IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, *Plaintiffs*, v. AMGEN INC., *Defendant.*	:	Civ. No. 17-1407- CFC, Consol.

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MEMORANDUM OPINION

February 11, 2020
Wilmington, Delaware

CONNOLLY, UNITED STATES DISTRICT JUDGE

These two consolidated patent cases were filed under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), 42 U.S.C. § 262. Plaintiffs Genentech, Inc. and City of Hope (collectively, Genentech) accuse Defendant Amgen Inc. of infringing 26 patents based on Amgen's submission of an Abbreviated Biologics License Application (aBLA) to the Food and Drug Administration (FDA) for approval to market a biosimilar of Genentech's biologic drug product Avastin®. C.A. No. 17-1407, D.I. 41; C.A. No. 17-1471, D.I. 39.[1] Amgen alleges in 29 declaratory judgment counterclaims and its third, fourteenth, and fifteenth affirmative defenses that the 26 asserted patents and two other patents held by Genentech are invalid and/or unenforceable. Pending before me is Genentech's motion to dismiss and/or strike pursuant to Federal Rules of Civil Procedure 12(b)(6), 12(b)(1), and 12(f) Amgen's counterclaims and these three affirmative defenses. C.A. No. 17-1407, D.I. 128; C.A. No. 17-1471, D.I. 126.

[1] Although these two actions have been consolidated, Genentech has not filed a consolidated complaint. Genentech asserts 25 patents in C.A. No. 17-1407 and one additional patent, for a total of 26, in C.A. No. 17-1471. Amgen filed in both actions affirmative defenses and counterclaims that are verbatim identical. *See* C.A. No. 17-1407, D.I. 120; C.A. No. 17-1471, D.I. 118. Accordingly, for convenience, I will discuss the two sets of affirmative defenses and counterclaims as if they were in a single pleading and cite only to the operative answer and counterclaims filed in C.A. No. 17-1407.

I. LEGAL STANDARDS

A. The BPCIA

The BPCIA is a complex statutory scheme that governs biologics and a subset of biologics called biosimilars. Biologics, also known as biological products, are drugs that are not chemically synthesized but instead are derived from biological sources such as animals and microorganisms. A biosimilar is a biologic that is highly similar to, and not meaningfully different in terms of safety, purity, or potency from, a biologic already approved by the FDA. As its title suggests, the BPCIA was designed to foster both price competition and innovation in the field of biologics. To that end, the BPCIA "establishes processes both for obtaining expedited FDA approval of biosimilars and for resolving patent disputes between manufacturers of licensed biologics and manufactures of biosimilars." *Sandoz, Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669–70 (2017).

The starting point of the FDA approval process begins with the filing of the aBLA by the manufacturer of the biosimilar (the applicant). The aBLA and the FDA approval process are said to be abbreviated because the biosimilar applicant does not need to show with independent (and costly) evidence such as clinical trial results that the biosimilar is safe, pure, and potent. Instead, the applicant can "piggyback on the showing made by the manufacturer (sponsor) of [the] previously licensed biologic (reference product)." *Id.* at 1670.

The BPCIA's patent dispute-resolution process—often referred to as "the patent dance"—is "a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Id.* at 1670. The dance kicks off "not later than 20 days" after the FDA notifies the biosimilar applicant that the FDA accepted the aBLA. 42 U.S.C. § 262(*l*)(2). At that point, the applicant "shall provide" to the reference product's sponsor a copy of the aBLA and "such other information that describes the process or processes used to manufacture the [biosimilar.]" § 262(*l*)(2)(A). "These disclosures enable the sponsor to evaluate the biosimilar for possible infringement of patents it holds on the reference product (i.e., the corresponding biologic)." *Sandoz*, 137 S. Ct. at 1670–71.

The Court in *Sandoz* summarized the remainder of the BPCIA's pre-litigation patent dance as follows:

> After the applicant makes the requisite disclosures [required by § 262(*l*)(2)(A)], the parties exchange information to identify relevant patents and to flesh out the legal arguments that they might raise in future litigation. Within 60 days of receiving the application and manufacturing information, the sponsor "shall provide" to the applicant "a list of patents" for which it believes it could assert an infringement claim if a person without a license made, used, offered to sell, sold, or imported "the biological product that is the subject of the [biosimilar] application." § 262(*l*)(3)(A)(i). The sponsor must also identify any patents on the list that it would be willing to license. § 262(*l*)(3)(A)(ii).
>
> Next, within 60 days of receiving the sponsor's list, the applicant may provide to the sponsor a list of patents that

> the applicant believes are relevant but that the sponsor omitted from its own list, § 262(*l*)(3)(B)(i), and "shall provide" to the sponsor reasons why it could not be held liable for infringing the relevant patents, § 262(*l*)(3)(B)(ii). The applicant may argue that the relevant patents are invalid, unenforceable, or not infringed, or the applicant may agree not to market the biosimilar until a particular patent has expired. *Ibid.* The applicant must also respond to the sponsor's offers to license particular patents. § 262(*l*)(3)(B)(iii). Then, within 60 days of receiving the applicant's responses, the sponsor "shall provide" to the applicant its own arguments concerning infringement, enforceability, and validity as to each relevant patent. § 262(*l*)(3)(C).

Id. at 1671 (first set of brackets added).

If the parties comply with these information exchange requirements, the BPCIA "channels the parties into two phases of patent litigation." *Id.* The specifics of these phases are not relevant to the pending motion. But it is relevant that the applicant has "substantial control" over both phases of the litigation. *See id.* (noting that the BPCIA's "process gives the applicant substantial control over the scope of the first phase of litigation"); *id.* at 1672 (noting that the applicant "wields substantial control over the timing of the second phase of litigation").

The Court noted in *Sandoz* that "[t]o encourage parties to comply with [the BPCIA's] procedural requirements," the Act "includes various consequences for failing to do so." *Id.* at 1672. Two of these consequences are set forth in § 262(*l*)(9)(C) and § 262(*l*)(9)(B) of the BPCIA. As the Court explained in *Sandoz*:

> Under § 262(*l*)(9)(C), if an applicant fails to provide its application and manufacturing information to the sponsor—thus effectively pretermitting the entire two-phase litigation process—then the sponsor, but not the applicant, may immediately 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." Section 271(e)(2)(C)(ii) facilitates this action by making it an artificial act of infringement, with respect to any patent that could have been included on the § 262(*l*)(3) lists, to submit a biosimilar application. Similarly, when an applicant provides the application and manufacturing information but fails to complete a subsequent step, § 262(*l*)(9)(B) provides that the sponsor, but not the applicant, may bring a declaratory-judgment action with respect to any patent included on the sponsor's § 262(*l*)(3)(A) list of patents (as well as those it acquired later and added to the list). As noted, it is an act of artificial infringement, with respect to any patent on the § 262(*l*)(3) lists, to submit an application to the FDA. *See* § 271(e)(2)(C)(i).

137 S. Ct. at 1672 (emphasis removed) (underline added). Thus, under §§ 262(*l*)(9)(B) and 262(*l*)(9)(C), when an applicant fails to comply with the information exchange requirements of the patent dance, it subjects itself to the uncertain timing and scope of a declaratory judgment infringement action brought by the reference sponsor and it loses the "substantial control" it would otherwise have been able to exert in the two phases of litigation established by the BPCIA. *See id.* at 1675 ("Section 262(*l*)(9)(C) thus vests in the sponsor the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation.").

B. Rule 12(b)(6)

Under Rule 12(b)(6), a party may move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). To survive the motion to dismiss, the complaint must contain sufficient factual matter "to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Twombly*, 550 U.S. at 555. In assessing the plausibility of a claim, the court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *In re Rockefeller Ctr. Prop., Inc. Sec. Litig.*, 311 F.3d 198, 215 (3d Cir. 2002). The court's review is limited to the allegations in the complaint, exhibits attached to the complaint, documents incorporated by reference, items subject to judicial notice, and matters of the public record. *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010).

C. Rule 12(b)(1)

The party asserting subject matter jurisdiction has the burden of proving its existence. *Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). "Challenges to subject matter jurisdiction under Rule 12(b)(1) may be facial or factual." *Id.* (quoting *Common Cause of Pa. v. Pennsylvania*, 558 F.3d 249, 257

(3d Cir. 2009)). A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests the sufficiency of jurisdictional facts. *Id.* Here, Genentech makes a factual attack. When reviewing a factual attack, the court may weigh and consider evidence outside the pleadings. *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). Finally, in a factual challenge, "no presumptive truthfulness attaches to plaintiffs' allegations." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

D. Rule 12(f)

Pursuant to Rule 12(f), "[t]he court may strike from a pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Motions to strike are generally disfavored and ordinarily denied "unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties." *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 402 (D. Del. 2009) (quoting *McInerney v. Moyer Lumber & Hardware, Inc.*, 244 F. Supp. 2d 393, 402 (E.D. Pa. 2002)). When ruling on a motion to strike, "the [c]ourt must construe all facts in favor of the nonmoving party . . . and deny the motion if the defense is sufficient under law." *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 697 F. Supp. 1360, 1362 (D. Del. 1988).

II. DISCUSSION

Genentech attacks various combinations of counterclaims and affirmative defenses on four different grounds. First, Genentech argues that Amgen did not comply with its pre-litigation production obligations under the BPCIA and, therefore, all of Amgen's declaratory judgment counterclaims are barred by § 262(*l*)(9)(C). D.I. 129 at 2–4. Second, Genentech argues that Amgen's invalidity counterclaims and corresponding third affirmative defense are barred by the BPCIA to the extent they are based on invalidity, unenforceability, and non-infringement contentions that Amgen did not disclose to Genentech in the patent dance as required by § 262(*l*)(3)(B). *Id.* at 5–9. Third, Genentech argues that Amgen has failed to state a claim for inequitable conduct and therefore Count 29 and the corresponding fourteenth and fifteenth affirmative defenses should be dismissed. *Id.* at 9–11. And finally, Genentech contends that the Court lacks subject matter jurisdiction over Counts 8 and 15 of Amgen's counterclaims. I address each argument in turn.

A. Declaratory Judgment Counterclaims

Genentech first alleges that Amgen failed to provide "such other information" that describes its biosimilar manufacturing process as required by § 262(*l*)(2)(A) and, therefore, Amgen is barred by § 262(*l*)(9)(C) from asserting counterclaims that seek a declaratory judgment that Genentech's patents are

invalid, unenforceable, and not infringed. D.I. 41 ¶ 5. Amgen disputes the factual premise of this argument, claiming that it sent Genentech its aBLA and "more than a million pages of technical details and batch records" describing the manufacturing processes. D.I. 120, Counterclaims ¶ 20.

I need not resolve the parties' factual disputes or decide whether Amgen complied with its § 262(*l*)(2)(A) obligations, because the filing of counterclaims does not constitute "bringing an action" and, therefore, is not barred by § 262(*l*)(9)(C). The terms of § 262(*l*)(9)(C) are clear:

> If a [biosimilar] applicant fails to provide the [aBLA] and information required under paragraph [§ 262(*l*)](2)(A), the reference product sponsor, but not the [biosimilar] applicant, may *bring an action* under section 2201 of Title 29, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

§ 262(*l*)(9)(C) (emphasis added). "The phrase 'bring an action' is defined as 'to sue; institute legal proceedings.'" *Jonathan H. v. The Souderton Area School Dist.*, 562 F.3d 527, 530 (3d. Cir. 2009) (quoting Black's Law Dictionary (8th ed. 2004)). It is the filing of a complaint—not a counterclaim—that institutes an action. *See* Fed. R. Civ. P. 3 ("A civil action is commenced by filing a complaint with the court."). Accordingly, Amgen's counterclaims are not barred by § 262(*l*)(9)(C).

B. Invalidity Counterclaims

Genentech next argues that Amgen's counterclaims should be dismissed under Rule 12(b)(6) and Amgen's invalidity and enforceability defenses should be struck under Rule 12(f) to the extent the counterclaims and defenses "rely on positions Amgen did not disclose during the 'patent dance.'" D.I. 129 at 9. Genentech faults Amgen for failing to comply with "the obligation to provide meaningful [§ 262](*l*)(3)(B)(ii)(I) contentions," *id.* at 7, and it contends that "[t]he statute does not permit this," *id.* at 5.

Genentech does not make clear in its briefing how Amgen's § 262(*l*)(3)(B)(ii) disclosures were deficient or what are the "new" contentions Amgen now seeks to make in support of its counterclaims and affirmative defenses. Nor does Genentech point to anything in the BPCIA or to case law interpreting the BPCIA that would support barring a biosimilar applicant from making in a BPCIA case contentions not disclosed in the patent dance. But, in any event, Genentech's argument that the BPCIA precludes an applicant from making contentions beyond the scope of its § 262(*l*)(3)(B)(ii) disclosures is foreclosed by § 262(*l*)(9)(B) and the Supreme Court's decision in *Sandoz*.

As discussed above, §§ 262(*l*)(9)(B) and 262(*l*)(9)(C) are remedial provisions in the BPCIA designed to encourage parties to comply with the disclosure requirements of the patent dance. Just as § 262(*l*)(9)(C) empowers "the

reference product sponsor, but not the [biosimilar] applicant," to "bring an action" for a declaratory judgment if the applicant "fails to provide the application and information required under [§ 262(*l*)](2)(A)," so, too, § 262(*l*)(9)(B) empowers "the reference product sponsor, but not the [biosimilar] applicant," to "bring an action" for a declaratory judgment if the applicant "fails to complete an action required . . . under [§ 262(*l*)](3)(B)(ii)." The two remedial provisions use identical language to establish the same consequence for non-compliance—i.e., the loss of control over the scope and timing of the patent litigation.

In *Sandoz* the Court held that a reference product sponsor could not obtain an injunction to compel an applicant to comply with § 262(*l*)(2)(A) because "§ 262(*l*)(9)(C) represents the exclusive remedy for an applicant's failure to provide [the] application and manufacturing information" required by § 262(*l*)(2)(A). 137 S. Ct. at 1675 n.2. The Court explained:

> The remedy provided by § 262(*l*)(9)(C) excludes all other federal remedies, including injunctive relief. Where, as here, "a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." The BPCIA's "carefully crafted and detailed enforcement scheme provides strong evidence that Congress did not intend to authorize other remedies that it simply forgot to incorporate expressly." The presence of § 262(*l*)(9)(C), coupled with the absence of any other textually specified remedies, indicates that Congress did not intend sponsors to have access to injunctive relief, at least as a matter of federal law, to enforce the disclosure requirement.

> Statutory context further confirms that Congress did not authorize courts to enforce § 262(*l*)(2)(A) by injunction. Section 262(*l*)(1)(H) provides that "the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation" of the rules governing the confidentiality of information disclosed under § 262(*l*). We assume that Congress acted intentionally when it provided an injunctive remedy for breach of the confidentiality requirements but not for breach of § 262(*l*)(2)(A)'s disclosure requirement.

137 S. Ct. at 1375 (citations and footnote omitted).

There is no material difference between § 262(*l*)(9)(B) and § 262(*l*)(9)(C). Accordingly, it follows from *Sandoz* that § 262(*l*)(9)(B) is the exclusive federal remedy available to the reference product sponsor to address an applicant's failure to comply with § 262(*l*)(3)(B)(ii). Thus, Genentech's sole remedy for Amgen's non-compliance with § 262(*l*)(3)(B)(ii) is to do what Genentech did here—bring a declaratory judgment action for artificial infringement. Nothing in § 262(*l*)(9)(B) or in any other provision of the BPCIA limits the defenses an applicant can assert in such an action. And in light of the BPCIA's "carefully crafted and detailed enforcement scheme," the fact that Congress did *not* expressly limit an applicant's defenses in a declaratory judgment action brought pursuant to § 262(*l*)(9)(B) "provides strong evidence that Congress did *not* intend" to limit those defenses. 137 S. Ct. at 1675. Accordingly, I will not preclude Amgen from asserting in this case contentions not disclosed in the patent dance, and I will deny Genentech's

request to dismiss Amgen's counterclaims and strike its defenses to the extent those counterclaims and defenses are based on contentions not disclosed in the patent dance.

C. Inequitable Conduct and Unclean Hands

Amgen has asserted a counterclaim and two affirmative defenses based on alleged misconduct by Genentech before the United States Patent & Trademark Office (PTO) during the prosecution of U.S. Patent No. 6,407,213 (the "#213 patent"). D.I. 120, Affirmative Defenses ¶¶ 14, 15–26 and Counterclaims ¶¶ 269–282. Specifically, in Count 29 of the counterclaims, Amgen seeks a declaratory judgement that the #213 patent is unenforceable based on inequitable conduct. D.I. 120, Counterclaims ¶¶ 269–82. And in the fourteenth and fifteenth affirmative defenses, Amgen asserts respectively unclean hands and inequitable conduct defenses based on the same allegations made in support of Count 29. D.I. 120. Genentech asks that I dismiss Count 29 and strike the fourteenth and fifteenth affirmative defenses for failure to state a claim.

The alleged misrepresentations underlying the inequitable conduct unenforceability claim and the two affirmative defenses concern two prior art references: U.S. Patent No. 5,530,101 (the "#101 patent") and Queen 1989. Amgen alleges that Genentech argued to the PTO that the #101 patent and Queen 1989 used "sequential numbering" and not "the Kabat numbering" when in fact

both references expressly refer to the Kabat numbering system. D.I. 120, Counterclaims ¶¶ 277, 279–82. Amgen further alleges that Genentech misled the examiner by providing him a comparison of the numbering systems used in Queen 1989 and the #213 patent that omitted the "62L" residue in both numbering systems. *Id.* at ¶ 281.

Genentech argues that these allegations fail to state cognizable claims of inequitable conduct and unclean hands, because they are based on "attorney argument" and because the patentee disclosed the prior art references in question and the examiner was free to reach his own conclusions about what the references taught. D.I. 129 at 9–11. "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." *Rothman v. Target Corp.*, 556 F.3d 1310, 1328 (Fed.Cir.2009) (internal quotation marks and citation omitted). Amgen has alleged with sufficient particularity that Genentech deliberately mischaracterized the prior art and made other misrepresentations during the prosecution. For purposes of Rule 12(b)(6) and Rule 12(f), I must assume that those allegations are true and interpret them in Amgen's favor. Accordingly, I will deny Genentech's motion insofar as it seeks to dismiss Count 29 and strike Amgen's inequitable conduct and unclean hands defenses.

D. Subject Matter Jurisdiction

Finally, Genentech argues that Counts 8 and 15 of Amgen's counterclaims should be dismissed for lack of subject matter jurisdiction. D.I. 129 at 11–12. These counterclaims seek a declaratory judgment that U.S. Patent Nos. 6,610,516 (the "#516 patent") and 7,323,553 (the "#553 patent") are invalid, unenforceable, and will not be infringed by Amgen's proposed biosimilar. D.I. 120, Counterclaims ¶¶ 118–24, 169–75.

Genentech had included the #516 and #553 patents in the list of patents it disclosed to Amgen under § 262(*l*)(3)(A) as part of the patent dance. *See* § 262(*l*)(3)(A) (requiring the reference product sponsor to provide the applicant with a list of the patents "for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted" if the applicant were to market its proposed biosimilar). But Genentech did not include the patents in its subsequent statement of contentions made pursuant to § 262(*l*)(3)(C). *See* § 262(*l*)(3)(C) (requiring the reference product sponsor within 60 days of receiving the applicant's § 262(*l*)(3)(B) disclosures to provide the applicant with the sponsor's infringement, validity, and enforceability contentions). As Genentech explained to Amgen in correspondence exchanged during the patent dance, "having reviewed your [§ 262](*l*)(3)(B) contentions, Genentech has not served infringement contentions for [the #516 and #553 patents] and does not intend to

assert them against [Amgen's proposed biosimilar]." D.I. 130-1, Ex. 2. Consistent with that correspondence, Genentech did not assert the #516 and #553 patents in these consolidated actions.

For a court to exercise jurisdiction under the Declaratory Judgment Act, there must be an "actual controversy." 28 U.S.C. § 2201(a). The controversy must be "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 2017 WL 2559735, at *1 (D. Del. June 13, 2017) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Genentech argues that there is no actual controversy regarding the #516 and #553 patents, because Genentech has already represented to Amgen that it does not plan to assert those patents against Amgen's proposed biosimilar and did not assert those patents in the complaints filed in this consolidated action. I agree.

Amgen argues that an actual controversary exists, because Genentech's representation that it does not intend to assert claims based on the #516 and #553 patents is not binding. D.I. 146 at 18–19. Under Amgen's theory, an actual controversy will exist until Genentech provides a covenant not sue. *Id.* Although "a defendant's failure to sign a covenant not to sue is one circumstance to consider in evaluating the totality of the circumstances, it is not sufficient to create an actual controversy." *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1341 (Fed.

Cir. 2008). I will therefore dismiss Counts 8 and 15 of Amgen's counterclaims for lack of subject matter jurisdiction.

III. CONCLUSION

For the foregoing reasons, I will grant in part and deny in part Genentech's motion to dismiss Amgen's first amended counterclaims and strike Amgen's third, fourteenth, and fifteenth affirmative defenses (C.A. No. 17-1407, D.I. 128; C.A. No. 17-1471, D.I. 126). I will grant Genentech's motion insofar as it seeks to dismiss Counts 8 and 15 of Amgen's counterclaims for lack of subject matter jurisdiction. I will deny the motion in all other respects.

The Court will issue an Order consistent with this Memorandum Opinion.