IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

[CORRECTED[1]] AMGEN'S OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS AND TO STRIKE AMGEN'S FIRST AMENDED COUNTERCLAIMS AND THIRD, FOURTEENTH, AND FIFTEENTH AFFIRMATIVE DEFENSES

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PRELIMINARY STATEMENT

After failing to provide complete infringement and validity disclosures as required by 42 U.S.C. § 262(*l*)(3)(C) of the Biologics Price Competition and Innovation Act ("BPCIA"), Plaintiffs Genentech and City of Hope filed two lawsuits against Amgen—one alleging infringement of twenty-six patents under 35 U.S.C. § 271(e)(2)(C) (Civ. No. 17–01471), and the other seeking declaratory judgment that Amgen's future commercial marketing of its biosimilar product will infringe twenty-four patents under 35 U.S.C. § 271(a) (Civ. No. 17–1407). Amgen answered both complaints, pleading invalidity and noninfringement affirmative defenses and counterclaims, which are typically asserted by patent defendants. Plaintiffs now seek to dismiss all of those counterclaims and to strike several affirmative defenses based largely on an unsupported and unproven allegation—repeated for nearly a year-and-a-half now—that Amgen failed to comply with the BPCIA's disclosure provision. However, a factual allegation concerning matters outside the pleadings cannot provide a basis for dismissal under Rule 12(b)(6). And in any event, even under Plaintiffs' broad reading of the BPCIA, Amgen has met all of its obligations under the statute, including its obligations under 42 U.S.C. § 262(*l*)(2)(A). At most, Plaintiffs have created a factual dispute concerning whether Amgen complied with the BPCIA, and that factual dispute cannot be resolved on a motion to dismiss.

Moreover, even if Plaintiffs' allegations were taken as true, the BPCIA does not provide for the dismissal of defenses or counterclaims as a result of failing to comply with the statute's disclosure scheme. To the contrary, the Supreme Court and this Court have explained that if a biosimilar applicant violates 42 U.S.C. § 262(*l*)(2)(A), the reference product sponsor's recourse is to bring a declaratory judgment action and receive discovery as part of that action. Having brought a declaratory judgment action, Plaintiffs have already received the relief they would be

entitled to if there were a violation of § 262(*l*)(2)(A). Although the BPCIA may also bar an applicant that fails to provide the requisite disclosures from "bring[ing] an action," that provision is irrelevant here because Amgen has merely brought counterclaims and defenses; the action was brought by Plaintiffs.

Plaintiffs' other challenges to Amgen's patent defenses and counterclaims all either rely on arguments already rejected by this Court or raise factual issues that cannot be properly resolved on a motion to dismiss. Plaintiffs' motion should be denied in its entirety.

1. Plaintiffs are not entitled to the wholesale dismissal of the declaratory judgment counterclaims on account of Amgen's purported violation of 42 U.S.C. § 262(*l*)(2)(A). As an initial matter, nothing in the record on this motion suggests that Amgen failed to meet its disclosure obligations under the BPCIA, and Plaintiffs' assertion that Amgen violated the statute at most raises a factual issue that cannot be resolved on a motion to dismiss. Moreover, as this Court concluded over a year ago, Plaintiffs' recourse for a BPCIA violation is to bring an action seeking declaratory relief during which they can pursue discovery to obtain the information allegedly missing from Amgen's disclosure. Having done so, Plaintiffs are not entitled to any additional relief. Although the BPCIA may bar Amgen from "bring[ing] an action" for declaratory judgment, that issue need not be resolved by the Court because Amgen has not brought any action here; to the contrary, it is Plaintiffs who brought this action, and Amgen has merely answered with counterclaims.

2. Plaintiffs also seek to restrict Amgen to pleading the invalidity theories expressly stated in its BPCIA disclosures. In so arguing, Plaintiffs ask the Court to hold Amgen to a higher standard than Plaintiffs because Plaintiffs have already been given one opportunity, and under the current scheduling order will get two additional opportunities, to supplement their

infringement contentions. Amgen likewise should be permitted to supplement its noninfringement and invalidity contentions based on discovery that it receives from Plaintiffs. This Court has previously declined to accept Plaintiffs' argument that Amgen is bound by its BPCIA disclosures and should do so again here. Plaintiffs point to no statutory text and fail to cite a single case supporting the proposition that a subsection (k) applicant should not be afforded the same opportunity to defend against assertions of patent infringement as any other patent defendant.

3. Plaintiffs do not dispute that Amgen's inequitable conduct theory was pled with particularity. Instead, they contend that their false statements to the Patent Office are properly characterized as permissible attorney argument, rather than inequitable misrepresentations. That factual issue cannot be resolved on a motion to dismiss, however. Taking the allegations in Amgen's Answer as true (as the Court is required to do on this motion), Amgen has adequately pled that Plaintiffs deliberately misled the Patent Office during prosecution and thus committed inequitable conduct.

4. Plaintiffs' attack on Amgen's unclean hands defense likewise falls short. It is black-letter law in this Circuit that an affirmative defense need not be pled with particularity but rather is adequately pled if it is merely raised in the Answer. Moreover, Plaintiffs' argument for striking unclean hands is identical to its argument against inequitable conduct. Inequitable conduct has been properly pled and thus so, too, has unclean hands. Furthermore, Amgen's unclean hands defense is broader than its inequitable conduct defense, and it therefore would survive a motion to dismiss even if the inequitable conduct theory were somehow infirm.

5. Finally, Plaintiffs are wrong that there is no case or controversy concerning the validity of U.S. Patent Nos. 6,610,516 and 7,323,553. Plaintiffs created a controversy by

identifying those two patents in the list of patents they believed a claim of patent infringement could reasonably be asserted if an unlicensed party made, used, sold, offered to sell, or imported the biosimilar product. *See* 42 U.S.C. § 262(*l*)(3)(A). Since creating the controversy, Plaintiffs have not disavowed their right to assert those patents against Amgen's product; instead, they merely state that it is not their present "intent" to assert them. Absent an enforceable promise not to sue, however, there remains a live controversy concerning those two patents. If Plaintiffs truly do not intend to assert the '516 and '553 patents, they should grant Amgen a covenant not to sue, which would moot any controversy and divest this Court of jurisdiction.

LEGAL STANDARDS

I. COUNTERCLAIMS

"In considering a Rule 12(b)(6) motion, courts must accept all factual allegations as true, construe the complaint in the light most favorable to the [non-movant], and determine whether, under any reasonable reading of the complaint, the [non-movant] may be entitled to relief." *Bruni v. City of Pittsburgh*, 824 F.3d 353, 360 (3d Cir. 2016) (quotation and citation omitted). This same standard applies on a motion to dismiss counterclaims raised in an Answer. *Shamrock Holdings v. Arenson*, 456 F. Supp. 2d 599, 604 (D. Del. 2006). To the extent that either party raises a factual question material to the dispute, dismissal is improper. *Principal Life Ins. Co. v. Lawrence Rucker 2007 Ins. Trust*, 674 F. Supp. 2d 562, 565 (D. Del. 2009) ("The purpose of a [12(b)(6) motion] is to test the sufficiency of a complaint, or in this case, a counterclaim, and not to resolve disputed facts or decide the merits of the case."); *Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, C.A. No. 17-1353, 2018 WL 1419082, at *8 n.2 (D. Del. Mar. 22, 2018) (denying motion to dismiss, *inter alia*, because of unresolved factual disputes raised by the parties' briefing).

II. AFFIRMATIVE DEFENSES

"[A]n affirmative defense generally need not be articulated with any rigorous degree of specificity, and is sufficiently raised for purposes of [Federal] Rule [of Civil Procedure] 8 by its bare assertion." *Moody v. Atl. City Bd. of Educ.*, 870 F.3d 206, 218 (3d Cir. 2017) (quotation and citation omitted); *see also Blonder-Tongue Labs. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971) (noting that the "purpose" of pleading an affirmative defense "is to give the opposing party notice of the plea"). The *Iqbal / Twombly* pleading standard does ***not*** extend to affirmative defenses. *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013) ("*Twombly* and *Iqbal* do not apply to affirmative defenses, which need not be plausible to survive." (quotation marks omitted)); *Internet Media Corp. v. Hearst Newspapers, LLC*, No. 10-cv-00690, 2012 U.S. Dist. LEXIS 126788, at *7 (D. Del. Sep. 6, 2012) (same).

ARGUMENT

I. AMGEN'S COUNTERCLAIMS ARE NOT BARRED BY THE BPCIA.

Plaintiffs' unproven allegation that Amgen violated the BPCIA does not provide a basis for the Court to dismiss Amgen's twenty-nine Counterclaims. Plaintiffs' position is that Amgen's declaratory-judgment counterclaims are barred by 42 U.S.C. § 262(*l*)(9)(C) because it did not disclose "such other information" about its manufacturing process as required by 42 U.S.C. § 262(*l*)(2)(A). That argument is flawed for at least two reasons.

First, the record on this motion does not show that Amgen violated § 262(*l*)(2)(A), and a motion to dismiss is not the proper vehicle for resolving Plaintiffs' allegation that a violation occurred. Second, even if the Court were to assume that Plaintiffs' allegation is true, Plaintiffs' remedy for a violation under the statute was to bring an action seeking declaratory relief; the statute does not provide for the dismissal of counterclaims.

A. The Record Does Not Show that Amgen Violated 42 U.S.C. § 262(l)(2)(A).

The primary flaw in Plaintiffs' argument is the premise that Amgen failed to disclose information required by the BPCIA. In reality, even under Plaintiffs' interpretation of the BPCIA, Amgen complied with the statute, and nothing in the Answer—which comprises the entire record for purposes of this motion—shows otherwise. Indeed, the well-pleaded facts in the Answer, which must be taken as true at this stage, *see Bruni*, 824 F.3d at 360, show that Amgen met its obligations.

Specifically, the Answer alleges that "Amgen timely sent to Genentech its disclosure pursuant to 42 U.S.C. § 262(*l*)(2)(A)." D.I. 124 at 43, ¶ 20. That disclosure contained, among other things, "extensive information regarding the manufacturing processes used to make Mvasi™[,]" including "(i) the source, history, and generation of the cell substrate, (ii) the cell culture harvest process, (iii) each and every purification process step, and (iv) the raw materials used during the manufacture of Mvasi™." *Id.* Amgen's production included not only its Biologic License Application ("BLA") but also additional information describing the manufacture of Amgen's product—including an updated manufacturing schedule, a detailed schedule specifying each manufacturing unit operation, and testing sites relating to Amgen's manufacture of Mvasi™. *Id.* Accepting those allegations as true (as the Court must on a Rule 12(b)(6) motion), the Answer shows that Amgen "produce[d] the aBLA and required 'other information,'" which is what Plaintiffs allege is necessary to comply with 42 U.S.C. § 262(*l*)(2)(A). *See* D.I. 129 at 2.[2]

Conversely, the record contains no indication that Amgen violated § 262(*l*)(2)(A). Instead, all that Plaintiffs can offer is an unsupported (and false) assertion in their brief that

[2] Amgen does not concede that Plaintiffs' reading of § 262(*l*)(2)(A) is correct, but it nevertheless has shown that it complied with the statute even under Plaintiffs' reading.

Amgen's non-compliance is supposedly "undisputed." D.I. 129 at 3. Plaintiffs' assertion is disputed, however. And Plaintiffs' attorney argument to the contrary cannot support a motion to dismiss. *See Zomolosky v. Kullman*, 70 F. Supp. 3d 595, 605 n.13 (D. Del. 2014) ("The court cannot find support for such statements in the [complaint] and, therefore, does not consider such attorney argument."); *see also Genentech, Inc. v. Amgen Inc.*, C.A. No. 17–00165, D.I. 17 at 21:1–3 (D. Del. Mar. 3, 2017) (Sleet, J.) ("[W]hat I have before me are arguments of lawyers, which is not the basis for the creation of a factual record."). At most, Plaintiffs' argument creates a factual dispute over whether Amgen complied with the statute, and such a factual dispute cannot be resolved on a motion to dismiss. *Pac. Biosciences of Cal.*, 2018 WL 1419082, at *8 n.2; *cf. O'Connor v. Sandy Lane Hotel Co., Ltd.*, 496 F.3d 312, 316 (3d Cir. 2007) (noting that, on a motion to dismiss, the non-moving party's "allegations [are] taken as true and all factual disputes [are] drawn in [their] favor" (quotation and citation omitted)).

Even if the record did show that Amgen failed to comply with the BPCIA, Amgen's document production in this litigation has cured any such deficiency. During discovery, Amgen has produced thousands of pages of documents related to its manufacturing processes, including additional batch records, laboratory notebooks, and standard operating procedures. *See* Declaration of Nancy J. Gettel ("Gettel Decl.") ¶ 3. The limitations on "bringing an action" for declaratory judgment under § 262(*l*)(9) invoked by Plaintiffs (*see* Point I.B, *infra*) are non-jurisdictional. *Celltrion Inc. v. Genentech Inc.*, C.A. No. 18–00276, 2018 WL 2448254, at *4 (N.D. Cal. May 9, 2018). Accordingly, factual developments occurring after the pleading can cure any alleged deficiencies. *See Union Pac. R.R. v. Bhd. of Locomotive Eng'rs*, 558 U.S. 67, 84 (2009) (noting that, if non-jurisdictional conditions for bringing a claim are not met, a

temporary stay "pending cure of any lapse" is the appropriate course of action). Therefore, even if there were any deficiency in Amgen's BPCIA disclosures, that deficiency has been cured.

At bottom, the record on this motion shows that Amgen complied with its obligations under the BPCIA, and Plaintiffs' argument that Amgen's counterclaims should be dismissed for non-compliance is therefore built on a faulty factual premise.

B. Plaintiffs' Remedy for a Violation of § 262(*l*)(2)(A) Was to Bring a Lawsuit.

Even if the record did show that Amgen violated the BPCIA and even if that violation had not been cured, Plaintiffs still would not be entitled to the relief that they seek here. Congress provided that if an applicant fails to disclose information required by 42 U.S.C. § 262(*l*)(2)(A), the reference product sponsor is entitled to bring an action "for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product," but the applicant cannot. 42 U.S.C. § 262(*l*)(9)(C). The Supreme Court has explained that "[t]he remedy provided by § 262(*l*)(9)(C) excludes all other federal remedies, including injunctive relief." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1675 (2017). This Court echoed that point in the earlier litigation between these parties, noting that Plaintiffs' remedy for an alleged BPCIA disclosure violation was to bring a declaratory judgment action. *Genentech, Inc. v. Amgen Inc.*, C.A. No. 17–00165, D.I. 17 at 25:16–23 (D. Del Mar. 3, 2017) (Sleet, J.). Accordingly, even if Amgen violated its disclosure obligations under the BPCIA, Plaintiffs' remedy was to sue for declaratory judgment, which they have now done.

Once Plaintiffs sued for declaratory judgment, they could "access the required information through discovery." *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 (Fed. Cir. 2015), *rev'd in part, vacated in part,* 137 S. Ct. 1664 (2017). Indeed, Plaintiffs have already served several sets of Requests for Production in this matter seeking specific protocols and other

broad categories of documents related to Amgen's manufacturing process. *See, e.g.*, Ex. A (Plaintiff Genentech's First Set of Requests for Production to Defendant Amgen).[3] Amgen has responded to each Request by agreeing to produce responsive, non-privileged documents and has produced such documents on a rolling basis. Ex. B (Amgen's Objections and Responses to Plaintiffs Genentech's First Set of Requests for Production); *see also* Gettel Decl. ¶ 3.

Plaintiffs are wrong in their reliance on § 262(*l*)(9)(C) as precluding Amgen's counterclaims. Section 262(*l*)(9)(C) speaks in terms of which party may "bring an action" seeking a declaratory judgment. "The phrase 'bring an action' is defined as 'to sue; institute legal proceedings.'" *Jonathan H. v. The Souderton Area Sch. Dist.*, 562 F.3d 527, 529 (3d Cir. 2009) (quoting Black's Law Dictionary (8th ed. 2004)). Thus, an action is "brought" for purposes of § 262(*l*)(9)(C) when the reference product sponsor sues seeking declaratory relief. *See id.* ("A civil action is commenced by filing a complaint with the court." (citing Fed. R. Civ. P. 3)); *see also Alexander v. Hillman*, 296 U.S. 222, 240 (1935) (noting that a suit is "brought by any original process or proceeding"). Amgen did not "bring an action" when it asserted its counterclaims. *See Amgen Inc. v. Sandoz Inc.*, Civ. No. 14–4741, 2015 WL 1264756, at *9 (N.D. Cal. Mar. 19, 2015) ("The BPCIA addresses only an applicant's ability to 'bring an action,' not to assert a counterclaim if placed in a position to defend against an infringement suit."), *aff'd in part, vacated in part, remanded* 794 F.3d 1347 (Fed. Cir. 2015), *rev'd in part, vacated in part*, 137 S. Ct. 1664 (2017). It is Plaintiffs—not Amgen—that have "brought" this action. *Hillman*, 296 U.S. at 240. Amgen has merely responded to Plaintiffs' action by asserting counterclaims. They were "filed only after [Plaintiffs] . . . initiated the case by bringing a civil action." *Jonathan H.*, 562 F.3d at 529 (citing Black's Law Dictionary (8th ed. 2004) (defining a

[3] All citations to "Ex." refer to the Exhibits attached to the Declaration of Siegmund Y. Gutman ("Gutman Decl.") filed herewith.

counterclaim as a "claim for relief asserted against an opposing party after an original claim has been made")). By its plain terms, § 262(*l*)(9)(C) says nothing about a subsection (k) applicant's ability to assert counterclaims in a responsive pleading. Accordingly, § 262(*l*)(9)(C)'s prohibition against an applicant "bring[ing] an action" does not apply to this case. Even if Amgen had violated § 262(*l*)(2)(A), which it has not, § 262(*l*)(9)(C) does not provide the relief Plaintiffs' seek.[4]

Absent evidence that Congress intended to depart from the plain meaning of "bringing an action," that plain meaning controls. *See Carcieri v. Salazar*, 555 U.S. 379, 387 (2009) (noting that when "the statutory text is plain and unambiguous" the court "must apply the statute according to its terms" (citations omitted)). By its terms, § 262(*l*)(9)(C) merely vests control over the timing and scope of an action seeking declaratory relief in the reference product sponsor; it does not eviscerate an applicant's ability to defend itself. Certainly if Congress had intended such a drastic penalty for failing to comply with the BPCIA's disclosure regime, it would have said so.

The cases cited by Plaintiffs are not to the contrary. *See* D.I. 129 at 4 (citing cases). In each of those cases, a court dismissed a litigation that (unlike this one) was initiated by a subsection (k) applicant.[5] Plaintiffs cite no case in which a court has dismissed an applicant's

[4] Notably, Plaintiffs' current position is diametrically opposed to the position they took in support of their motion to dismiss or stay in California. There, Plaintiffs represented to the California court that "Amgen suffers no harm from a stay; it can continue to assert the same claims and defenses it seeks to litigate in this action as counter-claims to Genentech's Delaware lawsuits." Ex. C (Plaintiffs' motion to dismiss Amgen's California Complaint) at 24.

[5] *See Celltrion Healthcare Co. v. Kennedy Tr. For Rheumatology Res.*, Civ. No. 14–2256, 2014 WL 6765996 (S.D.N.Y. Dec. 1, 2014) (dismissing action brought by applicant); *Celltrion, Inc. v. Genentech, Inc.*, Civ. No. 18–00276, D.I. 81 (May 9, 2018) (same); *Hospira, Inc. v. Janssen Biotech, Inc.*, Civ. No. 14–7049, 2014 WL 6766263 (S.D.N.Y. Dec. 1, 2014) (same); *Sandoz Inc. v. Amgen Inc.*, No. Civ. No. 13–2904, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013) (same).

responsive counterclaims pursuant to § 262(*l*)(9)(C). The relief sought by Plaintiffs is therefore both unprecedented and without any support in the BPCIA.

II. AMGEN IS NOT LIMITED TO THE INVALIDITY THEORIES ASSERTED IN ITS BPCIA DISCLOSURES.

Plaintiffs next assert that the BPCIA restricts Amgen to pleading only the invalidity theories stated in its BPCIA disclosures. According to Plaintiffs, the disclosures exchanged under the BPCIA "define the scope of the litigation," and Amgen is bound to argue only the theories that it previously disclosed. D.I. 129 at 8.

Plaintiffs point to nothing in the statutory text that supports that conclusion, however, and no court has ever held that BPCIA disclosures are binding. Nor would it make any sense for a subsection (k) applicant to be limited to the legal theories it discloses in the BPCIA exchange. Under the BPCIA's disclosure scheme, applicants' invalidity theories are disclosed once, before any consideration of the sponsor's positions and without any discovery or claim construction by a court. 42 U.S.C. § 262(*l*)(3)(B). A party's invalidity theories typically evolve when it receives discovery about the patents asserted against it, the research underlying those patents, the prior art, and the conduct surrounding the prosecution history. That is in part why local patent rules typically permit a defendant to amend its invalidity contentions for good cause. *See, e.g.*, N.D. Cal. Local Patent Rule 3-6. Under Plaintiffs' theory, however, Congress *sub silentio* decided to constrain a subsection (k) applicant's invalidity theories to those disclosed at the time of the BPCIA exchange (*i.e.*, the opinions held 60 days after receiving the 3A list of patents from the sponsor that in this case listed 27 patents). If Congress had intended such a draconian result, it surely would have said so in the statute. The contentions exchanged in the BPCIA process are to aid the parties in determining whether a litigation on one or more of the 3A listed patents can be avoided and if not, which patents should be part of an immediate litigation and which should be

deferred. If an immediate patent litigation is filed, as was done here, the object of the litigation is not to test the merits of the contentions exchanged pre-litigation. The object of the litigation is to finally adjudicate whether the asserted patent(s) are valid, enforceable and infringed.

Having no support in the statutory text or the case law for their argument that BPCIA disclosures are binding, Plaintiffs resort to a policy argument. According to Plaintiffs, unless subsection (k) applicants are restricted to litigating the theories stated in their BPCIA disclosures, they will have no incentive to provide accurate disclosures, and the entire BPCIA disclosure scheme will collapse. D.I. 129 at 7–8.

As an initial matter, policy arguments like Plaintiffs' are irrelevant to questions of statutory construction where, as here, the text of the statute is clear. *Carcieri v. Salazar*, 555 U.S. 379, 387 (2009) (where "statutory text is plain and unambiguous[,]" the Court "must apply the statute according to its terms") (citations omitted); *see also SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018) ("It is Congress's job to enact policy and it is this Court's job to follow the policy Congress has prescribed."). The BPCIA by its plain terms lays out a detailed disclosure scheme wherein: (1) the reference product sponsor provides a list of patents that it believes a claim of patent infringement could reasonably be asserted under 42 U.S.C. § 262(*l*)(3)(A); (2) the biosimilar applicant responds with a detailed statement of the factual and legal basis for the applicant's opinion that the claims of the listed patents are invalid, unenforceable, or not infringed, 42 U.S.C. § 262(*l*)(3)(B)(ii)(I); and (3) the reference product sponsor, in turn, provides a detailed statement of the factual and legal bases for the sponsor's opinion that the patents will be infringed and responds to the applicant's statement concerning validity and enforceability. 42 U.S.C. § 262(*l*)(3)(C). The statute says nothing about the parties being limited to the factual and legal bases set forth in their BPCIA pre-litigation statements, and

the import of that statutory silence is plain: Congress did not intend any such limitation.

Plaintiffs' policy argument is meritless in any event because it ignores the incentives that parties have to continue through the BPCIA process once the initial disclosure has been made. For example, both parties have an incentive to disclose under § 262(*l*)(3) to trigger the other side's disclosure obligations. For instance, when a subsection (k) applicant provides a detailed statement of patent invalidity or unenforceability under § 262(*l*)(3)(B)(ii)(I), it triggers the sponsor's obligation to provide a "response to the statement concerning validity and enforceability" as well as the basis for its belief that the applicant will infringe. 42 U.S.C. § 262(*l*)(3)(C). That ability to provoke a substantive response to invalidity contentions, as well as to learn the basis for the sponsor's infringement contentions, is sufficient incentive to encourage most applicants to genuinely participate in the BPCIA's exchange of detailed statements (recognizing that the applicant already made the choice to initiate the BPCIA process in the first place).

In short, the BPCIA's "carefully calibrated scheme" offers incentives for parties to provide full and accurate statements of their legal positions. *Sandoz*, 137 S. Ct. at 1675. This Court therefore should decline Plaintiffs' invitation to invent an additional incentive out of whole cloth by foreclosing invalidity theories that were not set forth in Amgen's 3B statement.

Notably, Plaintiffs were already ordered to amend their contentions once in this matter (although they failed to do so). And as a result of the July 11, 2018 hearing, Plaintiffs will now be afforded ***two*** additional opportunities to amend. Plaintiffs' request for a ***third*** opportunity to amend shows that Plaintiffs believe that parties should be permitted to amend their contentions after they receive additional information during discovery. That is to say, even Plaintiffs do not believe that parties should be restricted to their BPCIA disclosures. To the extent that Plaintiffs

argue that only subsection (k) applicants but not product sponsors are bound by their BPCIA disclosures, that extreme position is plainly unsupported by the statute.[6]

The cases cited by Plaintiffs where a court refused to allow a party to amend contentions are readily distinguishable. D.I. 129 at 6 n.3. In those cases, the party at issue failed to act diligently by attempting to amend its contentions late in the litigation well after having received discovery. For instance, in *Informatica Corp. v. Business Objects Data Integration, Inc.*, the party waited three years after receiving relevant discovery to amend its infringement contentions. No. 02-cv-3378, 2006 WL 463549, at *1 (N.D. Cal. Feb. 23, 2006); *see also O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1367 (Fed. Cir. 2006) (affirming finding of "lack of diligence" in attempt to amend contentions). Here, by contrast, the litigation is in its nascent stage, and Amgen has not received any meaningful discovery from Plaintiffs either during the BPCIA's information exchange or through discovery in this litigation. Under these facts, it cannot reasonably be said that Amgen has failed to act with diligence.[7]

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[6] As Plaintiffs concede, Amgen has never argued that subsection (k) applicants are bound by statements made during the BPCIA exchange. D.I. 129 at 8 n.5. Plaintiffs assert that Amgen's position in *Amgen v. Apotex* supports their argument here, but that case involved a different issue. *Apotex* involved a factual assertion made during the BPCIA exchange that was repudiated without explanation during trial. Amgen argued as an evidentiary matter that it was error for the trial court to exclude a factual admission contained in a BPCIA disclosure. Here, by contrast, Plaintiffs argue that the legal theories set out in a BPCIA disclosure ought to define the scope of litigation.

[7] Plaintiffs attempt to reargue the "unfairness" of the patent and claim narrowing steps (D.I. 129 at 8–9) that were extensively briefed and argued by the parties and ultimately adopted by the Court in its scheduling order. D.I. 106 at ¶ 2. If Plaintiffs truly believe the court-Ordered patent and claim narrowing to be "unworkable" and "unfair" (D.I. 129 at 8–9), the Court has already provided a recourse, namely, the opportunity to add two additional patents upon a showing of good cause. *Id.* Plaintiffs acknowledged that this recourse was an "acceptable" "way to address both parties' interests," and should not be heard to complain again now. Ex. D (Excerpts from May 7 Case Management Conference) at 52:9–23.

III. AMGEN'S INEQUITABLE CONDUCT COUNTERCLAIM IS ADEQUATELY PLED.

It is undisputed that Amgen has pled with particularity the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). For example, Amgen has alleged that during prosecution of U.S. Patent No. 6,407,213, Genentech deliberately misrepresented the teachings of one reference to overcome a rejection of pending claims, and further provided empirical information at the Examiner's request that conspicuously omitted a claim element disclosed in the prior art. D.I. 124 at 99–102, ¶¶ 269–82. Amgen has further pled that "[d]eceptive intent by Genentech is the single most reasonable inference to be drawn" from Genentech's conduct in prosecuting the '213 patent. *Id.* at 99, ¶ 272. This Court has upheld inequitable conduct counterclaims based on nearly identical allegations that a patentee "misrepresented the teachings of the prior art in a manner that would be recognized as false by a person of ordinary skill in the art, and also submitted incomplete, misleading, and internally inconsistent empirical data." *Wyeth Holdings Corp. v. Sandoz, Inc.*, No. 09-cv-00955, 2012 U.S. Dist. LEXIS 26912, at *28 (D. Del. Feb. 3, 2012).

Instead of challenging the particularity of the allegations underlying Amgen's inequitable conduct counterclaim, Plaintiffs resort to disputing the accuracy of those allegations. Specifically, Plaintiffs argue that their misleading statements to the Patent Office were not material misrepresentations made with deceptive intent (as Amgen alleges in its Amended Answer) but rather were attorney "argument." D.I. 129 at 9–11. In so contending, Plaintiffs raise a factual dispute that cannot be resolved on a motion to dismiss. *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs.*, No. 14-cv-01482, 2015 U.S. Dist. LEXIS 95148, at *15-16 (D. Del. July 22, 2015) (declining to dismiss inequitable conduct claim where the patentee merely

"disagree[d] with the factual representations made by [defendant]"); *IBM v. Priceline Grp., Inc.*, No. 15-cv-00137, 2017 U.S. Dist. LEXIS 54285, at *39-40 (D. Del. Apr. 10, 2017) ("[A patentee's] *factual disagreement* . . . does not support dismissal of Defendants' counterclaim at the pleading stage.") (emphasis in original)).[8]

For purposes of this motion, Amgen's allegations must be taken as true and viewed in the light most favorable to Amgen. *Bruni*, 824 F.3d at 360. Those allegations support a finding that Plaintiffs committed inequitable conduct. If Plaintiffs wish to challenge Amgen's factual allegations, the proper vehicle is a motion for summary judgment; but for purposes of this motion, Amgen's allegation that Genentech made false statements to the Patent Office with the intent to deceive must be accepted as true. Since there is no dispute concerning the sufficiency of Amgen's allegations, Plaintiffs' motion to dismiss must be denied.[9]

Plaintiffs argue that, as a matter of law, they could not have committed inequitable conduct because the misrepresented references were disclosed to, and could be independently evaluated by, the Examiner. D.I. 129 at 9–11. But that misstates the law. "Although an attorney is free to argue vigorously in favor of patentability without being subject to allegations of inequitable conduct, 'the law prohibits genuine misrepresentations of material fact.'" *Ring Plus,*

[8] Statements are actionable misrepresentations and not "arguments" if they contain "gross mischaracterizations or unreasonable interpretations" or are "demonstrably false." *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). Plaintiffs make no attempt to demonstrate that the statements at issue here are "attorney argument" akin to the statements in their cited cases. D.I. 129 at 10-11. At most, Plaintiffs raise a factual dispute about whether the statements are misrepresentations or argument, and that dispute cannot be resolved on this motion.

[9] The factual dispute raised by Plaintiffs is particularly inappropriate for resolution on a Rule 12(b)(6) motion because to date Amgen has not received any meaningful discovery into its inequitable conduct counterclaim. "Absent meaningful discovery, a party should not be penalized for" omitting details at the pleading stage, where such details "can still be ascertained with particularity." *Invensys Sys. v. Emerson Elec. Co.*, No. 12-cv-00799, 2014 U.S. Dist. LEXIS 196195, at *7 (E.D. Tex. July 9, 2014).

Inc. v. Cingular Wireless Corp., 614 F.3d 1354, 1360-61 (Fed. Cir. 2010). Accordingly, an attorney can commit inequitable conduct even when describing references that the Examiner is free to independently scrutinize. *Id.* (holding that statement misrepresenting the substance of two references before the Examiner was "outside the bounds of permissible attorney argument"). Moreover, even attorney argument can give rise to an actionable claim of inequitable conduct if it is made with an intent to deceive. *Southco, Inc. v. Penn Eng'g & Mfg. Corp.*, 768 F. Supp. 2d 715, 723 (D. Del. 2011) ("[Patentee's] arguments to the Examiner amounted to material representations because [patentee] knew its arguments were factually and patently false"). Here, Amgen has pled with particularity that Genentech deliberately mischaracterized the prior art and made other misrepresentations during prosecution. That is sufficient to state an inequitable conduct counterclaim.[10]

IV. AMGEN'S UNCLEAN HANDS DEFENSE IS ADEQUATELY PLED.

As an affirmative defense, unclean hands is "sufficiently raised for purposes of [Rule 8] by its bare assertion." *Moody*, 870 F.3d at 218. Plaintiffs do not dispute that black-letter law but instead assume that Amgen's unclean hands and inequitable conduct theories arise from the same factual allegations and thus "rise or fall together." D.I. 129 at 11. That assumption is false. Amgen's unclean hands defense encompasses a broader set of misconduct "involv[ing] the subject matter of the plaintiff's claim" and is not limited to misconduct during the prosecution of the patents-in-suit. *CIBA-Geigy Corp. v. Bolar Pharm. Co.*, 747 F.2d 844, 855 (3d Cir. 1984). Accordingly, Amgen's unclean hands defense does not "rise or fall" with inequitable conduct. Instead, it is a standalone defense that is adequately pled by its bare assertion. Moreover, even if

[10] This case is thus distinguishable from *Cellectis v. Precision Biosciences*, 883 F. Supp. 2d 526 (D. Del. 2012) (cited in D.I. 129 at 10). In *Cellectis*, the defendant failed to plead any facts supporting the deceptive intent prong of inequitable conduct. Here, by contrast, all of the elements of inequitable conduct have been pled with particularity.

unclean hands did rise or fall with inequitable conduct, Amgen's inequitable conduct counterclaim is adequately pled for the reasons stated above and therefore so, too, is unclean hands.

V. THERE IS A JUSTICIABLE CONTROVERSY BETWEEN THE PARTIES CONCERNING U.S. PATENT NOS. 6,610,516 AND 7,323,553.[11]

Finally, Plaintiffs are wrong that Amgen's counterclaims challenging the validity of the '516 and '553 patents fail to present a justiciable case or controversy. After reviewing Amgen's disclosure under § 262(*l*)(2)(A), Plaintiffs listed these two patents in their § 262(*l*)(3)(A) disclosure, putting Amgen on notice that Plaintiffs "believe a claim of patent infringement could reasonably be asserted" under these patents. 42 U.S.C. § 262(*l*)(3)(A)(i); *see* D.I. 124 at 67, ¶ 120; *id.* at 78, ¶ 171. That is more than sufficient to create a case or controversy. *See Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1330 (Fed. Cir. 2014) (holding that a case or controversy requires only that "the dispute be 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character'").

Plaintiffs have taken no steps to moot the controversy that they created when they included the '516 and '553 patents in their § 262(*l*)(3)(A) disclosure. As Plaintiffs admit in their opening brief, they have merely stated that they "do[] not ***intend*** to assert [the '516 and '553 patents] against ABP 215." D.I. 129 at 12 (emphasis removed and added). That non-binding statement of intent is insufficient as a matter of law to moot the controversy over these patents.

[11] Amgen understood that during the hearing that took place on July 11, 2018, Plaintiffs stated that they will not assert either the '516 or '553 patent (as well as claims from other patents in suit) against ABP 215/Mvasi™ now or in the future. (Transcript of July 11, 2018 hearing was unavailable at the time this brief was filed). If that is the case, Plaintiffs should agree to enter into a covenant-not-to-sue to reflect their position. Upon execution of a proper covenant-not-to-sue, Amgen would be willing to dismiss its counterclaims directed to the '516 and '553 patents.

It is elementary that "reliance upon a mere expression of future intention cannot be 'reasonable,' because such expressions do not constitute a sufficiently definite promise." *In re Phillips Petroleum Sec. Litig.*, 881 F.2d 1236, 1250 (3d Cir. 1989). Absent some enforceable promise, Amgen is left with nothing but uncertainty about whether these two patents will be asserted at some later date—likely timed to disrupt Amgen's plans to launch its biosimilar product or create further delays. Particularly given the parties' litigation history in this matter, there is a real and concrete dispute about whether these patents are, in fact, valid and infringed, and this Court therefore has jurisdiction to hear Amgen's counterclaims. *See Danisco*, 744 F.3d at 1331 (explaining that "a history of patent litigation between the same parties involving related technologies, products, and patents is another circumstance . . . which might weigh in favor of the existence of subject matter jurisdiction").

If Plaintiffs truly do not intend to assert the '516 and '553 patents and want to moot the controversy over those patents, they can grant Amgen a covenant not to sue—something that Amgen has requested repeatedly and which would divest this Court of jurisdiction. *See* Gutman Decl. ¶ 6. But without such a binding covenant, those patents remain in controversy. *See Danisco*, 744 F.3d at 1331 ("Nor has Novozymes offered any assurance, such as with a covenant not to sue, that it will not accuse Danisco's RSL products of infringement, which could potentially moot a controversy between the parties."); *DNP Int'l Co., Inc. v. Natural Alternatives Int'l, Inc.*, C.A. No. 11–1283, 2013 WL 12221938, at *1 n.1 (D. Del. Feb. 27, 2013) ("A covenant not to sue can certainly preclude a declaratory judgment action, but NAI's statement as to its present 'intention' does not rise to the level of such a covenant." (citations omitted)).

CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court deny Plaintiffs' motion to dismiss and to strike Defendant's counterclaims and its third, fourteenth, and fifteenth affirmative defenses.

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