

**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
	)	
PROLLENIUUM US INC. and	)	
PROLLENIUUM MEDICAL	)	
TECHNOLOGIES INC.,	)	
	)	
Defendants.	)	

**MEMORANDUM OPINION**

**I. INTRODUCTION**

Presently before the court in this patent infringement action is the motion of defendants Prolleium US Inc. and Prolleium Medical Technologies Inc. (“Prolleium”) for leave to amend the amended answer and counterclaim.<sup>1</sup> (D.I. 62) For the following reasons, I recommend that the court GRANT Prolleium’s motion to amend.

**II. BACKGROUND**

Allergan develops, manufactures, and distributes a line of dermal fillers under the JUVEDÈRM® mark. (D.I. 5 at ¶ 39) Allergan’s Juvedèrm products are injectable hyaluronic acid (“HA”) gels crosslinked with 1,4-butanediol diglycidyl ether (“BDDE”). (D.I. 62, Ex. 1 at ¶¶ 8, 40) The 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, 26) Allergan

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<sup>1</sup> The briefing for the pending motion can be found at D.I. 63, D.I. 66, and D.I. 68.

maintains the rights to six patents<sup>2</sup> (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 Juvederm products. (*Id.* at ¶¶ 41, 59)

On August 4, 2008, inventor Pierre Lebreton filed Provisional Application No. 61/085,956, which is directed to HA-based dermal and subdermal fillers including lidocaine gel. (D.I. 62, Ex. 1 at ¶ 108) Dr. Lebreton subsequently filed U.S. Application No. 12/393,884 (“the ’884 application”) in February 2009, which claims priority to the provisional application and is directed to HA-based dermal and subdermal fillers including an anesthetic agent. (*Id.* at ¶ 110) The ’884 application is the parent application of the patents-in-suit. (*Id.*) The examiner rejected the claims of the ’884 application as obvious in view of prior art references teaching crosslinked-HA dermal fillers combined with references teaching the possibility of adding lidocaine to other dermal fillers. (*Id.* at ¶ 112) Specifically, the examiner concluded that homogeneously 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. (*Id.* at ¶ 114)

In response to the final rejection, Dr. Lebreton submitted a declaration dated May 2, 2012 alleging that the prior art combination was not obvious. (*Id.* at ¶ 121) According to Dr. Lebreton, a person of ordinary skill in the art would anticipate that adding lidocaine to the HA composition would result in the degradation of the HA prior to administration of the injection. (*Id.* at ¶¶ 121-22) 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. (*Id.* at ¶ 121) For these reasons, Dr. Lebreton identified the combination of

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<sup>2</sup> The patents covering Allergan’s Juvederm 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 (collectively, the “patents-in-suit”).

lidocaine with HA in a stable dermal filler gel as an unexpected result of the '884 application. (*Id.* at ¶¶ 128-29) The examiner allowed the '884 application after concluding that Dr. Lebreton's declaration adequately established the existence of unexpected results. (*Id.* at ¶¶ 140-41) The '884 application issued as U.S. Patent No. 8,357,795 ("the '795 patent") on January 22, 2013. (*Id.* at ¶ 110)

In December 2018, Prolenium launched a dermal filler product called Revanesse® Versa+, which is an injectable HA gel containing small quantities of lidocaine. (D.I. 5 at ¶ 42) Allergan filed suit on January 22, 2019, alleging that Prolenium's Revanesse® Versa+ dermal filler products infringe the patents-in-suit. (D.I. 1; D.I. 5 at ¶ 44) Prolenium filed its answer, affirmative defenses, and counterclaims on May 6, 2019, alleging that the patents-in-suit are unenforceable because they were obtained as a result of inequitable conduct before the United States Patent and Trademark Office ("USPTO"). (D.I. 11 at ¶¶ 9-21, 58-64)

Allergan moved to dismiss Prolenium's inequitable conduct counterclaim and strike the affirmative defense, and Prolenium responded by amending its answer and counterclaim. (D.I. 20; D.I. 29) Again, Allergan moved for dismissal of Prolenium's amended pleading. (D.I. 34) The court issued a Report and Recommendation on December 30, 2019 recommending dismissal of the inequitable conduct counterclaim without prejudice. (D.I. 55) The District Judge adopted the Report and Recommendation. (D.I. 61) Prolenium now moves for leave to file its second amended answer and counterclaims ("SACC"). (D.I. 62)

### **III. LEGAL STANDARD**

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that a party may amend its pleading after a responsive pleading has been filed "only with the opposing party's written consent or the court's leave," and "[t]he court should freely give leave when justice so requires."

Fed. R. Civ. P. 15(a)(2). The decision to grant or deny leave to amend lies within the court's discretion. See *Foman v. Davis*, 371 U.S. 178, 182 (1962); *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). The Third Circuit has adopted a liberal approach to the amendment of pleadings. See *Dole v. Arco*, 921 F.2d 484, 486-87 (3d Cir. 1990). In the absence of undue delay, bad faith, or dilatory motives on the part of the moving party, the amendment should be freely granted, unless it is futile or unfairly prejudicial to the non-moving party. See *Foman*, 371 U.S. at 182; *In re Burlington*, 114 F.3d at 1434.

“An amendment is futile if it is frivolous, fails to state a claim upon which relief can be granted, or ‘advances a claim or defense that is legally insufficient on its face.’” *Intellectual Ventures I LLC v. Toshiba Corp.*, C.A. No. 13-453-SLR-SRF, 2015 WL 4916789, at \*2 (D. Del. Aug. 17, 2015) (quoting *Koken v. GPC Int'l, Inc.*, 443 F. Supp. 2d 631, 634 (D. Del. 2006)). The standard for analyzing futility of an amendment under Rule 15(a) is the same standard of legal sufficiency applicable under Rule 12(b)(6). *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000). Specifically, the amended pleading must fail to state a claim upon which relief could be granted even after the district court “take[s] all pleaded allegations as true and view[s] them in a light most favorable to the plaintiff.” *Winer Family Trust v. Queen*, 503 F.3d 319, 331 (3d Cir. 2007); see also *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 175 (3d Cir. 2010).

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 heightened pleading requirements of Rule 9(b) apply to causes of action for inequitable conduct. *See Senju Pharm.*, 921 F. Supp. 2d at 306 (applying Rule 9(b) standard to inequitable conduct).

#### **IV. ANALYSIS**

Prolenium moves the court for leave to amend its fourth affirmative defense and Count VII of the SACC for inequitable conduct. (D.I. 62) Inequitable conduct occurs when: (1) a specific individual with a duty of candor to the USPTO fails to disclose information or makes an affirmative misrepresentation to the USPTO 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 USPTO. *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. Material Misrepresentation**

Allergan contends that Prolenium’s proposed SACC does not identify a material misrepresentation by Dr. Lebreton sufficient to satisfy the “what” and “where” requirements of inequitable conduct. (D.I. 66 at 9) According to Allergan, the SACC fails to explain how Dr. Lebreton’s statements regarding the degradation of HA gel compositions during high temperature sterilization and long-term storage constitute a misrepresentation of the prior art. (*Id.* at 10) Instead, Allergan argues that these statements demonstrate Dr. Lebreton’s understanding of the state of the art at the time. (*Id.* at 10-11)

Prolenium argues that the SACC shows in detail how Dr. Lebreton made statements in his declaration to overcome the examiner’s obviousness rejections, despite knowing that those statements were false based on his understanding of the prior art. (D.I. 68 at 1-2) Prolenium contends that the SACC identifies high-temperature sterilization in an autoclave as the standard sterilization method for dermal fillers at the time, and it shows that a person of ordinary skill in the art would have expected prior art products containing lidocaine to be sterilized in this manner. (*Id.* at 4; D.I. 63 at 15)

The SACC adequately pleads that Dr. Lebreton misrepresented the state of the prior art in his declaration with respect to the stability and sterility of prior art HA compositions containing

lidocaine. (D.I. 62, Ex. 1 at ¶¶ 121-130) In his declaration, Dr. Lebreton represented that “[i]t was believed that lidocaine caused degradation of HA gel compositions during high temperature sterilization,” and “[i]t was not known whether HA compositions comprising lidocaine were stable or not after high temperature sterilization when placed in storage for any significant length of time.” (D.I. 62, Ex. 1 at Ex. A, ¶¶ 6-7) But the SACC cites more than one example of prior art products that could not have achieved regulatory approval without first undergoing heat sterilization and exhibiting shelf stability. (D.I. 62, Ex. 1 at ¶¶ 28-31) As discussed further at § IV.B, *infra*, the SACC also alleges that Dr. Lebreton was personally aware of the heat- and shelf-stability of crosslinked-HA products containing lidocaine due to his participation in an internal Allergan report in 2005 showing that “such a product could be sterilized in an autoclave without deterioration or degradation.” (*Id.* at ¶¶ 47-48; *see also* ¶¶ 63, 75-76)

Allergan challenges the sufficiency of Prolenium’s assertions made “on information and belief” regarding the standard sterilization methods at the time, particularly with respect to the Puragen Plus product available in 2005 as “a soft tissue dermal filler comprising hyaluronic acid including lidocaine.” (D.I. 66 at 12; D.I. 62, Ex. 1 at ¶ 59) The SACC suggests that, “on information and belief, Puragen Plus was heat sterilized” because “[h]eat sterilization in an autoclave was, in 2005, and remains today, the standard sterilization method for dermal fillers.” (*Id.*) But the Federal Circuit has held that “[p]leading on ‘information and belief’ is permitted under Rule 9(b) when essential information lies uniquely within another party's control,” so long as “the pleading sets forth the specific facts upon which the belief is reasonably based.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1330 (Fed. Cir. 2009). The SACC satisfies this standard by specifying that heat sterilization in an autoclave was, and is, the standard sterilization

method for dermal fillers. (D.I. 62, Ex. 1 at ¶ 59) Taking this factual allegation as true at this stage of the proceedings, it is reasonable to infer that Puragen Plus was heat sterilized in 2005.

In further support of the SACC, Prolenium contends that the prior art products containing lidocaine were FDA-approved, suggesting that there were no deficiencies in the sterility or stability of those products. (D.I. 63 at 13-14; D.I. 68 at 4-5) But Allergan responds that the SACC does not show how the FDA's regulatory stability and sterility requirements contradict the statements made in Dr. Lebreton's declaration. (D.I. 66 at 12-13) According to Allergan, an inventor may improve upon the stability of an existing product even if that product is otherwise sufficiently stable to obtain regulatory approval. (*Id.* at 13)

The SACC alleges "[a] person of ordinary skill in the art would understand that in order to obtain FDA approval for the products described above, it would have been necessary for these lidocaine-containing crosslinked-HA dermal fillers to be sterile and stable." (D.I. 62, Ex. 1 at ¶ 29; *see also* ¶¶ 10-15, 30-31) These allegations support the reasonable inference that prior art crosslinked-HA dermal fillers containing lidocaine were sufficiently heat- and shelf-stable to receive FDA approval before August 2008. This is enough to suggest that statements made in Dr. Lebreton's declaration regarding the degradation of crosslinked-HA gel compositions containing lidocaine were false. (D.I. 62, Ex. 1 at Ex. A, ¶¶ 5-7) Even if Dr. Lebreton's invention represented an improvement in the stability of crosslinked-HA dermal fillers containing lidocaine over the prior art products, the statements made in Dr. Lebreton's declaration go beyond suggesting a mere improvement in the sterility and stability of dermal fillers containing lidocaine. (*Id.*) Instead, Dr. Lebreton's declaration represents that stable HA compositions containing lidocaine were not yet known to be possible: "It was not known whether HA compositions comprising lidocaine were stable or not after high temperature sterilization



when placed in storage for any significant length of time.” (*Id.* at ¶ 7) Drawing all reasonable inferences in favor of Prollenium, the court concludes that the SACC’s allegations regarding FDA approval further bolster the assertion that Dr. Lebreton falsely represented the state of the prior art in his declaration.

Finally, Allergan argues that documents regarding Dr. Lebreton’s internal testing do not support Prollenium’s position that the statements made in Dr. Lebreton’s declaration were false, and Prollenium’s disagreement with Dr. Lebreton’s assessment of the state of the art is a validity argument that does not amount to inequitable conduct. (D.I. 66 at 14-15) But Prollenium notes that Dr. Lebreton’s laboratory testing showed the feasibility of incorporating lidocaine into existing HA dermal fillers in 2005, long before the relevant August 2008 timeframe. (D.I. 63 at 19) According to Prollenium, the results of Dr. Lebreton’s 2005 studies showing stability and lack of degradation in lidocaine-containing dermal fillers after high-temperature sterilization contradict the statements made in his declaration regarding stability and viscosity reductions resulting from the addition of lidocaine. (*Id.* at 20)

The SACC adequately alleges that the actual results of Dr. Lebreton’s experiments do not support the statements subsequently made in his declaration. (D.I. 62, Ex. 1 at ¶¶ 131-135) While Dr. Lebreton’s declaration suggests that mixing lidocaine in a shelf- and heat-stable HA gel was a surprising and unexpected discovery, (D.I. 62, Ex. 1 at Ex. A, ¶¶ 13-15), the SACC explains that the first sample in the experiment was an irrelevant uncrosslinked-HA mixture, and the remaining two samples did not show a loss in viscosity with the addition of lidocaine, (*id.*, Ex. 1 at ¶ 134). Any factual disputes regarding the SACC’s characterization of the testing results are not appropriately resolved at this stage of the proceedings. Based on the allegations made in

the SACC, it is reasonable to infer that Dr. Lebreton's description of his experiments in his declaration are contradicted by the results of the experiments themselves.

Assuming the truth of the factual allegations made in the SACC, it is reasonable to infer that Dr. Lebreton misrepresented the state of the prior art in his declaration to obtain allowance of the patent application. Drawing all reasonable inferences in favor of Prolenium, the SACC adequately pleads that the sterility and stability of prior art crosslinked-HA dermal fillers with lidocaine contradict the statements in Dr. Lebreton's declaration regarding the degradation of HA gel compositions containing lidocaine.

### **B. Specific Intent**

Allergan further contends that Prolenium's SACC makes only conclusory allegations that Dr. Lebreton knowingly acted with the specific intent to deliberately deceive the USPTO. (D.I. 66 at 16-17) According to Allergan, the SACC fails to allege Dr. Lebreton personally knew of invalidating prior art products and withheld that information from the USPTO, and instead the allegations amount to an invalidity argument rooted in Prolenium's disagreement with the statements made in Dr. Lebreton's declaration. (*Id.* at 17-18) Allergan explains that Dr. Lebreton's laboratory testing in 2005 reflects the inventor's own work in developing the claimed invention. (*Id.* at 19)

Prolenium contends that the allegations in the SACC support a reasonable inference that Dr. Lebreton knowingly intended to deceive the USPTO by showing that he was a person of ordinary skill in the art who also had actual, personal knowledge of the successful incorporation of lidocaine into prior art crosslinked-HA dermal fillers. (D.I. 63 at 17-19, 21; D.I. 68 at 9) Moreover, Prolenium argues that Dr. Lebreton's laboratory testing showed the feasibility of incorporating lidocaine into existing HA dermal fillers without degradation as early as 2005,

contradicting the representation in his declaration regarding the state of the art “shortly prior to August 4, 2008.” (D.I. 63 at 19-20; D.I. 62, Ex. 1 at Ex. A, ¶ 4)

The SACC adequately pleads that Dr. Lebreton had the requisite knowledge and specific intent to deceive the USPTO by submitting his false declaration. Both the SACC and Dr. Lebreton’s own declaration confirm that Dr. Lebreton is a person of ordinary skill in the art who should have been aware of the relevant prior art references described in the SACC showing the sterility and stability of HA compositions containing lidocaine. (D.I. 62, Ex. 1 at ¶¶ 36-43, 85, 87-89, 97-107; *see also* Ex. 1 at Ex. A at ¶ 4 (“I am familiar with the state of the art related to soft tissue fillers comprising crosslinked hyaluronic acid (‘HA’) shortly prior to August 4, 2008.”)). The SACC alleges that, as a person of ordinary skill in the art, Dr. Lebreton did not believe at the time of his declaration that adding lidocaine to HA gel compositions caused degradation of the HA or was otherwise not feasible. (D.I. 62, Ex. 1 at ¶¶ 122(a)-128(a)) To the contrary, the SACC confirms that a person of ordinary skill in the art would understand that lidocaine had already been successfully combined with crosslinked-HA dermal fillers. (*Id.* at ¶¶ 122(e)-128(e))

The SACC also establishes Dr. Lebreton’s personal familiarity with prior art crosslinked-HA dermal fillers containing lidocaine. (D.I. 62, Ex. 1 at ¶¶ 44-81) Specifically, the SACC describes a September 12, 2005 email from Dr. Lebreton acknowledging the “launch of the first hyaluronic acid-based product (PURAGEN Plus) to incorporate an anaesthetic, [sic],” and discussing plans to counter the launch of Puragen Plus by “incorporat[ing] lidocaine into the products of the SURGIDERM line.” (*Id.* at ¶ 53; *see also* ¶¶ 52, 54-55) Dr. Lebreton again acknowledged Puragen Plus as “the only hyaluronic acid-based product on the market in Canada that is formulated with an anesthetic for improved patient comfort” in a December 2005 email.

(*Id.* at ¶ 57; *see also* ¶¶ 56, 58-59) The SACC describes similar communications from Dr. Lebreton confirming his knowledge of other lidocaine-containing crosslinked-HA dermal fillers prior to August 2008. (*Id.* at ¶¶ 60-70) Communications by Dr. Lebreton made after August 2008, but before he signed and submitted his declaration to the USPTO, confirm that he had actual knowledge of crosslinked-HA products with lidocaine that were “widely utilized” before August 2008. (*Id.* at ¶¶ 71-81)

The allegations in the SACC regarding Dr. Lebreton’s own experiments and tests further support a reasonable inference that Dr. Lebreton intended to mislead the USPTO in his declaration. The SACC alleges that Dr. Lebreton’s experiments were performed in 2005, and those experiments showed that lidocaine could be successfully incorporated into products containing crosslinked-HA. (D.I. 62, Ex. 1 at ¶¶ 45-48, 122(c)) These facts give rise to a reasonable inference that Dr. Lebreton knew his declaration that such results amounted to a “surprising and unexpected discovery” three years later in August 2008 was false. (D.I. 62, Ex. 1 at Ex. A, ¶ 15) Based on the allegations made in the SACC, it is reasonable to infer that Dr. Lebreton misrepresented the results of his experiments with the specific intent to deceive the USPTO. *See Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1327 (Fed. Cir. 2009).

The allegations in the SACC regarding Dr. Lebreton’s experiments, the relevant prior art products, and Dr. Lebreton’s familiarity with those prior art products as a person of ordinary skill in the art support Prollenium’s position that its inequitable conduct counterclaim is more than a thinly veiled invalidity argument. Allergan stresses that the “mere fact that a patent applicant attempts to distinguish its patent from the prior art does not constitute a material omission or misrepresentation where the patent examiner has the prior art before him or her.” *Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, C.A. No. 17-275-LPS, 2019 WL

668843, at \*3 (D. Del. Feb. 19, 2019). Nonetheless, the facts alleged in the SACC suggest that Dr. Lebreton knew of several prior art crosslinked-HA products containing lidocaine at the time he represented in his declaration that “it was a surprising and unexpected discovery, not appreciated prior to the present invention, that certain cohesive HA gels, as defined in the application, when mixed with lidocaine, could be made to be heat and shelf stable.” (D.I. 62, Ex. 1 at Ex. A, ¶ 15) Far from repackaging an invalidity argument, these facts lead to the reasonable inference that Dr. Lebreton submitted his declaration with the intention of deliberately misleading the USPTO regarding the state of the prior art at the time of the invention. *See Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at \*7 (D. Del. Feb. 3, 2012) (“[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.”); *see also Zadro Prods. v. SDI Techs., Inc.*, C.A. No. 17-1406-WCB, 2019 WL 1100470, at \*5 (D. Del. Mar. 8, 2019) (“In this district, an inequitable conduct claim is rarely disallowed at the pleading stage due to the failure to adequately allege scienter.”).

In accordance with the foregoing analysis, the SACC sufficiently pleads material misrepresentations made by Dr. Lebreton in his declaration, and it adequately alleges that he had the specific intent to mislead the USPTO to obtain issuance of the patent. Having adequately pleaded a counterclaim for inequitable conduct, Prolenium’s SACC is not futile.

## **V. CONCLUSION**

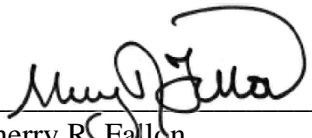
For the foregoing reasons, I recommend that the court GRANT Prolenium’s motion for leave to amend its answer and counterclaim. (D.I. 62)

Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Opinion under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Opinion should be redacted, the parties shall jointly submit a proposed redacted version by no later than **April 22, 2020**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would “work a clearly defined and serious injury to the party seeking closure.” *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within thirty (30) days of the date the Memorandum Opinion issued.

This Memorandum Opinion is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Opinion. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to ten (10) pages each.

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: April 15, 2020

  
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Sherry R. Fallon  
United States Magistrate Judge