IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
AMGEN INC.	)	C.A. No. 17-1407-GMS
	)	C.A. No. 17-1471-GMS
Defendant.	)	
	)	
	)	
	)	
	)	

OPENING BRIEF IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS AND TO STRIKE DEFENDANT'S FIRST AMENDED COUNTERCLAIMS AND THIRD, FOURTEENTH, AND FIFTEENTH AFFIRMATIVE DEFENSES

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NATURE AND STAGE OF PROCEEDINGS

This litigation concerns Amgen's plans to market Mvasi, a "biosimilar" version of Genentech's best-selling cancer medication Avastin® (bevacizumab). Following months of pre-litigation exchanges under the Biologics Price Competition and Innovation Act ("BPCIA"), Plaintiffs sued Amgen in October 2017 asserting that the manufacture, marketing, and sale of Mvasi infringes more than two dozen patents. Amended and Supplemental Complaints followed in December 2017.

The present Motion challenges certain aspects of the First Amended Counterclaims and Affirmative Defenses Amgen filed on June 5, 2018:

1. In twenty-nine counterclaims, Amgen seeks declaratory judgments of noninfringement, invalidity, or unenforceability on all of the patents-in-suit, plus two others. But the BPCIA forecloses such claims where the biosimilar applicant did not comply with its pre-litigation production obligations, in particular the timely production of both its Abbreviated Biologics License Application ("aBLA") *and* "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. §§ 262(*l*)(2)(A); (9)(C). It is undisputed that Amgen made no timely production of the latter category, and indeed disclaimed any requirement that it do so.

2. Even were these claims permissible, Amgen's validity challenges are facially deficient. In each of its counterclaims, Amgen purports to challenge validity on grounds the BPCIA does not permit.

3. Facial pleading deficiencies also infect Amgen's assertion that Genentech committed inequitable conduct during prosecution of one of the patents-in-suit by allegedly misrepresenting the content of the prior art. The Patent Office was fully aware of the references Amgen cites, and blackletter law holds that a patent owner cannot commit inequitable conduct

by making arguments that the Patent Office is free to accept or reject. Amgen's Fourteenth and Fifteenth Affirmative Defenses suffer from the same defects as the inequitable conduct counterclaim they parrot, and accordingly, must be dismissed.

4. There is no case or controversy, and therefore no subject-matter jurisdiction, over two counterclaims addressed to certain patents that Genentech has stated it will not assert against Amgen's Avastin® biosimilar.

ARGUMENT

I. AMGEN'S DECLARATORY JUDGMENT CLAIMS ARE BARRED UNDER THE BPCIA.

The BPCIA bars Amgen from seeking declaratory judgments under 28 U.S.C. § 2201 *et seq.*, challenging any of the patents-in-suit. For this reason Counterclaims 1–29 should be dismissed for failure to state a claim under Rule 12(b)(6).

The BPCIA requires innovators and biosimilar makers to engage in a robust pre-litigation exchange of information, starting with the applicant's production of its aBLA within twenty days after the FDA accepts it, along with "such other information that describes the process or processes used to manufacture the biological product," essential information for the innovator's fair evaluation of the full scope of potential infringement.[1] 42 U.S.C. § 262(*l*)(2)(A). To encourage compliance the statute provides carrots and sticks. For example, applicants who timely produce the aBLA and required "other information" on the prescribed schedule, and further comply with the statute's remaining requirements, are rewarded with substantial control

[1] As Amgen explained in other BPCIA litigation where it is the innovator and not the generic, the required information about the applicant's manufacturing processes is essential "to a full and complete evaluation of [an innovator's] patent portfolio," because the aBLA typically omits details about the applicant's manufacturing processes that may infringe the innovator's process patents. *See Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839-RGA, D.I. 1 (Complaint) (filed D. Del. Sept. 18, 2015).

over the timing and scope of any subsequent patent litigation. *Id*. §§ 262(*l*)(4), (*l*)(5), (*l*)(8). Conversely, applicants who fail to comply with the BPCIA's information disclosure requirements are prohibited from pursuing claims under the Declaratory Judgment Act:

> If a subsection (k) applicant fails to provide the application *and information* required under paragraph (2)(A), the reference product sponsor, *but not the subsection (k) applicant*, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

Id. § 262(*l*)(9)(C)(emphasis added).

Amgen's undisputed noncompliance with § 262(*l*)(2)(A) has been a central feature of proceedings in this Court since they started in February 2017. Amgen timely produced its aBLA but disputed Genentech's need for or entitlement to any "other information that describes the process or processes used to manufacture the biological product that is the subject of such application." When the Court pointed out to Amgen that "you don't get to constrain the flow of information to just the application, the statute does not permit that,"[2] Amgen argued that it could not be forced into compliance, and that Genentech's only recourse were the remedies set forth in the statute. *See* D.I. 11, Case No. 17-165-GMS (D. Del.) (D. Del. Feb. 27, 2017).

This Motion now invokes one of those statutory remedies. The BPCIA makes clear, and other courts have held, that "failure to comply with the information exchange requirements of the BPCIA bar[s] the applicant from bringing a declaratory judgment action against the reference product sponsor." *Celltrion Healthcare Co. v. Kennedy Tr. for Rheumatology Research*, 2014 WL 6765996, at *5 (S.D.N.Y. Dec. 1 2014) (dismissing declaratory judgment action); *see also*

[2] Ex. 1 at 25. All citations to "Ex." refer to the exhibits to the Declaration of Thomas S. Fletcher submitted herewith. *See also id.* at 23 ("[T]he statute doesn't say just the information in the application. With all due respect, Mr. Gutman, it doesn't say that, and that seems to be the way you're reading it. . . . That's not the way I read the statute."); 24 ("Now, you can write until the cows come home, Mr. Gutman, but you're not going to persuade me, aside from your procedural argument, that the statute doesn't say what the statute says.").

Celltrion, Inc. v. Genentech, Inc., 2018 WL 2448254, at *1 (N.D. Cal. May 9, 2018) (same).

> Under § 262(*l*)(9)(C), if an applicant fails to provide its application and manufacturing information to the sponsor under § 262(*l*)(2)(A), then the sponsor, but not the applicant, may immediately bring an action for a declaration of infringement, validity, or enforceability . . . .

Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1666 (2017); *see also Hospira, Inc. v. Janssen Biotech, Inc.*, 2014 WL 6766263 (S.D.N.Y. 2014) (dismissing declaratory judgment action); *Sandoz Inc. v. Amgen Inc.*, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013) (biosimilar applicant "cannot bring an action of declaratory relief until, at minimum, it has complied with its obligations under § 262(l)(2)(A)"), *aff'd on other grounds*, 773 F.3d 1274 (Fed. Cir. 2014). Every court to have considered this question has answered it the same way.

It is not correct, as Amgen appears to contend, that once an applicant provides notice of commercial marketing under 42 U.S.C. § 262(*l*)(8) "any limitation under the BPCIA on bringing an action [under the Declaratory Judgment Act] is lifted." *See* Countercl. ¶ 16. As Judge Wu held when he dismissed Amgen's anticipatory California lawsuit, the notice of commercial marketing explicitly abates only one of the limitations on an applicant's ability to seek declaratory relief: the limitation in (*l*)(9)(A); it does not lift the limitation in (*l*)(9)(C). *See Amgen Inc. v. Genentech, Inc.*, 2018 WL 910198, at *4 (C.D. Cal. Jan. 11, 2018) ("Amgen's argument that it was entitled to bring suit after providing its notice under § 262(*l*)(8)(A) but before completing the rest of the BPCIA's patent list exchange steps is rejected"). In other words, even fully compliant applicants have only a limited right to seek declaratory relief; noncompliant applicants like Amgen have none at all. Counts 1–29 should be dismissed on this basis.

II. AMGEN'S INVALIDITY CLAIMS EXCEED THE PERMISSIBLE SCOPE UNDER THE BPCIA.

The Counterclaims challenging the validity of all the patents-in-suit should be dismissed under Rule 12(b)(6), and Amgen's corresponding Third Affirmative Defense stricken under Rule 12(f), for an additional reason: Those allegations exceed the permissible scope under the BPCIA.

As part of the BPCIA dispute resolution process (commonly called the "patent dance"), the parties are required to exchange contentions on the merits of the infringement claims. Sixty days after the innovator identifies patents it believes to be infringed by the proposed biosimilar, the applicant provides non-infringement and invalidity/unenforceability contentions to all patents except those it plans to let expire before commercialization, 42 U.S.C. § 262(*l*)(3)(B). Sixty days after that the innovator provides responsive contentions for those patents it still believes are infringed, *id*. at § 262(*l*)(3)(C).

Amgen's Counterclaims and Affirmative Defenses treat the BPCIA contentions as having no force or effect, leaving Amgen free to assert validity positions it did not disclose as part of the statutory exchanges. *See, e.g.*, Affirmative Def. ¶ 3; Countercl. ¶ 102 (patents are invalid "for *at least* the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B)" (emphasis added)). The statute does not permit this.

The "unique and elaborate process for information exchange" enacted in the BPCIA, including the exchange of contentions concerning infringement, validity, and enforceability the parties completed last July, was designed and intended "to resolve patent disputes" prior to the commencement of litigation. *Amgen Inc. v. Sandoz, Inc.* 794 F.3d 1357, 1352 (Fed. Cir. 2015). Innovator companies, biosimilar applicants, and the courts depend on the exchange of information that occurs during this process to make these sprawling litigations manageable—

they determine which patents will be litigated, when they will be litigated, and how the litigation will unfold.[3] By participating in the "patent dance," the applicant obtains valuable information about the innovator's infringement and validity positions, can prevent the innovator from filing a declaratory judgment suit, and gains "substantial control over the scope of the first phase of litigation" by limiting the number of patents in that phase to as few as one. *Sandoz*, 137 S. Ct. at 1671 (citing § 262(*l*)(5)(B)(ii)); *see also id.* § 262(*l*)(9)(B). If the applicant identifies compelling invalidity or non-infringement positions, the sponsor may drop certain patents from the "patent dance." This is precisely what occurred here—after receiving Amgen's (*l*)(3)(B)(ii)(I) contentions as to nineteen patents, Genentech chose to serve its own responsive contentions for only seventeen of those patents, removing two patents from dispute. *See infra* Part IV. The exchange of contentions may also lead the parties to prioritize resolution of certain patent disputes, selecting them for the "immediate patent infringement action" described in § 262(*l*)(6) and leaving other patents to be addressed after the applicant provides notice under § 262(*l*)(8).

It would defeat these objectives and throw the statutory scheme into chaos if the parties' contentions became non-binding once the BPCIA litigation started, as Amgen's Counterclaims and Affirmative Defenses contemplate. Were applicants like Amgen allowed to provide new invalidity contentions after completion of the "patent dance," they easily could avoid the

[3] Even in the context of district courts' patent local rules, where contentions can be amended by leave of the court, parties are often held to the contentions they have made early in litigation. Indeed, courts routinely penalize attempts to deviate from the contentions required by the patent local rules, including by refusing to entertain claim-construction and infringement arguments made "after the relevant cut-off dates under the . . . [r]ules," *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1292 (Fed. Cir. 2005), striking claims that were not asserted in preliminary contentions, *Informatica Corp. v. Bus. Objects Data Integration, Inc.*, No. C 02-3378 JSW, 2006 WL 463549 (N.D. Cal. Feb. 23, 2006), and excluding "evidence because of the failure to comply with the disclosure deadlines required by the local patent rules." *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355 (Fed. Cir. 2006). The case for holding Amgen to its contentions is all the more compelling in the context of the BPCIA's *statutory* requirement to provide contentions to narrow the parties' disputes.

obligation to provide meaningful (*l*)(3)(B)(ii)(I) contentions, even for those potentially infringed patents the applicant fully intends to challenge. The applicant could, for example, provide limited contentions for the patents about which the applicant is most confident and then, for other patents, simply make the sort of boilerplate assertion found in Amgen's counterclaims—that the patent's claims "are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability." *E.g.*, Countercl. ¶ 102. The applicant could leave the sponsor in the dark about its true invalidity position while still forcing the sponsor to serve responsive contentions, expose its own litigation strategy, and select patents to litigate in the immediate infringement action and later preliminary injunction proceedings based on incomplete information. *See* 42 U.S.C. § 262(*l*)(6), (*l*)(8).

An applicant could even refrain from providing BPCIA contentions at all. That is precisely what Amgen did as to the eight patents for which Amgen represented under 42 U.S.C. § 262(*l*)(3)(B)(ii)(II) that "it does not intend to begin commercial marketing of its ABP 215 biosimilar product before the dates of expiration" of the patents.[4] Making that representation allowed Amgen to serve *no* invalidity contentions as to *any* of the eight patents in question. Yet after having failed to challenge the validity of these eight patents during the "patent dance," Amgen now claims the right to sandbag Plaintiffs with previously undisclosed grounds for invalidity. *See, e.g.*, Countercl. ¶ 71. No applicant would ever provide the contentions contemplated by § 262(*l*)(3)(B)(ii)(I) if it could instead simply make an illusory commitment not to commercially market its product and then challenge the validity of the sponsor's patents at a

[4] Those patents are U.S. Patent Nos. 6,054,297 (Counterclaim Count 1); 6,121,428 (Counterclaim Count 2); 6,242,177 (Counterclaim Count 3); 6,331,415 (Counterclaim Count 4); 6,884,879 (Counterclaim Count 11); 7,297,334 (Counterclaim Count 14); 7,375,193 (Counterclaim Count 16); 7,923,221 (Counterclaim Count 19).

later date without consequence.

In short, if the contentions exchanged during the "patent dance" do not define the scope of the litigation, what purpose do they serve?[5]

The Court has set an extremely accelerated schedule compared to similar BPCIA litigations involving comparable numbers of patents, including the only other case in which Amgen was a biosimilar applicant. *AbbVie Inc., et al. v. Amgen Inc., et al.*, C.A. No. 16-666-SLR, D.I. 26; *AbbVie Inc., et al. v. Boehringer Ingelheim Int'l, et al.*, C.A. No. 17-1065-MSG, D.I. 29. That schedule requires Plaintiffs, in the early stages of fact discovery, to narrow the case by selecting eight of the more than two dozen asserted patents to pursue. The notion that Plaintiffs must make that crucial selection without the assurance that Amgen's arguments are limited to those Amgen disclosed when it was narrowing disputes during the patent dance is unprecedented, unworkable, and unfair. The only realistic prospect for meeting the Court's schedule for narrowing and litigating this case is for the parties' disputes to shrink, not expand.

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[5] In a recent case where it was the innovator company, Amgen echoed many of these concerns to enforce a representation a generic applicant made during the "patent dance":

> It cannot be the case that a biosimilar applicant can simply disavow its own statements made during the statutory exchange, especially after such detrimental reliance on the part of the Reference Product Sponsor. . . . Otherwise, the purposes of the statutory information exchange—efficient resolution of patent issues—would be thwarted.

Amgen Inc. v. Apotex, Inc., 17-1010, ECF No. 28 at 45 (Fed. Cir. Dec. 5, 2016). The need to enforce an applicant's (*l*)(3)(B) contentions is, if anything, more pressing in this case. Amgen's grievance in *Apotex* concerned a question of fact (the concentration of a certain protein) that could be independently investigated. The Federal Circuit's unpublished decision in the *Apotex* case explicitly indicates that it was not asked to resolve, and did not resolve, the question presented by this motion. *See Amgen Inc. v. Apotex Inc.*, 712 F. App'x 985, 989 (Fed. Cir. 2017) ("Amgen does not argue that Apotex is legally bound by its statements about protein concentration [during the "patent dance"]; indeed, both in the district court and in this court, Amgen has disclaimed such an argument.").

Plaintiffs respectfully submit that the Court should hold Amgen to its previously served contentions and, to the extent they rely on invalidity positions Amgen did not disclose during the "patent dance," dismiss Amgen's invalidity allegations under Rule 12(b)(6), and strike its Third Affirmative Defense under Rule 12(f).

III. AMGEN FAILS TO PLEAD A VIABLE THEORY OF INEQUITABLE CONDUCT.

Count 29 seeks a declaration that one of the asserted patents, U.S. Patent No. 6,407,213 ("Carter/Presta"), is unenforceable for inequitable conduct. *See* Countercl. ¶¶269-82 (Count 29); *see also* Aff. Defs. ¶¶ 15-26 (Fourteenth and Fifteenth Affirmative Defenses asserting unclean hands and inequitable conduct based on same allegations in Count 29). Carter/Presta is a "composition of matter" patent that claims antibodies including bevacizumab, the active ingredient in Avastin® and the molecule Amgen has copied. Any manufacture of bevacizumab in the United States prior to Carter/Presta's expiry would be infringing.

Unlike the typical inequitable conduct case, *see, e.g.*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (*en banc*), Amgen does not allege that Genentech deliberately concealed references in its possession from the Patent Office. On the contrary, Amgen acknowledges that the Patent Office possessed and explicitly considered the two identified references—"Queen 1989" and the "'101 patent," Aff. Defs. ¶¶ 16-17—the Examiner having cited each of them as the basis for rejections during prosecution, Aff. Defs. ¶¶ 18, 20. Amgen's theory challenges Genentech's arguments about what these references teach. *Id.* ¶ 16; Countercl. ¶ 271.

This is a legally inadequate allegation of inequitable conduct. The Federal Circuit has held repeatedly that a patent applicant's characterizations of the prior art cannot as a matter of law give rise to inequitable conduct where the Examiner could review the reference and was able

to consider the argument and accept or reject it. *E.g.*, *Rothman v. Target Corp.*, 556 F.3d 1310, 1329 (Fed. Cir. 2009); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). "While the law prohibits genuine misrepresentations of material fact, a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." *Rothman*, 556 F.3d at 1328–29. This makes sense because the Examiner has the underlying references and the "discretion to reject or accept an applicant's arguments based on the examiner's own conclusions regarding the prosecution record." *Id.* at 1329; *see also Akzo N.V. v. ITC*, 808 F.2d 1471, 1482 (Fed. Cir. 1986) ("examiner was free to reach his own conclusion regarding the Blades process based on the art in front of him"). In *Innogenetics, N.V. v. Abbott Laboratories*, noting that "our precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of prior art," the Federal Circuit affirmed a summary judgment of no inequitable conduct and an award of attorneys' fees incurred in defending the charge. 512 F.3d 1363 (Fed. Cir. 2008). Trial courts including in this District now routinely dismiss or reject as a matter of law allegations that an applicant committed inequitable conduct by misrepresenting a reference before the Examiner.

> The court appreciates Precision's position that Shier and Paques expressly contradicted the teachings of Arnould. Precision does not cite authority demonstrating that this fact may substitute for independent evidence of intent to deceive, however, where the prior art at issue was a focus of the examination. Here, both examiners were free to credit or discount Shier and Paques' characterizations of Arnould in view of their own readings

Cellectis S.A. v. Precision Biosciences, 883 F. Supp. 2d 526, 535 (D. Del. 2012) ; *see also Bayer Schering Pharma AG v. Barr Labs., Inc.*, 2008 WL 628592, at *49 (D.N.J. Mar. 3, 2008)[6];

[6] "An applicant's arguments supporting its patent application do not constitute inequitable conduct when the examiner has the prior art before him throughout the prosecution and, despite the applicant's attempt to distinguish that prior art, the examiner was free to reach his own conclusion regarding the prior art."

Sepracor Inc. v. Teva Pharm. USA, Inc., 2010 WL 2326262, at *6 (D.N.J. June 7, 2010).[7]

Amgen's allegation of inequitable conduct should be dismissed for the same reason. Amgen accuses Genentech of mischaracterizing the antibody numbering methodology in the "'101 patent," "falsely distinguishing" the "Queen 1989" reference, and submitting an allegedly misleading comparison of Queen 1989 to the claimed sequences. Countercl. ¶¶ 271, 280-81. In all of these instances, the art was disclosed to and considered at length by the Examiner, who was free to reach its own contrary conclusion. An allegation of inequitable conduct cannot survive that acknowledged fact.

Amgen's unclean hands affirmative defense suffers from the same defect. Unclean hands and inequitable conduct "rise or fall together" when based on the same allegations. *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013); *see also The Medicines Co. v. Teva Parenteral Medicines, Inc.*, No. CV 09-750-ER, 2011 WL 13135647, at *23 (D. Del. Aug. 26, 2011). This case is complicated enough without injecting Amgen's unfounded and legally impermissible theories of prosecution misconduct. Count 29 should be dismissed with prejudice and Amgen's corresponding affirmative defenses (Numbers Fourteen and Fifteen) should be stricken.

IV. AMGEN'S COUNTERCLAIMS REGARDING UNASSERTED PATENTS SHOULD BE DISMISSED FOR LACK OF SUBJECT-MATTER JURISDICTION.

The Court lacks subject-matter jurisdiction over Counts 8 and 15 where Amgen seeks declaratory judgments of non-infringement and invalidity of U.S. Patent Nos. 6,610,516 and 7,323,553.

[7] "The second reason Wockhardt's inequitable conduct claim must be dismissed is because the oral toxicity study results were before the examiner, and he was entitled to reach his own conclusions on the study. [lengthy string citation omitted] Therefore, any mischaracterization of the data would not rise to the level of inequitable conduct."

Amgen takes the position that subject-matter jurisdiction exists because Genentech identified these two patents on its § 262(*l*)(3)(A) list, and then "refuse[d] to remove" them from the (*l*)(3)(A) list, or to "otherwise remove the existing case or controversy" surrounding these patents. Countercl. ¶¶ 120, 171. In fact, when Amgen asked about these patents during the "patent dance," Genentech informed Amgen that "having reviewed your (*l*)(3)(B) contentions, Genentech has not served infringement contentions for them and *does not intend to assert them against ABP 215*." Ex. 2 (emphasis added).[8] True to its word, Genentech has not asserted these patents in either pending case.

" '[A] counterclaimant must show a continuing case or controversy with respect to withdrawn or otherwise unasserted claims.' " *Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1307 (Fed. Cir. 2012) (quoting *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1282–83 (Fed. Cir. 2012). In *Fox Group*, the Federal Circuit vacated a declaratory judgment in favor of a counterclaimant who challenged patents that were not asserted. The same rationale requires dismissal here. The litigation over Mvasi is underway, and Genentech is not asserting either patent. Amgen's refusal to take "no" for an answer does not create a case or controversy.

[8] Although Amgen does not attach this document to its Counterclaims, the Court may consider it for purposes of determining whether a case or controversy exists as to the unasserted patents. *See United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.*, 839 F.3d 242, 251 (3d Cir. 2016) ("When a Rule 12(b)(1) motion is evaluated as a 'factual attack' on the Court's subject matter jurisdiction, 'the court may consider evidence outside the pleadings' in evaluating that attack." (quoting *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000))).

CONCLUSION

For the reasons stated, Plaintiffs respectfully request that the Court dismiss each of Amgen's Counterclaims and strike Amgen's Third, Fourteenth, and Fifteenth Affirmative Defenses.

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Respectfully Submitted,

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