IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. PFIZER INC., Defendant and Counterclaim Plaintiff.	C.A. No. 19-638-CFC [redacted] PUBLIC VERSION FILED: May 28, 2019
PFIZER INC., Counterclaim Plaintiff, v. HOFFMANN-LA ROCHE, INC., Counterclaim Defendant.	

PLAINTIFFS AND COUNTERCLAIM DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS AND TO STRIKE CERTAIN AFFIRMATIVE DEFENSES

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I. NATURE AND STAGE OF PROCEEDINGS

Plaintiff Genentech, Inc. ("Genentech") invented and developed the best-selling cancer drug Avastin® (bevacizumab). Seeking to profit from this groundbreaking work, Defendant Pfizer Inc. ("Pfizer") is seeking FDA approval to sell a biosimilar version of Avastin®. Because Pfizer's proposed product infringes patents held by or exclusively licensed to Genentech and Plaintiff City of Hope (collectively, "Plaintiffs")—including patents covering Avastin®, methods of using it, and methods of manufacturing it—Plaintiffs sued Pfizer for patent infringement on April 5, 2019. D.I. 1. Initiation of litigation followed months of pre-litigation exchanges under the Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119 ("BPCIA").

Pfizer filed its Answer, Affirmative Defenses, and Counterclaims on April 29, 2019. D.I. 14. In filing its Answer, Affirmative Defenses, and Counterclaims, Pfizer brought at least eight counterclaims against Hoffmann-La Roche, Inc. ("HLR")[1] as the owner of four of the patents-in-suit. D.I. 14 at Preamble; *see also id.* Counterclaim ¶¶ 7, 46, 50, 52, 58. HLR, however, did not file suit against Pfizer and has not joined this case as a plaintiff. Pfizer asserts forty-five counterclaims seeking declaratory judgments of noninfringement, invalidity, or unenforceability of all of the patents-in-suit. Pfizer also asserted corresponding affirmative defenses of noninfringement, invalidity, and unenforceability.

Plaintiffs and HLR now move under Rule 12(b)(6) to dismiss all of Pfizer's declaratory judgment counterclaims as barred by the BPCIA. Alternatively, Plaintiffs move under Rule 12(b)(6) to dismiss Pfizer's invalidity counterclaims and under Rule 12(f) to strike Pfizer's corresponding Third Affirmative Defense as barred by the BPCIA to the extent that those claims

[1] Pfizer incorrectly spelled Hoffmann-La Roche, Inc. throughout its Answer, Affirmative Defenses, and Counterclaims filed April 29, 2019 (D.I. 14).

are based on invalidity theories beyond those provided during the parties' pre-litigation exchanges. Plaintiffs also move under Rule 12(b)(6) to dismiss Pfizer's counterclaim for inequitable conduct and under Rule 12(f) to partially strike Pfizer's corresponding Fourth Affirmative Defense.

II. LEGAL STANDARD

"To survive a motion to dismiss" under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When evaluating a motion to dismiss, "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). A complaint cannot survive where a court can only infer that a claim is merely possible rather than plausible. *Iqbal*, 556 U.S. at 679.

Rule 12(f) authorizes the Court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Factual allegations underlying a defense must be construed in favor of the nonmoving party, but the Court "is not required to accept affirmative defenses that are mere bare bones conclusory allegations, and may strike such inadequately pleaded defenses." *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 408 (D. Del. 2009) (internal quotations omitted).

III. SUMMARY OF ARGUMENT

1. In forty-five counterclaims, Pfizer seeks declaratory judgments of noninfringement, invalidity, or unenforceability of all of the patents-in-suit. 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). Pfizer failed to comply with the section 262(*l*)(2)(A) exchange, and consequently is barred from bringing any of its declaratory judgment counterclaims. All forty-five counterclaims should accordingly be dismissed.[2]

2. Even if these claims were permissible, Pfizer's validity challenges are facially deficient. In twenty-three of Pfizer's counterclaims, Pfizer purports to challenge validity and unenforceability on grounds broader than what was disclosed during its pre-litigation exchanges during the "patent dance," which the BPCIA does not permit. For these reasons, Pfizer's invalidity and inequitable conduct counterclaims should be stricken or dismissed with prejudice. Pfizer's Third and Fourth Affirmative Defenses suffer from the same defect and likewise must be stricken.

3. Pfizer's Counterclaim 8 is also facially deficient and should be dismissed. That counterclaim asserts that Genentech committed inequitable conduct during prosecution of one of the patents-in-suit by allegedly misrepresenting the content of the prior art. Pfizer's Counterclaim is deficient because Pfizer fails to allege that Genentech made any misstatements to the Patent Office. Further, Pfizer fails to adequately plead either deceptive intent or but-for materiality of the references. For these reasons, Pfizer's Counterclaim 8 should be dismissed with prejudice. Pfizer's Fourth Affirmative Defense suffers from the same defects as the inequitable conduct counterclaim, and accordingly, must be stricken-in-part.[3]

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[2] Plaintiffs filed a motion in this Court to dismiss Amgen's counterclaims on similar grounds in *Genentech, Inc. and City of Hope v. Amgen Inc.*, Case No. 17-1471, D.I. 107 (D. Del.). That motion is currently pending.

[3] Plaintiffs moved this court to dismiss similar counter-claims and affirmative defenses in two cases against Amgen, and those motions are currently pending. *See Genentech, Inc. and City of Hope v. Amgen Inc.*, Case No. 17-1471, D.I. 107 (D. Del.); *Genentech, Inc. and City of Hope v. Amgen Inc.*, Case No. 18-924, D.I. 86 (D. Del.).

IV. BACKGROUND

A. Pfizer Seeks to Market a Biosimilar Version of Avastin®.

This patent dispute arises from Pfizer's plans to market a biosimilar version of Avastin®, a drug Genentech developed for the treatment of various cancers. Avastin® is a genetically engineered antibody covered by a multitude of patents that are either owned by or exclusively licensed to Plaintiffs.

Pfizer submitted an aBLA seeking FDA approval to market PF-06439535, a biosimilar version of Avastin®. *See* D.I. 14 Counterclaim ¶ 30. Through a series of exchanges under the BPCIA, known informally as the "patent dance," the parties are encouraged to narrow disputes over infringement, in part by ensuring the "reference product sponsor" (here, Genentech) has received enough information to be able to narrow the patents to be asserted before filing suit. *See Sandoz, Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670–71 (2017).

As part of the patent dance, the biosimilar applicant is required to produce to the reference product sponsor both "a copy of the application submitted . . . *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) (emphasis added); D.I. 14 Counterclaim ¶ 19. The patent dance also requires the biosimilar applicant to provide the reference product sponsor "a detailed statement that describes" why the applicant believes any relevant patent held by the sponsor will not be infringed or is invalid or unenforceable. 42 U.S.C. § 262(*l*)(3)(B); D.I. 14 Counterclaim ¶ 22. The reference product sponsor then must respond to the biosimilar applicant's detailed statement. 42 U.S.C. § 262(*l*)(3)(C); D.I. 14 Counterclaim ¶ 23. The reference product sponsor may drop patents from its responsive statement based on what the biosimilar applicant says in its own detailed statement. Failure by either the biosimilar applicant or the reference

product sponsor at any step of the patent dance carries consequences in that party's ability to bring suit or obtain certain remedies. *See* 42 U.S.C. § 262(*l*)(9); 35 U.S.C. § 271(e)(6).

B. Pfizer Failed to Comply with the Required Exchanges Under the BPCIA.

Fully aware of its production obligations under the BPCIA, Pfizer nevertheless failed to produce its entire aBLA or all "other information that describes the process or processes used to manufacture the biological product that is the subject of such application," as required by 42 U.S.C. § 262(*l*)(2)(A). Although Pfizer disputes the relevance of its entire aBLA, it is undisputed that that portions of Pfizer's aBLA were not produced. Despite Pfizer's apparent allegation that it fully complied with section 262(*l*)(2)(A), *see* D.I. 14 Counterclaim ¶ 32, when read in light of Pfizer's entire Answer, Affirmative Defenses, and Counterclaims, it is clear that Pfizer has not produced its entire aBLA.[4] This by itself constitutes a failure to comply with the requirement that the biosimilar applicant "*shall* provide to the reference product sponsor a copy *of the application* submitted . . . under subsection (k)." 42 U.S.C. § 262(*l*)(2)(A) (emphases added).

Despite Pfizer's non-compliance, the parties continued with the rest of the patent dance. Genentech timely provided its list of patents pursuant to section 262(*l*)(3)(A). *See* D.I. 14 Counterclaim ¶ 33.[5] Pfizer then provided non-infringement and invalidity/unenforceability contentions for some, but not all patents pursuant to section 262(*l*)(3)(B), *see id.* ¶ 34. Notably, Pfizer did not provide any such contentions for six of the patents Genentech listed on its list pursuant to section 262(*l*)(3)(A). On January 18, 2019, Pfizer provided notice of its intent to

[4] Pfizer in its Counterclaims "repeats and incorporates by reference each of the foregoing Paragraphs of Pfizer's Answer and Affirmative Defenses to the Complaint." D.I. 14 Counterclaim ¶ 2. As such, even though Pfizer has alleged that "in full compliance with 42 U.S.C. § 262(*l*)(2)(A), Pfizer provided Genentech with Pfizer's BLA," *see id.* ¶ 32, its contrary allegation in the same pleading is properly considered by the Court in dismissing these claims.

[5] HLR owns four of the patents-in-suit, and Genentech is the exclusive licensee of those patents.

commence commercial marketing within 180 days pursuant to section 262(*l*)(8)(A). *Id.* ¶ 35. Genentech responded by serving Pfizer with infringement and validity contentions as required by section 262(*l*)(3)(C)—dropping certain patents in the process and narrowing the dispute as the statute contemplates. *See id.* ¶ 36, Answer ¶¶ 12, 14. After Pfizer informed Genentech that negotiations over the patents had concluded, *see id.* Counterclaim ¶ 37, Plaintiffs brought this suit.

V. ARGUMENT

A. Pfizer's Declaratory Judgment Claims Are Barred Under the BPCIA.

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

The BPCIA, as explained above, 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. 42 U.S.C. § 262(*l*)(2)(A). To encourage compliance, the statute provides carrots and sticks. For example, applicants who timely produce their aBLA and required "other information" on the prescribed schedule, and further comply with the statute's remaining requirements, are rewarded with substantial control 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) (emphases added).

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*, No. 14 Civ. 2256, 2014 WL 6765996, at *5 (S.D.N.Y. Dec. 1, 2014) (dismissing declaratory judgment action). The Supreme Court similarly has explained that

> [u]nder § 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, 137 S. Ct. at 1666. Every court to consider this question has answered the same way.

It is undisputed that Pfizer failed to provide its entire aBLA to Genentech and for that reason alone it is in violation of section 262(*l*)(9)(C) and precluded from bringing an action for declaratory judgment. Additionally, Pfizer's refusal to provide "information required under paragraph (2)(A)" other than the application (which it failed to provide) constitutes an *additional* basis to find it has not complied with the statute.

This failure precludes Pfizer from asserting counterclaims in this matter. A counterclaim is indisputably an "action," and filing counterclaims constitutes "bring[ing] an action," as used in 42 U.S.C. § 262(*l*)(9)(C). As courts have recognized, seeking to assert counterclaims against a plaintiff "constitutes the initiation of a civil proceeding." *Krisa v. Equitable Life Assur. Soc.*, 109 F. Supp. 2d 316, 322 (M.D. Pa. 2000). Such an interpretation is also consistent with the legislative purpose behind the BPCIA's stick-and-carrot scheme of the patent dance; the BPCIA seeks to prohibit non-compliant subsection (k) applicants, such as Pfizer, from bringing protective

complaints or being able to keep a patent in litigation due to the filing of its own declaratory judgment counterclaim.[6]

Additionally, Pfizer's counterclaims constitute "bring[ing] an action" because Pfizer brought certain counterclaims against HLR. Indeed, Pfizer was required to formally serve HLR with a Summons and its Answer, Affirmative Defenses, and Counterclaims, and did so. *See* D.I. 18. Accordingly, all of Pfizer's counterclaims should be dismissed based on Pfizer's undisputed failure to provide information to Genentech under the BPCIA. As HLR has only been haled into court as a counterclaim defendant, HLR should correspondingly be dismissed as a party.[7]

B. Pfizer's Invalidity and Unenforceability Claims Exceed the Permissible Scope Under the BPCIA.

The Counterclaims challenging the validity of all the patents-in-suit, and the unenforceability of U.S. Patent No. 6,407,213 ("Carter/Presta") (Counterclaim 8) should be dismissed under Rule 12(b)(6), and Pfizer's corresponding Third and Fourth Affirmative Defenses stricken under Rule 12(f), for an additional reason—those allegations exceed the permissible scope under the BPCIA.

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[6] For at least this reason, the court's analysis in *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741, 2015 WL 1264756, at *9 (N.D. Cal. Mar. 19, 2015) (portion regarding non-infringement and invalidity counterclaims not appealed), disagreeing in two paragraphs with the argument being put forth in this motion is not persuasive. Similarly, the court's analysis on the meaning of "bring an action" in the context of another statute in *Jonathan H. v. Souderton Area Sch. Dist.*, 562 F.3d 527, 529 (3d Cir. 2009), is not dispositive. As the court in *Jonathan H.* acknowledged, "The meaning of statutory language, plaint or not, depends on context." *Id.* at 529 (citation omitted). Whereas the statutory provision at issue in *Jonathan H.* dealt with the time in which an aggrieved party could effectively appeal an administrative decision, the BPCIA—and section (*l*)(9)(C) in particular—are concerned with creating an efficient pathway for approval of biosimilar products and encouraging compliance with the elaborate statutory scheme.

[7] At a minimum, Counterclaims 18–19, 26–27, 30–31, and 42–43 should be dismissed as against HLR due to Pfizer's non-compliance with the BPCIA, and HLR dismissed as a party.

As part of the patent dance, as discussed above, the parties are required to exchange contentions on the merits of the infringement, validity and enforceability of the asserted claims. Pfizer's Counterclaims and Affirmative Defenses treat the exchanges under the BPCIA as having no force or effect, leaving Pfizer free to assert validity and enforceability positions it did not disclose as part of the statutory exchanges. *See, e.g.*, D.I. 14 Third Defense ("All claims of the asserted patent [sic] are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 *et seq.*, including *without limitation* §§ 101, 102, 103, 112 and/or any judicially-created doctrine of invalidity include obviousness-type double patenting.") (emphasis added); *id.* Counterclaim ¶ 62 ("The claims are invalid for failure to satisfy *one or more* provisions of Title 35 of the United States Code, including *but not limited to* 35 U.S.C. §§ 102, 103, and/or 112, and/or under the doctrine of obviousness-type double patenting.") (emphasis added); *see also* D.I. 14 Counterclaim ¶¶ 119–36 and Fourth Defense ("All claims of one or more of the asserted patents are unenforceable at least due to inequitable conduct and/or prosecution laches.") The statute does not permit this. Pfizer already provided its bases for contesting the validity of the patents-in-suit in its detailed statement pursuant to section 262(*l*)(3)(B), and in fact failed to provide any such bases for five of the patents-in-suit. [redacted] It cannot now exceed those positions in its counterclaims and affirmative defenses before this Court.

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 in March, 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 litigations manageable—they determine which patents will be litigated, when they will be litigated, and how the litigation will unfold. 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 42 U.S.C. § 262(*l*)(5)(B)(ii)); *see also* 42 U.S.C. § 262(*l*)(9)(B). If the applicant identifies compelling invalidity or non-infringement positions, the sponsor may drop certain patents from the "patent dance." Indeed, that narrowing occurred here as based on the arguments and representations in Pfizer's section (*l*)(3)(B)(ii)(I) contentions, Genentech declined to serve responsive contentions for certain patents, removing them from the scope of this dispute. 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 section 262(*l*)(6) and leaving other patents to be addressed after the applicant provides notice under section 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 Pfizer's Counterclaims and Affirmative Defenses contemplate. Were applicants like Pfizer allowed to provide new invalidity or unenforceability contentions after completion of the "patent dance," they easily could avoid the obligation to provide meaningful section 262(*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 Pfizer's counterclaims—"The claims are invalid for failure to satisfy one or more provisions of Title 35 of the United States

Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112, and/or under the doctrine of obviousness-type double patenting." *E.g.*, D.I. 14 Counterclaim ¶ 62; *see also id.* ¶¶ 119–36. The applicant could leave the reference product sponsor in the dark about its true invalidity positions, or whether it would allege unenforceability, 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). Indeed, Pfizer took precisely this approach here. [redacted]

Furthermore, an applicant could even refrain from providing contentions during the patent dance at all. That is precisely what Pfizer did as to the five patents for which Pfizer represented under 42 U.S.C. § 262(*l*)(3)(B)(ii)(II) that "it did not begin commercial marketing of the drug product described in Pfizer's BLA prior to the expiration" of the patents, and now admits that "it manufactured some aBLA product before the expiry" of the patents.[8] *See, e.g.*, D.I. 14 Answer ¶ 39. Yet after having failed to challenge the validity of these five patents during the "patent dance," Pfizer now claims the right to sandbag Plaintiffs with previously undisclosed grounds for invalidity. *See, e.g.*, D.I. 14 Counterclaim ¶ 62. Absent a requirement to disclose their invalidity and unenforceability positions fully during the exchanges, applicants could game the system and severely disadvantage innovator companies who narrowed their infringement cases and selected patents in reliance on the basis of incomplete assertions. Congress did not intend this.

[redacted]

In short, the contentions serve to focus the parties' negotiations; provide the basis for the parties to select which patents to litigate; ensure the orderly resolution of the narrowed disputes; and provide the parties and the court with an approximate timetable in which to conduct the litigation and obtain rulings before the biosimilar applicant changes the market irreversibly by commercializing its product. By stark contrast, under Pfizer's apparent interpretation in broadly pleading its Counterclaims and Affirmative Defenses, the contentions serve no limiting purpose. They cannot meaningfully "resolve patent disputes," *Amgen*, 794 F.3d at 1352, because the true scope of those disputes will not be clear until well after litigation has begun. This is an "absurd result" that the Court should reject. *See, e.g.*, *Lawson v. Suwannee Fruit & S.S. Co.*, 336 U.S. 198, 201 (1949) (rejecting interpretation that would "destroy one of the major purposes" of statute).

This Court should hold Pfizer to its previously served contentions and dismiss Pfizer's invalidity and unenforceability allegations under Rule 12(b)(6), and strike its corresponding Third and Fourth Affirmative Defenses under Rule 12(f).

C. Pfizer Fails to Adequately Plead Inequitable Conduct.

Counterclaim 8 seeks a declaration that one of the asserted patents, Carter/Presta, is unenforceable for inequitable conduct. *See* D.I. 14 Counterclaim ¶¶ 119–36; *see also id.* at Fourth Affirmative Defense (alleging-in-part that all of the asserted patents are unenforceable for inequitable conduct). Carter/Presta is a "composition of matter" patent that claims antibodies including bevacizumab, the active ingredient in Avastin® and the molecule Pfizer has copied. Any manufacture or use of bevacizumab in the United States prior to Carter/Presta's expiry would be infringing. Pfizer alleges in its counterclaims (but not in its section (*l*)(3)(B) contentions) that during prosecution, Genentech misrepresented the teachings of a prior art reference it had disclosed to the Examiner, U.S. Patent No. 5,530,101 (the "'101 Patent"). D.I. 14 Counterclaim ¶¶ 131–33. Although Pfizer claims these statements were "material to patentability" and that

Genentech made the alleged misrepresentations "with the specific intent to mislead or deceive the Patent Office," *id.* ¶ 120, it does not provide any substantive allegations in support.

Pfizer's allegations fail in multiple ways. *First*, Pfizer pleads a claim based on attorney argument, which cannot form the basis of an inequitable conduct claim. *Second*, even if attorney argument could be the basis for a claim, Pfizer does not plead that Genentech actually made a misstatement to the Examiner in response to her rejection. *Third*, even if the attorney argument were actionable misrepresentation, Pfizer has failed to adequately plead deceptive intent and but-for materiality—two required elements of a claim for inequitable conduct. Any of these provides a basis for the Court to dismiss Counterclaim 8 and partially strike Pfizer's Fourth Affirmative Defense.[9]

1. Attorney Argument Is Not Actionable Misconduct.

Pfizer does not allege that Genentech deliberately concealed any reference in its possession from the Patent Office. On the contrary, Pfizer acknowledges that the Patent Office possessed and explicitly considered the identified reference—the '101 Patent, D.I. 14 Counterclaim ¶ 121—the Examiner having cited the '101 Patent as the basis for rejections during prosecution, *id.* ¶¶ 125, 128. Rather, Pfizer's theory challenges Genentech's *arguments* about what that reference teaches. *Id.* ¶¶ 121, 133.

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.

[9] Pfizer's Fourth Affirmative Defense asserts both "inequitable conduct and/or prosecution laches." D.I. 14 at Fourth Defense. This motion does not address prosecution laches, and as such there is no request to strike that portion of the defense.

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. U.S. Int'l Trade Comm'n.*, 808 F.2d 1471, 1482 (Fed. Cir. 1986) ("The 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*, 512 F.3d 1363 (Fed. Cir. 2008), 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. *Id.* at 1379.

Trial courts including in this District 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) (citing, *inter alia*, MPEP § 716.01(c) ("The arguments of counsel cannot take the place of evidence in the record.")); *see also Bayer Schering Pharma AG v. Barr Labs., Inc.*, Civ. No. 05-2308, 2008 WL 628592, at *49 n.44 (D.N.J. Mar. 3, 2008) ("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.") (internal quotation marks omitted); *Sepracor Inc. v. Teva Pharm. USA, Inc.*, Civ. No. 09-1302, 2010 WL 2326262, at *6 (D.N.J. June 7, 2010) (dismissing an inequitable conduct claim where study results were in front of the examiner, such that "any mischaracterization of the data would not rise to the level of inequitable conduct").

Pfizer's allegation of inequitable conduct should be dismissed for the same reason. Pfizer accuses Genentech of mischaracterizing the antibody numbering methodology for a particular antibody in the '101 Patent and submitting an allegedly misleading comparison of the '101 Patent to the claimed sequences. D.I. 14 Counterclaim ¶¶ 121, 133. In all of these instances, the art was disclosed to and considered at length by the Examiner, who was free to reach her own contrary conclusion.

This case is thus unlike cases that involve misrepresentations or omissions uniquely within the knowledge of the prosecuting attorney, and that the examiner is not able to evaluate on her own. *See, e.g.*, *Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *12 (D. Del. Feb. 3, 2012). Here, the alleged misrepresentations or omissions concerned disclosures on the face of the references that the Examiner was capable of evaluating on her own. Nor are the allegations in this case analogous to cases like *Ring Plus, Inc. v. Cingular Wireless Corp.*, 614 F.3d 1354, 1359–61 (Fed. Cir. 2010), where the patent specification itself contained false statements concerning the disclosure of the prior art and the patent examiner made no independent evaluation of those references during prosecution. *See WesternGeco L.L.C. v. ION Geophysical Corp.*, No. 09-cv-1827, 2012 WL 567430, at *19 & n.10 (S.D. Tex. Feb. 21, 2012) (distinguishing *Ring Plus* from "situations such as this, where the prior art being interpreted by the prosecuting attorney has been provided to the Examiner in full, the attorney's characterizations of

the prior art can be considered only attorney argument, and therefore cannot give rise to a cause of action of inequitable conduct"). Accordingly, Pfizer's allegations in this case are insufficient as a matter of law to support a claim of inequitable conduct, and the Court therefore should dismiss Counterclaim 8 and strike Pfizer's inequitable conduct affirmative defense. *See Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307–08 (D. Del. 2013) (granting motion to dismiss unenforceability counterclaim and corresponding affirmative defense, where the only allegation of misrepresentation could not, on its face, constitute a basis for inequitable conduct).

2. Pfizer Fails to Plead Any Misrepresentation.

Even if the attorney argument could be considered the basis for an inequitable conduct claim, Pfizer fails to adequately plead that Genentech made any misrepresentation to the Examiner. "The court is not obligated to accept as true 'bald assertions,' 'unsupported conclusions and unwarranted inferences,' or allegations that are 'self-evidently false' at the motion to dismiss stage. *Senju*, 921 F. Supp. 2d at 304 (quoting *Rader v. ShareBuilder Corp.*, 772 F. Supp. 2d 599, 603 (D. Del. 2011)).[10]

The Examiner rejected certain of the proposed claims of Carter/Presta in view of the '101 Patent because she believed that a humanized antibody disclosed in the '101 Patent, called "anti-Tac," contained amino acid substitutions at a certain position that Genentech had claimed. *See* D.I. 14 Counterclaim ¶ 128; Ex. A (Oct. 25, 2000 Non-Final Rejection) at 7 ("PN=5,530,101, teach [sic] humanized anti-Tac antibody, wherein amino acid 93 is substituted in heavy chain . . .

[10] Because Pfizer has quoted directly from the prosecution history and its claim of inequitable conduct is based on statements in the prosecution history, consideration of the prosecution history does not convert this motion into one for summary judgment. *See Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014); *ING Bank, fsb v. PNC Fin. Servs. Grp., Inc.*, 629 F. Supp. 2d 351, 354 (D. Del. 2009); *see also* Fed. R. Civ. P. 10(c).

(column 45).") The '101 Patent discloses a number of different antibodies, and uses two different numbering schemes in referring to the amino acids contain in the antibodies—some are identified using sequential numbering, and some are identified using what is known as Kabat numbering.[11] *See* D.I. 14 Counterclaim ¶ 132 (identifying Kabat and sequential numbering in the '101 Patent).

The anti-Tac antibody in the '101 Patent on which the Examiner based her rejection was numbered using sequential numbering, whereas Genentech had used Kabat numbering to identify the substitutions in its proposed claimed antibody. Genentech in its response pointed out this difference in numbering schemes to the Examiner. D.I. 14 Counterclaim ¶ 129 (quoting Ex. B (Apr. 25, 2001 Amend.) at 7). Genentech further explained that, as a result of those different numbering conventions, the specific amino acid substitution at the 93H position that the Examiner believed that the anti-Tac antibody possessed did not actually correspond with what was covered by Genentech's proposed claims. *Id.* Genentech also provided to the Examiner charts and sequence alignments which identified the sequential numbering and Kabat numbering for many of the amino acid substitutions in the antibodies disclosed in the '101 Patent. *Id.* ¶ 126; Ex. C (Oct. 6, 1997 Suppl. Amend.) at 6–10. The Examiner subsequently allowed Genentech's proposed claims to issue over the '101 Patent. D.I. 14 Counterclaim ¶ 130.

Even accepting Pfizer's facts as true for the purposes of this motion, Pfizer has not pleaded facts showing any ***actual*** misrepresentation or omission by Genentech. Pfizer never alleges that

[11] There are different ways to identify the amino acid positions in an antibody sequence. "Sequential numbering" involves consecutively numbering the amino acids in the sequence; due to sequence variations across antibodies, the amino acid positions identified by sequential numbering may be different from one antibody to another. As Carter/Presta explains, "Kabat numbering" (named for the scientist who devised this numbering convention) is a standardized approach to antibody sequence numbering that assigns fixed numbers to certain positions in the antibody amino acid sequence as determined by amino acid sequence alignments. D.I. 1-1, Ex. D, '213 Patent, 10:46–11:16. A sequence alignment compares the amino acid sequences of multiple antibodies by matching the overlapping portions of the sequences. *See, e.g.*, *id.* at 10:58–11:16.

Genentech misrepresented that the '101 Patent used a sequential numbering convention when referring to a substitution at position 93H in the humanized anti-Tac antibody (it does). And in any event, even if one were to apply Kabat numbering to the humanized anti-Tac antibody in the '101 Patent addressed by Genentech, Pfizer never alleges that it actually has a substitution at 93H under Kabat numbering (it does not). Instead, Pfizer points to ***different*** portions of the '101 Patent that utilized Kabat numbering when describing ***different*** humanized antibodies (not the humanized anti-Tac antibody that Genentech was addressing in its comments to the Examiner) to assert that Genentech misrepresented the contents of the '101 Patent. *See id.* ¶ 131–33 (referring to Table 5 and Figures 2B, 6B, 30A, and 40B in the '101 Patent that describe various humanized and murine antibodies, none of which is humanized anti-Tac). Those factual allegations do not add up to a misrepresentation by Genentech; the statements that are the basis for Pfizer's inequitable conduct defense were addressing a different issue for different antibodies.

Because Pfizer's non-conclusory allegations, taken as true, fail to allege that Genentech made a misrepresentation or omission to the Patent Office, Counterclaim 8 must be dismissed and the Fourth Affirmative Defense partially stricken.

3. Pfizer Fails to Plead All the Necessary Elements of Inequitable Conduct.

Pfizer's allegations of inequitable conduct also fail because Pfizer fails to plead deceptive intent or but-for materiality of the statements.

a) Pfizer has not pleaded facts sufficient to show a specific intent to deceive.

To prove inequitable conduct, Pfizer must demonstrate a "specific intent to deceive the PTO," and intent may not be inferred "solely from materiality." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). As the court held in *Cellectis*, however, even where the allegation is that the applicants "expressly contradicted the teachings" of

a prior art reference, that does not "substitute for independent evidence of intent to deceive . . . where the prior art at issue was a focus of the examination." 883 F. Supp. 2d at 535. Pfizer alleges just that—that the Court should infer deceptive intent based on the existence of purported "misrepresentations". *See* D.I. 14 Counterclaim ¶ 133. Pfizer has alleged no other evidence of a specific intent to deceive; indeed, it cannot, as Genentech's statements were not erroneous as explained above. For this reason alone, Pfizer's inequitable conduct allegation should fail, Counterclaim 8 should be dismissed, and Pfizer's Fourth Affirmative Defense correspondingly partially struck.

b) Pfizer has not pleaded facts sufficient to show the alleged mischaracterization was "but-for" material.

In addition to deceptive intent, Pfizer is required to adequately plead "but-for materiality" in order to establish inequitable conduct. *Therasense*, 649 F.3d at 1291. Pfizer's counterclaim fails to do so. Allegations that an applicant mischaracterized a reference that is before the examiner fail to demonstrate but-for materiality. *See SunPower Corp. v. PaneClaw, Inc.*, C.A. No. 12-1633-MPT, 2016 WL 5107029, at *10 (D. Del. Sept. 19, 2016). And as explained above, Pfizer relies solely on allegations of mischaracterization (which are inaccurate) to allege inequitable conduct.

Even if allegations of mischaracterization could feasibly provide the necessary but-for materiality, the only allegation Pfizer offers in support of materiality—that the Examiner would not have withdrawn her rejection absent Genentech's alleged mischaracterization, *see* D.I. 14 Counterclaim ¶ 134—is inadequate. As Pfizer concedes, the alleged misrepresentation on April 25, 2001 cites back to similar earlier arguments Genentech provided to the Examiner on October 7, 1997. *See id.* ¶ 129. By Pfizer's own concession, Genentech's arguments were specifically rejected at least once, as there was a Non-Final Rejection in October 25, 2000, *after* these arguments were submitted to the Examiner. *Id.* ¶ 128. And a full examination of the file history

available on Public PAIR (https://portal.uspto.gov/pair/PublicPair) reveals that there was an additional rejection on December 23, 1997 after Genentech first made its argument to the Examiner about the numbering of amino acids in the anti-Tac antibody in question in the '101 Patent.[12] Where the PTO has considered and rejected an argument, the argument cannot be but-for material, and thus cannot support a claim for inequitable conduct. *See Courtesy Prods. LLC v. Hamilton Beach Brands Inc.*, C.A. No. 13-2012-SLR-SRF, 2015 WL 6159113, at *6 (D. Del. Oct. 20, 2015) (citing *Unverferth Mfg. Co., Inc. v. Par-Kan Co.*, No. 3:13-cv-97-TLS, 2014 WL 2206922, at *4–5 (N.D. Ind. May 27, 2014)). In light of the PTO's initial rejection of the claims after Genentech first submitted the alleged mischaracterization, the argument cannot provide the but-for materiality Pfizer needed to plead. Accordingly, Counterclaim 8 should be dismissed, and Pfizer's Fourth Affirmative Defense correspondingly partially struck.

VI. CONCLUSION

Plaintiffs and Counterclaim Defendants respectfully request that the Court dismiss each of Pfizer's Counterclaims, fully strike Pfizer's Third Affirmative Defense, partially strike Pfizer's Fourth Affirmative Defense, and dismiss HLR as a party to this case.

[12] Moreover, in its section (*l*)(3)(B) contentions, Pfizer did not assert that the '101 Patent either anticipates Carter/Presta or, in combination with other art, renders obvious the claims of Carter/Presta.

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on May 20, 2019 on the following counsel in the manner indicated:

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