IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC and CITY OF HOPE, Plaintiffs, v. AMGEN INC., Defendant.	)	C.A. No. 18-00924-GMS

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS DEFENDANT'S UNENFORCEABILITY COUNTERCLAIMS AND TO STRIKE DEFENDANT'S ELEVENTH AFFIRMATIVE DEFENSE

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I. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Genentech, Inc. ("Genentech") invented and developed the drug Herceptin®, which is a first-of-its-kind biologic therapy that specifically targets a protein associated with an aggressive form of breast cancer. Seeking to profit from this groundbreaking work, Defendant Amgen, Inc. ("Amgen") is seeking FDA approval to sell a biosimilar version of Herceptin®. Because Amgen's proposed product infringes patents held by Genentech and Plaintiff City of Hope (collectively, "Plaintiffs")—including patents covering Herceptin®, methods of using it, and methods of manufacturing it—Plaintiffs sued Amgen for patent infringement on June 21, 2018. D.I. 1. Plaintiffs amended their complaint shortly thereafter to reduce the number of patents-in-suit to eighteen. D.I. 15.

Amgen filed its answer to the amended complaint on August 2, 2018. D.I. 19. As an Eleventh Affirmative Defense, it asserts that "Plaintiffs' Complaint, and each of its purported causes of action is barred by Plaintiffs' unclean hands, in view of at least the reasons relating to Genentech's inequitable conduct." D.I. 19, Aff. Defs. ¶ 11. In support of that defense, however, Amgen only identifies alleged conduct with respect to one of the eighteen patents that Genentech has asserted, U.S. Patent No. 6,407,213 ("the '213 patent"). D.I. 19, Aff. Defs. ¶¶ 11-23. Amgen also asserts counterclaims seeking declaratory judgment of unenforceability for each of the eighteen asserted patents. D.I. 19, Countercls., Counts 1-18. But Amgen's counterclaims include no factual allegations of their own—they simply incorporate the rest of Amgen's pleading by reference. *See, e.g., id.* ¶¶ 48-54. The only factual allegations about unenforceability in Amgen's eighteen counterclaims therefore relate to the '213 patent.

Plaintiffs now move to strike Amgen's "unclean hands/inequitable conduct" affirmative defense under Federal Rule of Civil Procedure 12(f) and move to dismiss Amgen's

unenforceability counterclaims under Federal Rule of Civil Procedure 12(b)(6). This is Plaintiffs' opening brief in support of that motion.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(f) authorizes the Court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Facts 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).

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 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)). The Court should assume the veracity of the factual allegations, but it must reject conclusory allegations. *LEO Pharma A/S v. Actavis Labs. UT, Inc.*, No. CV 16-333-JFB-SRF, 2018 WL 1045816, at *2 (D. Del. Feb. 26, 2018) (citing *Iqbal*, 556 U.S. at 675, 678). In addition, the Court need not accept "'a legal conclusion couched as a factual allegation.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555).

The inequitable conduct and unclean hands doctrines are remedies for fraud on the Patent Office. *See, e.g.*, *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-29 (Fed. Cir. 2009); *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). The patent-specific inequitable conduct doctrine, like the more general unclean hands doctrine, prevents a patent holder from enforcing its patent if the patent holder engaged in "egregious misconduct" in procuring the patent. *Therasense*, 649 F.3d at 1287. It requires a

showing of both intent to deceive and materiality. *Id.* at 1290. "[T]he remedy for inequitable conduct is the 'atomic bomb' of patent law"—unenforceability. *Id.* at 1288-89.

Because a claim of unenforceability is "a common litigation tactic" with "far-reaching consequences," the Federal Circuit has held that the standard for pleading intent and materiality is high. *Id.* at 1289-90; *see also Exergen*, 575 F.3d at 1326-29. Moreover, under well-established Federal Circuit precedent, an applicant's arguments to the patent examiner concerning the teachings of the prior art do not give rise to inequitable conduct where the patent examiner has the reference before her and has all of the information necessary to evaluate the teachings of the prior art. *See Rothman v. Target Corp.*, 556 F.3d 1310, 1328-29 (Fed. Cir. 2009); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007).

Whether in an affirmative defense or a counterclaim, "inequitable conduct . . . must be pled with particularity" according to Federal Rule of Civil Procedure 9(b). *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003);[1] *see also Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013). "[I]n pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1327. It also "requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted" with "(1) knowledge of the withheld material information or of the falsity of the material misrepresentation, and (2) specific intent to deceive the PTO." *Id.*

[1] Federal Circuit law controls the pleading standard for inequitable conduct. *Exergen*, 575 F.3d at 1318.

III. SUMMARY OF ARGUMENT

Trial courts, including in this District, routinely dismiss at the pleadings stage or reject as a matter of law allegations that an applicant committed inequitable conduct by misrepresenting a reference before the examiner:

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

Cellectis S.A. v. Precision Biosciences, 883 F. Supp. 2d 526, 535 (D. Del. 2012); *see also Bayer Schering Pharma AG v. Barr Labs., Inc.*, No. 05-cv-2308 (PGS), 2008 WL 628592, at *49-50 (D.N.J. Mar. 3, 2008); *Sepracor Inc. v. Teva Pharm. USA, Inc.*, No. 09-cv-01302 (DMC)(MF), 2010 WL 2326262, at *6 (D.N.J. June 7, 2010). The Court should reach the same result here because Amgen's unclean hands/inequitable conduct defense and unenforceability counterclaims rest on the same legally deficient theory that was fatal to the defendants' inequitable conduct defense in those prior cases.

As to the '213 patent—the only patent for which Amgen has even attempted to plead facts in support of its inequitable conduct defense—Amgen's unenforceability theory is insufficient as a matter of law because it does not refer to any alleged misrepresentation or omission that the patent examiner was incapable of evaluating on her own. Rather, Amgen's defense depends solely on characterizations of the prior art by prosecution counsel that the patent examiner had before her. Even assuming that Amgen had pleaded facts sufficient to show that Genentech mischaracterized the references to the patent examiner (which Amgen has not), Amgen's unenforceability defense is insufficient as a matter of law to raise an inference of materiality or deceptive intent—two essential elements of any claim for inequitable conduct. As

Amgen acknowledges in its pleading, the Patent Office explicitly considered the references that Amgen now says were "mischaracterized." The patent examiner reviewed the references and independently evaluated their content, and Amgen concedes that Genentech provided the patent examiner with exactly the information that it now alleges was misrepresented. The Federal Circuit has long held that an applicant's arguments about the teachings of the prior art cannot, as a matter of law, support a finding of inequitable conduct—particularly where, as here, the examiner had all of the information necessary to evaluate the disclosure of the prior art herself. Amgen's unenforceability counterclaim for the '213 patent should therefore be dismissed, and its related "unclean hands/inequitable conduct" affirmative defense should be stricken.

As to the remaining seventeen asserted patents, Amgen fails to include any factual allegations whatsoever in support of its unenforceability counterclaims—it simply recites boilerplate language referencing a statement about the asserted patents' validity that Amgen provided to Genentech before this suit was filed (*i.e.*, as part of the statutory information-exchange procedures that govern biosimilar applications). But that statement—like Amgen's responsive pleading—is devoid of any factual allegations supporting Amgen's unenforceability theories for these patents. Accordingly, any defense or counterclaim as to "unclean hands" or "inequitable conduct" as to these patents must be dismissed.

IV. BACKGROUND

A. Amgen Is Alleging That The Patents-In-Suit Are Unenforceable To Clear The Way For Its Biosimilar Version Of Genentech's Blockbuster Drug Herceptin®.

This patent dispute arises from Amgen's efforts to market a biosimilar version of Herceptin®, a drug Genentech developed for the treatment of breast cancer. Herceptin® is a genetically engineered antibody that represents a profound breakthrough in the treatment of cancer. After the FDA approved Herceptin®, the scientific community hailed it as "the

beginning of a whole new wave of biological drugs that modulate the causes of cancer" and as a sign that "the whole field of cancer research has turned a corner." D.I. 15 ¶ 4. Herceptin® has transformed the treatment of breast cancer and has become the standard of care for its patient population.

Amgen has submitted an Abbreviated Biologics License Application ("aBLA") seeking FDA approval to market a "biosimilar" of Herceptin® called ABP 980. *See* D.I. 15 ¶ 19; D.I. 19, Countercl. ¶¶ 8-9. A biosimilar is a drug that is similar enough to the innovator product (here, Herceptin®) that the FDA will allow the biosimilar applicant to rely upon the innovator's clinical trials during the approval process—thereby saving the developer of a biosimilar drug the time and expense of extensive clinical development. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017). Amgen is seeking the same label and indicated uses as Genentech's Herceptin®. *See* D.I. 15 ¶ 7.

Congress created an abbreviated pathway for approval of biosimilar drugs under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The filing of an aBLA is a technical act of patent infringement, but the BPCIA provides for a series of exchanges and negotiation before any litigation commences. *See* 35 U.S.C. § 271(e)(2); 42 U.S.C. §§ 262(k)-(*l*); *see also Sandoz,* 137 S. Ct. at 1670-72; *Genentech, Inc. v. Amgen Inc.*, No. 17-1407-GMS, 2018 WL 503253, at *1-2 (D. Del. Jan. 22, 2018). These exchanges, known informally as the "patent dance," are designed 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,* 137 S. Ct. at 1670-71.

As part of the patent dance, the biosimilar applicant is required to provide the reference product sponsor "a detailed statement that describes" why the applicant believes any relevant

patent held by the sponsor is unenforceable. *See* 42 U.S.C. § 262(*l*)(3)(B). This is commonly known as a 3B Statement, based on the statutory provision that requires it. Amgen's 3B Statement did not include unenforceability allegations for seventeen of the eighteen patents asserted in this case. For the remaining patent, the '213 patent, Amgen's 3B Statement alleged that it is unenforceable because during prosecution Genentech supposedly misrepresented the teachings of two prior art references, U.S. Patent No. 5,530,101 ("the '101 patent") and a related scientific publication called "Queen 1989." Amgen acknowledged, however, that both the '101 patent and the Queen 1989 reference were provided to and considered by the patent examiner before the '213 patent issued.

When Amgen filed its answer, it repeated its unenforceability allegations for the '213 patent in its inequitable conduct/unclean hands affirmative defense (*i.e.*, it's Eleventh Affirmative Defense). *See* D.I. 19, Aff. Defs. ¶¶ 11-23. Amgen's counterclaims identify no further allegations to support an unenforceability theory, but they each incorporate Amgen's affirmative defenses and its 3B Statement by reference. Because Amgen's affirmative defenses and 3B Statement only include unenforceability allegations for the '213 patent, Amgen's counterclaims include no factual allegations supporting its unenforceability claims for the other seventeen patents-in-suit.

B. The Only Factual Allegations In Amgen's Unenforceability Defenses And Counterclaims Relate To The '213 Patent.

Amgen's unenforceability allegations for the '213 patent, the only patent for which it provides unenforceability allegations, arise from communications between Genentech and the Patent Office while Genentech was applying for the patent. The '213 patent claims humanized

antibodies with amino acid substitutions at certain specified positions.[2] During prosecution, Genentech disclosed—and the examiner considered—prior art references describing humanized antibodies made by others in the field. Those references included the '101 patent and the related Queen 1989 publication. D.I. 19, Aff. Defs. ¶¶ 15, 17 (describing patent examiner's consideration of the '101 patent and Queen 1989).

The patent examiner rejected Genentech's proposed patent claims in view of the '101 patent and Queen 1989 because she believed that a humanized antibody disclosed in both of those references, called "anti-Tac," contained amino acid substitutions at the positions that Genentech had claimed. *See id.* In response, Genentech pointed out that the numbering convention that the examiner had used to identify the location within the antibody for those substitutions (*i.e.*, sequential numbering) in the humanized anti-Tac antibody was different from how Genentech had identified the substitutions in its proposed claims (*i.e.*, Kabat numbering).[3] *Id.* ¶ 19. Genentech further explained that, as a result of those different numbering conventions, the specific amino acid position that the examiner believed that the anti-Tac antibody disclosed ("93H") did not actually correspond with what was covered by Genentech's proposed claims. *Id.*

[2] Antibodies are molecules produced by the immune system. As the '213 patent explains, a "humanized" antibody is a molecule that can be created through molecular engineering techniques that incorporates certain amino acids from a non-human antibody (*e.g.*, a mouse) into a human antibody framework. D.I. 15, Ex. C, '213 patent, col. 8, ll. 11-51.

[3] An antibody is a protein consisting of amino acids arranged in a particular order. 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 the '213 patent 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. 15, Ex. C, '213 patent, col. 10, l. 46 - col. 11, l. 16. A sequence alignment compares the amino acid sequences of multiple antibodies by matching the overlapping portions of the sequences. *See, e.g.*, D.I. 15, Ex. C, '213 patent, col. 10, l. 58 - col. 11, l. 16.

Genentech also identified all of the amino acid substitutions in the antibodies disclosed in the '101 patent and Queen 1989 in charts and in sequence alignments that Genentech provided to the patent examiner. *Id.* ¶ 23 & n.1. The patent examiner subsequently allowed Genentech's proposed claims to issue over the '101 patent and Queen 1989. *Id.* ¶ 20.

Amgen asserts that Genentech's arguments to the patent examiner concerning the teachings of the '101 patent and Queen 1989 were misleading in two respects. D.I. 19, Aff. Defs. ¶¶ 13-14. First, Amgen asserts that Genentech supposedly misrepresented the teachings of the '101 patent and Queen 1989 by arguing those references used sequential numbering to identify amino acid substitutions as opposed to Kabat numbering. *Id.* Second, Amgen asserts that Genentech omitted an amino acid substitution ("62L") when describing the substitutions disclosed in Queen 1989. *Id.* ¶ 14.

Even accepting Amgen's well-pleaded facts as true for purposes of this motion, Amgen has not pleaded facts showing any misrepresentation or omission by Genentech. Amgen never alleges that Genentech misrepresented that the '101 patent and Queen 1989 used a sequential numbering convention when referring to a substitution at position 93 in the humanized anti-Tac antibody (they do). And in any event, even if one were to apply Kabat numbering, Amgen never alleges that the humanized anti-Tac antibody that was addressed in Genentech's statements to the examiner actually has a framework substitution at 93H under Kabat numbering (it does not). Instead, Amgen points to a ***different*** portion of the '101 patent that utilized Kabat numbering when describing ***different*** humanized antibodies that are not the humanized anti-Tac antibody that Genentech was addressing in its comments to the examiner. *Id.* ¶ 21 (referring to Table 5 in the '101 patent that describes the humanized antibodies called "Fd79" and "Fd138-80," not humanized anti-Tac). Those factual allegations thus do not add up to a misrepresentation by

Genentech; the statements that are the basis for Amgen's inequitable conduct defense were simply addressing a different issue for a different humanized antibody.[4]

Amgen also has not pleaded facts to support that Genentech "conspicuously omitted a key residue ('62L') disclosed in the prior art" when describing Queen 1989. *Id.* ¶¶ 14, 23. There is no substitution at position 62L under Kabat numbering in the humanized anti-Tac antibody described in Queen 1989, and Amgen has not pleaded any facts to suggest otherwise. The reference to position "62 of the light chain" that Amgen cites (*id.* ¶ 23) refers to the amino acid position in the ***mouse*** anti-Tac antibody under ***sequential*** numbering, not the amino acid position in the ***humanized*** anti-Tac antibody under ***Kabat*** numbering (which is actually 63L and is what Genentech disclosed to the patent examiner).

But for purposes of this Rule 12 motion, the Court need not address the sufficiency of Amgen's allegations as a factual matter because the entire premise of Amgen's inequitable conduct defense rests on a legally deficient theory. Amgen's inequitable conduct defense for the '213 patent rests ***solely*** on Genentech's arguments concerning the teachings of prior art references, which as described below is insufficient as a matter of law to find inequitable conduct in these circumstances—particularly where, as here, the examiner had all of the information before her necessary to evaluate those arguments.

[4] Amgen concedes that Genentech disclosed to the patent examiner the sequences using Kabat numbering for the humanized antibodies described in the '101 patent and Queen 1989. *Id.* ¶ 23 ("At the Examiner's request, Genentech submitted a comparison of the different numbering systems purportedly utilized in Queen 1989 and the pending claims."); *id.* ¶ 23 n.1 ("As requested by the Examiner in the interview, alignments of heavy chain variable domain (Exhibit A) and light chain variable domain (Exhibit B) sequences of the 101 patent (including the sequences for the murine and humanized anti-Tac antibody of Queen *et al.*) with sequential and Kabat residue numbering is attached."). Amgen cannot contend that Genentech intended to mislead the patent examiner regarding how the Kabat numbering convention applies to the antibodies disclosed in the '101 patent and Queen 1989 when Amgen acknowledges that Genentech provided that exact information to the patent examiner.

V. ARGUMENT

A. Because Amgen's Unenforceability Theory For The '213 Patent Is Legally Deficient, Its Eleventh Affirmative Defense Should Be Stricken And Its Unenforceability Counterclaim For The '213 Patent Should Be Dismissed.

Amgen has not pleaded sufficient facts to support its unclean hands/inequitable conduct defense. It should therefore be stricken under Rule 12(f), and Amgen's counterclaim that incorporates the affirmative defense by reference should be dismissed under Rule 12(b)(6).

Amgen's Eleventh Affirmative Defense rests on Genentech's statements to the patent examiner made during prosecution of the '213 patent. D.I. 19, Aff. Defs. ¶¶ 11-23. However, unlike a typical case of inequitable conduct, Amgen does not allege that Genentech deliberately concealed references in its possession from the Patent Office. *See, e.g.*, *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1334 (Fed. Cir. 2012) (upholding district court's determination of inequitable conduct for intentionally withholding references from the PTO). To the contrary, Amgen acknowledges that the Patent Office had and explicitly considered the two identified references—"Queen 1989" and the '101 patent. D.I. 19, Aff. Defs. ¶¶ 13-23.

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. *See, e.g.*, *Rothman*, 556 F.3d at 1328-29; *Young*, 492 F.3d at 1349 ("We therefore fail to see how the statements . . . which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact."). 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." *Rothman*, 556 F.3d at 1329; *see also Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986) (noting

that 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*, for example, the Federal Circuit affirmed the grant of summary judgment of no inequitable conduct and an award of attorneys' fees incurred in defending the charge, 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." 512 F.3d 1363, 1379 (Fed. Cir. 2008).

Here, Amgen's inequitable conduct defense falls squarely within this well-established precedent barring claims of inequitable conduct based upon an applicant's characterizations of prior art before the examiner. Amgen's defense rests solely on statements that Genentech made concerning the teaching of references that were before the examiner. D.I. 19, Aff. Defs. ¶¶ 11-23. And the examiner had all of the information before her necessary to evaluate the references and Genentech's arguments distinguishing them from the patent claims that Genentech was seeking. Indeed, as Amgen concedes, Genentech provided the examiner with the amino acid sequences of the humanized antibodies disclosed in the '101 patent and Queen 1989 and specifically identified the Kabat numbering for those sequences (D.I. 19, Aff. Defs. ¶ 23 & n.1), which is exactly the information that Amgen now argues that Genentech supposedly misrepresented through its arguments to the examiner.

This case is thus unlike those where an inequitable conduct defense survived a motion to dismiss, which typically involve misrepresentations or omissions uniquely within the knowledge of the prosecuting attorney and that the examiner is not able to evaluate on her own. For example, in *Wyeth Holdings Corp. v. Sandoz, Inc.*, No. 09-955-LPS-CJB, 2012 WL 600715, at *12 (D. Del. Feb. 3, 2012), the patentee allegedly mischaracterized "internal testing procedures and protocols" that were inconsistent with representations about the invention. The defendant

there also alleged that certain relevant data "was never provided by [the applicant] to the examiner in any form." *Id.* Similarly, in *Southco, Inc. v. Penn Engineering & Manufacturing Corp.*, 768 F. Supp. 2d 715 (D. Del. 2011), the patentee submitted a photo of relevant prior art, but failed to disclose a physical sample of it in his possession, "which would have demonstrated the falsity of [the patentee's] arguments." *Id.* at 722. Unlike those cases, the alleged misrepresentations or omissions here concerned disclosures on the face of the references that the patent examiner was capable of evaluating on her own.

Nor are the allegations in this case analogous to the situation presented in *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").[5] Accordingly, Amgen's allegations in this case are insufficient as a matter of law to support a claim of inequitable conduct, and the Court therefore should strike Amgen's inequitable conduct affirmative defense. *See Senju*, 921 F. Supp. 2d at 307-08 (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).

[5] After *Ring Plus* was decided, the en banc Federal Circuit "tighten[ed] the standards for finding" inequitable conduct. *Therasense*, 649 F.3d at 1290. As a result, it is not even clear that *Ring Plus* remains good law today.

Amgen also asserts unclean hands "in view of at least the reasons relating to Genentech's inequitable conduct." D.I. 19, Aff. Defs. ¶ 11. That defense should be stricken for the same reasons as Amgen's legally deficient inequitable conduct defense. To the extent Amgen claims this is a separate defense based on facts not included in its inequitable conduct allegations, it is inadequately pleaded. Even under the notice pleading standard of Federal Rule of Civil Procedure 8, "[a] defense may be deemed meritless because it is simply a conclusory allegation which fails to provide an appropriate statement of facts or to allege the necessary elements of the claims." *Sonos, Inc. v. D&M Holdings Inc.*, No. 14-1330-RGA-MPT, 2016 WL 4249493, at *2 (D. Del. Aug. 10, 2016). Amgen's conclusory affirmative defense fails to provide any notice as to what alleged "conduct involving fraud, deceit, unconscionability, or bad faith" is at issue, *see Sun Microsystems*, 630 F. Supp. 2d at 410, or how this conduct "injures" Amgen, *see id*. It should be stricken for that reason. *See Sonos*, 2016 WL 4249493, at *5-6 (striking unclean hands defense for insufficient facts); *O'Gara v. Countrywide Home Loans, Inc.*, No. 08-113-JJF, 2010 WL 3070211, at *2 (D. Del. July 30, 2010) (same).

Amgen's counterclaim for the '213 patent includes no unenforceability allegations of its own; it merely incorporates the allegations in Amgen's affirmative defenses. *See* D.I. 19, Countercl. ¶ 68. Amgen's affirmative defense and counterclaim of inequitable conduct thus "rise or fall together." *Senju*, 921 F. Supp. 2d at 306; *see also Medicines Co. v. Teva Parenteral Meds., Inc.*, No. 09-750-ER, 2011 WL 13135647, at *5-6, *22-23 (D. Del. Aug. 26, 2011). Because Amgen's affirmative defense of unenforceability is legally deficient, its counterclaim is too. Amgen's counterclaim for unenforceability of the '213 patent should therefore be dismissed.

B. Amgen's Remaining Counterclaims For Unenforceability Should Be Dismissed.

Amgen's counterclaims seeking a declaration that each of the remaining seventeen patents-in-suit are "unenforceable"[6] should be dismissed because they are based on only boilerplate allegations that fail to meet Rule 9(b)'s heightened pleading standard. For these patents, Amgen has not pleaded or disclosed ***any*** facts that would support an unenforceability counterclaim. Each of Amgen's counterclaims includes the same seven paragraphs, as illustrated by Amgen's first counterclaim below, and none of those paragraphs include facts related to unenforceability:

> **Count 1**
> **Non-Infringement and Invalidity of U.S. Patent No. 6,331,415**
>
> 48. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.
>
> 49. Plaintiffs have alleged that Genentech and City of Hope co-own U.S. Patent No. 6,331,415 ("the '415 patent").
>
> 50. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '415 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).
>
> 51. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '415 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

[6] D.I. 19, Countercl. 1-2, 4-18, ¶¶ 53-54; 60-61, 74-75, 81-82, 88-89, 95-96, 102-103, 109-110, 116-117, 123-124, 130-132, 138-140, 146-147, 153-154, 160-161, 167-168, and 174-175; *see also* Prayer for Relief E.

> 52. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '415 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.
>
> 53. The claims of the '415 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons and/or based on the references set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).
>
> 54. Amgen is entitled to a judgment that the claims of the '415 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons and/or based on the references set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

D.I. 19, Countercl. ¶¶ 48-54 (highlighting added); *see also id.* ¶¶ 60-61, 74-75, 81-82, 88-89, 95-96, 102-103, 109-110, 116-117, 123-124, 130-132, 138-140, 146-147, 153-154, 160-161, 167-168, 174-175.

Amgen's vague reference to "the reasons . . . set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B)" (*i.e.*, its 3B Statement) fails to cure this deficiency. Even assuming that Amgen's allegations, which are not in the record, can be incorporated by reference,[7] Amgen's 3B Statement contains no allegations to support a claim of unenforceability for any of

[7] Amgen failed to attach its 3B Statement to its counterclaims, despite Rule 10(c)'s requirement that a pleading may only incorporate by reference material that is "elsewhere in the same pleading or in any other pleading or motion." Amgen cannot rely on allegations that are not in the record to satisfy its obligations under Rule 9(b).

the remaining seventeen patents-in-suit. Amgen's 3B Statement only includes unenforceability allegations for the '213 patent, so there is nothing to incorporate by reference for the other patents.

In reiterating the high bar for pleading inequitable conduct, the en banc Federal Circuit observed that "the inequitable conduct doctrine has plagued not only the courts but also the entire patent system[] [b]ecause allegations of inequitable conduct are routinely brought on the slenderest grounds." *Therasense*, 649 F.3d at 1289 (quotation marks omitted). Here, Amgen failed to provide even slender grounds for its seventeen unenforceability counterclaims—it provides none. Amgen therefore has not met its "obligation to provide the grounds of his entitle[ment] to relief." *Senju*, 921 F. Supp. 2d at 301. Its baseless and boilerplate assertions do not meet the pleading requirements of Federal Rule of Civil Procedure 12(b)(6), much less the heightened pleading burden of Federal Rule of Civil Procedure 9(b) that is required for claims of inequitable conduct. Each of Amgen's counterclaims for unenforceability should therefore be dismissed.

VI. CONCLUSION

Plaintiffs respectfully request that the Court dismiss each of Amgen's counterclaims for unenforceability and strike Amgen's Eleventh Affirmative Defense and Prayer for Relief E, which seeks a declaration that the claims of the patent-in-suit are unenforceable.

Dated: August 23, 2018

Respectfully submitted,

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