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. 1:19-cv-00638-CFC
PFIZER INC., Counterclaim Plaintiff, v. HOFFMANN-LA ROCHE, INC., Counterclaim Defendant.	)	

DEFENDANT'S OPPOSITION TO PLAINTIFFS AND COUNTERCLAIM DEFENDANTS' MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS AND TO STRIKE CERTAIN AFFIRMATIVE DEFENSES

HEYMAN ENERIO
GATTUSO & HIRZEL LLP
Dominick T. Gattuso (No. 3630)
300 Delaware Ave., Suite 200
Wilmington, DE 19801
(308) 472-7300
dgattuso@hegh.law

OF COUNSEL:

WILLKIE FARR & GALLAGHER
LLP
Thomas J. Meloro
Michael W. Johnson
Dan Constantinescu
787 Seventh Avenue
New York, NY 10019
(212) 728-8000

Attorneys for Defendant and Counterclaim Plaintiff Pfizer Inc.

Dated: June 3, 2019

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes

PRELIMINARY STATEMENT

After completing the information exchange and negotiation provisions ("Patent Dance") of the Biologics Price Competition and Innovation Act ("BPCIA") as outlined in 42 U.S.C. § 262(*l*),[1] Genentech, Inc. ("Genentech") and City of Hope (collectively, "Plaintiffs") brought suit against Pfizer Inc. ("Pfizer") alleging infringement of 22 patents. D.I. 1. In response, Pfizer served its Answer, Affirmative Defenses, and Counterclaims. D.I. 14. Because four of the asserted patents are owned by Hoffmann-La Roche, Inc. ("HLR"), Pfizer's Counterclaims concerning those four patents were directed against Genentech and HLR.

Now, Plaintiffs move to dismiss Pfizer's counterclaims and certain affirmative defenses based largely on unsupportable interpretations of the BPCIA.[2] The Patent Dance as provided in 42 U.S.C. § 262(*l*) is designed to encourage the exchange of information between the subsection (k) applicant and the reference product sponsor. If the subsection (k) applicant chooses to participate in the Patent Dance, it gains the ability to exert substantial control over the scope and the timing of the resulting litigation. If, however, the subsection (k) applicant chooses not to participate in the Patent Dance or fails to make the required disclosures, the statute provides a clear and specific remedy—the reference product sponsor, but not the

[1] "§ 262" refers to 42 U.S.C. § 262 unless stated otherwise.
[2] Identical statutory interpretation questions are also pending in *Genentech, Inc. v. Amgen Inc.*, No. 18-00924-CFC; No. 17-1407-CFC; and No. 17-1471-CFC.

subsection (k) applicant, can bring a declaratory judgment action. This is the only prescribed penalty should the subsection (k) applicant choose to forego the Patent Dance or fail to make any of the required disclosures.

Plaintiffs now seek a draconian remedy, apparently irrespective of whether the subsection (k) applicant has complied with the Patent Dance provisions or not, that would tie the hands of a subsection (k) applicant in the resulting patent litigation. However, neither the statutory text nor the congressional intent behind the carefully balanced statutory scheme support Plaintiffs' extreme position.

Plaintiffs' other challenges to Pfizer's affirmative defenses and counterclaims raise factual issues that cannot be properly resolved on a motion to dismiss. Plaintiffs' motion should be denied in its entirety.

I. SUMMARY OF THE ARGUMENT

1. The Court should deny Plaintiffs' request for dismissal of Pfizer's counterclaims because Pfizer complied with § 262(*l*)(2)(A) and § 262(*l*)(9)(C) does not preclude Pfizer's counterclaims. First, the record on this motion does not establish Plaintiffs' allegation that Pfizer failed to comply with § 262(*l*)(2)(A). At most, Plaintiffs raise a factual issue that cannot be resolved on a motion to dismiss. Second, even if Pfizer had failed to comply with § 262(*l*)(2)(A), Plaintiffs' only recourse under the BPCIA was to bring an action seeking declaratory judgment of infringement, validity, and enforceability, which they have done. The remedy of

precluding counterclaims in defense of the action brought by Plaintiffs is inconsistent with the language and the purpose behind the BPCIA.

2. The Court should deny Plaintiffs' request for dismissal of Pfizer's counterclaims and certain affirmative defenses because the BPCIA does not limit Pfizer to only the legal theories in its detailed statement pursuant to § 262(*l*)(3)(B) ("3(B) Statement"). Plaintiffs point to no statutory text or legislative history to support such an extreme measure and only proffer a policy argument. Because the statutory text is plain and unambiguous on this issue, the Court should apply the statute according to its terms. Not only did Congress not intend to regulate a subsection (k) applicant's rights during litigation in such a manner, Plaintiffs' position defies common sense and fairness and cannot be squared with the careful balance of the parties' interests that Congress designed.

3. The Court should also deny Plaintiffs' request for dismissal of Pfizer's inequitable conduct argument regarding U.S. Patent No. 6,407,213 because Pfizer has adequately pled the claim based on Genentech's demonstrably false statements to the U.S. Patent and Trademark Office ("PTO") that the prior art '101 patent does not use the Kabat numbering system. The pleadings show that these statements were affirmative, material misrepresentations of facts and the law does not allow Genentech to avoid the consequences of its statement merely because the prior art was before the Examiner. The pleadings support a reasonable inference

that Genentech had specific intent to deceive the PTO based on use of repeated misrepresentations to mislead the Examiner into allowing a claim with a substitution at position 93H. Finally, the pleadings establish that the patent would not have issued without the misrepresentations because Genentech provided no other arguments to overcome the '101 patent rejection.

II. LEGAL STANDARDS

"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). Dismissal under Rule 12(b)(6) is improper where there is a factual question material to the dispute. *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."); *see also IBM v. Priceline Grp., Inc.*, No. 15-cv-00137, 2017 WL 1349175, at *14 (D. Del. Apr. 10, 2017) ("*factual disagreement* . . . does not support dismissal of Defendants' counterclaim at the pleading stage") (emphasis in original); *Cornell University v. Illumina, Inc.*, C.A. No. 10-433-LPS-MPT, 2016 WL 3046258, at *9 (D. Del. May 27, 2016) ("At the pleadings stage,

plaintiffs' evidence is irrelevant and the court can not address the merits of that evidence"); *Pac. Biosciences of Cal, Inc. v. Oxford Nanopore Techs., Inc.*, C.A. No. 17-1353, 2018 WL 1419082, at *8 n.3 (D. Del. Mar. 22, 2018) (denying motion to dismiss, inter alia, because of unresolved factual disputes raised by the parties' briefing).

"[A]n affirmative defense generally need not be articulated with any rigorous degree of specificity, and is sufficiently raised for purposes of Rule 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. Inc. 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"). Affirmative defenses are not subject to the *Iqbal*/*Twombly* pleading standard and "need not be plausible to survive." *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 303 (D. Del. 2013); *see, also*, *Internet Media Corp. v. Hearst Newspapers, LLC*, No. 10-cv-00690, 2012 WL 3867165, at *3 (D. Del. Sep. 6, 2012).

III. PFIZER'S COUNTERCLAIMS ARE NOT BARRED UNDER THE BPCIA.

Plaintiffs' request for relief should be denied because it is based on the incorrect premise that Pfizer violated § 262(*l*)(2)(A**)** and, separately, because it is based on an incorrect interpretation of § 262(*l*)(9)(C) that is inconsistent with the plain language, and Plaintiffs point to no support in the legislative history to

suggest a departure from the plain language.

A. Pfizer Has Not Violated 42 U.S.C. § 262(*l*)(2)(A)

Plaintiffs' request to dismiss Pfizer's counterclaims is based on the incorrect premise that Pfizer failed to comply with the requirements of § 262(*l*)(2)(A). Specifically, Plaintiffs assert that Pfizer "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)." D.I. 20 at 5. Plaintiffs fail to cite to any pleadings that establish noncompliance with § 262(*l*)(2)(A) and, in fact, Plaintiffs admit that Pfizer pled that it fully complied with § 262(*l*)(2)(A). *Id*. Indeed, the facts pled in Pfizer's Counterclaims show that Pfizer complied with § 262(*l*)(2)(A). For example, Pfizer's Counterclaims plead:

> On September 14, 2018, within 20 days of the FDA's notice and in full compliance with 42 U.S.C. § 262(*l*)(2)(A), Pfizer provided Genentech with Pfizer's BLA, which included over 565,000 pages of information on Pfizer's Product and the processes used to manufacture it. The produced information completely 'describe[d] the process or processes used to manufacture the biological product that is the subject of such application' as contemplated by the BPCIA.

D.I. 14 at 52 ¶ 32; *see also* D.I. 14 at 4 ¶ 8. The pleadings, which must be accepted as true, do not establish Plaintiffs' allegation that Pfizer violated § 262(*l*)(2)(A).

Plaintiffs allege that "[i]t is undisputed that Pfizer failed to provide its entire

aBLA to Genentech." D.I. 20 at 7. But, as Pfizer's Counterclaims show, Pfizer disputes that its production of its application pursuant to § 262(*l*)(2)(A) was deficient in any way. D.I. 14 at 52 ¶ 32. At most, Plaintiffs' attorney argument raises a factual issue that cannot be resolved on a motion to dismiss. *Pac. Biosciences of Cal. Inc.*, 2018 WL 1419082, at *8 n.3. The Court should deny Plaintiffs' request for relief on this basis alone.

B. The BPCIA Does Not Bar a Subsection (k) Applicant from Filing Counterclaims for Declaratory Relief.

Even if Pfizer had violated § 262(*l*)(2)(A), Plaintiffs are not entitled to the relief they seek because § 262(*l*)(9)(C) does not preclude Pfizer from filing counterclaims for declaratory judgement in response to Plaintiffs' complaint. Plaintiffs argue that because Pfizer allegedly failed to comply with § 262(*l*)(2)(A), § 262(*l*)(9)(C) not only bars Pfizer from "bring[ing] an action" for declaratory judgment, but also bars Pfizer from filing counterclaims for declaratory judgment in response to the action brought by Plaintiffs.[3] Section 262(*l*)(9)(C) provides:

> 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.

[3] Plaintiffs do not and cannot base their request for relief on any other provision in the BPCIA or other federal statute. 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).

(emphasis added). The plain language of § 262(*l*)(9)(C) prohibits a subsection (k) applicant that has failed to comply with § 262(*l*)(2)(A) from "bring[ing] an action" under section 2201 of title 28, but says nothing about filing counterclaims for declaratory judgement after the subsection (k) applicant has been sued. Indeed, the language "bring an action" does not refer to filing counterclaims once a party has been sued. "The phrase 'bring an action' is defined as 'to sue; institute legal proceedings.'"[4] *Jonathan H. v. Souderton Area Sch. Dist.*, 562 F.3d 527, 529 (3d Cir. 2009) (quoting Black's Law Dictionary (8th ed. 2004)). In *Jonathan H.*, the court interpreted the language "shall have the right to *bring a civil action*" in a different federal statute to exclude the filing of counterclaims in response to a complaint. *Id*. The court explained, citing FED. R. CIV. P. 3 and Advisory Committee Notes, that "an action is 'brought' when plaintiff files a complaint, which is the first step that invokes the judicial process" and that "[u]nlike the proactive nature of a complaint, a counterclaim is reactive because it is filed only after the plaintiff has initiated the case by bringing a civil action." *Id*.

Plaintiffs' reliance on the court's statement in *Jonathan H.* that "[t]he meaning of statutory language, plain or not, depends on context" in order to argue

[4] The only other time that "bring an action" appears in § 262(*l*) is in the context of the reference product sponsor bringing an infringement action pursuant to § 262(*l*)(6). *See Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 501 (1998) ("similar language contained within the same section of a statute must be accorded a consistent meaning").

that *Jonathan H.* is not dispositive here, is misplaced. D.I. 20 at 8 n.6. The "context" that the court referred to is the impact of the term "bring" on the meaning "action," not the general subject matter of statutes.[5] *Jonathan H.*, 562 F.3d at 529. The Court acknowledged that "action" encompasses counterclaims, but concluded that the phrase "bring a civil action," does not. *Id*. at 529-530 (emphasis added). Plaintiffs provide no rationale for why the outcome should differ here. Indeed, the context here is the same as in *Jonathan H.* because § 262(*l*)(9)(C) recites "bring an action," not merely "action" in a vacuum.[6]

Thus, an action is "brought" pursuant to § 262(*l*)(9)(C) when the reference product sponsor sues seeking declaratory judgment. *See id.* ("A civil action is commenced by filing a complaint with the court." (citing Fed. R. Civ. P. 3)). Indeed, the only other court that has reached a determination on this specific issue rejected the exact argument that Plaintiffs proffer here. *Amgen Inc. v. Sandoz Inc.*,

[5] Genentech's argument that the BPCIA is "concerned with creating an efficient pathway for approval of biosimilar products . . .," whereas the statute in *Jonathan H.* "dealt with the time in which an aggrieved party could effectively appeal an administrative decision" does not support a different meaning for "bring an action" here.

[6] Genentech's reliance on *Krisa v. Equitable Life Assurance Society*, 109 F. Supp. 2d 316 (M.D. Pa. 2000) is, however, unpersuasive. D.I. 20 at 7. In *Krisa*, the court interpreted a state statute that does not include the language "bring an action." *Krisa*, 109 F. Supp 2d at 321. Indeed, Genentech's emphasis of the importance of "context" in statutory interpretation undercuts the relevance of *Krisa*.

Civ. No. 14-4741, 2015 WL 1264756, at *9 (N.D. Cal. Mar. 19, 2015) *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) ("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."). The *Sandoz* court also explained that Plaintiffs' reading of § 262(*l*)(9)(C) would result in the waiver of compulsory counterclaims and that "barring such claims in particular raises 'real due process concerns.'" *Id*. (citing *U.S. ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 505 F. Supp. 2d 20, 26 (D.D.C. 2007)). Plaintiffs assert that the reasoning in *Sandoz* is "unpersuasive," but do not explain why that is. D.I. 20 at 8 n.6.

In any case, the meaning of "bring an action" in § 262(*l*)(9)(C) is clear and unambiguous. *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)). Plaintiffs point to nothing in the legislative history of the BPCIA to support a departure from the plain and unambiguous language of § 262(*l*)(9)(C).

Plaintiffs' reliance on *Celltrion Healthcare Co. v. Kennedy Trust For Rheumatology Research*, Civ. No. 14-2256, 2014 WL 6765996 (S.D.N.Y. Dec. 1, 2014) and its assertion that "every court to consider this question has answered the same way" misses the mark completely. D.I. 20 at 7. The *Celltrion* decision and

other similar decisions dismissed an action for declaratory judgment brought by a non-compliant subsection (k) applicant who had filed a complaint. *See Celltrion*, 2014 WL 6765996, at *5. Thus, the decisions Plaintiffs reference simply confirm that a non-compliant subsection (k) applicant may not "bring an action" for declaratory judgement, but say nothing about the issue Plaintiffs raise here—whether a non-compliant subsection (k) applicant is also precluded from filing counterclaims after the reference product sponsor has brought an action. Further, Plaintiffs' quotation to the Supreme Court's *Sandoz* decision is inapposite for the same reason—the issue Plaintiffs raise here was not before the Court, and in any case, the Court's statement says nothing about the filing of counterclaims. *Sandoz Inc.*, 137 S. Ct. at 1666.

Indeed, the outcomes in *Sandoz* and *Celltrion* are completely consistent with the careful balancing of the parties' interests in the BPCIA framework. The BPCIA provides subsection (k) applicants, who choose to comply with § 262(*l*)(2)(A), with control over the timing of litigation and the number of patents that will be the subject of the litigation. Consequently, if the subsection (k) applicant fails to comply with § 262(*l*)(2)(A), then § 262(*l*)(9)(C) takes away that benefit by permitting only the reference product sponsor to immediately bring a suit seeking declaratory judgement for any patent that claims the biological product or a use of the biological product. Thus, control over the timing and scope of the

litigation is shifted to the reference product sponsor, who may choose to delay bringing an action and force the subsection (k) applicant to delay launch or launch at risk in the absence of any patent certainty—the relief for non-compliance is proportional to the benefit provided to the subsection (k) applicant. Precluding the subsection (k) applicant from pleading counterclaims in response to an action brought by the reference product sponsor would be disproportionate and upend the balance inherent in the BPCIA framework.

Plaintiffs' argument that Pfizer's counterclaims constitute "bring[ing] an action" because Pfizer brought certain counterclaims against HLR is also unconvincing. HLR owns some of the patents that Plaintiffs assert in this action. D.I. 14 at 48 ¶ 11. Pfizer's counterclaims against HLR are duplicative of the counterclaims against Genentech and were filed defensively in response to Genentech's allegations of infringement of the patents owned by HLR. Thus, Pfizer's counterclaims against HLR arise from the same case or controversy in regards to which Plaintiffs brought this action. Plaintiffs provide no rationale for why Pfizer's counterclaims against HLR merit a different outcome, other than that Pfizer was required to formally serve HLR with a Summons and its Answer, Affirmative Defenses, and Counterclaims. D.I. 20 at 8. Plaintiffs do not explain the import of that circumstance and provide no precedent supporting that the filing of counterclaims against HLR that are duplicative of those filed against Plaintiffs

constitutes "bring[ing] an action" any more than the filing of Pfizer's counterclaims against Plaintiffs does. Rather, interpreting the BPCIA to regulate the rights of a subsection (k) applicant with respect to other parties not substantively involved in the Patent Dance would also upend Congress's careful balancing of the parties' interests.

For these reasons, Plaintiffs' argument that the BPCIA precludes Pfizer from filing counterclaims in response to Plaintiffs' Complaint fails.

IV. THE BPCIA DOES NOT LIMIT PFIZER'S INFRINGEMENT, INVALIDITY, AND UNENFORCEABILITY THEORIES IN LITIGATION.

Plaintiffs ask the Court to dismiss all of Pfizer's counterclaims and strike its Third and Fourth Affirmative Defenses concerning invalidity and unenforceability because the BPCIA allegedly limits Pfizer's legal theories to those included in Pfizer's 3(B) Statement. D.I. 20 at 9. However, the statutory text and legislative history do not contemplate such relief. Indeed, Plaintiffs' position would upend Congress's careful balancing of the parties' interests and discourage participation in the Patent Dance.

As an initial matter, Plaintiffs do not identify any language in the statute that supports their positions. That is unsurprising because there is no statutory text that even remotely suggests that a subsection (k) is limited as Plaintiffs contend. Nor do Plaintiffs point to any legislative history that supports their position. Rather,

Congress clearly laid out the information exchange procedures under § 262(*l*)(2)-(3) and (7) and the negotiation procedures leading to initiation of litigation under § 262(*l*)(4)-(6). Those provisions are unambiguous and there is no suggestion that any of the procedures affect the subsection (k) applicant's ability to raise noninfringement, invalidity, and unenforceability theories during subsequent litigation. When "statutory text is plain and unambiguous[,]" the Court "must apply the statute according to its terms." *Carcieri*, 555 U.S. at 387 (citation omitted). The absence of any support in the unambiguous text of the statute or legislative history for Plaintiffs' position is reason alone to reject its policy-based argument. D.I. 20 at 10.

Had Congress intended to limit the rights of subsection (k) applicants in subsequent litigation, as Plaintiffs suggest, it would have expressly stated so. Indeed, where Congress believed it was important to regulate conduct and rights after the initiation of litigation, it clearly did so. For example, § 262(*l*)(1)(F) provides that the confidentiality provisions of the BPCIA remain in force "until such time as a court enters a protective order regarding the information" and expressly prohibits the inclusion of confidential information in any publicly available complaint or other pleading. Further, § 262(*l*)(1)(G) expressly prescribes the outcome if there is a violation of the confidentiality provisions. Another example is 35 U.S.C. § 271(e)(6), which was enacted under the BPCIA and limits

the reference product sponsor's remedies for patent infringement to a reasonable royalty if the reference product sponsor fails to initiate a lawsuit within the 30-day period prescribed in § 262(*l*)(6). In view of these provisions, Congress's silence with respect to the extreme relief that Plaintiffs request undercuts their argument.

Plaintiffs' interpretation of the BPCIA is further undercut by the unreasonableness of the consequences it creates in the context of the BPCIA framework. For example, the BPCIA expressly permits the subsection (k) applicant to opt out of the Patent Dance. *Sandoz Inc.*, 137 S. Ct. at 1675. If the subsection (k) applicant chooses to opt out, § 262(*l*)(9)(C) prescribes that the reference product sponsor, but not the subsection (k) applicant, can immediately bring a declaratory judgment action. Under Plaintiffs' interpretation, the subsection (k) applicant who opts out of the Patent Dance would be precluded from alleging *any* defenses or counterclaims in response to the reference product sponsor's allegations of infringement because it did not provide a 3(B) Statement. Plaintiffs' position effectively turns the centuries-old practice of adversarial patent litigation into an *ex parte* proceeding where the reference product sponsor is permitted to offer unchallenged allegations of patent infringement. It is unfathomable that Congress intended to upend biologics patent litigation in such a draconian manner without even the remotest suggestion in the statutory text or legislative history of such a monumental change.

The same absurd outcome would occur in the situation where a subsection (k) applicant chooses to participate in the Patent Dance and provides "a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires" for one or more patents pursuant to § 262(*l*)(3)(B)(ii)(II). If the reference product sponsor sues the subsection (k) applicant on such patents, like Plaintiffs have done here on five such patents, the subsection (k) applicant would have offered no "contentions" during the patent exchange process, and thus, would be precluded from alleging any defenses or counterclaims in subsequent litigation. Indeed, Plaintiffs argue that should be the outcome so that they are not "sandbag[ged]":

> 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 expiration' of the patents . . . ." Pfizer now claims the right to sandbag Plaintiffs with previously undisclosed grounds for invalidity.

D.I. 20 at 11. The irony is that the intended purpose of a statement under § 262(*l*)(3)(B)(ii)(II) is for a subsection (k) applicant to be able to assert that it has or will respect one or more patents so as to remove the patent(s) from the resulting litigation. Plaintiffs' interpretation of the BPCIA self-servingly turns that well-reasoned purpose on its head by turning § 262(*l*)(3)(B)(ii)(II) into a hidden trap

that effectively prescribes a favorable determination for the reference product sponsor and practically reads § 262(*l*)(3)(B)(ii)(II) out of the BPCIA since no subsection (k) applicant would ever consider choosing such a path.

Nor would it make any sense if Plaintiffs' interpretation of the BPCIA were applied only to subsection (k) applicants who choose to engage in the Patent Dance and provide a detailed statement pursuant to § 262(*l*)(3)(B)(ii)(I). That approach would discourage participation by significantly shifting the careful balance that Congress created in the information exchange process in favor of reference product sponsors. As explained above, the Patent Dance is an optional procedure designed to encourage the exchange of information between the subsection (k) applicant and the reference product sponsor in order to narrow the parties' disputes. To encourage participation by subsection (k) applicants, the BPCIA provides applicants who choose to participate the benefit of substantial control over the scope and timing of the resulting litigation. However, if the subsection (k) applicant chooses not to participate or fails to make the required disclosures, that benefit is lost. Thus, Congress created a delicate balance to motivate participation in the Patent Dance through specific prescribed benefits and penalties.

Precluding only subsection (k) applicants who have provided a 3(B) Statement from asserting any legal theories not included in the 3(B) Statement would significantly shift the balance in favor of reference product sponsors.

Compliant subsection (k) applicants would be worse off than nonparticipating applicants, since the latter would be subject to an immediate action for declaratory judgement under § 262(*l*)(9)(C), but would be able to assert any and all noninfringement, invalidity, and unenforceability theories. The possibility of such a harsh consequence would be a strong deterrent to participation in the Patent Dance, which would subvert its very purpose. That is not what Congress intended.

Further, it is also important to note that the information exchange prescribed in the BPCIA is not intended to serve the same purpose as "final contentions" during litigation, which is to put the opposing party on notice of the arguments that could be made at trial. Accordingly, the term "contentions" does not appear anywhere in the BPCIA. Rather, the purpose of the information exchange is simply to assist the parties in identifying and narrowing the patents that are potentially relevant to the subsection (k) applicant's product and process of manufacture. That is achieved by allowing the subsection (k) applicant to put forth a credible position that one or more of the patents is invalid, unenforceable and/or not infringed, through the information. The preclusion that Plaintiffs propose is not necessary to effectuate this purpose.

For example, the subsection (k) applicant is heavily incentivized to follow through with the information exchange, as Pfizer has done here. As explained, the BPCIA gives a compliant subsection (k) applicant control over the timing and

scope of the litigation, but takes away that benefit if the subsection (k) applicant does not comply with the information exchange requirements.[7] Further, the subsection (k) applicant is also incentivized to exchange the prescribed information because it triggers the reference product sponsor's duty to exchange information. For example, exchange of the application under § 262(*l*)(2) triggers the exchange of the list of patents that the reference product sponsor reasonably believes could be asserted pursuant to § 262(*l*)(3)(A). Exchange of the "detailed statement" under § 262(*l*)(3)(B) triggers the exchange of a detailed statement by the reference product sponsor under § 262(*l*)(3)(C). Thus, Plaintiffs' concern that in the absence of its proposed penalty, subsection (k) applicants will game the system to the detriment of reference product sponsors is untenable.

It would also be manifestly unfair and prejudicial to require the subsection (k) applicant to set forth its final contentions for numerous patents (33 patents in this case) within a period of 60 days, *see* § 262(*l*)(3)(B), in the absence of any fact discovery and without having any idea what infringement, claim construction, validity, and enforceability positions the reference product sponsor will pursue. In actual practice, the legal theories of a defendant in a patent litigation often evolve

[7] Genentech agrees that this penalty is a "real hammer" that "essentially provides a major incentive for the applicant to participate in the information exchanges, to provide its bases for noninfringement and invalidity of the listed patents." Transcript of Nov. 27, 2018 Conference at 25:11-15, *Genentech, Inc. v. Amgen Inc.*, No. 17-1407 (D. Del. Mar. 1, 2019), ECF No. 280, Ex. D.

early in the litigation based on the discovery that it obtains about the patent, the prosecution history, the conception and reduction to practice of the alleged invention, the prior art, etc. Plaintiffs' legal theories also typically evolve. Unlike Plaintiffs' hypothetical problems, Pfizer's concerns are practical and real. Thus, policy concerns actually counsel against Plaintiffs' extreme interpretation of the BPCIA.

Notably, in the Hatch-Waxman litigation context, Courts have held that an Abbreviated New Drug Application (ANDA) applicant is not limited to the legal theories included in a "paragraph IV notice letter" pursuant to 21 U.S.C. § 355(j)(2)(B).[8] *Minnesota Mining & Mfg. Co v. Barr Labs., Inc.*, 289 F.3d 775, 782 (Fed. Cir. 2002) ("we cannot enforce the requirement of paragraph IV certifications in an infringement suit"); *see also Abbott Labs. v. Lupin Ltd.,* 2011 WL 1897322, at *7 (D. Del. May 19, 2011) ("the Court has no authority to penalize deficiencies in Paragraph IV notice letters"); *see also*, *Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928, 2000 WL 257125, at *1 (S.D.N.Y. Mar. 8, 2000). The outcome should be the same here.

For these reasons, the Court should reject Plaintiffs' argument that the BPCIA limits Pfizer in this litigation to the legal theories included in its 3(B)

[8] 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires the paragraph IV notice letter to include "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."

Statement.

V. PFIZER ADEQUATELY PLED ITS INEQUITABLE CONDUCT COUNTERCLAIM.

A. The Pleadings Establish that Genentech Made Demonstrably False Statements to the PTO.

Plaintiffs are incorrect that, as a matter of law, Genentech could not have committed inequitable conduct because the misrepresented references were disclosed to, and could be independently evaluated by, the Examiner. D.I. 20 at 13-16. An applicant is "not relieved of responsibility for any alleged misstatements simply because the [prior art reference was] before the PTO." *Wyeth Holdings Corp. v. Sandoz, Inc.*, No. 09-955-LPS, 2012 WL 600715, at *11 (D. Del. Feb. 3, 2012); *see also Southco, Inc. v. Penn Eng'g & Mfg. Corp.*, 768 F. Supp. 2d 715, 723 (D. Del. 2011) (finding that misrepresentations regarding prior art disclosed to the PTO, even if categorized as attorney argument, were "sufficient to satisfy the requirements of [Rule 9(b)]"). Indeed, "it is not possible for a patent applicant to misrepresent the teaching of the prior art unless the material is before the PTO in the first place." *Wyeth*, 2012 WL 600715, at *11. "To countenance [Plaintiffs'] approach would create a perverse incentive, where applicants would be free to falsely characterize such documents, but then claim immunity from a later charge of inequitable conduct because the mischaracterized material was before the PTO." *Id.*

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). In their motion to dismiss, Plaintiffs argue that Genentech's statements to the PTO are attorney argument without analysis, but Genentech's statements are not only gross mischaracterizations, but demonstrably false as shown in the pleadings. For example, Genentech stated to the PTO on multiple occasions that the '101 patent does not use the Kabat numbering system. D.I. 14 at 69-73 ¶¶ 121, 126, 129, and 133. This statement is demonstrably false because the '101 patent uses the Kabat numbering system, including for a substitution at the 93H FR residue. *Id.* at 71-73 ¶¶ 131, 132, and 133. In fact, Plaintiffs admit that the '101 patent "uses two different numbering schemes in referring to the amino acids contain [sic] in the antibodies – some are identified using sequential numbering, and some are identified using what is known as Kabat numbering." D.I. 20 at 17 (emphasis added). As a result, the statements are demonstrably false, actionable misrepresentations.

The cases cited by Plaintiffs are inapposite because the statements in those cases were not demonstrably false. Additionally, *Cellectis S. A. v. Precision Biosciences* focuses on intent to deceive as opposed to attorney argument. 883 F. Supp. 2d 526, 535 (D. Del. 2012). In *Separacor Inc. v. Teva Pharmaceuticals*

USA, Inc., the "most important" factor was that the statements were considered irrelevant by the Examiner. No. 09-1302, 2010 WL 2326262 (D.N.J. June 7, 2010). Finally, *Bayer Schering Pharma AG v. Barr Laboratories., Inc.*, was a decision on the merits as opposed to a motion to dismiss. Civ. No. 05-2308, 2008 WL 628592 (D.N.J. Mar. 3, 2008).

Plaintiffs dispute that Genentech's statements were incorrect. D.I. 20 at 16-18. But "[i]n 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.). On the merits, Plaintiffs are wrong because they misstate the scope of Genentech's misrepresentations. As stated in the counterclaim, "Genentech told the Examiner that the '101 patent does not use the Kabat numbering system." D.I. 14 at 69-73 ¶¶ 121, 126, 129, 133. Genentech's statements were not limited to the anti-Tac antibody, but expressly state that "[t]he cited references use a sequential numbering system, rather than the Kabat numbering system claimed herein." *Id.* at 129 (emphasis added). Plaintiffs now admit that these statements were incorrect. D.I. 20 at 17.

B. Pfizer Has Adequately Pled Specific Intent.

To plead deceptive intent, the pleading must include sufficient allegations of underlying facts from which a court may reasonably infer a specific intent to deceive the PTO. *Wyeth*, 2012 WL 600715, at *7 (finding that the Federal Circuit decision in *Therasense, Inc. v. Betcon, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc) regarding the intent prong created an "*evidentiary* standard that must be satisfied at the proof stage, not a pleading standard") (emphasis in original)). Inequitable conduct claims are rarely disallowed at the pleading stage due to the failure to adequately allege scienter. *See Cornell*, 2016 WL 3046258, at *9. "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." *Cornell*, 2016 WL 3046258, at *9. "To meet the pleading standard, defendant need only allege facts from which the Court could *reasonably infer* that the patent applicant made a deliberate decision to deceive the PTO." *Id.* (emphasis in original) (quotations omitted).

The pleadings state that "[d]eceptive intent by Genentech is the single most reasonable inference to be drawn in light of the fact that the '101 patent discloses sequences numbered according to the Kabat system and expressly describes a substitution at 93H using the Kabat system." D.I. 14 at 73 ¶ 133. This inference is reasonable because Genentech misrepresented to the Examiner that "the substituted 93 FR residue in the ['101 patent] is not 93H 'utilizing the numbering system set forth in Kabat,'" despite the express teaching in the '101 Patent of a substitution at

93H using the Kabat system. *Id.* at 73 ¶ 133. The pleadings establish that Genentech previously deleted references to substitutions at 93H in response to a rejection that included Queen 1989. *Id.* at 69 ¶ 124. Then, Genentech made material misrepresentations that the '101 patent used "sequential numbering for the variable domain residues of the antibodies described in these references." *Id.* at 70 ¶ 126. Genentech subsequently included the 93H residue in new claims which explicitly claimed the Kabat numbering system and reiterated their misrepresentation to overcome the '101 patent as prior art. *Id.* at 70 ¶¶ 127, 128. This misled the Examiner into accepting claims with the substitution at 93H. *Id.* at 71 ¶ 130. This court has upheld inequitable conduct counterclaims based on similar allegations that a patentee's representations regarding information before the patent office were "designed to mislead the Examiner into issuing the [patent-at-issue] on a faulty premise." *Wyeth*, 2012 WL 600715, at *13; *see also Cornell*, 2016 WL 3046258, at *9 (finding specific intent adequately pled where applicant submitted misrepresentations in response to rejection that ultimately led to allowance).

C. Pfizer Has Adequately Pled But-For Materiality.

To plead but-for materiality, Plaintiff must plead sufficient facts to allow a reasonable inference that the patent would not have issued but for the alleged misrepresentations. *Wyeth*, 2012 WL 600715, at *10. Pfizer has met this standard.

Plaintiffs first argue that, as a general rule, allegations of mischaracterization cannot be material. D.I. 20 at 19. This misstates the law. Many courts have found but-for materiality related to an applicant's misstatements regarding matters before the PTO. *See, e.g. Wyeth*, 2012 WL 600715, at *9-10 (finding but-for materiality where misrepresentations successfully overcame the previous rejection); *Cornell*, 2016 WL 3046258, at *8 (finding materiality where "there are no other apparent materials on which the Examiner could have based his reversal on patentability"). The pleadings establish that Genentech overcame a rejection based on its material misrepresentation when "Genentech provided no other arguments to distinguish the '101 patent from the claimed subject matter. . . ." D.I. 14 at 73 ¶ 134. Therefore, it is a reasonable inference that the patent would not have issued but-for the misrepresentations.

Plaintiffs also argue that Pfizer has failed to establish but-for materiality because the Examiner "rejected" the arguments. D.I. 20 at 19-20. But instead of preventing Pfizer from adequately pleading but-for materiality, the December 23, 1997 Rejection actually confirms the materiality of the representation.[9] In the

[9] This information is not necessary for Pfizer to adequately plead inequitable conduct, but is included to rebut incorrect factual assertions made by Plaintiffs in their motion to dismiss. Plaintiffs' factual assertions underscore that Plaintiffs' inequitable conduct arguments are inappropriate arguments on the merits where Pfizer's allegations must be taken as true and viewed in the light most favorable to Pfizer. *Bruni*, 824 F.3d at 360.

rejection, the Examiner explicitly stated that "[i]f the applicant wishes to distinguish over the ['101 patent], they may do so by claiming the actual numbering system used in the actual claim." December 23, 1997 Final Rejection at 4. Genentech then "recited the numbering system of Kabat in independent claims" to overcome the rejection, including citing the Kabat numbering system in new claims for substitutions of residue 93H. August 23, 1998 Applicant Remarks in Amendment at 12-13; D.I. 14 at 70 ¶ 127. Therefore, the pending rejection underscores that the PTO considered Genentech's misrepresentation that the '101 patent does not use the Kabat numbering system to be sufficient to overcome an anticipation rejection by the '101 patent.[10]

VI. CONCLUSION

For these reasons, Pfizer respectfully requests that the Court deny Plaintiffs and HLR's motion to dismiss Pfizer's counterclaims and to strike its third and fourth affirmative defenses.

[10] The cases cited by Plaintiffs are distinguishable as cases where the Examiner actually rejected the misrepresentation. *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); *Unverferth Mfg. Co. v. Par-Kan Co.*, No. 3:13-cv-97-TLS, 2014 WL 2206922, at *4-5 (N.D. Ind. May 27, 2014).

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

Attorneys for Pfizer Inc.

OF COUNSEL:

WILLKIE FARR & GALLAGHER LLP
Thomas J. Meloro
Michael W. Johnson
Dan Constantinescu
787 Seventh Avenue
New York, NY 10019
(212) 728-8000

Dated: June 3, 2019

CERTIFICATION OF COMPLIANCE

This brief complies with the type and number limitations set forth in Judge Connolly's Patent Case Form Scheduling Order for Cases Where Infringement is Alleged – Revised April 22, 2019. This brief includes 6,518 words in 14-point, Times New Roman typeface, excluding the cover page, table of contents, and table of authorities. Using 12-point Times New Roman typeface, this brief would be 20 pages in compliance with Delaware Local Rule 7.1.3(a)(4).

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

Attorney for Pfizer Inc.

Dated: June 3, 2019