

defense of inequitable conduct under FED. R. CIV. P. 12(f).² The court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under 35 U.S.C. § 1 *et seq.*,³ and personal jurisdiction over defendant, who is a Delaware corporation.⁴ Venue is proper under 28 U.S.C. §§ 1391(c) and 1400(b).⁵ This Report and Recommendation is issued pursuant to 28 U.S.C. § 636(b)(1)(B), FED. R. CIV. P. 72(b)(1), and D. DEL. LR 72.1.⁶ For the reasons stated below, it is recommended that plaintiff's motion be denied.

II. BACKGROUND

A. Parties

Plaintiff is a corporation organized and existing under the laws of the State of Maryland, with its principal place of business in Rehoboth, Delaware.⁷ Defendant is a Delaware corporation, with its principal place of business in Summit, New Jersey.⁸

B. Patent-in-suit

Plaintiff asserts that it currently holds and has held all rights to the patent-in-suit

² See D.I. 86 at 1.

³ See 28 U.S.C. § 1331 (federal question jurisdiction); § 1338(a) (“The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . .”).

⁴ See *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 482 (1985) (finding personal jurisdiction where the defendant “availed himself of the benefits and protections” of the forum’s laws).

⁵ 28 U.S.C. § 1391(c) (“[A]n entity . . . , whether or not incorporated, shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court’s personal jurisdiction with respect to the civil action”); § 1400(b) (“Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.”).

⁶ 28 U.S.C. § 636(b)(1)(B); FED. R. CIV. P. 72(b)(1); D. DEL. LR 72.1.

⁷ D.I. 79, counterclaims ¶ 2.

⁸ *Id.* at ¶ 1.

by assignment from inventors Peter J. Andrulis, Jr. (“Andrulis”) and Murray W. Drulak (“Drulak”) since the issuance of the ‘346 patent’s from the United States Patent and Trademark Office (“PTO”) on October 31, 2000.⁹ The ‘346 patent, titled “Treatment of Cancer with Thalidomide Alone or in Combination with Other Anti-Cancer Agents,” claims a “novel method for the treatment of certain cancers, including multiple myeloma, which comprises administering therapeutically-effective amounts of the drug thalidomide in combination with an alkylating agent,” such as cisplatin or carboplatin.¹⁰

During the review of the corresponding application (“‘813 application”) of the ‘346 patent, the examiner initially rejected claims “directed to a combination of thalidomide and cisplatin (an alkylating agent) as obvious over U.S. Patent No. 5,399,363 to Liversidge *et al.* (‘Liversidge’),” which disclosed that “anticancer agents can be used . . . in combination” and that thalidomide and cisplatin are among the anticancer agents.¹¹ The examiner concluded that evidence demonstrating a “greater than additive effect” was necessary to overcome the obviousness rejection.¹²

In response to the Office Action, the claims were amended to require an “enhanced effective amount” of thalidomide. Appendix A was attached to the Response to illustrate “the success of thalidomide in combination with anticancer agents” in a way not taught by the Liversidge Patent.¹³ Appendix A included the

⁹ D.I. 12 ¶¶ 12-13.

¹⁰ *Id.* at ¶¶ 12, 14.

¹¹ *Id.* (citing Ex. 1, ANDRULIS-00000094).

¹² *Id.*; see also *Classified Cosmetics, Inc. v. Del Laboratories, Inc.*, 208 F. App’x 939, 942 (Fed. Cir. 2006) (A greater than additive effect occurs where “the effect of the combination [is] greater than that of an equivalent amount of either component by itself.”).

¹³ D.I. 79, counterclaims ¶ 28 (quoting Ex. 2, ANDRULIS-00000101-103).

following:

- (1) **1996 NYU Proposed Study Concept Sheet**, which proposed a Phase I/II study “to document [the] safety and potential efficacy of the combination” of thalidomide and carboplatin (an alkylating agent).¹⁴
- (2) **1996 NYU Study Interim Report**, which outlined the study’s parameters and included both the interim data results¹⁵ and a “Conclusions” heading appearing without the substance of the conclusions.¹⁶
- (3) **1999 Dow Jones Article Regarding Celgene**, which reported the results of similar studies.¹⁷
- (4) **1999 USA Today Article Regarding Thalidomide**, which reported the updated data results of the 1996 NYU Study and mentioned that NYU researchers were “blown away” by the results.¹⁸

On December 27, 1999, the Response was submitted to the PTO, and ultimately the ‘346 patent was issued on October 31, 2000.¹⁹

C. Defendant’s Counterclaim and Defense

Defendant alleges inequitable conduct as both a counterclaim and defense.²⁰

¹⁴ D.I. 79, Ex. 2, ANDRULIS-00000105-106.

¹⁵ *Id.* at Ex. 2, ANDRULIS-00000107 (citing a 40-53% response rate for carboplatin alone, while finding a 70% (12/17) response rate for the combination of thalidomide and carboplatin).

¹⁶ *Id.* at Ex. 2, ANDRULIS-00000108 (omitting the conclusion that both the safety profile and response rate of the combination “is similar to that seen with carboplatin alone at the dose level used”).

¹⁷ *Id.* at Ex. 2, ANDRULIS-00000109-111 (citing a 32-36% response rate for thalidomide alone and a 75% response rate for thalidomide and chemotherapy together, according to other studies).

¹⁸ *Id.* at Ex. 2, ANDRULIS-00000113 (showing a 70% (37/53) response rate and increased survival time from 11 to 40 weeks for the combination of thalidomide and carboplatin, and citing another study in which researchers found a 50% response rate for thalidomide alone).

¹⁹ *Id.* at Ex. 2, ANDRULIS-00000103; D.I. 12 ¶¶ 12-13.

²⁰ D.I. 79 at 28-29, counterclaims ¶¶ 7-42.

Defendant asserts that the inventors Andrulis and Drulak, as well as prosecution counsel, Isaac Angres (“Angres”), were “subject to a duty of candor before the PTO during [the] prosecution of the ‘346 patent,” including the ‘813 application.²¹ Defendant avers that Andrulis and Angres engaged in inequitable conduct when they submitted the December 27, 1999 Response to the PTO, which omitted the substantive conclusions of the 1996 NYU interim report, and purported to show the “enhanced” effect of thalidomide and carboplatin.²² Although the interim report attached to the Response contained a heading labeled “Conclusions” at the bottom of its second page, the report’s third page, containing the substance of the conclusions, was not submitted to the PTO.²³

Defendant deems this omission material because the report’s third page stated that the combination had a “similar effect,” while plaintiff argued that the combination had an enhanced effect.²⁴ As such, defendant insists this omission was done deliberately “with the specific intent to deceive the PTO into believing that the claimed combination had an ‘enhanced’ effect.”²⁵ Defendant maintains that but for this omission, the PTO would not have issued the ‘346 patent.²⁶

III. STANDARD OF REVIEW

A. Motion to Dismiss Under Rule 12(b)(6)

FED. R. CIV. P. 12(b)(6) governs a motion to dismiss for failure to state a claim

²¹ *Id.* at ¶¶ 24-25.

²² D.I. 79, counterclaims ¶¶ 30, 35-36.

²³ *Id.* at Ex. 2, ANDRULIS-00000108-109.

²⁴ *Id.* at counterclaims ¶¶ 35-36.

²⁵ *Id.* at ¶ 40.

²⁶ *Id.* at ¶ 41.

upon which relief can be granted. The purpose of a motion under Rule 12(b)(6) is to test the sufficiency of the claim, not to resolve disputed facts or decide the merits of the case.²⁷ “The issue is not whether a claimant will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims.”²⁸ A motion to dismiss may be granted only if, after “accepting all well-pleaded allegations in the [pleading] as true, and viewing them in the light most favorable to the [claimant], [the claimant] is not entitled to relief.”²⁹ While the court draws all reasonable factual inferences in the light most favorable to the claimant, it rejects unsupported allegations, “bald assertions,” and “legal conclusions.”³⁰

To survive a motion to dismiss, a claimant's factual allegations must be sufficient to “raise a right to relief above the speculative level”³¹ Claimants are therefore required to provide the grounds of their entitlement to relief beyond mere labels and

²⁷ *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993).

²⁸ *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotations and citations omitted); see also *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 563 n.8 (2007) (“[W]hen a complaint adequately states a claim, it may not be dismissed based on a district court's assessment that the plaintiff will fail to find evidentiary support for his allegations or prove his claim to the satisfaction of the factfinder.”).

²⁹ *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (citing *Burlington*, 114 F.3d at 1420).

³⁰ *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (citations omitted); see also *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (citations omitted) (rejecting “unsupported conclusions and unwarranted inferences”); *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983) (“It is not . . . proper to assume [plaintiff] can prove facts that it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged.”).

³¹ *Twombly*, 550 U.S. at 555 (citations omitted); see also *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (citing *Twombly*, 550 U.S. at 555).

conclusions.³² Although heightened fact pleading is not required, “enough facts to state a claim to relief that is plausible on its face” must be alleged.³³ A claim has facial plausibility when a claimant pleads factual content sufficient for the court to draw the reasonable inference that the opposing party is liable for the misconduct alleged.³⁴ Once stated adequately, a claim may be supported by showing any set of facts consistent with the allegations in the complaint.³⁵ Courts generally consider only the allegations contained in the pleading, exhibits attached to the pleading, and matters of public record when reviewing a motion to dismiss.³⁶

B. Motion to Strike Under Rule 12(f)

Pursuant to FED. R. CIV. P. 12(f), on a party’s motion, “[t]he court may strike from a pleading any insufficient defense”³⁷ or any affirmative defense “where a party has failed to state a corresponding claim upon which relief can be granted.”³⁸ Therefore, a defendant’s counterclaim and affirmative defense for inequitable conduct “rise or fall together.”³⁹ Additionally, the court must construe all facts in favor of the nonmoving

³² See *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

³³ *Twombly*, 550 U.S. at 570; see also *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (“In its general discussion, the Supreme Court explained that the concept of a ‘showing’ requires only notice of a claim and its grounds, and distinguished such a showing from ‘a pleader’s bare averment that he wants relief and is entitled to it.’”) (quoting *Twombly*, 550 U.S. at 555 n.3).

³⁴ *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 556).

³⁵ *Twombly*, 550 U.S. at 563 (citations omitted).

³⁶ See, e.g., *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (citations omitted).

³⁷ FED. R. CIV. P. 12(f).

³⁸ *Wyeth Holdings Corp. v. Sandoz, Inc.*, No. 09-995-LPS-CJB, 2012 U.S. Dist. LEXIS 26912 at *5 (D. Del. Feb. 3, 2012) (citation omitted).

³⁹ *Senju Pharm. Co. Ltd. v. Apotex Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013)

party.⁴⁰

C. Pleading Inequitable Conduct Under Rule 9(b)

Patent applicants and their counsel, or those involved in the preparation and prosecution of patent applications, owe a duty of candor, honesty and good faith to the PTO. This duty includes the obligation to disclose information known to patent applicants or their attorneys, which is material to the examination of the patent application.⁴¹ Omitted information is deemed material if “but-for” its omission, the PTO would not have allowed the patent claim to issue.⁴²

Because inequitable conduct is a claim sounding in fraud, it must be pled with particularity under FED. R. CIV. P. 9(b). Therefore, the pleading must identify “the specific who, what, when, where and how” of the material omission, by including “sufficient allegations of underlying facts” from which the court may reasonably infer that an individual “knew of the withheld material information” and withheld “this information with a specific intent to deceive the PTO.”⁴³ A reasonable inference is “one that is plausible and that flows logically from the facts alleged.”⁴⁴

IV. ANALYSIS

A. Pled with Particularity

As an initial matter, defendant adequately identifies the “the specific who, what,

⁴⁰ *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 697 F. Supp. 1360, 1362 (D. Del 1988) (citations omitted).

⁴¹ *Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999).

⁴² *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011).

⁴³ *Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009).

⁴⁴ *Id.* at 1329 n.5.

when, where and how” of the material omission.⁴⁵ Concerning the “who,” defendant identifies Andrulis and Angres, who owe a duty of candor to the PTO, as the individuals responsible for the omission.⁴⁶ Regarding the “what,” defendant points to the omission of the substantive conclusions from the Response, with “when” the omission occurred, as within the Response submitted to the PTO on December 27, 1999.⁴⁷ As for “where” the omission occurred, defendant cites the incomplete interim report in the Response.⁴⁸ Finally, defendant explains “how a reasonable examiner would have used the information allegedly concealed:”⁴⁹ to determine that the combination “did not have [an] enhanced effect relative to the effect of [carboplatin] alone.”⁵⁰ Therefore, defendant pleads inequitable conduct with the requisite particularity.

B. Material Omission

Defendant also alleges sufficient underlying facts from which the court may reasonably infer but-for materiality. In *Wyeth Holdings Corp. v. Sandoz, Inc.*, this court addressed the type of factual allegations sufficient to plead an inequitable conduct counterclaim and defense.⁵¹ In that case, the patentee’s representatives “omitted key information regarding experimental error rate and discrepancies in data,” along with making other affirmative representations, to evidence the drug’s “unexpected results” and overcome the obviousness rejection.⁵² The counterclaim-plaintiff explicitly alleged

⁴⁵ *Exergen*, 575 F.3d at 1328-29.

⁴⁶ D.I. 79, counterclaims ¶¶ 24-25.

⁴⁷ *Id.* at ¶¶ 35-36.

⁴⁸ *Id.*

⁴⁹ *Wyeth Holdings Corp.*, 2012 U.S. Dist. LEXIS 26912, at *10.

⁵⁰ D.I. 79, counterclaims ¶¶ 30, 35-36.

⁵¹ *Wyeth*, 2012 U.S. Dist. LEXIS 26912, at *1-2.

⁵² *Id.* at *3.

but-for materiality, introduced facts regarding the omissions and representations constituting the material representation, and noted that the examiner relied on the latter in deciding to issue the patent.⁵³ The court determined that the counterclaim-plaintiff asserted sufficient underlying facts in support of inequitable conduct.⁵⁴

In the instant matter, defendant contends that but-for the omission of the conclusions, the patent would not have issued.⁵⁵ In support, it notes the conclusion by the researchers that the response rate for the combination was similar to the administration of carboplatin alone.⁵⁶ Defendant further points to plaintiff's omission of that conclusion and representation that the interim results instead showed an enhanced effect, on which the examiner relied in deciding to issue the '346 patent.⁵⁷ Defendant reasons that absent such conduct, the patent would not have issued.⁵⁸ Therefore, it properly alleges a material omission.

Plaintiff's arguments are unpersuasive. First, it claims that the examiner did not rely on the interim results to support its finding of enhanced effect because the interim results documented the treatment's safety rather than its efficacy.⁵⁹ The study, however, explicitly states that its purpose was "to document [the] safety and *potential efficacy* of the combination."⁶⁰

Plaintiff further argues that the examiner did not rely on the interim results

⁵³ *Id.* at *9-11.

⁵⁴ *Id.*

⁵⁵ D.I. 79, counterclaims ¶ 41.

⁵⁶ *Id.* at ¶ 37.

⁵⁷ *Id.* at ¶¶ 30-33.

⁵⁸ *Id.* at ¶ 41.

⁵⁹ D.I. 86 at 8-9. D.I. 79, Ex. 2 at ANDRULIS-00000106.

⁶⁰ D.I. 79, Ex. 2 at ANDRULIS-00000106, (emphasis added).

because the “updated material results” were provided in the Response.⁶¹ Nevertheless, plaintiff fails to show that it ever submitted an updated report to the PTO. Rather, plaintiff asks the court to assume that the examiner extracted and relied on the updated results from the USA Today article provided in the Response.⁶² At this stage, the court is unwilling to make this assumption, and instead finds it equally reasonable to infer that the examiner relied on the incomplete interim report.

Plaintiff also maintains the omission of the interim conclusions was immaterial because both the interim results and subsequent updated results were included in the Response.⁶³ Consistent with the findings in *Wyeth*, however, a patentee’s duties of candor, good faith, and honesty are not relieved merely because data was provided to the examiner during his review. Otherwise, this would lead to the contrary and perverse result that applicants could freely mischaracterize materials provided to the PTO.

Plaintiff next insists that the researchers’ amazement with the updated results evidences the immateriality of the interim conclusions.⁶⁴ Because the examiner was never advised that the researchers concluded there was a similar effect at the interim stage, an inference of but-for materiality remains reasonable.⁶⁵

Plaintiff lastly argues that defendant’s reliance on *Wyeth* is misplaced because the case concerned “affirmative, material, misrepresentations,” while the present matter

⁶¹ D.I. 86 at 7.

⁶² *Id.*

⁶³ *Id.* (Plaintiff assumes PTO extracted and relied on updated results from USA Today article included in Response).

⁶⁴ *Id.*

⁶⁵ *Id.* at 10.

involves an omission.⁶⁶ Its reasoning is flawed. *Wyeth* addressed both affirmative representations and omissions.⁶⁷ Although *Wyeth* found that “arguments to the [e]xaminer that are not unreasonable interpretations or demonstrably false . . . do not amount to ‘misrepresentations,’” plaintiff misconstrues its application by suggesting that omitting conclusions contrary to the applicant’s position as acceptable where the data does not provide the examiner notice of those findings.⁶⁸ The court concludes that defendant properly alleges a material omission.

C. Intent to Deceive

Defendant sufficiently alleges that plaintiff knew of and withheld material information with a specific intent to deceive the PTO. It is undisputed that plaintiff knew of the substantive conclusions of the interim report, which were not submitted to the examiner. Defendant relies on several underlying facts as evidence of plaintiff’s intent to deceive. These facts include: the interim conclusions were not submitted to the examiner, the conclusions found a similar, rather than enhanced, response rate, and plaintiff argued the interim data showed an enhanced effect.⁶⁹ Defendant concludes such conduct sufficiently demonstrates, under Rule 12(b)(6), an intent to deceive the examiner into finding that the combination of thalidomide and an alkylating agent resulted in an enhanced effect in treating certain cancers. Although plaintiff contends this is a conclusory assertion of deceptive intent, the court finds the factual allegations

⁶⁶ D.I. 115 at 6.

⁶⁷ *Wyeth Holdings Corp. v. Sandoz, Inc.*, No. 09-995-LPS-CJB, 2012 U.S. Dist. LEXIS 26912, at *1-2 (D. Del. Feb. 3, 2012).

⁶⁸ See *Wyeth*, 2012 U.S. Dist. LEXIS 26912, at *11 (finding omission material where examiner had no way of independently learning the omitted information).

⁶⁹ D.I. 79, counterclaims ¶¶ 30, 35, 37.

sufficient to reasonably infer an intent to deceive.

Plaintiff maintains that an inference of deceptive intent is unreasonable. Plaintiff argues that by including the conclusions heading on the second page, it gave the examiner notice of the omission of the third page, since no conclusions followed.⁷⁰ Plaintiff also contends that including the heading evidences a lack of intent to conceal this omission from the examiner.⁷¹ Even if the heading gave the examiner notice of an omission, it did not provide the examiner notice that the omitted information conflicted with plaintiff's characterization of the data. Further, the fact that plaintiff included the heading does not discredit defendant's assertion that plaintiff intended to conceal the *substance* of the conclusions. Because plaintiff conveniently omitted the only page containing information contrary to its position, the court finds an inference of deceptive intent reasonable.

D. Motion to Strike

The court may strike an affirmative defense "where a party has failed to state a corresponding claim upon which relief can be granted,"⁷² thereby linking defendant's counterclaim and affirmative defense for inequitable conduct.⁷³ Since the court finds that defendant adequately states a claim of inequitable conduct, plaintiff's motion to strike defendant's affirmative defense fails for the reasons expressed above.

⁷⁰ See D.I. 79, Ex. 2 at ANDRULIS-00000108-109, (interim report attached to Response included heading labeled "Conclusions" at the bottom of its second page, but failed to include report's third page containing the substance of the conclusions).

⁷¹ D.I. 86 at 8.

⁷² *Wyeth Holdings Corp. v. Sandoz, Inc.*, No. 09-995-LPS-CJB, 2012 U.S. Dist. LEXIS 26912 at *5 (D. Del. Feb. 3, 2012) (citation omitted).

⁷³ *Senju Pharm. Co. Ltd. v. Apotex Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013).

V. RECOMMENDED DISPOSITION

Consistent with the findings herein, it is recommended that plaintiff's motion to dismiss Count IV of defendant's counterclaim for failure to state a claim of inequitable conduct under FED. R. CIV. P. 12(b)(6) and to strike defendant's ninth affirmative defense for asserting an insufficient defense of inequitable conduct under FED. R. CIV. P. 12(f) (D.I. 85) be denied.

Pursuant to 28 U.S.C. § 636(b)(1)(A) and (B), FED. R. CIV. P. 72(b) and D. DEL. LR 72.1, any objections to the Report and Recommendation shall be filed within fourteen (14) days limited to ten (10) pages after being served with the same. Any response is limited to ten (10) pages.

The parties are directed to the court's Standing Order in Non-Pro Se matters for Objections Filed under FED. R. CIV. P. 72 dated October 9, 2013, a copy of which is available on the court's website, www.ded.uscourts.gov.

Dated: July 16, 2015

/s/ Mary Pat Thyng
UNITED STATES MAGISTRATE JUDGE