IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS COUNT I OF THE AMENDED COMPLAINT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

I. NATURE AND STAGE OF THE PROCEEDING 1

II. SUMMARY OF ARGUMENT 1

III. STATEMENT OF FACTS 2

A. In the BPCIA, Congress balanced innovator companies' rights and the public's interest in access to biosimilars 2

B. Hospira failed to provide Amgen with the information required by the BPCIA 4

C. Hospira violated the 180-day notice requirement of the BPCIA by refusing to give notice 5

IV. LEGAL STANDARDS 6

A. Rules 12(b)(1) and 12(b)(6) 6

B. Federal Circuit law governs the interpretation of the BPCIA 6

V. ARGUMENT 7

A. This Court has subject matter jurisdiction over Amgen's claims, which arise under the BPCIA, a federal statute 7

B. This Court can grant injunctive relief enforcing the notice requirement of paragraph (8)(A), just as the Federal Circuit did in *Amgen v. Sandoz* 9

C. Congress intended to create a private cause of action under paragraph (8)(A) because 8(A) provides rights specifically for the benefit of an RPS like Amgen that can only be enforced through a private remedy 9

1. Congress intended the notice requirement of (8)(A) for the especial benefit of an RPS like Amgen 10

2. Congress intended to create an implied private remedy to enforce the mandatory requirement of paragraph (8)(A), which offers no other means of enforcement 12

a. An implied remedy is necessary to enforce the mandatory notice requirement of paragraph (8)(A) 12

b. Section 262(*l*)(9)(B) does not provide a remedy for failure to give notice 13

(i) Paragraph (9)(B) does not apply here because Hospira failed to comply with paragraph (2)(A).....14

(ii) Even if paragraph (9)(B) applied here, it does not provide a remedy for Hospira's failure to give notice 14

c. Administrative enforcement is unavailable.....17

d. Section 262(*l*)(1)(H) does not provide an express private cause of action 17

e. The limitation of remedies provided under 35 U.S.C. § 271(e) does not apply here 18

3. Hospira conflates whether there is an implied private cause of action with the merits of Amgen's claims 18

4. The Hatch-Waxman cases that Hospira cites are irrelevant because that statute expressly says that it does *not* provide a private cause of action 19

VI. CONCLUSION 20

TABLE OF AUTHORITIES

Page(s)

Cases

3M v. Barr Labs., Inc.,
289 F.3d 775 (Fed Cir. 2002).....20

Alexander v. Sandoval,
532 U.S. 275 (2001) .....passim

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

Arroyo-Torres v. Ponce Fed. Bank, F.B.S.,
918 F.2d 276 (1st Cir. 1990).....8

Bell v. Hood,
327 U.S. 678 (1946) 7

Brown v. Meredith,
No. CIV. A. 08-171-JJF, 2009 WL 347394 (D. Del. Feb. 11, 2009).....6

Burks v. Lasker,
441 U.S. 471 (1979) 7

California v. Sierra Club,
451 U.S. 287 (1981) 9, 10, 12

Cannon v. Univ. of Chicago,
441 U.S. 677 (1979) 10, 12, 13, 18

Cort v. Ash,
422 U.S. 66, 78 (1975).....10

Gould Elecs. Inc. v. United States,
220 F.3d 169 (3d Cir. 2000).....6, 8

In re Spalding Sports Worldwide, Inc.,
203 F.3d 800 (Fed. Cir. 2000).....7

Ind. Protection & Advocacy Servs. v. Ind. Family & Social Serv. Admin.,
603 F.3d 365 (7th Cir. 2010) (en banc) 13, 17

Int'l Ass'n of Machinists & Aerospace Workers v. Northwest Airlines, Inc.,
673 F.2d 700 (3d Cir. 1982).....8

Int'l Union of Operating Engineers v. Ward,
563 F.3d 276 (7th Cir. 2009).....11, 18

Mortensen v. First Federal Savings & Loan Ass'n,
549 F.2d 884 (3d Cir. 1977).....6, 8

Mylan Pharms., Inc. v. Thompson,
268 F.3d 1323 (Fed Cir. 2001).....19, 20

Northwest Airlines, Inc. v. Transp. Workers Union of Am.,
451 U.S. 77 (1981).....12

Parus Holdings, Inc. v. Sallie Mae Bank,
No. 14-1427-SLR, 2015 WL 5886179 (D. Del. Oct. 8, 2015).....6

Purdue Pharma L.P. v. Boehringer Ingelheim GmbH,
237 F.3d 1359 (Fed. Cir. 2001).....16

Robert Bosch LLC v. Pylon Mfg. Corp.,
659 F.3d 1142 (Fed. Cir. 2011).....15

Till v. Unifirst Fed. Savings. & Loan Ass'n,
653 F.2d 152 (5th Cir. 1981).....8

United States v. Mezzanatto,
513 U.S. 196 (1995).....13

Universal Am. Corp. v. Partners Healthcare Solutions Holdings, L.P.,
61 F. Supp. 3d 391 (D. Del. 2014).....6

Statutes

21 U.S.C. § 355(j)(2)(A)(vii).....20

21 U.S.C. § 355(j)(2)(B)(i).....20

28 U.S.C. § 1331.....7

35 U.S.C. § 271(e).....18

35 U.S.C. § 271(e)(4).....18

42 U.S.C. § 262(k).....2, 3

42 U.S.C. § 262(k)(7)(A).....3

42 U.S.C. § 262(k)(7)(B).....3

42 U.S.C. § 262(*l*).....7

42 U.S.C. § 262(*l*)(1)(B)(i) 3

42 U.S.C. § 262(*l*)(1)(H) 17

42 U.S.C. § 262(*l*)(2)(A) 4, 5

42 U.S.C. § 262(*l*)(3) 3

42 U.S.C. § 262(*l*)(3)(A) 4

42 U.S.C. § 262(*l*)(4)-(6) 3

42 U.S.C. § 262(*l*)(7) 3

42 U.S.C. § 262(*l*)(8)(A) ..... passim

42 U.S.C. § 262(*l*)(8)(B) 16

42 U.S.C. § 262(*l*)(9)(B) 14, 15, 16

Rules

Federal Rule of Civil Procedure 12(b)(6) 6, 8

Federal Rule of Civil Procedure 12(b)(1) 8

I. NATURE AND STAGE OF THE PROCEEDING

Amgen brought this action against Hospira on September 18, 2015 for violations of the Biologics Price Competition and Innovation Act ("BPCIA") and for patent infringement. This case is one of the first actions involving the BPCIA, and the first such action in this District. On November 6, 2015, Amgen filed its Amended Complaint (D.I. 11). On November 12, 2015, Hospira filed a Motion to Dismiss Count I of the Amended Complaint (D.I. 15). This is Amgen's Answering Brief in Opposition to that motion.

II. SUMMARY OF ARGUMENT

Hospira's motion to dismiss Count I of Amgen's Amended Complaint invites legal error and should be denied because it is grounded on an interpretation of the BPCIA that is contrary to the Federal Circuit's holding in *Amgen v. Sandoz*. If Hospira receives FDA approval to market its "biosimilar" version of Amgen's biologic Epogen® (epoetin alfa), paragraph 262(*l*)(8)(A) of the BPCIA requires that Hospira then provide Amgen with at least 180-days' notice of the date on which Hospira will first commercially market its biosimilar product. The Federal Circuit held that this notice requirement is a "mandatory," "standalone" provision that serves the purpose of allowing an RPS like Amgen "a period of time to assess and act upon its patent rights." *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1359-60 (Fed. Cir. 2015).

Despite this binding precedent, Hospira says it is not obligated to—and will not—provide any notice under paragraph (8)(A). And now, by its Motion to Dismiss, Hospira also says that this Court has no power to force Hospira to comply with paragraph (8)(A). These arguments are wrong—the Federal Circuit interpreted the (8)(A) notice provision to be mandatory and, in view of its interpretation of the statute, compelled compliance by a recalcitrant applicant through injunctive relief.

In enacting the BPCIA, Congress provided innovator companies like Amgen with an

implied private right to enforce paragraph (8)(A). Congress's intent to provide such a private right is evidenced by the fact that it enacted the (8)(A) notice requirement to benefit a specific class, "reference product sponsors" like Amgen, rather than the general public, and by the fact that Congress did not provide any alternative means to enforce this requirement.

Congress's purpose in enacting the BPCIA also supports finding an implied private right here: if an RPS like Amgen cannot ask a court to enforce (8)(A), a biosimilar applicant like Hospira could reap the benefits of the BPCIA while avoiding its obligations to the RPS. That scenario would upend the balance that Congress struck between the interest of consumers in having access to biosimilars and the interest of an RPS like Amgen in having a defined period of time during which it can assess and act upon its patent rights to prevent the launch of a biosimilar. (D.I. 11 ¶¶ 37-67.)

III. STATEMENT OF FACTS

A. In the BPCIA, Congress balanced innovator companies' rights and the public's interest in access to biosimilars

The BPCIA created a new, abbreviated pathway for the approval of "biosimilars" (biological products that are highly similar to previously-licensed innovative biological products). The abbreviated pathway in 42 U.S.C. § 262(k) ("the subsection (k) pathway") allows a biosimilar applicant to secure a license from the FDA by relying on the clinical-trial data generated by, and the prior license granted to, the innovator company (the "reference product sponsor" or "RPS") for its innovative biological product. (D.I. 11 ¶ 8.)

Before enactment of the BPCIA in 2010, an innovator RPS enjoyed permanent and exclusive rights to its clinical trial data and FDA license. The BPCIA advanced the public's interest in price competition among biologics in part by diminishing these rights, allowing a biosimilar applicant to "reference" the innovator RPS's clinical-trial data rather than incurring

the delay and costs of generating its own clinical data. (D.I. 11 ¶ 30.)

In exchange for diminishing the rights of the RPS in its data and license, Congress included a detailed process in the BPCIA to protect the interests of the RPS in assessing and acting upon its patent rights. Congress tied this process to the biosimilar applicant's choice to utilize, and gain the benefit of, the abbreviated § 262(k) pathway. 42 U.S.C. § 262(*l*)(1)(B)(i). A biosimilar applicant that chooses the abbreviated pathway is obligated to provide the RPS with its aBLA and a defined set of information shortly after the FDA accepts the aBLA for review. (D.I. 11 ¶ 33.)

The RPS and the applicant are then to engage in a series of private information exchanges regarding relevant patents and the parties' contentions regarding infringement and validity of those patents. § 262(*l*)(3). This process culminates in a negotiation between the RPS and the applicant regarding which patents should be the subject of an immediate patent infringement lawsuit. § 262(*l*)(4)-(6). The RPS also has an ongoing obligation to supplement its list of relevant patents with any newly-issued or licensed patents. § 262(*l*)(7).

Unlike the Hatch-Waxman Act, which governs abbreviated applications for small-molecule generic drugs, the BPCIA does not provide for an automatic stay of FDA approval of the biosimilar product while the parties resolve their patent disputes: the FDA continues to review the aBLA while the BPCIA patent exchanges and the immediate phase of patent litigation take place. Because an aBLA can be filed as early as 4 years after the date that the innovator product was approved, § 262(k)(7)(B), and the innovator RPS has exclusive rights to its data for 12 years after approval, § 262(k)(7)(A), there could be up to 8 years available for supplementation of patent lists and resolution of patent disputes before the FDA approves the biosimilar product.

Paragraph (*l*)(8)(A) then requires that after receiving FDA approval, the applicant must give the RPS at least 180-days' notice prior to first marketing its biosimilar product. During this

notice period, paragraph (*l*)(8)(B) and (C) permit the RPS to seek a preliminary injunction and discovery, if necessary, with respect to patents that were not initially listed for the immediate phase of patent litigation, including patents that were later issued or licensed by the RPS.

B. Hospira failed to provide Amgen with the information required by the BPCIA

Amgen's Epogen® (epoetin alfa) drug is used to treat patients with anemia. (D.I. 11 ¶ 19.) Amgen obtained FDA approval for Epogen® (epoetin alfa) in 1989 only after committing enormous resources to satisfying demanding FDA requirements to demonstrate the drug's safety and efficacy. (D.I. 11 ¶¶ 22-24.)

Hospira seeks approval from the FDA to market a "biosimilar" version of Epogen® (epoetin alfa) by taking advantage of the abbreviated pathway under the BPCIA. (D.I. 11 ¶ 25.) In December 2014, Hospira submitted its Biologic License Application No. 125545 ("the Hospira BLA") to the FDA, seeking the benefits of the subsection (k) pathway. (D.I. 11 ¶¶ 10, 37.) After the FDA accepted Hospira's BLA for filing, Hospira provided a copy of the Hospira BLA to Amgen on March 3, 2015, as required by § 262(*l*)(2)(A). (*Id.* ¶ 43.) But § 262(*l*)(2)(A) required Hospira to provide Amgen with the BLA *and* "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." Despite requests from Amgen, which expressly described the aspects of the manufacturing process for which information was missing in the BLA, Hospira repeatedly refused to provide Amgen with this "other information." (D.I. 11 ¶¶ 45-48.)

By refusing to provide the "other information" required under § 262(*l*)(2)(A), Hospira deprived Amgen of the opportunity to fully evaluate its patent portfolio and, pursuant to § 262(*l*)(3)(A), identify all patents for which Amgen "believes a claim of patent infringement could reasonably be asserted" if Hospira engages in "the making, using, offering to sell, selling, or importing into the United States" the biological product that is the subject of Hospira's BLA.

(D.I. 11 ¶¶ 50-51.)

C. Hospira violated the 180-day notice requirement of the BPCIA by refusing to give notice

After refusing to provide Amgen with all of the information required under § 262(*l*)(2)(A), Hospira informed Amgen that it would also refuse to comply with the notice requirement under § 262(*l*)(8)(A). Once its application is approved, Hospira must provide Amgen with at least 180-days' notice before marketing its biosimilar product. § 262(*l*)(8)(A). Hospira's obligation to provide this notice is not conditioned on any other act, and Hospira is not permitted to provide the notice until the FDA approves its biosimilar application. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015) ("[U]nder paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product."); *id.* at 1359-60 ("Paragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*).").

Despite its obligation under (8)(A), Hospira provided Amgen with a purported (8)(A) notice on April 8, 2015, even though Hospira had not (and still has not) received FDA approval for its biosimilar product. (D.I. 11 ¶ 62.) And Hospira has since informed Amgen that it will give no further notice if it receives FDA approval. Despite the Federal Circuit's decision in *Amgen v. Sandoz*, Hospira has taken the position that it is under no obligation to, and will not, provide *any* notice under (8)(A). (*Id.* ¶ 64.)

Count I of Amgen's Amended Complaint addresses Hospira's violation of the notice requirement of paragraph (8)(A). For purposes of the Motion to Dismiss, the Court should accept as true Amgen's allegation in its Amended Complaint that Hospira has not complied with 8(A), because Hospira only challenges whether Amgen can state a private cause of action to enforce 8(A), not the merits of whether Hospira has complied with its obligations under 8(A).

IV. LEGAL STANDARDS

A. Rules 12(b)(1) and 12(b)(6)

"When reviewing a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept the Complaint's factual allegations as true." *Universal Am. Corp. v. Partners Healthcare Solutions Holdings, L.P.*, 61 F. Supp. 3d 391, 395 (D. Del. 2014). "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." *Id.* The Court must view the factual allegations of the complaint in the light most favorable to plaintiff. *Parus Holdings, Inc. v. Sallie Mae Bank*, No. 14-1427-SLR, 2015 WL 5886179, at *1 (D. Del. Oct. 8, 2015).

Likewise, in "reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply." *Brown v. Meredith*, No. CIV. A. 08-171-JJF, 2009 WL 347394, at *1 (D. Del. Feb. 11, 2009). Here, Hospira's jurisdictional challenge is a facial challenge, not a factual challenge, because Hospira has not come forward with any factual evidence to challenge the facts alleged in the Amended Complaint. *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 177 (3d Cir. 2000) ("If the defendant raises no challenge to the facts alleged in the pleadings, the court may rule on [a Rule 12(b)(1) motion] by accepting the allegations as true."). Instead, in its Statement of Facts, Hospira relies exclusively on the facts in Amgen's Amended Complaint. (D.I. 16 at 3-10.) Therefore, because Hospira's 12(b)(1) argument raises only a facial challenge, not a factual challenge, the Court should afford Amgen the same safeguards as under 12(b)(6): the Court "must consider the allegations of the complaint as true" and draw "all inferences favorable to plaintiff." *Mortensen v. First Federal Savings & Loan Ass'n*, 549 F.2d 884, 91 (3d Cir. 1977).

B. Federal Circuit law governs the interpretation of the BPCIA

Federal Circuit law, not the law of the regional circuit, controls the interpretation of 42

U.S.C. § 262(*l*). When reviewing district court judgments, the Federal Circuit applies its law "to issues of substantive patent law," as well as procedural issues that pertain to patent law, if the procedural issue "bears an essential relationship to matters committed to our exclusive [jurisdiction] by statute, or if it clearly implicates the jurisprudential responsibilities of this court in a field within its exclusive jurisdiction." *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 803 (Fed. Cir. 2000).

Because § 262(*l*) is part of the integrated regime under the BPCIA that governs the identification and assertion of patents infringed by the act of submitting an application seeking approval of a biological product, it bears an "essential relationship" to patent infringement claims. Federal Circuit law therefore applies when interpreting § 262(*l*).

V. ARGUMENT

A. This Court has subject matter jurisdiction over Amgen's claims, which arise under the BPCIA, a federal statute

Under 28 U.S.C. § 1331, this Court has "original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." Because 42 U.S.C. § 262(*l*) is a federal law, Count 1, alleging violations of that law, arises under federal law, thereby conferring subject matter jurisdiction. Hospira's contention that Amgen cannot bring a private cause of action to enforce the statute does not deprive the Court of subject matter jurisdiction. Where the right of plaintiffs "to recover under their complaint will be sustained if the . . . laws of the United States are given one construction and will be defeated if they are given another[,] . . . the district court has jurisdiction." *Bell v. Hood*, 327 U.S. 678, 685 (1946). "For it is well settled that the failure to state a proper cause of action calls for a judgment on the merits and not for a dismissal for want of jurisdiction." *Id.* at 682; *Burks v. Lasker*, 441 U.S. 471, 476 n.5 (1979) ("[W]hether a cause of action exists is not a question of jurisdiction."); *Arroyo-Torres v. Ponce Fed. Bank,*

F.B.S., 918 F.2d 276, 280 (1st Cir. 1990) ("[I]t has long been recognized that where a plaintiff asserts that a private right of action is implied from federal law, federal courts do have the requisite subject matter jurisdiction to determine whether such a federal remedy exists." (quoting *Till v. Unifirst Fed. Savings. & Loan Ass'n*, 653 F.2d 152, 155 n.2 (5th Cir. 1981))).

To the extent that Hospira's motion raises a challenge under 12(b)(1), it is a facial challenge only, because Hospira has brought forward no factual evidence to controvert the allegations of Amgen's Amended Complaint. *Int'l Ass'n of Machinists & Aerospace Workers v. Northwest Airlines, Inc.*, 673 F.2d 700, 711 (3d Cir. 1982) (a motion "supported by a sworn statement of facts" raises a factual challenge). Hospira's motion, therefore, is a facial challenge, not a factual challenge, to the Court's subject matter jurisdiction, and the procedural protections afforded under a Rule 12(b)(6) motion apply. *Mortensen*, 549 F.2d at 890-91. This means the Court must accept as true the allegations in Amgen's Amended Complaint and draw all inferences favorable to Amgen. *Id.* at 891; *see also Gould*, 220 F.3d at 177.

Accepting as true the allegations in the Amended Complaint and drawing all inferences in Amgen's favor, Amgen has stated a claim that arises under federal law. Paragraph 8(A) requires Hospira to provide notice to Amgen "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." (D.I. 11 ¶ 80.) This notice can only be legally effective if given after FDA product approval. *Amgen*, 794 F.3d at 1358. Yet Hospira has categorically represented to Amgen that it does not intend to provide Amgen with notice of commercial marketing after the FDA licenses Hospira's product. (D.I. 11 ¶ 83.) This dispute arises under § 262(*l*)(8)(A), a federal statute.

Therefore, this Court has subject matter jurisdiction.

B. This Court can grant injunctive relief enforcing the notice requirement of paragraph (8)(A), just as the Federal Circuit did in *Amgen v. Sandoz*

In *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), the Federal Circuit interpreted the parties' respective rights and obligations under paragraph (8)(A) and granted injunctive relief against Sandoz consistent with its interpretation of the notice provision. After holding that an operative notice of commercial marketing can only be given after FDA licensure, that the (8)(A) notice is mandatory, and that the (8)(A) provision is a standalone notice provision (nothing in the provision conditions the notice requirement on any other provision of subsection 262(*l*)), the Federal Circuit entered an injunction without bond prohibiting Sandoz from marketing its biosimilar product until the end of the 180-day period following Sandoz's FDA approval. *Id.* at 1361-62.

Here, Amgen likewise seeks injunctive relief to enforce the (8)(A) notice requirement. As in *Amgen*, a private cause of action must exist to permit the Court to enforce the statute. If the (8)(A) notice requirement, which the Federal Circuit found to be "mandatory," *id.* at 1359, could not be enforced through a private cause of action, this notice and the statutory window prior to launch, when the fully crystallized controversy exists, could *never* be enforced. That result would be at odds with *Amgen*, where the Federal Circuit entered injunctive relief against Sandoz. *Id.* at 1360-61.

C. Congress intended to create a private cause of action under paragraph (8)(A) because 8(A) provides rights specifically for the benefit of an RPS like Amgen that can only be enforced through a private remedy

By definition, an *implied* cause of action is not expressly stated in a statute. Instead, 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." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001); *California v. Sierra Club*, 451 U.S. 287, 297 (1981) ("[T]he ultimate issue

is whether Congress intended to create a private right of action.").

Paragraph (8)(A) implies a private cause of action because, when properly construed based on its language, structure, and purpose, it is evident that: (1) Congress intended to create rights in favor of the RPS (Amgen); and (2) a private remedy is the only way to enforce those rights (the statute provides no mechanism to enforce the notice requirement of (8)(A) other than via a private cause of action).

1. Congress intended the notice requirement of (8)(A) for the especial benefit of an RPS like Amgen

To determine whether Congress has displayed an intent to create a private right to enforce paragraph 8(A), this Court should consider whether Amgen is "one of the class for whose especial benefit the statute was enacted." *Sierra Club*, 451 U.S. at 293 (quoting *Cort v. Ash*, 422 U.S. 66, 78 (1975)); *Cannon v. Univ. of Chicago*, 441 U.S. 677, 690 (1979). Congress intended a statute for the "especial benefit" of a particular group if the statute contains "rights-creating" language. *Alexander*, 532 U.S. at 288. This factor is satisfied where the statute "expressly identifies the class Congress intended to benefit," instead of merely providing "for the protection of the general public." *Cannon*, 441 U.S. at 690. For example, in *Cannon*, the Court found this factor satisfied where the statute conferred a benefit on "persons discriminated against," rather than the general public. *Id.* at 690-94.

Here, paragraph (8)(A) provides an express benefit to an RPS like Amgen by requiring the biosimilar applicant to provide notice to the RPS on or after the biosimilar product is licensed and at least 180 days prior to first commercial marketing of that product. The Federal Circuit found that this post-approval notice "once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court."

Amgen, 794 F.3d at 1358. There can be no doubt that Congress intended this mandatory requirement to benefit a particular class, not the general public: an RPS is the only one that can assess and act upon its own patent rights.

Congress used its power to create a requirement on the applicant to give notice to the RPS. Congress did not act through the FDA to require that it implement regulations to ensure the RPS is notified. Paragraph (8)(A) creates rights for the RPS because it imposes a *duty* on the applicant to give the RPS notice, creating a corresponding *right* in the RPS beneficiary to receive that notice. Courts have found that similar rights-creating language supports finding an implied private right of action. For example, a "statute that imposes fiduciary *duties* necessarily implies corresponding *rights* in the beneficiaries. The statute's focus is thus not solely on the persons being regulated but also on those whose interests are protected . . . ." *Int'l Union of Operating Engineers v. Ward*, 563 F.3d 276, 286 (7th Cir. 2009) (finding implied cause of action).

The case on which Hospira principally relies to argue that paragraph (8)(A) contains no rights-creating language, *Alexander v. Sandoval*, is readily distinguishable. In *Alexander*, the Court held that a statute did not create a right in favor of any particular person; instead, it created a regulatory scheme under which federal agencies were tasked with enforcing the law. 532 U.S. at 289. The notice requirement of (8)(A) is unlike the regulatory scheme in *Alexander*, because (8)(A) directly (not through a regulatory agency) creates an obligation (notice) on one private individual (the applicant) that confers a right (information and a statutory window before product launch) in favor of another private individual (the RPS). Rather, (8)(A) is like the statute in *Cannon*, which conferred rights on a specified group. *Id.* at 690 (statute was intended to benefit a special group because it contained rights-creating language).

The other cases cited by Hospira in which the Court found no implied private cause of

action are also distinguishable. For example, in *Northwest Airlines, Inc. v. Transp. Workers Union of Am.*, the Court held that the Equal Pay Act and Title VII statutes, which are "directed against employers," could not possibly be for the especial benefit of employers. 451 U.S. 77, 91-92 (1981). Likewise, in *Sierra Club*, the Court held that a statute was not intended to benefit a particular class of persons because "it was intended to benefit the *public at large* through a general regulatory scheme to be administered by the then Secretary of War." 451 U.S. at 297-98 (emphasis added).

Paragraph (8)(A) is unlike those statutes because it states that the RPS is to receive the benefit of notice of commercial marketing. Congress's intent, the Federal Circuit held, was to "allow[] the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court" and to "ensure[] the existence of a fully crystallized controversy regarding the need for injunctive relief" at the time of any such preliminary injunction motion. *Amgen*, 794 F.3d at 1358.

2. Congress intended to create an implied private remedy to enforce the mandatory requirement of paragraph (8)(A), which offers no other means of enforcement

Congress intended to create a private remedy to enforce paragraph (8)(A) because there is no alternative way to enforce this "mandatory" provision. When an implied "remedy is necessary or at least helpful to the accomplishment of the statutory purpose, the Court is decidedly receptive to its implication under the statute." *Cannon*, 441 U.S. at 703.

a. An implied remedy is necessary to enforce the mandatory notice requirement of paragraph (8)(A)

Where a biosimilar applicant refuses to provide an RPS the benefit of the 180-day notice period guaranteed by paragraph (8)(A), a private remedy that achieves the specific statutory purpose of the provision is at least consistent with, if not necessary, to the accomplishment of the

broader purpose of the statute. If a private remedy were not implied here, the purpose of the provision and the unique benefit it confers on an RPS would *never* be achieved, despite the Federal Circuit having found it to be mandatory.

A mandatory statutory requirement gives rise to a private remedy where necessary to enforce the statute. For example, a statute that provides that an organization "shall" have access to certain records implies a private cause of action for that organization to seek injunctive relief to obtain access to those records. *Ind. Protection & Advocacy Servs. v. Ind. Family & Social Serv. Admin.*, 603 F.3d 365, 375 (7th Cir. 2010) (en banc). In *Indiana Protection*, the court rejected the defendant's attempt to ignore the statute by refusing access to records and then arguing that the plaintiff could not, through a private cause of action, enforce the statute to gain access to those records. This Court should similarly reject Hospira's attempt to refuse to provide the mandatory notice and then argue that Amgen cannot enforce the statute to receive that notice.

The need for a private remedy to enforce (8)(A) is like the need for a remedy in *Cannon*, where the Court concluded that an individual remedy would "provide effective assistance to achieving the statutory purpose" because a private remedy was "consistent with—and in some cases even necessary to—the orderly enforcement of the statute." 441 U.S. at 705-06. In contrast, in *Alexander*, the Court found that Congress did not "manifest an intent to create a private remedy" because the purpose of the statute was to empower "agencies to enforce their regulations," including through termination of federal funding. 532 U.S. at 289. There is no analogous remedy available under (8)(A).

b. Section 262(*l*)(9)(B) does not provide a remedy for an applicant's failure to give an operative (8)(A) notice

Hospira contends that compliance with (8)(A) cannot be privately enforceable because another provision of the BPCIA, paragraph (9)(B), allegedly provides the RPS a remedy for an

applicant's failure to provide notice. This argument fails for two reasons. First, paragraph (9)(B) applies, if at all, only after a biosimilar applicant complies with the disclosure requirements of paragraph (2)(A), which Hospira has not done in this case. Second, even if (9)(B) applied here, it does not remedy the injury that Amgen will suffer if Hospira is permitted to launch its biosimilar product without giving Amgen "a period of time to assess and act upon its patent rights" as paragraph (8)(A) requires. *Amgen*, 794 F.3d at 1360.

(i) Paragraph (9)(B) does not apply here because Hospira failed to comply with paragraph (2)(A)

In *Amgen*, the Federal Circuit said that paragraph (9)(B) "specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A)" but "it does not apply . . . where [the applicant] did not comply with paragraph (*l*)(2)(A) to begin with." *Amgen*, 794 F.3d at 1359 (emphasis in original). Here, it must be accepted, for purposes of Hospira's Motion to Dismiss, that Hospira failed to comply with paragraph (2)(A) by not producing the "other information" regarding "the process or processes used to manufacture" Hospira's biological product. (D.I. 11 ¶¶ 44-48.)

In its Amended Complaint, Amgen explained how Hospira failed to comply with paragraph (2)(A) by withholding certain manufacturing information. (*Id.*) Amgen was unable to provide a complete list of paragraph (3)(A) patents because Hospira did not satisfy its paragraph (2)(A) obligation to provide manufacturing information to Amgen. (D.I. 11 ¶¶ 50-51.) Accordingly, on this Motion to Dismiss, whether or not paragraph (9)(B) specifies a "consequence" is irrelevant. Paragraph (9)(B) does not apply here, just as the Federal Circuit found that it did not apply in *Amgen*.

(ii) Even if paragraph (9)(B) applied here, it does not provide a remedy for Hospira's failure to give notice

Even if paragraph (9)(B) was factually relevant, it is not dispositive of Hospira's motion.

Paragraph (9)(B) removes a limitation on the RPS's right to file a declaratory judgment action for patent infringement against an applicant that launches without notice. This is no remedy for failure to provide notice for two reasons. First, that limitation on the RPS's right to file a declaratory judgment action is removed by the time of the biosimilar product launch both in the circumstance of the applicant having provided the (8)(A) notice or not. *Compare* (*l*)(9)(A) *with* (B). Second, removing a limitation on the ability to file a declaratory judgment action after an applicant has launched without notice cannot cure the injury to the RPS of not having had an opportunity to seek a preliminary injunction to prevent that launch in the face of the exclusionary right granted by the RPS's patent(s). As the Federal Circuit recognized in *Amgen v. Sandoz*, a 180-day period after FDA approval and before the licensed biosimilar product is launched is a unique time when an RPS may seek an injunction on a fully crystallized controversy and "the court and the parties can fairly assess the parties' rights." *Id*. at 1358.

It is no remedy to interpret paragraph (9)(B) as limiting an RPS to seeking an injunction via a declaratory judgment *after* a biosimilar has been approved and launched into the market. As an unbroken string of Federal Circuit decisions recognizes, a product launch of a lower-priced version of a branded product causes irreparable injury to the branded competitor. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155 (Fed. Cir. 2011) ("[M]oney damages alone cannot fully compensate" plaintiff for "irreparable harm due to lost market share, lost business opportunities, and price erosion."); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (upholding district court's finding of irreparable harm where there was a "likelihood of price erosion and loss of market position without corresponding market expansion from the introduction of [the competitor's] product"). Moreover, there is nothing in paragraph (9)(B) to suggest removing a limitation on declaratory judgment is the

exclusive "remedy" available to the RPS. Unlike the circumstances of the Federal Circuit's consideration of a failure to comply with (*l*)(2)(A) and the implication of (*l*)(9)(C) in *Amgen*, nowhere is (8)(A) referred to in 35 U.S.C. § 271(e)(2)(C). And therefore, the remedy limiting language of § 271(e)(4) cannot be properly interpreted as applying to (*l*)(9)(B)

The "especial benefit" that (8)(A) provides to Amgen is sufficient advance notice of the launch of Hospira's biosimilar product so that Amgen has time to obtain preliminary injunctive relief to *prevent* that launch. Paragraph (9)(B) does not provide any method of enforcing the notice requirement and does nothing to put Amgen in the position it would have been in had Hospira given proper notice.

If Hospira were correct that an RPS cannot enforce the (8)(A) notice requirement, there would be little reason for a biosimilar applicant to ever give notice. If the applicant *does* give notice, the RPS is entitled to seek a preliminary injunction on patents to prohibit the applicant from commercial manufacture or sale of the approved product until the court decides the issues of infringement, validity, and enforceability. § 262(*l*)(8)(B). If the applicant does *not* give notice, the purported "remedy" of a (9)(B) declaratory judgment action provides no remedy at all for the applicant's failure to afford the RPS the benefit of a 180-day, post-approval notice period in which to seek a preliminary injunction after the applicant has received FDA approval. This outcome would frustrate Congress's intent in enacting the 180-day notice provision of (8)(A).

If Hospira were correct, and an applicant could choose not to give 180 days' notice of commercial marketing, that would mean three things: (i) no applicant would give the mandatory notice (so as to avoid a preliminary injunction of its product launch); (ii) faced with the imminent launch of a biosimilar competitor and the ensuing irreparable harm, the RPS would not seek a declaratory judgment, but would instead run to court to seek a temporary restraining order

against the launch, as well as to file a patent infringement suit; and (iii) the ensuing chaotic motion practice would rob the RPS, the court, and the public of the "defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." *Amgen*, 794 F.3d at 1358.

c. Administrative enforcement is unavailable

Hospira suggests that the BPCIA is a "regulatory law over which an agency or other governmental entity has the power of enforcement." (D.I. 16 at 12.) Conspicuously, Hospira cites no basis for its assertion. In fact, the BPCIA provides no mechanism for the enforcement of (8)(A) by regulatory action. Neither the FDA nor any other governmental entity has indicated that it could enforce (8)(A). The unavailability of administrative enforcement weighs in favor of finding an implied private cause of action. Otherwise, (8)(A) is wholly unenforceable, which cannot be what Congress intended.

The case law supports this conclusion. Courts have declined to find a private right of action where a statute is enforceable by a federal agency, but have found a private right of action where a statute lacks an administrative enforcement mechanism. *Compare Alexander*, 532 U.S. at 289 (denying an implied cause of action because the regulatory scheme created under the statute was enforced by federal agencies), *with Ind. Protection*, 603 F.3d at 379 (finding an implied private right because, among other things, there were no "separate administrative enforcement mechanisms").

d. Section 262(*l*)(1)(H) does not provide an express private cause of action

Hospira contends that because Congress included a private cause of action in another provision of the BPCIA (paragraph (1)(H)), Congress did not intend to include one under paragraph (8)(A). (D.I. 16 at 13.) That is wrong. Paragraph (1)(H) does not include an express

private cause of action; instead, it only provides that a court shall consider the disclosure of confidential information in violation of the statute as justifying "immediate injunctive relief." If anything, this provision underscores the fact that Congress anticipated that the provisions of the BPCIA would be privately enforceable in district court, without agency oversight of the required information exchanges and notice of commercial marketing.

In any event, the "fact that other provisions of a complex statutory scheme create express remedies has not been accepted as a sufficient reason for refusing to imply an otherwise appropriate remedy under a separate section." *Cannon*, 441 U.S. at 711; *see also Int'l Union*, 563 F.3d at 287 (an express statutory cause of action created for one group did not foreclose an implied cause of action for another group).

e. The limitation of remedies provided under 35 U.S.C. § 271(e) does not apply here

Lastly, Hospira contends that the BPCIA includes amendments to the Patent Act that provide remedies for violation of paragraph (8)(A). Indeed, Hospira argues that the remedies afforded under § 271(e)(4) are the exclusive remedies available under the BPCIA. (D.I. 16 at 13, 17.) Not so. Section 271(e)(4) limits the remedies available for an act of *patent infringement* under § 271(e)(2). *Amgen*, 794 F.3d at 1360. However, § 271(e)(4) in no way limits what remedies are available for a violation of (8)(A), where Hospira attempts to deprive Amgen of the statutory notice period following approval. Not only did the *Amgen* decision not address this issue, but the Federal Circuit entered injunctive relief in Amgen's favor to prevent a violation of (8)(A). *Amgen*, 794 F.3d at 1360-61.

3. Hospira conflates whether there is an implied private cause of action with the merits of Amgen's claims

In its motion, Hospira repeatedly disputes the merits of Amgen's allegation that Hospira failed to comply with (8)(A). But those issues need not be decided to determine whether (8)(A)

implies a private cause of action for its enforcement. Hospira's argument that it "is not required to provide any notice of commercial marketing" is misplaced. (D.I. 16 at 16.) Putting aside the fact that this argument is directly at odds with the Federal Circuit's holding in *Amgen v. Sandoz*, this is a question that goes to the merits of Amgen's claims, not the threshold question raised by Hospira's motion, which is whether Amgen has stated a cause of action.

If a court can *ever* award injunctive relief to enforce the (8)(A) notice requirement, as the Federal Circuit did in *Amgen*, a private cause of action must be available to an RPS like Amgen.

4. The Hatch-Waxman cases that Hospira cites are irrelevant because that statute expressly says that it does *not* provide a private cause of action

Hospira relies on two cases from the Hatch-Waxman context to argue that there is no implied private cause of action under paragraph (8)(A). (D.I. 16 at 13-15.) Actually, both cases support finding a private cause of action here. In each case, the court relied on express language in the statute saying that a private cause of action does *not* exist to enforce it; instead, Congress included express language in the statute requiring that all enforcement actions be brought by the U.S. government.

In stark contrast, after more than a decade of experience with Hatch-Waxman, Congress chose *not* to include such language in the BPCIA.

As Hospira itself says (D.I. 16 at 14), in *Mylan*, the Federal Circuit found no implied private cause of action because the Federal Food, Drug, and Cosmetic Act ("FFDCA") expressly provides that all enforcement proceedings "shall be by and in the name of the United States." *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1330 (Fed. Cir. 2001). Mylan sought an injunction ordering that an ineligible patent be removed from an Orange Book listing. The parties conceded that "such an action would be a private right of action barred by the FFDCA." *Id.* The only dispute was whether such relief could be sought in a counterclaim to a patent

infringement claim, an issue not presented here.

Likewise, in *3M v. Barr Labs., Inc.*, 289 F.3d 775, 783 (Fed. Cir. 2002), the court ruled that "[l]ike Mylan, 3M here attempts to assert a private right of action under the FFDCA because of another party's alleged failure to comply with the statute." As in *Mylan*, the court found such a claim barred under the express language of the FFDCA requiring that all enforcement actions be brought "by and in the name of the United States." *Id.* at 783 (quoting *Mylan*, 268 F.3d at 1332).

In contrast, the BPCIA does *not* contain express language limiting enforcement actions to those brought by the government. Indeed, comparisons to Hatch-Waxman only serve to underscore the importance of a private cause of action under the BPCIA. Under Hatch-Waxman, a generic applicant *must* certify to the FDA that it will give notice to the brand company when it files an Abbreviated New Drug Application. 21 U.S.C. § 355(j)(2)(A)(vii), (B)(i). Without that certification, the FDA will not approve the generic application. In contrast, under the BPCIA, an applicant's failure to give notice of commercial marketing under (8)(A) does not prevent the FDA from approving the biosimilar product. Thus, unlike under Hatch-Waxman, where no private cause of action is needed to enforce the provisions of the statute, under Hospira's interpretation of the BPCIA, the RPS would be left without a remedy if the applicant refused to follow the rules.

VI. CONCLUSION

The Court has jurisdiction over Count I of the Amended Complaint and authority to declare the parties' respective rights and obligations. Because (1) an RPS like Amgen is a member of a special group that Congress intended to benefit under § 262(*l*)(8)(A); and (2) the legislative scheme can only be enforced through a private remedy, paragraph (8)(A) contains an implied private cause of action, and Amgen has properly stated a cause of action for its enforcement.

The Court should deny Hospira's Motion to Dismiss.

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December 3, 2015

CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2015, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 3, 2015, upon the following in the manner indicated:

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