IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC. and ALLERGAN INDUSTRIE SAS,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 19-126-CFC-SRF
PROLLENIUM US INC. and PROLLENIUM MEDICAL TECHNOLOGIES INC.,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

Presently before the court in this patent infringement action is the motion of plaintiffs Allergan USA, Inc. and Allergan Industrie SAS ("Allergan") to dismiss the inequitable conduct counterclaim and strike the inequitable conduct affirmative defense of defendants Prollenium US Inc. and Prollenium Medical Technologies Inc. ("Prollenium").[1] (D.I. 34) For the following reasons, I recommend that the court grant Allergan's motion to dismiss and strike without prejudice.

II. BACKGROUND

Allergan develops, manufactures, and distributes a line of dermal fillers under the JUVEDÈRM® mark that are injected into facial tissue to smooth wrinkles and folds. (D.I. 5 at ¶¶ 36, 39) Allergan's JUVEDÈRM® products are injectable hyaluronic acid ("HA") gels crosslinked with 1,4-butanediol diglycidyl ether ("BDDE"). (D.I. 29 at ¶¶ 8, 10) The

[1] The briefing for the pending motion can be found at D.I. 35, D.I. 40, and D.I. 42.

JUVEDÈRM® products contain a small amount of a local anesthetic called lidocaine to mitigate the pain and discomfort associated with the dermal filler injection. (*Id.* at ¶¶ 8, 10-11)

Allergan maintains the rights to six patents[2] (the "patents-in-suit") directed to HA-based compositions including lidocaine which are used as dermal and subdermal fillers. (D.I. 5 at ¶¶ 12-37) The patents-in-suit cover Allergan's JUVEDÈRM® products, and they claim priority to Provisional Application No. 61/085,956, which was filed by inventor Pierre Lebreton on August 4, 2008. (*Id.* at ¶¶ 41, 59; D.I. 35, Ex. A at 1) The provisional application is directed to HA-based dermal and subdermal fillers including lidocaine gel. (D.I. 35, Ex. A at 1) In the specification, the provisional application identifies several prior art references, including U.S. Application No. 10/743,557 by Sadozai *et al.* ("Sadozai"). (*Id.* at 2) Sadozai describes "a process for making an HA-based composition including lidocaine which includes hydrating dried HA particles with a phosphate buffer containing lidocaine." (*Id.*)

About six months after filing the provisional application, Dr. Lebreton filed U.S. Application No. 12/393,884 ("the '884 application"), which claims priority to the provisional application and is directed to HA-based dermal and subdermal fillers including an anesthetic agent. (D.I. 29 at ¶ 13; D.I. 35, Ex. B) The '884 application is the parent application of the patents-in-suit. (D.I. 29 at ¶ 13) Unlike the provisional application, the specification of the '884 application omits any reference to Sadozai. (D.I. 35, Exs. B & C) However, the applicant disclosed Sadozai in an August 2009 Information Disclosure Statement ("IDS") submitted to the U.S. Patent & Trademark Office ("PTO"). (*Id.*, Ex. H) The examiner initialed the IDS to

[2] The patents-in-suit covering Allergan's JUVEDÈRM® products are United States Patent Nos. 8,450,475, 8,357,795, 8,822,676, 9,089,519, 9,238,013, and 9,358,322.

indicate that he had considered the references listed on it, including the Sadozai reference. (*Id.*, Ex. D)

The examiner rejected the claims of the '884 application as obvious in view of prior art references teaching BDDE-crosslinked HA dermal fillers combined with references teaching the addition of lidocaine to other dermal fillers. (D.I. 29 at ¶ 14; D.I. 26, Ex. A at 5-9) Specifically, the examiner concluded that homogenously combining an HA composition and lidocaine would be obvious to a person of ordinary skill in the art at the time of the invention to anesthetize the tissue at the surgery site. (D.I. 29 at ¶ 15; D.I. 26, Ex. A at 7-8)

In response to the final rejection, Dr. Lebreton submitted a declaration dated May 2, 2012 which alleged that the prior art combinations were not obvious. (D.I. 26, Ex. B) According to Dr. Lebreton, a person of ordinary skill in the art would expect the addition of lidocaine to the HA composition to result in degradation of the HA prior to administration of the injection. (D.I. 29 at ¶¶ 17-18; D.I. 26, Ex. B at ¶ 5) Dr. Lebreton also represented that it was not known at the time whether HA compositions with lidocaine were stable in storage after undergoing high temperature sterilization. (D.I. 29 at ¶¶ 17, 19-20; D.I. 26, Ex. B at ¶¶ 6-7) For these reasons, Dr. Lebreton identified the combination of lidocaine with HA in a stable dermal filler gel as an unexpected result of the '884 application. (D.I. 29 at ¶¶ 22-24; D.I. 26, Ex. B at ¶¶ 9-10, 15) The examiner allowed the '884 application after concluding that Dr. Lebreton's declaration adequately established the existence of unexpected results. (D.I. 29 at ¶¶ 26-27; D.I. 26, Ex. D at 3) The '884 application issued as U.S. Patent No. 8,357,795 ("the '795 patent") on January 22, 2013. (D.I. 29 at ¶ 13, 16)

In December 2018, Prollenium launched a dermal filler product called Revanesse® Versa+, which is an injectable HA gel containing small quantities of lidocaine. (D.I. 5 at ¶ 42; D.I. 29 at ¶ 42) Allergan filed suit on January 22, 2019, alleging that Prollenium's Revanesse® Versa+ dermal filler products infringe the patents-in-suit. (D.I. 1; D.I. 5 at ¶ 44) Prollenium filed its answer, affirmative defenses, and counterclaims on May 6, 2019, alleging, among other things, that the patents-in-suit are unenforceable because they were obtained as a result of inequitable conduct before the PTO. (D.I. 11 at ¶¶ 9-21, 58-64) Allergan subsequently filed a motion to dismiss Prollenium's inequitable conduct counterclaim and affirmative defense, and Prollenium responded by amending its answer and counterclaim. (D.I. 20; D.I. 29) Allergan now moves to dismiss Prollenium's amended counterclaim and affirmative defense for inequitable conduct. (D.I. 34)

III. LEGAL STANDARDS

A. Rule 12(f)

Rule 12(f) permits "[t]he court [to] strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). The court must construe all facts in favor of the nonmoving party and deny the motion unless the defense is clearly insufficient as a matter of law. *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009). "A decision to grant or deny a motion to strike a pleading is vested in the trial court's discretion," but motions to strike under Rule 12(f) are generally disfavored. *Aoki v. Benihana, Inc.*, 839 F. Supp. 2d 759, 764 (D. Del. 2012) (internal citations and quotation marks omitted); *Fesnak & Assocs., LLP v. U.S. Bank Nat'l Ass'n*, 722 F. Supp. 2d 496, 502 (D. Del. 2010).

In this case, Allergan moves to strike Prollenium's affirmative defense of inequitable conduct. Affirmative defenses for inequitable conduct are subject to the heightened pleading standard of Rule 9(b). *See Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013) ("Just as a claim for inequitable conduct must meet the heightened pleading requirements of Rule 9(b), a defendant is also required to plead this affirmative defense with particularity under Rule 9(b)."). Pursuant to the heightened pleading requirement of Rule 9(b), sufficiently pleading an affirmative defense of inequitable conduct requires identification of the "specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009).

B. Rule 12(b)(6)

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and view them in the light most favorable to the plaintiff. *See Umland v. Planco Fin. Servs., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). "Courts use the same standard in ruling on a motion to dismiss a counterclaim under Rule 12(b)(6) as they do in assessing a claim in a complaint." *Goddard Sys., Inc. v. Gondal*, C.A. No. 17-1003-CJB, 2018 WL 1513018, at *4 (D. Del. Mar. 27, 2018).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to "state a claim to relief that

is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555-56.

The court's determination is not whether the non-moving party "will ultimately prevail," but whether that party is "entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal citations and quotation marks omitted). This "does not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the necessary element]." *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). The court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. 663-64.

Allegations of fraud are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). *U.S. ex rel. Whatley v. Eastwick Coll.*, 657 F. App'x 89, 93 (3d Cir. 2016). Under Rule 9(b), a plaintiff must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). This heightened pleading standard was meant to "place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of . . . fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mack Corp.*, 742 F.2d 786, 791 (3d Cir. 1984). Accordingly, the complaint must provide "all of the essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where, and how' of the events at issue."

Whatley, 657 F. App'x at 93 (quoting *In re Rockefeller Ctr. Prop., Inc. Sec. Litig.*, 311 F.3d 198, 215 (3d Cir. 2002)). "The use of boiler plate and conclusory allegations will not suffice." *Kuhn Constr. Co. v. Ocean & Coastal Consultants, Inc.*, 844 F. Supp. 2d 519, 530 (D. Del. 2012) (internal quotation marks and citations omitted). The particularity requirement of Rule 9(b) applies to the affirmative defense of inequitable conduct. *See Senju Pharm.*, 921 F. Supp. 2d at 306.

IV. ANALYSIS

Allergan moves the court to strike Prollenium's fourth affirmative defense and dismiss Count VII of its amended counterclaims for inequitable conduct. (D.I. 34) Inequitable conduct occurs when: (1) a specific individual with a duty of candor to the PTO fails to disclose information or makes an affirmative misrepresentation to the PTO during prosecution of the patent application; (2) the misrepresentation or omission is material to the examiner's decision to allow the patent; and (3) the individual has the specific intent to deceive the PTO. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

A pleading alleging inequitable conduct must satisfy the particularity requirements of Rule 9(b) by setting forth the "who, what, when, where, and how" of the material misrepresentation or omission. *Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). Although Rule 9(b) permits general averments of malice, intent, knowledge, and other conditions of the mind, the pleading must allege sufficient underlying facts to support a reasonable inference that the party acted with the requisite state of mind. *Id.* at 1327. "The relevant 'conditions of mind' for inequitable conduct include: (1) knowledge of . . . the falsity of

the material misrepresentation, and (2) specific intent to deceive the PTO." *Id.* (citing *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

A. Misrepresentations of Material Fact

As a preliminary matter, there is no dispute that the removal of the Sadozai reference from the specification of the '884 application does not amount to an omission of a prior art reference in the context of the inequitable conduct inquiry. (D.I. 35 at 13-14; D.I. 40 at 11-12) Only references withheld from the PTO can constitute an omission amounting to inequitable conduct. *See Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000) (holding that the applicant's disclosure of a prior art reference on the IDS form was sufficient to disclose the reference, and "[a]n applicant is not required to tell the PTO twice about the same prior art, on pain of loss of the patent for inequitable conduct."). Here, it is undisputed that Sadozai and several other prior art references were disclosed in the provisional application, which remained part of the prosecution history before the examiner during prosecution of the '884 application. (D.I. 35, Ex. A at 2-3) It is also undisputed that the Sadozai reference was disclosed in the IDS before the examiner. (*Id.*, Ex. D) Consequently, Prollenium's amended counterclaim for inequitable conduct fails to plead a material omission.

The inequitable conduct counterclaim presently before the court is based on allegedly material misrepresentations in Dr. Lebreton's declaration. *See Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *9 (D. Del. Feb. 3, 2012) (addressing the sufficiency of an inequitable conduct claim based on alleged misrepresentations of the teachings of the prior art, as opposed to the more common failure to disclose relevant prior art). To plead

an actionable material misrepresentation with the requisite particularity under Rule 9(b), the counterclaim must identify the "who, what, when, where, and how" of the material misrepresentation. *Exergen*, 575 F.3d at 1328. Here, the parties dispute whether Prollenium's inequitable conduct counterclaim adequately identifies material misrepresentations regarding the teachings of the prior art in the declaration Dr. Lebreton submitted to the PTO during prosecution of the '884 application.

In support of the motion to dismiss, Allergan alleges that the inequitable conduct counterclaim fails to plead a misrepresentation of the prior art because it does not identify how Dr. Lebreton's declaration contradicts previous representations made by Dr. Lebreton during prosecution of the '884 application. (D.I. 35 at 15; 12/10/19 Tr. at 17:12-17, 16:9-17, 12:6-22) According to Allergan, Prollenium's disagreement with the statements made in Dr. Lebreton's declaration does not turn Dr. Lebreton's statements into material misrepresentations. (12/10/19 Tr. at 10:22-11:3)

In response, Prollenium contends that the pleading identifies affirmative misrepresentations of fact in Dr. Lebreton's declaration about the state of the prior art at the time of the invention and the claimed unexpected results. (D.I. 40 at 11) Prollenium argues that the omission of the prior art references from the specification of the '884 application goes to the specific intent requirement, and is not itself a misrepresentation. (*Id.* at 11-12) Instead, Prollenium emphasizes that Dr. Lebreton's declaration misrepresented the state of the art at the time of the invention by stating that a person of ordinary skill in the art would expect the combination of lidocaine and HA gel compositions to result in degradation of the HA gel prior to injection. (12/10/19 Tr. at 21:22-22:2, 25:5-21)

Prollenium's inequitable conduct counterclaim contains particularized facts identifying the "who" and the "when." *See Easton Tech. Prods., Inc. v. FeraDyne Outdoors, LLC*, C.A. No. 18-1222-RGA, 2019 WL 1513463, at *3 (D. Del. Apr. 8, 2019). The counterclaim identifies Dr. Lebreton by name as the "who" of the misrepresentations. (D.I. 29 at ¶ 17) This allegation satisfies the requirement that "a pleading must name a specific individual associated with the patent application." *See Exergen*, 575 F.3d at 1329. The pleading also adequately asserts the "when" of the misrepresentation by specifying the date Dr. Lebreton submitted his declaration to the PTO, on June 14, 2012. (*Id.* at ¶¶ 24-25); *see Wyeth Holdings Corp.*, 2012 WL 600715, at *9 (finding that the "when" implicates the date the declaration was submitted).

In *Exergen*, the Federal Circuit defined the "what" as the "claims, and [the] limitations in those claims, the [misrepresentations] are relevant to." *Exergen*, 575 F.3d at 1329. Allergan argues that Prollenium's counterclaim fails to identify any specific claims of the '795 patent that would have been affected by the alleged misrepresentations. (D.I. 35 at 14) However, the counterclaim expressly alleges that "the Examiner allowed original claims 23-32, 34-36, 38, 40-50, and 55-67, specifically finding that Lebreton's assertions of unexpected results were sufficient to overcome the rejection." (D.I. 29 at ¶ 26) Thus, the pleading adequately identifies the specific claims of the '795 patent to which the alleged misrepresentations would be material. *See Exergen*, 575 F.3d at 1329.

In a case from this district specifically addressing alleged misrepresentations, the court defined the "what" as "the alleged misrepresentations regarding the state of prior art." *Wyeth*, 2012 WL 600715, at *9. Prollenium's counterclaim identifies a series of alleged misrepresentations regarding the state of the prior art as set forth in Dr. Lebreton's declaration.

(D.I. 29 at ¶¶ 18-24) The counterclaim alleges Dr. Lebreton "argued that a person of skill in the art would not have been motivated to combine these HA dermal fillers with lidocaine because they would have expected that such a combination would have had negative effects, such as unacceptable viscosity reduction and degradation," and he submitted a declaration to the PTO to this effect. (*Id.* at ¶¶ 16-17) Specifically, the counterclaim sets forth Dr. Lebreton's alleged misrepresentations that: (1) adding lidocaine to HA gel compositions caused degradation of the HA prior to injection; (2) lidocaine caused degradation of HA gel compositions during high temperature sterilization; (3) it was not known whether HA compositions containing lidocaine were stable in storage after high temperature sterilization; (4) the instability of HA would have caused a viscosity reduction of the HA, making it unsuitable as a dermal filler; (5) a person of ordinary skill in the art would have expected a dermal filler comprising HA and lidocaine would not remain sufficiently stable for use as a dermal filler; and (6) the heat and shelf stability of HA gels mixed with lidocaine was a surprising and unexpected discovery. (*Id.* at ¶¶ 18-24)

However, the pleaded basis for these alleged misrepresentations is facially inaccurate. The counterclaim alleges that each of these representations is false because, "[a]t the time of the invention, it was well-known to persons of ordinary skill in the art that crosslinked HA-lidocaine fillers performed equally well as, if not better than, crosslinked HA dermal fillers not containing lidocaine." (*Id.* at ¶ 30) In support of this assertion, the counterclaim refers to Dr. Lebreton's provisional application, representing that Dr. Lebreton "admitted that [Sadozai] disclosed that adding lidocaine to crosslinked HA dermal fillers performed equally well as crosslinked HA dermal fillers without lidocaine." (*Id.* at ¶ 31)

This representation conflicts with the language of the provisional application itself, which the court may consider as a matter of public record. *See Sound View Innovations, LLC v. Facebook, Inc.*, 204 F. Supp. 3d 655, 658 (D. Del. 2016) (concluding that the court may take judicial notice of the prosecution history, which is a matter of public record). In the provisional application, Dr. Lebreton stated that Sadozai "discloses a process for making an HA-based composition including lidocaine which includes hydrating dried HA particles with a phosphate buffer containing lidocaine." (D.I. 35, Ex. A at 2) Contrary to the allegations in Prollenium's inequitable conduct counterclaim, Dr. Lebreton's summary of the Sadozai reference in the provisional application makes no representations about the efficacy of HA dermal fillers with or without lidocaine, and it does not discuss the heat or shelf stability, or the viscosity, of HA gel compositions containing lidocaine. (D.I. 35, Ex. A at 2; 12/10/19 Tr. at 10:1-21)

The inequitable conduct counterclaim also fails to identify with specificity "where" in the misrepresented prior art references the material information is found. *See Exergen Corp.*, 575 F.3d at 1329; *see also Wyeth*, 2012 WL 600715, at *9. The pleading represents that HA dermal fillers containing lidocaine were known in the art at the time of the invention, and it discloses a list of nine prior art references and practices. (D.I. 29 at ¶¶ 10-12) But the pleading fails to associate these prior art references with the alleged misrepresentations in Dr. Lebreton's declaration regarding the viscosity reduction and degradation of HA gel compositions in response to high temperature sterilization and storage.[3] Moreover, the pleading makes no assertion about what is disclosed in the Sadozai reference, apart from its inaccurate

[3]During oral argument, counsel for Prollenium represented that Prollenium "can allege in more detail that Lebreton and his team knew about the other products that we have already alleged were in the market, knew about many scientific studies that pre-exist the patent in his declaration." (12/10/19 Tr. at 39:2-6)

representation about how the provisional application describes the Sadozai reference. This failure to "explain where in the . . . prior art references the information material to the Patents-in-Suit can be found" is fatal to the counterclaim. *Easton*, 2019 WL 1513463, at *4.

B. Materiality

To satisfy the materiality requirement at the pleadings stage, the party pleading inequitable conduct must explain "why" the misrepresentation is material, and "how" the examiner would have used the information in reaching a patentability determination. *See Front Row Techs., LLC v. NBA Media Ventures, LLC*, 163 F. Supp. 3d 938, 983 (D.N.M. 2016) (quoting *Exergen*, 575 F.3d at 1329). "[A]s a general matter, the materiality required to establish inequitable conduct is but-for materiality." *Therasense*, 649 F.3d at 1291.

Allergan contends Prollenium's inequitable conduct counterclaim does not adequately plead that the examiner would not have allowed the '884 application but for the submission of Dr. Lebreton's declaration. Specifically, Allergan argues that the counterclaim fails to allege the Sadozai reference is not cumulative of prior art references already considered by the examiner.[4] (D.I. 35 at 15-16) According to Allergan, the counterclaim does not identify particular claim limitations in Sadozai that are otherwise absent from the prior art references discussed by the examiner to show how the examiner would have rejected the '884 application in view of Sadozai. (*Id.*)

Prollenium contends that its inequitable conduct counterclaim sufficiently alleges that, but for the statements made in Dr. Lebreton's declaration, the examiner would not have allowed

[4] The examiner's § 103 rejection and subsequent notice of allowance discuss the Wang (U.S. Patent Application Publication No. 2005/0271729), Calias (U.S. Patent No. 6,521,223), and Lebreton (U.S. Patent Application Publication No. 2006/0194758) references. (D.I. 35 at 16; Ex. G at 3; D.I. 26, Ex. A at 5-9)

the claims of the '884 application to issue. (D.I. 40 at 14) Prollenium cites the examiner's notice of allowance showing that the examiner only allowed the claims of the '884 application after considering Dr. Lebreton's declaration alleging unexpected results. (*Id.* at 14-15)

Prollenium's inequitable conduct counterclaim satisfies the pleading standard with respect to materiality because it alleges that, but for Dr. Lebreton's allegedly false declaration, the PTO would not have allowed the '884 application to issue:

> As a result of the Inventor Declaration as well as the Applicant's related arguments, on August 6, 2012, the Examiner allowed original claims 23-32, 34-36, 38, 40-50, and 55-67, specifically finding that Lebreton's assertions of unexpected results were sufficient to overcome the rejection. . . . In other words, but for the statements made in the Declaration by Lebreton, the Examiner would not have allowed, and in fact had already rejected, the above-mentioned claims.

(D.I. 29 at ¶ 26) The allegations in the counterclaim are supported by the prosecution history of the '884 application, which was incorporated by reference into Prollenium's pleading. (D.I. 26, Ex. D) Specifically, the examiner's notice of allowance confirms that the examiner withdrew the § 103 rejection "in view of the claim amendments and unexpected results presented by Applicant." (*Id.* at 3) The examiner cited the understanding of a person of ordinary skill in the art, consistent with Dr. Lebreton's declaration, in outlining the reasons for allowance:

> The following is an examiner's statement of reasons for allowance: Applicant argues that one of ordinary skill in the art would have expected degradation of the hyaluronic acid gel with addition of lidocaine during sterilization, as this was what was known in the prior art. Applicant unexpectedly found that a hyaluronic acid gel crosslinked, but not with a non-hyaluronic acid biopolymer, mixed with lidocaine and sterilized does not degrade.

(D.I. 26, Ex. D at 4) The examiner's description of the applicant's understanding of the state of the art at the time of the invention corresponds with the representations in Dr. Lebreton's

declaration that a person of ordinary skill in the art would have expected degradation of an HA composition containing lidocaine. (D.I. 26, Ex. B at ¶¶ 5-10, 15)

Allergan's focus on the Sadozai reference in relation to materiality is misplaced. The alleged misrepresentations were made in Dr. Lebreton's declaration. The counterclaim alleges, and the evidence shows, that the examiner relied on Dr. Lebreton's declaration in allowing the '884 application. The Sadozai reference is primarily relevant to show Dr. Lebreton's knowledge about the state of the prior art at the time he made his declaration—Dr. Lebreton disclosed the Sadozai reference in the provisional application, and Sadozai describes a crosslinked HA composition containing lidocaine. (D.I. 35, Ex. A at 2) In contrast, the materiality analysis focuses on the examiner's reasons for allowance. *See Therasense*, 649 F.3d at 1291.

C. Specific Intent

Allergan contends that the inequitable conduct counterclaim contains only conclusory allegations regarding Dr. Lebreton's intent to deceive the PTO. (D.I. 35 at 16) Allergan further argues that Dr. Lebreton's disclosure of the Sadozai reference in the provisional application and the IDS undercuts Prollenium's assertion that Dr. Lebreton intentionally misrepresented the state of the art to the examiner during prosecution, and the pleading does not allege that Dr. Lebreton removed the Sadozai reference or considered its disclosure when he drafted his declaration. (*Id.* at 16-17)

In response, Prollenium contends that Dr. Lebreton knew he was submitting a false declaration to the PTO because he was a named inventor on the provisional application discussing the Sadozai reference, which discloses a shelf-stable HA-based composition including lidocaine. (D.I. 40 at 17) Accordingly, Prollenium alleges Dr. Lebreton knew that adding

lidocaine to crosslinked HA compositions was achieved in the prior art without degradation of the dermal filler prior to injection. (*Id.* at 17-18) Prollenium's inequitable conduct counterclaim states that Dr. Lebreton deliberately removed mention of the Sadozai reference from the '884 application's specification. (*Id.* at 18)

"[T]o adequately plead the intent prong of an inequitable conduct defense, the claimant need only allege facts from which the Court could *reasonably infer* that the patent applicant made a deliberate decision to deceive the PTO." *Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *7 (D. Del. Feb. 3, 2012) (emphasis in original). The allegations must nonetheless meet the particularity standard of Rule 9(b), and the facts must support a plausible inference that the claim will ultimately satisfy the clear and convincing burden of proof. *See Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, C.A. No. 17-275-LPS, C.A. No. 17-1353-LPS, 2019 WL 668843, at *2 (D. Del. Feb. 19, 2019).

Prollenium's inequitable conduct counterclaim fails to adequately allege specific intent. The counterclaim alleges that Dr. Lebreton's provisional application describes the Sadozai reference, but Dr. Lebreton removed the description of the Sadozai reference from the specification of the '884 application before submitting his declaration describing the state of the art at the time of the invention. (D.I. 29 at ¶ 31) According to Prollenium's counterclaim, "[t]he Applicant's removal of what was known in the prior art from U.S. Application No. 12/393,884 demonstrates . . . that Lebreton knew information contrary to the statements he made in his declaration and that the misrepresentations in the Inventor Declaration and the related assertions by the Applicant were made with the intent to deceive the Patent Office." (*Id.* at ¶ 32; *see also* ¶¶ 72-73)

These allegations do not support a reasonable inference of the specific intent required to support an inequitable conduct claim. Prollenium's pleading fails to acknowledge or explain why Dr. Lebreton submitted an IDS disclosing the Sadozai reference after he removed it from the specification of the '884 application if his intent was to deceive the PTO by removing the reference.[5] (D.I. 35, Ex. H) The undisputed facts are that Dr. Lebreton removed the discussion of the Sadozai reference from the '884 application when the application was filed in February 2009, more than three years before he signed his declaration. (D.I. 35, Ex. C; D.I. 26, Ex. B) The undisputed facts further demonstrate that Dr. Lebreton disclosed the Sadozai reference as prior art in an IDS submitted to the PTO in August 2009, after he removed mention of the Sadozai reference from the '884 application, but before he signed and submitted his declaration. (D.I. 35, Ex. H) Counsel for Prollenium conceded at oral argument that there is no requirement to disclose in a nonprovisional application all prior art references disclosed in the preceding provisional application. (12/10/19 Tr. at 23:1-9) Thus, removal of the Sadozai reference from the '884 application does not inherently suggest inequitable conduct, and Dr. Lebreton's subsequent disclosure of the Sadozai reference in the IDS suggests that he lacked the specific intent to misrepresent his understanding of the prior art to the PTO.

Also, the inequitable conduct counterclaim does not establish with particularity that Dr. Lebreton's understanding of the prior art mirrors Prollenium's conclusory assertions regarding

[5] The court may consider the prosecution history of the '884 application on a motion to dismiss because it is a matter of public record. "In deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010). "A court may also take judicial notice of the prosecution histories, which are 'public records.'" *Sound View Innovations, LLC v. Facebook, Inc.*, 204 F. Supp. 3d 655, 658 (D. Del. 2016) (quoting *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526 (D. Del. 2014), *aff'd sub nom. Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016)).

the state of the prior art. (D.I. 29 at ¶¶ 18-24) As previously stated at § IV.A, *supra*, Dr. Lebreton's brief and general description of the Sadozai reference in the provisional application does not directly contradict the representations made in his declaration regarding the state of the prior art. (D.I. 35, Ex. A at 2; D.I. 26, Ex. B at ¶¶ 5-10) In fact, Dr. Lebreton cites his own experiments in his declaration, which show that "certain HA gels, when mixed with lidocaine, degraded and became substantially less viscous after high temperature sterilization." (D.I. 26, Ex. B at ¶ 13) Prollenium's counterclaim fails to establish with particularity that Dr. Lebreton understood the prior art to overcome the problems with viscosity and stability as noted in his own experiments.

Absent allegations reconciling the chronology of events and providing more specifics regarding Dr. Lebreton's understanding of Sadozai and other prior art references, it is not reasonable to infer that Dr. Lebreton intended to deceive the PTO by way of his declaration. For this reason, I recommend that the court grant Allergan's motion to dismiss.

D. Affirmative Defense

I recommend that the court grant Allergan's motion to strike Prollenium's fourth affirmative defense of inequitable conduct. Just as a counterclaim for inequitable conduct must meet the heightened pleading standard of Rule 9(b), a defendant is also "required to plead this affirmative defense with particularity under Rule 9(b)." *See Bayer CropScience AG v. Dow AgroSciences* LLC, C.A. No. 10-1045-RMB, 2011 WL 6934557, at *3 (D. Del. Dec. 30, 2011). As a result, Prollenium's "counterclaim and affirmative defense of inequitable conduct rise or fall together." *See Courtesy Prods. L.L.C. v. Hamilton Beach Brands, Inc.*, C.A. No. 13-2012-SLR-SRF, 2015 WL 6159113, at *5 (D. Del. Oct. 20, 2015) (citing *XpertUniverse, Inc. v. Cisco*

Sys., Inc., 868 F. Supp. 2d 376, 379-83 (D. Del. 2012); *Southco, Inc. v. Penn Eng'g & Mfg. Corp.*, 768 F. Supp. 2d 715, 721-24 (D. Del. 2011)).

V. CONCLUSION

For the foregoing reasons, I recommend that the court grant Allergan's motion to dismiss Count VII of Prollenium's counterclaims for inequitable conduct and grant Allergan's motion to strike Prollenium's fourth affirmative defense of inequitable conduct without prejudice. (D.I. 34)

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objection and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: December 30, 2019

Sherry R. Fallon
United States Magistrate Judge