IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. Defendant.	C.A. No. 1:15-cv-00839-RGA [redacted] **REDACTED - PUBLIC VERSION** Dated: 07/06/17

HOSPIRA'S ANSWERING BRIEF IN OPPOSITION TO AMGEN'S MOTION FOR A PRELIMINARY INJUNCTION

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I. NATURE AND STAGE OF PROCEEDINGS

Hospira is seeking FDA approval to market a biosimilar version of Amgen's Epogen (epoetin alfa) product. Amgen has sued Hospira for infringing two expired patents, U.S. Patent Nos. 5,756,349 (the "'349 Patent") and 5,856,298 (the "'298 Patent"). Amgen also has alleged that Hospira violated the Biologics Price Competition and Innovation Act (the "BPCIA") by failing to provide an effective notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A) of the Act.

The BPCIA provides that a BLA applicant shall provide notice of commercial marketing at least 180 days before the date of first commercial marketing. The United States Supreme Court recently held that this notice can be provided before the applicant has FDA approval. Hospira submitted its abbreviated biologics application ("BLA") on December 16, 2014 and provided its notice of commercial marketing on April 8, 2015 (the "Notice" or "Hospira's Notice"). Hospira has thus satisfied section 8(A).

Hospira's proposed biosimilar has not been approved to date by the FDA. Amgen originally filed its *Motion for a Preliminary Injunction* on May 26, [redacted] That position was squarely rejected by the Supreme Court's *Sandoz v. Amgen* decision on June 12, 2017. Now that the Supreme Court has eviscerated Amgen's first preliminary injunction argument, Amgen has conjured up a new argument to support its request for an injunction based on arguments that were raised for the first time in the present motion and that contradict the clear factual record and Amgen's prior statements. (D.I. 262.)

II. SUMMARY OF ARGUMENT

The Court should deny Amgen's motion. First, Amgen is unlikely to succeed on the merits. The Supreme Court recently confirmed in *Sandoz v. Amgen* that a BLA applicant may

send a notice of commercial marketing prior to obtaining FDA approval, which Hospira undisputedly did on April 8, 2015. There is no basis in the BPCIA or the Supreme Court's *Sandoz* opinion for the additional requirements Amgen now asks this Court to impose—none of which were raised in Amgen's initial request for a preliminary injunction.

Hospira provided its Notice in April 2015 and never rescinded or withdrew it. Amgen knows that fact so well that it pointedly complained about it in its Second Amended Complaint filed in October 2016. [redacted] Amgen's reliance on one out-of-context quotation from a letter cannot change Hospira's consistent position in correspondence with Amgen and before this Court and Amgen's acknowledgement of that position. Thus, Amgen's first argument that it will succeed on the merits fails.

Amgen's second argument fails because it has no statutory support. The BPCIA does not require Hospira to provide an additional notice of commercial marketing after it receives and responds to a complete response letter ("CRL"). Amgen's argument rehashes the same rationale that the Supreme Court squarely rejected in *Sandoz*. Indeed, in rejecting Amgen's argument that notice can only be properly provided after FDA approval because that is when the properties of a biosimilar product can be known, the Court explained that "nothing in §262(*l*)(8)(A) turns on the precise status or characteristics of the biosimilar application." *Sandoz Inc. v. Amgen Inc.*, No. 15-1039, slip op. at 17 (U.S. June 12, 2017). Thus, Amgen's motion is completely baseless.

Second, Amgen will not suffer any irreparable harm that is cognizable under the BPCIA. Hospira provided a proper Notice more than 180 days ago and can launch its product upon FDA approval. If Amgen loses any sales to Hospira, that is not cognizable "harm"—that is the intended consequence of the BPCIA, which seeks to get competitive biosimilar products into the hands of consumers in a timely fashion. Moreover, Amgen's argument ignores crucial facts about the marketplace—[redacted]

Amgen also suggests that it will face irreparable harm because it may have more patents waiting in the wings. But no such patents were disclosed to Hospira under the BPCIA exchanges, and Amgen has repeatedly told investors that its last material patent on Epogen expired when the '349 patent expired in May 2015.

Third, the balance of equities favors Hospira, not Amgen. Hospira complied with the BPCIA's notice of commercial marketing requirements. Hospira diligently pursued its BLA, including responding to questions from the FDA. As contemplated by the BPCIA, Hospira should now be permitted to launch its product as soon as it obtains approval. Amgen has had patent protection for Epogen since it was launched in 1989, almost thirty years ago. Now, with the only patents that Amgen thought it could assert against Hospira having expired, Amgen improperly is attempting to use the notice of commercial marketing to eke out another six months of market exclusivity, when the Supreme Court has clearly ruled against this. Granting Amgen further exclusivity by issuing an injunction would be improper and inequitable.

Fourth, the public interest does not favor an injunction. The BPCIA created a framework for biosimilar drug product approval with the potential to save billions of dollars in public health costs. The public interest is greatly served by biosimilar drug competition; the public does not

benefit from enjoining competitive biosimilars without any factual or legal basis, particularly following a three-decade run of unfettered market exclusivity.

Finally, if an injunction is granted, the Court should require Amgen to post a significant bond, as required by the Federal Rules and Third Circuit case law. However, the Court should address the amount of a bond if and when the scope and timing of an injunction are determined. If the Court were to require Hospira to send a further notice of commercial marketing, it could potentially keep Hospira from launching its product when it obtains FDA approval. That would cause great financial harm to Hospira. In fact, being prevented from launching for even *one day* after approval would cause unwarranted and significant harm to Hospira. [redacted] If, at some point, the Court were to decide to issue an injunction, it should allow the parties to present detailed evidence on the bond amount.

III. STATEMENT OF FACTS

A. Hospira Provided Notice of Commercial Marketing on April 8, 2015.

Hospira provided its notice of commercial marketing to satisfy Section 262(*l*)(8)(A) of the BPCIA on April 8, 2015. (Ex. 1.)[1] Amgen does not contest the fact that Hospira sent its Notice on that date. For ease of reference, Sections 262(*l*)(8)(A)-(B)[2] are set forth below:

> **(8) Notice of commercial marketing and preliminary injunction**
>
> **(A) Notice of commercial marketing**
> 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).

[1] "Ex." refers to Exhibits to the Declaration of Michael W. Johnson, dated June 26, 2017, and submitted herewith.

[2] All references to the BPCIA are at 42 U.S.C. § 262 (2017), unless otherwise noted.

> **(B) Preliminary injunction**
>
> After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—
>
> (i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and
>
> (ii) not included, as applicable, on—
> (I) the list of patents described in paragraph (4); or
> (II) the lists of patents described in paragraph (5)(B).

Paragraph (8)(A) specifies that the applicant shall provide notice to the reference product sponsor (RPS) "*not later than*" 180 days before first commercial marketing. Paragraph (8)(B) then specifies that, after receiving the notice, the RPS may seek a preliminary injunction on certain patents—ones that were included in the parties' (3)(A) or (3)(B) lists and *not* included on the paragraph (4) or (5)(B) lists. These lists are part of the "patent dance" exchanges specified in Section 262(*l*) of the BPCIA.

In addition, Section 262(*l*)(7) specifies that, if a new patent that could reasonably be asserted against the applicant is issued to or licensed by the RPS after the (3)(A) list, the RPS shall supplement its (3)(A) list within 30 days, the applicant shall supplement its (3)(B) list, and such patent shall be subject to paragraph (8). Here, Hospira is the subsection (k) applicant and Amgen is the RPS. The parties exchanged (3)(A) and (3)(B) lists, engaged in good faith negotiations, and reached agreement on three patents that could be involved in this suit. (*See, e.g.*, Ex. 2, Amgen's May 1, 2015 Disclosure Under § 262(*l*)(3)(A); Ex. 3, Hospira's June 19, 2015 Disclosure Under § 262(*l*)(3)(B); Ex. 4, Hospira's August 19, 2015 Letter.) Amgen could

have brought suit on all three patents, but Amgen asserted only two of those patents on September 18, 2015. (D.I. 1.)

Because the parties agreed that Amgen could have asserted all three patents, there were no patents eliminated during the negotiation process. Therefore, there were no paragraph (4) or (5)(B) lists as referenced in Section 262(*l*)(8)(A), as those lists are only created if the parties cannot reach agreement on the patents to include in any suit. In addition, Amgen has not notified Hospira of any newly issued or licensed patents pursuant to Section 262(*l*)(7). In short, there are currently no patents for which Amgen can seek a preliminary injunction under (8)(B).

On August 18, 2015, shortly after the Federal Circuit issued its decision in *Amgen v. Sandoz*, [redacted]

Amgen understood and recognized that Hospira's April 2015 Notice remained in place and has referenced that Notice numerous times throughout this litigation. Amgen's Second Amended Complaint, dated October 5, 2016, acknowledges that Hospira provided its Notice on April 8, 2015, and has not withdrawn it. Amgen *complained* about that fact:

> 71. Despite its obligation under § 262(*l*)(8)(A), Hospira provided Amgen with a purported (8)(A) notice on April 8, 2015, *before* Amgen had provided its initial disclosure of patents under (3)(A) and *before* Hospira received FDA approval for its Hospira Epoetin Biosimilar Product. On May 8, 2015, Amgen objected to this premature attempt to provide notice, but Hospira has repeatedly refused to withdraw it.

(D.I. 139, ¶ 71) (emphasis in original). Amgen took the same position in its Amended Complaint, dated November 6, 2015, and its Complaint, dated September 18, 2015. (D.I. 11, ¶ 62; D.I. 1, ¶ 62.)

Amgen has also acknowledged in briefing before this Court that "Hospira provided Amgen with a purported (8)(A) notice on April 8, 2015," and that Hospira informed Amgen after the Federal Circuit's *Amgen v. Sandoz* decision that it would "give no ***further notice*** if it receives FDA approval." (D.I. 17 at 5) (emphasis added). [redacted]

Amgen filed its motion for a preliminary injunction on May 26, 2017, and reiterated its understanding that Hospira had provided a pre-approval notice of commercial marketing on April 8, 2015, [redacted] (D.I. 213 at 5.) [redacted]

[redacted] On June 12, 2017, the Supreme Court confirmed Hospira's position that its pre-approval notice of commercial marketing was legally effective, holding that an "applicant may provide notice either before or after receiving FDA approval." *Sandoz*, No. 15-1039, slip op. at 16. Amgen then filed an amended brief in support of its motion for a preliminary injunction [redacted] (D.I. 262 at 10.)

B. Hospira Provided Additional Data and Information to FDA in Response to a Complete Response Letter.

As explained in the attached Declaration of Tracy Dianis, Director of Global Regulatory Affairs Biosimilars, Pfizer Essential Health, which is being filed contemporaneously with this brief, Hospira filed its BLA on December 16, 2014. (Dianis Decl. ¶ 3.)[3] [redacted]

[redacted]

A CRL is a letter that combines comments from all of the FDA disciplines that review a pending application. (Dianis Decl. ¶ 4.) As indicated in FDA regulations, "a complete response letter will describe all of the deficiencies that the agency has identified in a biologics license application or supplement." (*Id.*) "When possible, a complete response letter will recommend actions that the applicant might take to place its biologics license application or supplement in condition for approval." (*Id.*) [redacted]

[3] "Dianis Decl." refers to the Declaration of Tracy L. Dianis, dated June 26, 2017, and submitted herewith.

After receiving a CRL, an applicant may submit additional information to the FDA, addressing all deficiencies identified in the CRL, or withdraw the application. (Dianis Decl. ¶ 5.) The FDA refers to this submission of additional information as a "resubmission" because it restarts the review clock for the FDA to review the application with the additional information provided. (*Id.*) A "resubmission" is not a new application. (*Id.*) A "resubmission" is defined by the FDA as a "submission to an NDA, BLA, or efficacy supplement that purports to answer all of the deficiencies that need to be addressed by the applicant before approval as set forth in the complete response letter." (*Id.*) [redacted]

IV. ARGUMENT

A. Amgen Is Unlikely To Succeed On The Merits.

The Court should deny Amgen's motion because Amgen is unlikely to succeed on the merits. The U.S. Supreme Court recently clarified that "[t]he BPCIA facilitates litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes." *Sandoz*, No. 15-1039, slip op. at 3. To accomplish this goal, the BPCIA sets forth a "carefully calibrated scheme" to resolve patent issues and provide notice of commercial marketing to the RPS. *Id.*, slip op. at 4. Amgen's latest argument that Hospira failed to comply with that statutory scheme is legally baseless and relies on egregious factual misrepresentations.

[4] [redacted]

In *Sandoz*, the Supreme Court held that a biosimilar applicant may provide an 8(A) notice of commercial marketing prior to obtaining FDA approval. *Id.*, slip op. at 16. Hospira provided its Notice in April 2015. Hospira's pre-approval Notice was effective and was never withdrawn, and thus Hospira can launch upon approval. Nevertheless, in a desperate attempt to overcome the implications of *Sandoz*, Amgen now claims for the first time that two "subsequent events" rendered Hospira's Notice ineffective. (D.I. 262 at 10.)

1. [redacted] But the Federal Circuit had not yet held that the (8)(A) notice of commercial marketing was mandatory for applicants that participate in the (2)(A) information exchange. *See Amgen Inc., et al. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016). [redacted]

[redacted] Amgen has repeatedly and consistently asserted that Hospira sent its notice of commercial marketing in April 2015, but that Hospira's notice was ineffective because it was sent prior to obtaining FDA approval. Amgen acknowledged Hospira's April 2015 notice in its Complaint, its Amended Complaint, and Second Amended Complaint, and *complained* in all three that Hospira has "repeatedly refused to withdraw" its Notice. (D.I. 1, ¶ 62; D.I. 11, ¶ 62; D.I. 139, ¶ 71.) Amgen also acknowledged in briefing before the Federal Circuit that Hospira "serv[ed] a purported 'notice of commercial marketing' before its biosimilar product is licensed," arguing that Hospira's Notice was ineffective because "a biosimilar applicant may only give effective notice of commercial marketing after the FDA has licensed its product." Amgen's Opp. Br. at ¶¶ 66 & 81, *Amgen Inc. v. Hospira, Inc.*, App. No. 16-2179 (Fed. Cir. July 18, 2016) (ECF No. 14). [redacted]

Accordingly, Amgen's argument [redacted] contradicts the factual record, its own position before this Court and the Federal Circuit, and its communications with Hospira prior to the Supreme Court's decision in *Sandoz v. Amgen*.

2. Hospira's CRL Response Did Not Trigger an Obligation to Provide Further Notice of Commercial Marketing.

Second, Amgen claims that providing additional information and testing data to FDA in response to the CRL obligated Hospira to provide yet another notice of commercial marketing. (Amgen Br. at 10-11.) Amgen's argument has no factual or legal basis. To the extent Amgen suggests that a new notice of commercial marketing was required because Hospira's response to the CRL was a "resubmission" of its BLA, that is not correct. Hospira did not withdraw its BLA—"resubmission" is simply the terminology used by FDA when an applicant responds to FDA questions and restarts the review clock. (Dianis Decl. ¶ 5.) Moreover, Amgen's present argument is simply a repackaged version of its argument in *Sandoz*, which was explicitly rejected by the Supreme Court. *Sandoz*, No. 15-1039, slip op. at 16. While Amgen now links its argument to the submission of additional data and information to the FDA, rather than the date of FDA approval, the Supreme Court clearly stated that "*nothing* in § 262(*l*)(8)(A) turns on the precise *status* or *characteristics* of the biosimilar application." *Id.*, slip op. at 17 (emphasis added).

Amgen's current attempts to sidestep the Supreme Court's *Sandoz* decision cannot change the law. There is no BPCIA provision that a proper notice somehow loses its effect when a CRL is received, or that a new notice must be given when a CRL response is submitted. As the Supreme Court held in *Sandoz*, "Section 262(*l*)(8)(A) contains a single timing requirement: The applicant must provide notice at least 180 days prior to marketing its biosimilar." *Sandoz*, No. 15-1039, slip op. at 16. Amgen cites no legal support for its argument that a CRL triggers an

obligation to provide further notice of commercial marketing, and that argument should be rejected.

3. Amgen Is Not Entitled to an Injunction Under Section 262(*l*)(8)(B).

Amgen's motion is also flawed because it incorrectly assumes that Amgen could seek an injunction under §262(*l*)(8)(B). A preliminary injunction under § 262(*l*)(8)(B) may *only* be sought with respect to: (i) any patent that is included in the parties' respective (3)(A) or (3)(B) lists and not in the lists described in (4) or (5)(B) or (2); or (ii) any newly issued or licensed patent for which 30-day notice and a supplemental (3)(A) list was provided under 262(*l*)(7). As the Supreme Court explained in *Sandoz*, "the BPCIA channels the parties into two phases of patent litigation." *Sandoz*, No. 15-1039, slip op. at 5. The first phase identifies patents that the parties want to litigate immediately; the second phase is triggered by the applicant's notice of commercial marketing and "involves any patents that were *included* on the parties' § 262(*l*)(3) lists but *not* litigated in the first place." *Id.* (emphasis added). In the second phase, either party may sue for declaratory relief and, prior to the date of first commercial marketing, the RPS may seek a preliminary injunction under § 262(*l*)(8)(B) on any patent that was included in the (*l*)(3) lists but not litigated in the first phase. *Id.*, slip op. at 7.

There are no "second phase" patents here. The parties exchanged (3)(A) and (3)(B) lists, engaged in good faith negotiations, and agreed on three patents that could be involved in this suit. (*See* Exs. 1-4.) Amgen then brought suit on two of those patents on September 18, 2015 (D.I. 1), thereby waiving its right to bring suit on the third patent. Amgen has not sent notice of any newly issued or licensed patents nor updated its (3)(A) list since that time. Thus, Amgen has already brought suit on *all* the patents for which it is entitled to bring suit pursuant to the BPCIA. Amgen has not identified any patents it could assert in a second phase of litigation or on which it may seek to obtain a preliminary injunction under (8)(B).

Amgen speculates that it may be able to assert new patents depending on the outcome of its interlocutory appeal to the Federal Circuit. But Amgen told the Federal Circuit during oral argument that it has no Rule 11 basis to assert additional patents:

> Q. Just curious is there anything that's preventing you right now from filing another complaint under 271(e)(2)(C)(2), for any patents that you have that relate to manufacturing the biological product?
>
> A. Yes, Your Honor, what's preventing us from bringing such a suit is that we can't tell whether there is infringement, and as we understand the entire statutory regime that would apply here, and would apply to any lawsuit, there has to be a reasonable basis to meet Rule 11 and put that patent in play.

Oral Argument at 4:05-4:39, *Amgen Inc. v. Hospira Inc.*, No. 16-2179 (Fed. Cir. Apr. 3, 2017), *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2016-2179.mp3.

Amgen's suggestion that it deserves an injunction because it wishes that it someday might have a Rule 11 basis to assert some unidentified patent is untenable. Amgen's position is particularly unjustified because it has told its investors and the public repeatedly that its last material patent for Epogen would expire in December 2015. (*See, e.g.*, Ex. 8, Heeb Ex. 10.) In any event, the BPCIA provides for preliminary injunction proceedings following an 8(A) notice for patents which have been identified and listed by the reference product sponsor. Here, Amgen has no such patents.

For all of the foregoing reasons, Amgen is unlikely to succeed on the merits.

B. Amgen Would Not Suffer Cognizable Irreparable Harm.

Amgen makes a variety of purported economic arguments about irreparable harm. But at the end of the day, Amgen has not shown that it will suffer any legally cognizable harm at all, let alone harm that is caused by Hospira and that could not be satisfied with money damages.

As discussed above, Hospira provided a proper Notice and can launch its product upon approval. If Amgen loses sales to Hospira, that is not cognizable "harm"—that is the intended consequence of the BPCIA, which seeks to get competitive biosimilar products into the hands of consumers in a timely fashion. This is especially true here, where Amgen is not asserting any unexpired patents. In addition, Amgen's motion ignores the economic realities of the marketplace in which Epogen competes. Amgen assumes that any sales by Hospira will directly translate into lost sales of Epogen, the product at issue in this case, and Aranesp, Amgen's long-acting erythropoiesis-stimulating agent ("ESA") that is not covered by the patents in suit.

[redacted] These factors are confirmed in Amgen's 10K filings and news articles. (*See* Ex. 10, Billen Ex. 41; Ex. 11, Billen Ex. 42; Ex. 12, Billen Ex. 43; Ex. 13, Billen Ex. 45; Ex. 14, Billen Ex. 47 at 7-8; Ex. 15, Billen Ex. 48 at 43.)

[redacted]

[redacted] Importantly, Amgen has also licensed its '349 Patent to competitors. Amgen granted a royalty-bearing license to Ortho, which allows Ortho to sell Procrit in the oncology sector. (Ex. 16, Heeb Dep. Tr. 69:15-21.) Amgen also granted a royalty-free license to Roche as part of a settlement agreement, which enabled Roche to launch its competing Mircera product prior to expiration of the patents-in-suit. (*Id.* at 76:14-77:4; 215:22-216:18.)

The Federal Circuit recently affirmed that prior licenses can weigh against a finding of irreparable harm. *Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328, 1343 (Fed. Cir. 2017). In *Nichia,* the Federal Circuit upheld a district court decision denying a permanent injunction where the patent holder licensed "'significant competitors' who posed major threats to [its] flagship products." *Id.* Amgen's 10-K lists Procrit and Mircera as "significant competitors" to Aranesp and Epogen. (Ex. 8, Heeb Ex. 10 at 8; Ex. 16, Heeb Dep. Tr. 120:22-121:13.) As Amgen's economic expert Dr. Heeb admitted, Roche has capacity and interest in selling Mircera regardless of whether Hospira ever launches. (Ex. 16, Heeb Dep. Tr. 100:8-11; 100:22-25.) Amgen's licensing to significant competitors weighs against a finding of irreparable harm.

Moreover, Amgen's arguments concerning the extent to which Hospira's proposed biosimilar will affect Amgen's sales are speculative. [redacted]

Finally, Amgen's original motion for a preliminary injunction raised a brand-new product that has never been identified or discussed in this litigation—PARSABIV, a product that is

purportedly approved for a different indication in dialysis patients. (D.I. 213 at 18.) Although Amgen has dropped this baseless argument from its brief, it is still referenced in its economist's declaration. (D.I. 216, Gaier Decl., ¶¶ 50-51.) Aside from the fact that Amgen should not be permitted to rely on information about a product that it did not disclose in discovery,[5] it is pure speculation to say that sales of Hospira's proposed biosimilar product will affect Amgen's marketing capabilities for an unrelated drug and cause Amgen "long-lasting" harm. Amgen's own expert admits that "[r]eliably forecasting future outcomes in ESA markets is particularly difficult," in light of the fact that "there is virtually no experience with biosimilar entry in U.S. markets from which to learn." (D.I. 216, Gaier Decl. ¶ 55.) But fear of the unknown is not a basis for enjoining biosimilar competition.

Finally, Amgen suggests that it will be harmed because it may have additional patents it wants to assert. As discussed above, there are simply no patents on which Amgen could seek an injunction under 8(B). Speculation about patents that may or may not exist does not create cognizable harm, and thus this argument also fails.

Thus, Amgen has failed to demonstrate that it would suffer irreparable harm and its motion should be denied.

C. The Balance of Equities Favors Hospira.

Amgen argues that the balance of equities favors Amgen because it simply wants Hospira to comply with the law and provide an effective notice. (Amgen Br. at 18.) But Amgen is not

[5] Amgen provided no information or discovery about this product prior to this motion. Hospira specifically served Interrogatory No. 19 directed to any request for injunctive relief, but received no information about PARSABIV. (*See* Ex. 18, Amgen's Answer to Hospira's Interrogatory No. 19.) Amgen also never raised PARSABIV in Dr. Heeb's damages report or deposition. The Court should not allow Amgen to rely on PARSABIV, or any other facts and evidence that were not provided in discovery.

seeking to apply the law—it is making up new requirements in a desperate effort to overcome an adverse Supreme Court decision.

Hospira complied with the BPCIA's notice of commercial marketing requirements.

[redacted] Hospira should be permitted to launch its product as soon as it obtains approval, as contemplated by the BPCIA. Amgen is trying to use the notice provision to stretch out the market exclusivity it has already enjoyed for almost thirty years, even though its patents have expired. Amgen has repeatedly told investors that its last material patent on Epogen expired when the '349 Patent expired in May 2015. (Ex. 14, Billen Ex. 47 at 7-8; Ex. 15, Billen Ex. 48 at 43; Ex. 8, Heeb Ex. 10.) Amgen's suggestion now that it has more patents to assert—patents that were never disclosed to Hospira, the Court, or investors—is pure speculation.

Amgen also inexplicably argues that its pending appeal before the Federal Circuit should affect the Court's decision to grant an injunction because "the Supreme Court noted that a district court may consider a biosimilar applicant's violation of the § 262(*l*)(2)(A) disclosure requirement when assessing the balance of equities." (Amgen Br. at 18.) The Supreme Court said no such thing and explicitly "express[ed] ***no view*** on whether a district court could take into account an applicant's violation of § 262(*l*)(2)(A) . . . in deciding whether to grant a preliminary injunction ***under 35 U.S.C. § 271(e)(4)(B) or § 283*** against marketing the biosimilar." *Sandoz*, No. 15-1039, slip op. at 13 n.2 (emphasis added). Not only did the Supreme Court explicitly take no position on this point, but the footnote Amgen cites is unrelated to injunctive relief under Section 262(*l*)(8)(B).

The purpose of the (8)(A) notice of commercial marketing is to allow the RPS to seek an injunction on the particular patents discussed above—patents from the (3)(A) and (3)(B) lists

that were not newly issued or licensed patents on the (4) or (5)(B) lists. *Sandoz*, No. 15-1039, slip op. at 5-7. In this litigation, there are no such patents. The only rationale for Amgen to seek an injunction is to delay legitimate competition and deprive the public of a competitive epoetin alfa biosimilar. The equities therefore favor Hospira.

D. The Public Interest Favors Hospira.

The public interest also favors Hospira. Hospira is seeking approval to market a competitive biosimilar and has complied with the BPCIA. The BPCIA created an abbreviated licensing process similar to the Hatch-Waxman Act, which would create market competition and a reduction in prices, possibly saving the federal government up to $14 billion in drug costs. (Ex. 17, Judith A. Johnson, Cong. Research Serv., FDA Regulation of Follow-On Biologics Federal Regulation of Follow-On Biologics, RL34045, at Summary, 1 & 4 (Apr. 26, 2010); *see also Sandoz*, No. 15-1039, slip op. at 3.) Competition in the marketplace would be furthered by Hospira obtaining approval and launching its product as quickly as possible; preventing or delaying that launch would harm the public interest.

E. Amgen Should Be Required to Post A Bond.

Amgen makes a cursory dismissal of the bond requirement, but Fed. R. Civ. P 65(c) provides that the Court may order a preliminary injunction "only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." This bond requirement is strictly enforced in the Third Circuit, and cannot be waived in this case.

Amgen's reliance on *Temple University* is misleading. In *Temple University v. White*, 941 F.2d 201, 219-20 (3d Cir. 1991), the Third Circuit recognized an exception to the mandatory bond requirement of Rule 65(c) that other circuits applied in non-commercial and public interest cases. *Id.* at 219-20 & n.25. The court held that an exception to the bond requirement can apply

"under certain narrowly drawn circumstances," such as "to enforce important federal rights or public interests arising out of comprehensive federal health and welfare statutes." *Id.* at 219-20 (internal quotations and citation omitted). In that case, the movant was a hospital on the brink of financial ruin that would have become insolvent absent a preliminary injunction. *Id.* at 219.

Amgen cannot meet this narrow public-interest exception. The Third Circuit has distinguished *Temple University* in commercial cases, explaining: "We have never excused a District Court from requiring a bond where an injunction prevents commercial, money-making activities." *Zambelli Fireworks Mfg. Co., Inc. v. Wood*, 592 F.3d 412, 426 (3d Cir. 2010); *see also PharMethod, Inc. v. Caserta*, 382 Fed. Appx. 214, 222 (3d. Cir. 2010). Contrary to Amgen's arguments, "a district court lacks discretion under Rule 65(c) to waive a bond requirement except in the exceptionally narrow circumstance where the nature of the action necessarily precludes any monetary harm to the defendant, and that such bond shall be issued irrespective of any request by the parties." *Zambelli Fireworks*, 592 F.3d at 426.

Thus, the Court has no discretion to deny a bond in this case. If the Court were to enjoin Hospira now for a period lasting at least 180 days after FDA approval, based on a yet-to-be-asserted patent, Hospira would suffer significant financial harm. In fact, in light of the Supreme Court's ruling in *Sandoz* indicating that Hospira's pre-approval notice of commercial marketing was effective, being enjoined for even *one day* after approval would cause unwarranted harm to Hospira. Nevertheless, if this Court were to decide at some point in the future to enter an injunction, the Court should allow the parties to provide detailed evidence on the proper amount of a bond. That can only be done once the scope and timing of any injunction are determined.

V. CONCLUSION

Hospira respectfully asks the Court to deny Amgen's motion.

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CERTIFICATE OF SERVICE

I, Dominick T. Gattuso, Esquire, hereby certify that on the 26th day of June, 2017, a copy of Hospira's Answering Brief in Opposition to Amgen's Motion for a Preliminary Injunction was served upon counsel of record via electronic mail.

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