ii) of Hatch-Waxman, which requires that an ANDA applicant must "provide a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." *Id.* at 777. 3M argued that the detailed statement provided by Barr Labs was insufficient and therefore did not comply with Hatch-Waxman's requirements. The Federal Circuit did not agree, and held that "§ 355(j)(2)(B) cannot be enforced by a private party in a patent infringement action, but must be enforced, if at all, only in the context of an action under the Administrative Procedure Act." *Id.* Thus, the Federal Circuit found that a private party "cannot

seek a judicial determination" of whether a private party's certification complies with that statutory provision.

In the Hatch-Waxman context, the Federal Circuit declined to create a private right of action where the statute did not explicitly provide one. Similarly, there is no evidence here that Congress intended to create a private right of action to enforce compliance with paragraph (8)(A).

The framework created by subsection (*l*) of the BPCIA creates a streamlined process designed to allow a subsection (k) applicant and an RPS to determine which patents should be part of a patent litigation. Congress also specifically created a remedy for any failure to act under any provision of Section (*l*)—namely, the institution of a lawsuit for patent infringement. Viewing the BPCIA framework as a whole, it is clear that Congress did not intend to create (and did not, in fact, create) a private right of action to enforce compliance with paragraph (8)(A). As the Federal Circuit recognized in the context of Hatch-Waxman, to the extent that a private right of action is needed to enforce the patent disclosure and exchange provisions of the BPCIA, it is the responsibility of Congress, not the courts, to create one.

B. CONGRESS DID NOT CONFER A PRIVATE RIGHT OF ACTION TO ENFORCE COMPLIANCE WITH PARAGRAPH (8)(A)

According to its Amended Complaint, Amgen seeks "[a] declaration that the notice of commercial marketing that Hospira provided on April 9, 2015 is ineffective under 42 U.S.C. § 262(*l*)(8)(A)." (Am. Compl. at 25.) Amgen is also seeking "[a]n injunction requiring Hospira to provide Amgen, on or after FDA licensure of the Hospira Epoetin Biosimilar Product, notice of the date of the first commercial marketing of the Hospira Epoetin Biosimilar Product thereby complying with 42 U.S.C. § 262(*l*)(8)(A) and prohibiting Hospira from commencing first commercial marketing of the licensed Hospira Epoetin Biosimilar Product until a date that is 180 days after Hospira provides this notice to Amgen . . . ." (*Id*. at 25-26.)

Amgen's claims fail, however, because paragraph (8)(A) contains no "rights-creating language" entitling Amgen to bring a private right of action to remedy that alleged injury. *See Alexander*, 532 U.S. at 288 (quotation omitted). The sole remedy provided for in the BPCIA for an alleged breach of paragraph 8(A) once a biosimilar applicant has provided its aBLA to the RPS is specified in paragraph (9)(B), which permits a declaratory action for infringement based on the patents listed in paragraph (3)(A). Amgen is unable to show that Congress ever intended to provide any other remedy, including injunctive relief, for the failure to provide commercial marketing notice under paragraph (8)(A). *See id.* Any other interpretation of the BPCIA would render paragraph (9)(B) unnecessary, and statutes are to be interpreted, if possible, to avoid rendering any provision superfluous. *See Sandoz*, 794 F.3d at 1356 (citing *Marx v. Gen. Revenue Corp.*, 568 U.S. __, 133 S. Ct. 1166, 1178 (2013) ("[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme."); *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." (internal quotation marks omitted))).

A plain reading of the BPCIA (and of *Sandoz*) also reveals that Hospira, which timely produced its aBLA to Amgen, is not required to provide any notice of commercial marketing.[15] Even if a notice of commercial marketing was required in this situation, which it is not, paragraph (9)(B) provides the sole remedy for any subsequent failure to act:

> (B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (K) APPLICANT—If a subsection (k) applicant fails to complete an action required of the subsection

[15] Hospira provided a notice of commercial marketing to Amgen prior to the approval of its aBLA and the *Sandoz* decision. Under the holding in *Sandoz*, Hospira's notice of commercial marketing is ineffective. Hospira reserves the right to argue that the Federal Circuit's interpretation of this portion of the BPCIA is incorrect, however, the Court need not address this issue here as it is not necessary to the resolution of the motion *sub judice*.

> (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 subsection (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). (emphasis added).

Paragraph (8)(A) is a step following a biosimilar applicant's disclosure of its aBLA to the RPS pursuant to paragraph (2)(A). Thus, if a biosimilar applicant provides its aBLA to the RPS but fails to complete any of the next steps, paragraph (9)(B) applies as the remedy for noncompliance with the notice provisions. However, Amgen ***has already*** availed itself of this remedy by asserting patent infringement claims against Hospira in the Amended Complaint.

Consequently, where Congress has provided the sole remedy for a failure to comply with paragraph (8)(A), any other interpretation would render unnecessary both paragraph (9)(B) and the BPCIA-conforming amendment codified at 35 U.S.C. § 271(e)(2)(C)(ii). There simply is no evidence that Congress intended to provide any remedy for the failure to provide notice under paragraph (8)(A) other than the remedy specified in paragraph (9)(B). Because Congress did not create or intend to create a private right of action, Count I, which concerns the alleged violation of paragraph (8)(A), should be dismissed with prejudice for lack of subject matter jurisdiction and/or for failing to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(1) and/or 12(b)(6).

CONCLUSION

For the reasons set forth above, Hospira respectfully requests that the Court dismiss Count I with prejudice, and grant Hospira such other and further relief as the Court deems just and proper.

PROCTOR HEYMAN ENERIO LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (# 3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300

Counsel for Defendant Hospira, Inc.

OF COUNSEL:

WILKIE FARR & GALLAGHER LLP

Thomas J. Meloro
Michael W. Johnson
787 Seventh Avenue
New York, NY 10019
(212) 728-8000

Dated: November 12, 2015