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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and AMGEN MANUFACTURING LIMITED, *Plaintiffs*, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, *Defendants*.	CASE NO. 2:16-cv-01276-SRC-CLW **REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS**

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Defendant Sandoz Inc., ("Sandoz") hereby submits this Reply in support of its motion to dismiss Plaintiffs', Amgen Inc. and Amgen Manufacturing Limited (collectively "Plaintiffs" or "Amgen") Complaint for lack of standing under Fed. R. Civ. P. 12(b)(1) or in the alternative under Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted.[1]

I. INTRODUCTION

Amgen spends twenty-seven pages attempting to obscure the fact that, at most, this case concerns a theoretical difference of opinion regarding how a statute might be interpreted in future cases. Amgen's repeated references to "recurring controversy" and "future cases" underscore that what it is seeking is an improper advisory ruling about the BPCIA statute unconnected to any live case or controversy between the parties to this case. Amgen concedes it has already received all of the tangible relief it originally sought, and Amgen's concern that this statutory issue may arise in future cases between these or other litigants – for different products and under different circumstances – does not create a basis for maintaining this lawsuit.

There is literally nothing left (if anything existed in the first place) to litigate with respect to the specific dispute and facts that formed the basis for Amgen's complaint – the patent-

[1] Amgen noted that there is additional information it will seek in discovery as this case progresses as support for why this motion should not be converted into one for summary judgment. (Opp. Br. at 17.) Sandoz disagrees. As an issue of statutory interpretation, no factual evidence is required for the Court to determine this issue. *See. e.g.*, *Peavy v. WFAA–TV, Inc.*, 221 F.3d 158, 168 (5th Cir. 2000) ("Whether the [ECPA] authorizes a private civil action for procurement is a legal issue of statutory interpretation, which requires no presentation of evidence."). Discovery from Sandoz has no bearing on the Court's statutory interpretation. *See, e.g.*, *Reeves v. City of Georgetown*, No. CIV.A. 12-126-JBC, 2012 WL 3962334, at *3 (E.D. Ky. Sept. 10, 2012), *aff'd sub nom. Reeves v. City of Georgetown*, 539 F. App'x 662 (6th Cir. 2013) ("[B]ecause this action is being resolved on a matter of statutory interpretation, a party's interpretation of an ordinance—or alleged communications with counsel regarding such interpretation—is not relevant to the court's holding."); *United States v. Farley*, 11 F.3d 1385, 1391 (7th Cir. 1993) (holding that "a matter of statutory interpretation" is "a process which does not require the court to review the postulations of agency staff members as to the meaning of the investment-only exemption").

exchange process regarding Sandoz's pegfilgrastim product. Despite entirely disagreeing with its position, Sandoz fully complied (and Amgen does not dispute this) with the BPCIA patent-exchange steps, even under Amgen's interpretation of the statute, for this product. Amgen has now filed patent litigation in the Northern District of California ("NDCA") against Sandoz regarding its Pegfilgrastim Product, and the parties agree that Amgen has complied with the 30-day requirement under 262(*l*)(6) in bringing this suit. There is no BPCIA dispute left to talk about. The only live controversy between Amgen and Sandoz with respect to Sandoz's Pegfilgrastim Product is Amgen's NDCA patent infringement suit.

At best, Amgen is asking this Court to issue a purely advisory legal ruling on statutory interpretation disconnected from the facts of the case; at worst, Amgen is asking for an order to compel Sandoz to do what it has already done. Because Amgen fails to plead a claim upon which relief can be granted, and because this Court lacks jurisdiction to provide an advisory ruling in the absence of a live controversy and without any properly alleged injury in fact, this case must be dismissed.

II. STATEMENT OF ADDITIONAL FACTS

In addition to the facts set forth in its memorandum in support of the motion to dismiss, (Dkt. No. 28-2), Sandoz sets forth the following additional facts: After Sandoz moved to dismiss this litigation, Amgen commenced a patent infringement suit against Sandoz and the other named defendants in this action in the NDCA under BPCIA section 262(*l*)(6), essentially conceding that Sandoz had completed the patent exchange process on Amgen's terms. (Exhibit A, Compl., ¶74, *Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 3:16-cv-02581-RS (N.D. Cal. May 12, 2016.) In its Complaint, Amgen asserted that Sandoz has infringed U.S. Patent Nos. 8,940,878 ("the '878 Patent") and 5,824,784 ("the '784 Patent"). (*Id.* ¶78.)

III. ARGUMENT

Amgen does not dispute that hypothetical future events are not a live case or controversy. Amgen also does not seem to dispute that whatever controversy may have existed when this lawsuit was filed has since been resolved between the parties. Nevertheless, Amgen asserts there was once a controversy between the parties "about how the BPCIA should be applied" when "an Applicant ... refuses to follow subparagraph 262(*l*)(3)(C)and paragraphs (*l*)(4) and (*l*)(5) and thus prevents a Sponsor from timely filing a paragraph (*l*)(6) lawsuit" and then asks this court to give an advisory opinion on how it might rule should this issue come up in some future litigation.[2] Amgen's arguments fail on multiple grounds.

A. Sandoz Never Violated The BPCIA.

Simply put: Sandoz always complied with the BPCIA's patent dance. First, at the time Amgen commenced this action, the next step in the patent exchange process was theirs. Indeed, a plain reading of the statute shows that § 262(*l*)(3)(C), the next step in the patent exchange at the time Amgen commenced this suit, is directed to the Sponsor, Amgen, not Sandoz. It is therefore unclear how Amgen was ever "prevented" from moving forward with its 262(*l*)(3)(C) response, thus necessitating this suit.

Second, even if Amgen was right that Sandoz had somehow not complied with the BPCIA by virtue of the positions it had taken in correspondence, the Federal Circuit in *Amgen v Sandoz* makes it clear that "non-compliance" is not a "violation" of the BPCIA. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1355-1356 (Fed. Cir. 2015). Such action instead allows the

[2] Amgen also states that a mandatory injunction until patent expiry is only available in a subparagraph (*l*)(6) lawsuit pursuant to 35 U.S.C. § 271(e)(4)(D). However, section 271(e)(4)(D) is not applicable in this case because it requires that "the biological product has not yet been approved because of Section 351(k)(7) of such Act." Amgen's NEULASTA® was approved in 2002.

reference product sponsor to bring a declaratory judgment action for patent infringement on patents and at a time of their sole choosing. (*Id.*)

Third, notwithstanding the above, Sandoz's position was *always* that it has effectively received Amgen's 262(*l*)(3)(C) response. When Amgen listed the '878 patent on their (*l*)(3)(A) list, Sandoz considered Amgen was highly likely to commence a patent suit in relation to pegfilgrastim. Sandoz wanted to ensure any lawsuit on that patent was expeditiously heard together with the ongoing lawsuit in the NDCA under that same patent *to avoid unnecessary delay* and *to preserve judicial and party resources*. Sandoz specifically represented that it "effectively already has Amgen's [262(*l*)(3)(C)] positions" in light of the previous exchange in the ongoing related filgrastim litigation in which the same patent is at issue and contentions had already been exchanged, thereby completing 262(*l*)(3)(C). (Dkt. 28-3 at 4.) Sandoz further *agreed* that the two patents Amgen identified in Amgen's 262(*l*)(3)(A) list shall be the subject of (*l*)(6) litigation—"at Amgen's discretion." (*Id.*) Thus, the parties were also already in agreement under 262(*l*)(4) as to the patents that could be the subject of a (*l*)(6) litigation – Sandoz having agreed *ab initio* to Amgen's decision to sue on either or both (or neither) of its two patents. Moving on to the next step in the exchange was entirely consistent with the BPCIA, namely the commencement of any patent litigation under (*l*)(6). In no way, did Sandoz "prevent" Amgen from filing a paragraph (*l*)(6) lawsuit – in fact, it was acting in a way that allowed Amgen to bring such a suit earlier than would otherwise have been possible.

Further, Amgen's position that it has been injured by being "prevent[ed]… from bringing an immediate patent infringement action under paragraph (l)(6)" is puzzling. (Opp. Br. at 25.) In its own words, Amgen did file the NDCA suit "pursuant to 42 U.S.C. § 262(*l*)(6)(A)." (Ex. A, ¶74.) Amgen's own pleadings belie their alleged injuries. What's more, in the *Enbrel* lawsuit,

Amgen filed an immediate patent suit despite the fact that it considered (again incorrectly) that not all steps of the BPCIA's subsection (k) pathway were fulfilled. (*See* Opp. Br. at 15; *Immunex Corp. v. Sandoz Inc.*, No. 2:16-cv-01118-CCC-JBC (D.N.J. filed Feb. 26, 2016)). Amgen cannot have it both ways—asserting that it was injured in being prevented from bringing suit here, but clearly feeling able to bring an immediate patent suit elsewhere under the same circumstances.

Amgen's assertion that Sandoz "extinguish[ed] Plaintiffs' ability to consider and respond to Sandoz Inc.'s contentions regarding the patents that Plaintiffs had properly identified" is also erroneous. (Opp. Br. at 25.) Amgen had already considered and responded to those contentions with respect to the filgrastim litigation as to the '878 Patent. Not surprisingly, Amgen essentially repeated its infringement contentions from the filgrastim litigation in its 262(*l*)(3)(C) response, confirming this step was already satisfied by the filgrastim contentions, as Sandoz originally stated. No response was necessary with respect to the '784 Patent either because Sandoz stated that it would not commercialize the pegfilgrastim product until after the patent's expiration.

B. No Live Controversy Exists Regarding the Pegfilgrastim Patent Exchange Process.

Even if Amgen was right that the parties' disagreement regarding the BPCIA requirements properly gave rise to this lawsuit in March (and it is not), any such dispute (and correspondingly, jurisdiction) has been extinguished by Sandoz's full acquiescence to follow the BPCIA steps as Amgen insisted was necessary for the Pegfilgrastim Product.

The doctrine of mootness is centrally concerned with the court's ability to grant effective relief: "If developments occur during the course of adjudication that eliminate a plaintiff's personal stake in the outcome of the suit or prevent a court from being able to grant the requested relief, the case must be dismissed as moot." *Cnty. of Morris v. Nationalist Movement*, 273 F.3d

527, 533 (3d Cir. 2001). Under this framework, where events materialize following the initiation of a suit that provides the relief plaintiff originally sought, the claims should be found moot. *Wayne Educ. Ass'n v. Wayne Bd. of Educ.*, No. CIV. 14-492 KSH, 2015 WL 3965600, at *1 (D.N.J. June 30, 2015) (dismissing complaint as moot where, since defendant sought declaratory relief regarding the constitutionality of a policy, "the policies have since been revised in a manner satisfactory to the [plaintiff]"); *Am. Littoral Soc'y v. EPA*, 199 F. Supp. 2d 217, 246 (D.N.J. 2002) (finding claim moot where the "EPA ha[d] provided plaintiffs 'with what they sought to attain in bringing this suit'").

In this case, to the extent there may have been a live controversy when the Complaint was filed (which Sandoz disputes), such controversy is now moot because the BPCIA process was carried out in the manner in which Amgen insisted, providing for the relief Amgen originally sought from this Court. Specifically, Amgen sought a declaratory judgment that Sandoz failed to comply with the (*l*)(4) and (*l*)(5) steps of the BPCIA. (Dkt. 1 at 26.) But, as Amgen concedes, the (*l*)(4) step has been carried out and (*l*)(5) was inapplicable. (*See* Opp. Br. at 7.) This suit is therefore moot at least as to those forms of relief related to steps (*l*)(4) and (*l*)(5). (*See* Compl., ¶¶ A-B, D-E). As to the relief Amgen seeks in ¶C of the Complaint, such a declaration would amount to an advisory opinion given that Sandoz has agreed not to challenge the availability of remedies to Amgen under § 271(e)(6). (*See* Dkt. 28-4 at 3.) There is nothing left, based on the facts alleged *in this case*, for the Court to resolve or redress.

C. There is No Threat of Recurrence Because There Was Never An Alleged Violation to Speak Of.

In another effort to create a live controversy, Amgen wrongly asserts that Sandoz has failed to show that the allegedly wrongful behavior could not reasonably be expected to recur.

(Opp. Br. at 21-22.) But the cases Amgen cites for this proposition are inapposite, and Amgen merely speculates that the alleged violations that gave rise to this lawsuit will recur.

As discussed above, Sandoz did not violate the BPCIA and, therefore, there is simply no "alleged violation" that could possibly recur. Further, the BPCIA process is now complete to Amgen's satisfaction, and the current dispute cannot recur again because the parties have now finished the "patent dance" and are litigating the timely-brought (*l*)(6) infringement suit in the NDCA. *Goldenberg v. Indel, Inc.*, No. CIV. 09-5202 JBS/AMD, 2012 WL 2466567, at *9 (D.N.J. June 27, 2012) (finding reasonable assurance satisfied where, despite not changing their "substantive stance" with regard to the alleged illegality of the alleged practices, the defendants fully satisfied the plaintiffs of all claimed injury).

Moreover, the facts of this case make it unlikely that a future different biosimilar case will present the same legal and factual issues for a court to resolve. For this case to recur again, the following circumstances would have to be met: two biosimilar products that in all substantive respects, have identical manufacturing processes; the same reference product sponsor for both biosimilars; the same biosimilar applicant for both biosimilars; at least one of the same asserted patents for both biosimilars; and timing such that the biosimilar applicant had previously received contentions for the patent-in-common, just to name a few. Because of the unique similarities between the two biosimilar products filgrastim and pegfilgrastim and the preexisting exchange of infringement contentions of the one, non-expired patent asserted by Amgen, Sandoz sought to proceed through the BPCIA as expeditiously as possible to immediate patent litigation so that the patent infringement and invalidity issues may be decided on the merits. It is hard to imagine another case recurring with these facts, and Amgen would be certain to try to distinguish this case from future cases if the rulings were to go against Amgen. As a result, Amgen's

"recurrence" cases are inapplicable and the present case is moot. *Cnty. of Los Angeles v. Davis*, 440 U.S. 625, 633-634 (1979) (claim held moot involving a unique situation that was no longer present and was unlikely to recur); *Resnick v. Patton*, 258 Fed. App'x. 789, 793–94 (6th Cir. 2007) (unpublished) (scenario complained of was so fact-specific and unlikely to recur that mootness exception did not apply); *Spivey v. Barry*, 665 F.2d 1222, 1234–35 (D.C. Cir. 1981) (claim held moot was "sharply focused on a unique factual context" unlikely to recur).

Close review of Amgen's cases – most of which it cites without any detailed discussion – confirms that they are distinct from the situation here. For example, in *Delaware Audubon Soc., Inc. v. Sec'y of U.S. Dep't of Interior*, the court specifically noted that the court must consider the "character of past violations" amongst other factors in considering the impact of voluntary cessation on mootness. 612 F. Supp. 2d 442, 448 (D. Del. 2009). The court doubted the defendant's sudden change of heart where the defendant's recurring violations spanned multiple years and took place eight months after being put on notice of its alleged violations. *Id*. at 448-449. Likewise, in *United States v. Gov't of Virgin Islands*, the Third Circuit found no mootness where defendant terminated the challenged repair contract "with litigation lurking a couple of days away" after "two decades of litigation, years of flagrant violations, and too many promises with no real progress" related to the pollution violations the contract purported to remedy. 363 F.3d 276, 285, 291 (3d Cir. 2004). In contrast, this is not a case characterized by even a single violation, let alone a host of repeated violations regarding the same facts.

Moreover, Amgen's cases are further distinct because they involve situations in which the "voluntary cessation" did not cure the effects of the alleged injuries and it was possible that the party could restart its prior activities once the suit was dropped. *Cf. Phillips v. Pennsylvania Higher Educ. Assistance Agency*, 657 F.2d 554, 570 (3d Cir. 1981) (finding claim not moot

where changes in the defendant's leadership might lead to reinstitution of the allegedly offending policy and there remained outstanding complaints of the alleged violation); *Brill v. Velez*, No. 1:13-CV-05643 NLH/AMD, 2014 WL 2926086, at *4 (D.N.J. June 27, 2014) (finding no mootness where the effects of the alleged violation had not been completely or irrevocably cured). Here the parties are now in the exact same position if Sandoz had never sought to accelerate the start of any BPCIA litigation and there is no means for Sandoz to "undo" its participation in the BPCIA steps according to Amgen's interpretation, which has completely cured any purported violation.

Finally, Amgen's plea for "guidance" on behalf of the biopharmaceutical industry directly conflicts with the Declaratory Judgment Act's purpose and prohibition against advisory opinions. *Armstrong World Indus., Inc. ex. rel. Wolfson v. Adams*, 961 F.2d 405, 410 (3d Cir. 1992) (holding Article III "stands as a direct prohibition on the issuance of advisory opinions"). The fact that Sandoz or another party might assert the allegedly incorrect interpretation against an unrelated third party is not sufficient to prevent a finding of mootness. *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 724 (2013) (holding case was moot where defendant executed covenant not to sue plaintiff and its distributors customers for infringement of a trademark and its colorable imitations, despite the fact that the covenant did not apply to unrelated third parties). Amgen's Complaint is nothing more than an untenable attempt to get an advisory opinion to use in future, as-yet nonexistent suits against BPCIA applicants.

D. Amgen Misstates the Facts of the *Amgen v. Sandoz* Federal Circuit Litigation.

In *Amgen v. Sandoz*, the Federal Circuit expressly held that 42 U.S.C. § 262(*l*)(9) and 35 U.S.C. § 271(e) provide exclusive patent-based remedies for an applicant's failure to engage in the disclosure requirements of the BPCIA, foreclosing other actions to enforce compliance. 794

F.3d at 1356-57 (*e.g.*, " the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)"; "mandating compliance with paragraph (*l*)(2)(A) in all circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous.").

Amgen contends that Sandoz posited the opposite argument in its pending petition for certiorari, but this is incorrect. (Opp. Br. at 23). The issue Sandoz has put before the Supreme Court is narrow: whether an applicant can provide notice of commercial marketing pursuant to section 282(*l*)(8)(A) prior to FDA approval, and whether the Federal Circuit erred by inferring a *de facto* injunctive remedy that delays market entry by 180 days in all cases. There, as here, Sandoz argues that the only remedies for non-compliance with the BPCIA requirements – including, but not limited to the notice of commercial marketing – are the ability to initiate declaratory judgment actions of *patent infringement* in accordance with section 282(*l*)(9). Read in context, the statement Amgen quotes makes clear that Sandoz's arguments have been entirely consistent throughout: the Federal Circuit erred in implying an extra-textual remedy to enforce compliance with the BPCIA disclosure requirements. (*See, e.g.*, Sandoz Petition for Writ of Certiorari, *Amgen Inc. v. Sandoz Inc.*, No. 15-1039 (Feb. 16, 2016) at 32 ("the Federal Circuit fashioned an injunctive remedy not contemplated by the statute and layered it on top of the remedies the statute does provide")). This issue remains pending before the Supreme Court.

E. Amgen Has Pleaded No Cognizable Injury and Any Alleged Injury Related to Patent Infringement Will Be Determined in its Pending Suit.

Amgen has not pleaded any cognizable injury, and even if some alleged injury exists, it is now part of the suit now pending in NDCA. There is no live dispute, threatening any possible injury to Amgen, upon which this Court has jurisdiction to rule. Because "[t]he Court will not entertain a claim seeking a declaration that the [defendant] acted wrongfully when there is no redressable injury arising therefrom," Amgen's claims should be dismissed. *See A.S. v. Harrison*

Twp. Bd. of Educ., 66 F. Supp. 3d 539, 548 (D.N.J. 2014). Otherwise, "[d]eclaratory relief here would amount to nothing more than an advisory opinion." *See id*.

Attempting to manufacture some injury, Amgen claims that Sandoz "extinguish[ed] Plaintiffs' ability to consider and respond to Sandoz Inc.'s contentions regarding the patents that Plaintiffs had properly identified." (Opp. Br. at 25.) But this is no more an "injury" providing a basis for suit than any temporary disagreement parties may have regarding the requirements about a particular statutory requirement. In fact, there was no injury because Amgen already had and took the opportunity to consider and respond to those contentions in the filgrastim litigation as to the '878 Patent. Moreover, Sandoz acquiesced in Amgen's interpretation and continued through the patent-exchange steps that Amgen claimed were necessary. There was no injury with respect to the '784 Patent either—Sandoz stated that it would not commercialize the Pegfilgrastim Product until after the patent's expiration, so no (*l*)(3)(C) response was necessary.

With respect to Amgen's alleged injury relating to remedies under 35 U.S.C. § 271(e)(6), the series of hypothetical events that must be met before the issue of damages can occur, (*see* Dkt. 28-2 at 15), will – if needed – be decided in the currently pending case in the NDCA. Indeed, Amgen concedes that the damages-related relief it seeks "depend on Amgen filing [a patent infringement] suit and prevailing." (Opp Br. at 25.)

It therefore makes little sense for this litigation to continue. The Court should therefore decline to exercise jurisdiction in this case. *Eisai Co., Ltd. v. Mut. Pharm. Co. Inc.*, No. CIV.A. 06-3613(HAA), 2007 WL 4556958, at *15 (D.N.J. Dec. 20, 2007) (explaining that the court "retains the discretion pursuant to the Declaratory Judgment Act to decline declaratory judgment jurisdiction."); *see Del. State Univ. Student Hous. Found. v. Ambling Mgmt. Co.*, 556 F. Supp. 2d 367, 375 (D. Del. 2008) (declining to exercise declaratory relief jurisdiction where the ultimate

remedy sought by the declaratory claim would be resolved through a different claim). In that way, the resources of the parties and this Court will be best utilized.

For the foregoing reasons, Defendant Sandoz Inc. respectfully requests that the Court grant its motion to dismiss and any such other and further relief as the Court deems appropriate.

Respectfully submitted,

Dated: June 20, 2016

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Defendant Sandoz Inc. by its undersigned counsel hereby certifies pursuant to Local Civil Rule 11.2 that the matter in controversy in the present action is not the subject of any other action pending in any court, or of any other arbitration or administrative proceeding.

Dated: June 20, 2016

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