IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXALTA INCORPORATED, BAXALTA US INC., and NEKTAR THERAPEUTICS, Plaintiffs and Counterclaim Defendants, v. BAYER HEALTHCARE LLC, Defendant and Counterclaim Plaintiff.	)	Civil Action No. 17-1316-RGA-SRF

REPORT AND RECOMMENDATION

I. INTRODUCTION

Presently before the court in this patent infringement action is the motion of plaintiffs Baxalta Incorporated, Baxalta US Inc. (together, "Baxalta"), and Nektar Therapeutics ("Nektar") (collectively, "Plaintiffs") to dismiss and strike certain counterclaims and affirmative defenses in defendant Bayer Healthcare LLC's ("Bayer") amended answers and counterclaims or, in the alternative, to bifurcate those issues.[1] (D.I. 383) For the following reasons, I recommend that the court GRANT Plaintiffs' motion to dismiss and strike.

II. BACKGROUND

Hemophilia A is a congenital bleeding disorder characterized by defective coagulation of the blood resulting from a deficiency in factor VIII protein. (D.I. 281 at ¶ 63) Plaintiffs and Bayer have developed and launched a number of factor VIII replacement therapies in the United States to treat hemophilia A. Baxalta manufactures and sells ADYNOVATE®, which is "a

[1] The briefing associated with the pending motion can be found at D.I. 385, D.I. 396, and D.I. 400.

human antihemophilic factor indicated in children and adults with hemophilia A (congenital factor VIII deficiency) for on-demand treatment and control of bleeding episodes, perioperative management, and routine prophylaxis to reduce the frequency of bleeding episodes." (*Id.* at ¶ 65) ADYNOVATE® is an extended half-life ("EHL") factor VIII replacement product comprising PEGylated[2] factor VIII that was launched in 2015. (*Id.*) Bayer manufactures and sells Jivi®, which is a factor VIII replacement therapy for the treatment of hemophilia A which was approved by the Food and Drug Administration ("FDA") on August 29, 2018. (D.I. 333 at ¶ 62) Jivi® comprises PEGylated factor VIII with an extended half-life designed to prolong the duration of the factor VIII effect. (*Id.*)

Nektar is a developer of PEGylation technology that supplies PEG reagents to pharmaceutical companies to use in the development of new products. (D.I. 333 at ¶ 34) Bayer entered into a Research Agreement (the "Agreement") with Nektar in December 2003. (D.I. 333 at ¶ 51) Pursuant to the Agreement, Bayer and Nektar agreed to work together to increase the half-life of factor VIII while simultaneously preserving its coagulation activity levels. (*Id.*) Bayer sent Nektar batches of Bayer's recombinant factor VIII in early 2004.[3] (*Id.* at ¶ 54) These batches included both BDD factor VIII and full-length factor VIII.[4] (*Id.*) Nektar subsequently informed Bayer on February 26, 2004 that the PEGylation of Bayer's factor VIII was not effective in binding a large PEG molecule to the amino acid cysteine of factor VIII. (*Id.* at ¶ 55)

[2] "Pegylation is a method by which polyethylene glycol ('PEG') molecules are attached to active biologic or chemical entities in an effort to impart certain unique properties, such as potentially preventing degradation of the therapeutic product to extend its half-life." (D.I. 333 at ¶ 12)
[3] "Recombinant technology allows for production of proteins in large quantities using cells engineered to contain the gene encoding the protein of interest." (D.I. 333 at ¶ 54)
[4] "BDD factor VIII is a type of factor VIII in which most or all of the segment of factor VIII known as the 'B domain' has been removed, whereas full-length factor VIII refers to a factor VIII protein with the B domain." (D.I. 333 at ¶ 54)

On the same day, Nektar filed Patent Application No. 10/789,956 (the "Bossard Non-Provisional Application") which was directed to the use of a large PEG molecule on factor VIII. (*Id.*) Bayer contends that the Bossard Non-Provisional Application is based on discoveries that Nektar learned from Bayer regarding the use of fewer large PEG molecules to pegylate factor VIII. (*Id.* at ¶ 56)

Nektar is the assignee of U.S. Patent Nos. 7,026,440 ("the '440 patent");[5] 7,872,072; 8,273,833; 8,809,453; and 9,187,569 (collectively, the "Bentley Patents"), and Baxalta licenses the Bentley Patents from Nektar. (D.I. 381 at ¶ 139) The Bentley Patents are generally directed to certain branched reactive polymers possessing a defined chemical structure and biologically active conjugates containing such polymers. Nektar is also the assignee of U.S. Patent Nos. 7,199,223 ("the '223 patent"); 7,863,421; 8,143,378; 8,247,536; 8,519,102; 8,618,259; 8,889,831; and 9,999,657 (collectively, the "Bossard Patents"), and Baxalta licenses the Bossard Patents from Nektar. (D.I. 333 at ¶ 66; D.I. 381 at ¶ 69) The Bossard Patents are generally directed to certain novel conjugates of PEG bound to factor VIII, as well as compositions containing such conjugates.

On September 4, 2019, Plaintiffs filed the operative second amended complaint against Bayer, alleging that Bayer's Jivi® product infringes the Bossard Patents. (D.I. 281) On August 31, 2018, Plaintiffs filed another complaint against Bayer, alleging that Bayer's Jivi® product infringes the Bentley Patents. (C.A. No. 18-1355-RGA, D.I. 1) Bayer filed its third amended answer, affirmative defenses, and counterclaims to both complaints in the consolidated action on

[5] In its pleading, Bayer alleges that Plaintiffs waived their assertion of the '440 patent "after the deposition of its lead inventor, Michael Bentley, revealed Dr. Bentley's knowledge of material prior art that was knowingly not disclosed to the USPTO." (D.I. 381 at ¶¶ 75, 164) According to Bayer, "[t]he act of dropping the '440 Patent is intended to mask the ongoing scheme by Nektar and Baxalta to assert unenforceable patents against Bayer." (*Id.*)

October 11, 2019, asserting *Walker Process* fraud and antitrust allegations in addition to allegations of inequitable conduct and unclean hands. (D.I. 333; D.I. 381)

The parties subsequently filed their motions for summary judgment and *Daubert* motions, which are fully briefed. (D.I. 447; D.I. 450) On June 30, 2020, Bayer filed a motion to correct inventorship pursuant to 35 U.S.C. § 256 and a Rule 12(b)(1) motion to dismiss. (D.I. 483) Plaintiffs filed a motion to strike Bayer's motion to correct inventorship and motion to dismiss. (D.I. 490) Briefing is not yet complete on the motion to correct inventorship and the motion to strike. (D.I. 493) A jury trial is currently scheduled to begin on the liability issues on September 21, 2020. (D.I. 446)

III. LEGAL STANDARDS

A. 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 heightened pleading requirements of Rule 9(b) apply to causes of action for inequitable conduct, unclean hands, and *Walker Process* claims. *See Senju Pharm.*, 921 F. Supp. 2d at 306 (applying Rule 9(b) standard to inequitable conduct); *Cephalon, Inc. v. Slayback Pharma Ltd. Liab. Co.*, C.A. No. 17-1154-CFC, 2019 WL 3497105, at *1 (D. Del. Aug. 1, 2019) (applying Rule 9(b) standard to causes of action for unclean hands based on allegations of inequitable conduct); *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, (Fed. Cir. 2005), *rev'd on other grounds*, 549 U.S. 118 (2007) ("Like all fraud-based claims, *Walker Process* allegations are subject to the pleading requirements of Fed. R. Civ. P. 9(b).").

B. Rule 12(f)

Plaintiffs move to strike Bayer's affirmative defenses for inequitable conduct, unclean hands, and *Walker Process* fraud based on the same allegations made in support of their counterclaims. The sufficiency of the affirmative defenses is evaluated under Rule 12(f), which provides that the court "may strike from a pleading any insufficient defense." Fed. R. Civ. P. 12(f). When a party fails to state a corresponding claim under Rule 12(b)(6), the court may strike the associated affirmative defense under Rule 12(f). *See Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *4 (D. Del. Feb. 3, 2012) (citing *Power Integrations, Inc. v. Fairchild Semiconductor Int'l Inc.*, C.A. No. 08-309-JJF-LPS, 2009 WL 4928024, at *8-10 (D. Del. Dec. 18, 2009)).

IV. ANALYSIS

A. Inequitable Conduct

Plaintiffs move the court to strike Bayer's fourteenth affirmative defense and dismiss its first amended counterclaim for inequitable conduct regarding the '440 patent in the Bentley action. Plaintiffs similarly move the court to strike Bayer's fifteenth affirmative defense and dismiss its first counterclaim regarding the '223 patent in the Bossard action.[6] (D.I. 385 at 7-17) Inequitable conduct occurs when: (1) a specific individual with a duty of candor to the United States Patent and Trademark Office ("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

[6] Bayer's inequitable conduct affirmative defenses rise and fall with its inequitable conduct counterclaims. *See Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013). Accordingly, I recommend that the court strike the affirmative defenses for inequitable conduct to the extent that the counterclaims are dismissed.

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)).

1. Concealed information

a. "Who"

Bayer's counterclaims identify seven references allegedly withheld from the examiner during prosecution of the Bentley Patents, and four references allegedly withheld from the examiner during prosecution of the Bossard Patents.[7] (D.I. 381 at ¶¶ 19-30, 96-131; D.I. 333 at ¶¶ 19-29, 89-119) Plaintiffs contend that Bayer fails to plead with particularity the "who" of the allegedly concealed information. (D.I. 385 at 8-9) According to Plaintiffs, Bayer's allusion to "the Applicants" lacks the specificity required to state a claim for inequitable conduct, and the pleading's identification of "one or more of" Dr. Harris, Dr. Bentley, Dr. Charles, Dr. Bossard, Ms. Zhang, Mr. Wilson, and Ms. Evans also fails to satisfy Rule 9(b). (*Id.*) In response, Bayer alleges that the pleading identifies specific individuals by name who owed a duty of candor to the USPTO and who were aware of the allegedly concealed material art. (D.I. 396 at 8-9)

Bayer's Bentley pleading fails to sufficiently plead "who" allegedly concealed the specific invalidating prior art references. The Bentley pleading attributes the acts of concealment to the "Applicants," a term that is not formally defined in the pleading.[8] (D.I. 381 at ¶¶ 77-87)

[7] At oral argument, Bayer also identified additional omissions during prosecution of the Bentley and Bossard Patents which were discovered after the pleading deadline. (3/11/2020 Tr. at 47:3-17)

[8] The term "Applicants" is used inconsistently throughout the Bentley pleading. For example, certain paragraphs refer to "the Applicants" as if the term was defined (D.I. 381 at ¶ 91), whereas other paragraphs refer to "[t]he applicants" as a general term, (*id.* at ¶¶ 92-93). Likewise, inconsistencies abound as to whether the term is singular or plural in the possessive. (*Compare* D.I. 381 at ¶ 78 *with id.* at ¶ 80)

For example, Bayer's Bentley pleading states that "[t]he Applicant's concealment of the Harris/Bentley '237 Patent . . . was but-for material because it discloses a branched PEG. . . . This PEG structure contains each limitation of claim 1 of the '440 Patent. . . ." (*Id.* at ¶ 80) Bayer's Bentley pleading sets forth similar allegations regarding the Monfardini/Harris reference (*id.* at ¶ 81), the 1995 Shearwater Catalog (*id.* at ¶ 82), a prior sale to and printed publication by Veronese (*id.* at ¶ 83), a prior sale to and printed publication via Genentech (*id.* at ¶ 84), and a prior sale and printed publication via Roche (*id.* at ¶ 86). The court is left to assume that Dr. Harris, Dr. Bentley, Mr. Wilson, Ms. Evans, and Mr. Humphrey collectively constitute the "Applicants," because the pleading itself provides no guidance as to whether the term encompasses the inventors, both the inventors and prosecution counsel, or some other combination of individuals with a duty to disclose under 37 C.F.R. § 1.56.[9] Such an assumption would be inconsistent with Rule 9(b).

Even in cases where a pleading has defined a collective term such as "the Applicants," courts have rejected the sufficiency of the inequitable conduct allegations where "they allege a mishmash of facts without sorting them out in relation to particular acts of particular individuals." *See Alza Corp. v. ParPharm., Inc.*, C.A. No. 13-1104-RGA, 2014 WL 12908353, at *1 (D. Del. May 27, 2014) (rejecting counterclaimant's "repeated reference to 'the Applicants,' which [was] loosely defined as named inventors or identified inventors or one or more of their agents or attorneys or other persons involved in the prosecution of the applications including the Prosecuting Attorneys."). Although the allegations in Bayer's Bentley pleading refer to specific inventors and prosecuting attorneys by name when discussing each individual's

[9] Such an assumption would be particularly inappropriate in this case because the face of the '440 patent identifies additional inventors who were presumably "Applicants" but who were not individually identified in the pleading.

knowledge of the prior art references, the pleading only refers to the undefined term "Applicants" when discussing who bore responsibility for concealing those references. This lack of connection between the allegations of knowledge by particular individuals and contentions regarding concealment directed broadly to the "Applicants" is fatal to the claim.

The counterclaims further allege that the Bentley patents are unenforceable due to the inequitable conduct of "one or more of Drs. Harris and Bentley, and prosecution counsel Mr. Humphrey, Ms. Evans, and Mr. Wilson." (D.I. 381 at ¶¶ 183, 189, 195, 201, 207) But courts have held that this "one or more" language leaves open the possibility that any one of these individuals, or combinations of the individuals, did not know "about the prior sales and art and their materiality . . . at all." *XpertUniverse*, 868 F. Supp. 2d at 381. Allegations styled in this manner do not "allege[ ] that any *one* of those individuals necessarily committed the particular act" and fail to plead "any joint concert of action." *Drew Techs., Inc. v. Bosch, L.L.C.*, 2014 WL 562458, at *3 (E.D. Mich. Feb. 13, 2014); *see also Emerson Elec. Co. v. Suzhou Cleva Elec. Appliance Co., Ltd.*, 2014 WL 3600380, at *3 (E.D. Mo. July 22, 2004).

Bayer contends that such a view of the pleading ignores other portions of the counterclaims identifying a number of individuals by name and explaining with specificity how each named individual knew of the allegedly invalidating information. (3/11/2020 Tr. at 41:13-20) For example, Bayer's Bentley pleading explains that Dr. Bentley knew of the '237 patent because he was an inventor of that patent (D.I. 381 at ¶ 108), and he knew of the Monfardini/Harris reference, the 1995 Shearwater Catalog, the Veronese sale and printed publication, and the Genentech sale and printed publication due to his role as Manager of Drug Delivery Division at Shearwater from 1997-1999 (*id.* at ¶¶ 109-112). Although these allegations

sufficiently state that Dr. Bentley knew of the withheld prior art references, the Bentley pleading is devoid of allegations associating Dr. Bentley by name with the concealment of those references. Instead, pleaded paragraphs directed to the concealment of the references attribute the act of concealment to the "Applicants." (3/11/2020 Tr. at 11:15-19); *see XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 381 (D. Del. 2012) (requiring allegations that a specific individual withheld the information with the intent to deceive the USPTO).

The same analysis extends to Bayer's pleading in the Bossard case. The Bossard pleading identifies how Dr. Harris (D.I. 333 at ¶¶ 89-94), Dr. Bentley (*id.* at ¶¶ 95-99), Dr. Bossard (*id.* at ¶¶ 100-104), Ms. Zhang (*id.* at ¶¶ 105-109), Mr. Wilson (*id.* at ¶¶ 110-114), and Ms. Evans (*id.* at ¶¶ 115-119) knew of the prior art Martinez Patent, the '440 patent, and the '330 Nektar patent.[10] However, the pleading attributes the act of concealing these references generally to "the Applicants," without defining who falls within the scope of the term or specifying that any of the named individuals knew the references were material. (*Id.* at ¶¶ 74-78) For the reasons previously stated, attributing the alleged concealment to "one or more of Drs. Harris, Bentley, Charles, and Bossard, and Ms. Zhang, and prosecution counsel Mr. Wilson and Ms. Evans" does not provide greater specificity. (*Id.* at ¶¶ 173, 178, 183, 188, 193, 198, 203, 208); *see XpertUniverse*, 868 F. Supp. 2d at 381.

b. "When"

Plaintiffs next argue that Bayer's pleadings fail to identify "when" the allegedly concealed information should have been disclosed because the pleading does not identify

[10] In accordance with the analysis of the Bentley pleading, allegations of each individual's knowledge in the Bossard pleading should conform with the standard set forth in *XpertUniverse*, and should not be based solely on the individual's role in a particular company. 868 F. Supp. 2d at 381.

specific dates on which submissions to the USPTO should have identified the allegedly concealed information. (D.I. 385 at 9-10) Bayer responds that pleading a specific date of concealment is not required, and the pleadings adequately establish that the individuals did not disclose the references at any time during the prosecution. (D.I. 396 at 9)

Bayer's pleadings sufficiently identify when the allegedly concealed information should have been disclosed. Bayer's Bentley pleading alleges that the Applicants were aware of the prior art references more than one year before the November 2001 filing date of the Bentley Provisional Application, yet those references were not disclosed to the USPTO at any time during prosecution of the application leading to the '440 patent. (D.I. 381 at ¶¶ 79-87) Similarly, Bayer's Bossard pleading alleges that the Applicants were aware of the prior art references more than one year before the February 2003 filing date of the Bossard Provisional Application, yet those references were not disclosed to the USPTO at any time during prosecution of the application leading to the '223 patent. (D.I. 333 at ¶¶ 75-78) Allegations that acts of concealment occurred during prosecution of the patent at issue are sufficient to plead the "when" under *Exergen*. *See CertusView Techs., LLC v. S&N Locating Servs., LLC*, 107 F. Supp. 3d 500, 516 (E.D. Va. 2015) (finding the "when" satisfied by allegations that individuals never disclosed the prior art to the USPTO during prosecution of their patent applications); *MedImmune, Inc. v. Centocor, Inc.*, 271 F. Supp. 2d 762, 772 (D. Md. 2003) ("MedImmune pleads the time and place of the alleged inequitable conduct with the statement, '[D]uring prosecution before the PTO.'"); *Coolsystems, Inc. v. Nice Recovery Sys. LLC*, 2016 WL 6091577, at *5 (N.D. Cal. Oct. 19, 2016) (finding pleading's statement of "during prosecution of the '910 patent" sufficient to satisfy the "when" requirement under *Exergen*).

Plaintiffs rely on cases suggesting that a pleading must identify a specific date on which each prior art reference should have been disclosed to the USPTO to satisfy the "when" requirement. *See Allergan USA, Inc. v. Prollenium US Inc.*, C.A. No. 19-126-CFC-SRF, 2019 WL 7298569, at *5 (D. Del. Dec. 30, 2019); *Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *9 (D. Del. Feb. 3, 2012). But these cases both involved an affirmative misrepresentation, namely, the submission of allegedly fraudulent declarations to the USPTO, as opposed to acts of concealment regarding prior art references. *Id.* While it may be necessary to identify the specific submission date of an affirmatively fraudulent declaration to satisfy the "when," the act of concealing prior art from the USPTO does not lend itself to a precise date because of the applicant's continuing obligation to disclose references throughout prosecution. *Id.*; *see also* 37 C.F.R. § 1.56(a) ("The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned."). Because the allegedly withheld references in this case were concealed from the USPTO for the duration of the prosecution, the period of patent prosecution is sufficient to satisfy the "when."

Plaintiffs also cite the court's decision in *XpertUniverse*, which suggested that the "when" in a case involving the concealment of prior art references is the date the information disclosure statement ("IDS") is submitted to the USPTO. 868 F. Supp. 2d at 381. The court's analysis was based on the pleaded allegation that the information should have been disclosed in the IDS: "On information and belief, XU personnel . . . intentionally failed to disclose the [alleged prior art] to the U.S.P.T.O. as required by 37 C.F.R. § 1.56(a) [R–2] in any Information Disclosure Statement U.S.P.T.O. form 1449 and did so with intent to deceive." *Id.* The court

determined that, "[a]ssuming that the [IDS] reference is sufficient to describe the "where," the date the IDS was submitted is necessary to satisfy the "when." *Id.* Because the pleading did not identify the date of submission of the IDS to the USPTO, the court determined that the pleading did not adequately identify the "when." *Id.* In contrast, the pleadings in the instant matter do not identify one particular document, such as a declaration or an IDS, in which the Applicants failed to disclose a material reference. Instead, they refer to the Applicants' obligation to disclose the prior art references for the duration of the prosecution of the Bentley Patents and the Bossard Patents. (D.I. 381 at ¶¶ 79-87; D.I. 333 at ¶¶ 75-78) Under these circumstances, identifying the span of patent prosecution is sufficient to satisfy the "when." *See CertusView Techs., LLC v. S&N Locating Servs., LLC*, 107 F. Supp. 3d 500, 516 (E.D. Va. 2015); *MedImmune, Inc. v. Centocor, Inc.*, 271 F. Supp. 2d 762, 772 (D. Md. 2003); *Coolsystems, Inc. v. Nice Recovery Sys. LLC*, 2016 WL 6091577, at *5 (N.D. Cal. Oct. 19, 2016).

2. False statements

Next, Plaintiffs contend that Bayer's pleadings fail to allege with particularity the "who," "how," and "what" of the purportedly false statements made to the USPTO during prosecution of the Bossard and Bentley Patents. (D.I. 385 at 10-12) According to Plaintiffs, the "who" allegations regarding the misstatements are inadequate for the same reasons those allegations were deficient with respect to the concealment allegations. (*Id.* at 10-11) For the reasons set forth at § IV.A.1, *supra*, I recommend that the court grant the motion to dismiss for failure to sufficiently define the scope of the pleadings' references to the "Applicants" and "one or more" of various individuals. (D.I. 381 at ¶¶ 91-94, 183, 189, 195, 201, 207; D.I. 333 at ¶¶ 80-86, 173, 178, 183, 188, 193, 198, 203, 208)

Regarding the "how" and the "what," Plaintiffs argue that Bayer fails to identify the patent claims and limitations impacted by the allegedly false statements, or how a reasonable examiner would have used the allegedly false statements in assessing patentability. (D.I. 385 at 11-12) In response, Bayer contends that affirmative misrepresentations amount to egregious misconduct which is considered material as a matter of law. (D.I. 396 at 10)

Bayer's pleadings satisfy the "what" by identifying the affirmative misrepresentations: (1) the false statement regarding the invention of larger PEGs up to 150 kDa (D.I. 381 at ¶¶ 92, 154; D.I. 333 at ¶¶ 81, 140, 145); (2) the false inventorship allegations omitting Dr. Harris and Dr. Tomic as inventors of the Bentley and Bossard Patents (D.I. 381 at ¶ 93; D.I. 333 at ¶ 86); (3) the false statement regarding pegylation at cysteines (D.I. 333 at ¶ 82); (4) the false statement regarding the achievement of a cysteine pegylation yield of 33% (*id.* at ¶¶ 83-84); (5) the false statement that conjugates were bioactive with between 0.1% and 100% bioactivity (*id.* at ¶ 84); and (6) the false disclosure that the prior art Dalborg patent did not disclose 1-3 large PEGs conjugated to factor VIII (*id.* at ¶ 85). Identifying the misrepresentations is sufficient to satisfy the "what" of the false statements at the pleading stage. *See Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *9 (D. Del. Feb. 3, 2012) ("The 'what' in this case refers to the alleged misrepresentations regarding the state of prior art . . . and the tigecycline stabilization data that was submitted to and discussed with the PTO."); *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013) (holding that the pleadings satisfied the "what" of the misrepresentation by identifying "what the misrepresentation was."); *Cyber Acoustics, LLC v. Belkin Int'l, Inc.*, 988 F. Supp. 2d 1236, 1245 (D. Ore. 2013) (holding that pleading adequately pled the "what" by alleging inventorship issue and asserting that "the

entire patent would not have issued but for" the misrepresentation regarding inventorship); *SynQor v. Artesyn Techs., Inc.*, 2010 WL 3860131, at*8 (E.D. Tex. Sept. 10, 2010) (finding pleading of "specific misstatements that form the basis of the inequitable conduct defenses" was sufficient, even though the pleading "did not include claim charts matching the prior art to the specific claim limitations.").

Bayer's pleadings also satisfy the "how" requirement. As they pertain to the false inventorship allegations, the pleadings allege that Dr. Harris[11] and Milan Tomic conceived of each limitation of claim 1 of the '440 patent and claim 1 of the '223 patent prior to the filing of the Bentley and Bossard provisional applications. (D.I. 381 at ¶ 79; D.I. 333 at ¶ 75) The pleadings also specify how this false information affected the prosecution of the Bentley and Bossard Patents: "If the Applicants had disclosed Bayer's discoveries, the Examiner would not have allowed the Asserted [Bentley / Bossard] Patents to issue because they are anticipated by, or rendered obvious by, and derived from, Bayer's discoveries or would have required the Applicants to correct inventorship to add at least Milan Tomic as the inventor." (*Id.*) By explaining how and why Milan Tomic and Dr. Harris should have been named inventors of the Bentley and Bossard Patents, Bayer satisfies the "how" requirement set forth in *Exergen*. *See Theranos, Inc. v. Fuisz Pharma LLC*, 876 F. Supp. 2d 1123, 1137 (N.D. Cal. 2012) (finding sufficient pleaded allegations of inequitable conduct based on exclusion of individuals who should have been named inventors); *see also Cyber Acoustics, LLC v. Belkin Int'l, Inc.*, 988 F. Supp. 2d 1236, 1245 (D. Ore. 2013) (holding that pleading adequately pled inequitable conduct

[11] For the reasons set forth at § IV.A.5, *infra*, I recommend that the court find the allegations regarding Dr. Harris' duty of candor sufficiently pleaded.

by asserting that "the entire patent would not have issued but for" the misrepresentation regarding inventorship).

The balance of the pleaded allegations regarding the false statements also sufficiently establish "how" the misrepresentations were material to the examiner's allowance of the Bentley and Bossard Patents. *See Exergen*, 575 F.3d at 1330. For example, Bayer's pleadings allege that "[t]he applicants falsely told the USPTO that they invented large molecular weight PEGs up to 100 kDa . . . when no such PEGs were ever created, possible, or 'typical,'" and this misrepresentation "impact[s] all the Asserted Claims of all the Asserted [Bentley and Bossard] Patents." (D.I. 381 at ¶¶ 92, 154; D.I. 333 at ¶¶ 81, 140, 145) The pleadings cite testimony substantiating the falsity of the representation, including that of a named inventor who "admitted that Nektar could not itself make the underlying PEG," and "the largest molecular weight PEG that was available or sold from Nektar was 40 kDa." (D.I. 381 at ¶ 92; D.I. 333 at ¶ 81) The pleadings allege that the misrepresentation regarding the PEG size and other falsified test results, as well as a false statement regarding the disclosure of a prior art reference, "mischaracterize the novelty and scope of the claimed invention." (D.I. 333 at ¶¶ 80-85) False statements of this nature, made directly to the USPTO in the specifications of the Bentley and Bossard Patents, reflecting the results of tests that were never actually performed, amount to egregious misconduct. In this regard, the pleaded allegations in the Bentley and Bossard cases amount to affirmative acts of egregious misconduct comparable to the filing of a false affidavit in *Therasense*. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (finding that affirmative acts of egregious misconduct are material).

3. Specific intent

"[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).

According to Plaintiffs, Bayer's pleadings do not set forth sufficient facts to support a reasonable inference of a deliberate decision to withhold or falsify material information with the specific intent to deceive the USPTO. (D.I. 385 at 13) Plaintiffs argue that allegations regarding certain individuals who may have had an incentive to conceal or falsify information are insufficient to satisfy the pleading standard for specific intent in the inequitable conduct analysis. (*Id.*) In response, Bayer contends that the pleadings describe a pattern of activity and an incentive to conceal or falsify information to deceive the USPTO, which gives rise to a reasonable inference of specific intent, and an express admission of deceptive intent is not required. (D.I. 396 at 13-14)

Bayer's inequitable conduct counterclaims adequately allege specific intent. For example, the counterclaims contain detailed allegations regarding Dr. Harris' incentives for omitting his name from the applications for the Bentley and Bossard Patents to avoid the discovery that: (1) he improperly disclosed Bayer's confidential information to the named inventors, and (2) UAH has an ownership interest in the patents. (D.I. 381 at ¶¶ 134-150; D.I.

333 at ¶¶ 122-138) The pleadings set forth similarly detailed allegations regarding the incentives of Dr. Bentley, Dr. Bossard, Ms. Zhang, Mr. Wilson, Ms. Evans, and Mr. Humphrey to make false statements about the claimed inventions and / or conceal material information to secure the Bentley and Bossard Patents. (D.I. 381 at ¶¶ 151-160; D.I. 333 at ¶¶ 139-150) Specifically, the Bossard pleading alleges that Dr. Bentley had an incentive to conceal material information regarding various prior art references "to secure the Asserted Bossard Patents." (D.I. 333 at ¶ 139) These allegations give rise to the reasonable inference that each of the named individuals had an incentive to conceal and / or misrepresent information relevant to the prosecution of the Bentley and Bossard Patents, which is sufficient to plead specific intent at this stage of the proceedings. *See Wyeth Holdings*, 2012 WL 600715, at *7 (determining that, "to 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.").

Plaintiffs rely on the Federal Circuit's decision in *In re Metoprolol Succinate Patent Litigation* for the proposition that having an incentive to withhold or falsify material information before the USPTO is not sufficient to constitute the specific intent required for inequitable conduct. 494 F.3d 1011, 1021 (Fed. Cir. 2007) ("[T]he district court erred in equating the presence of an incentive with an intent to deceive on summary judgment."). But Plaintiffs misconstrue the significance of the case to the facts presently before this court. In *In re Metoprolol*, the Federal Circuit vacated and remanded the district court's finding of inequitable conduct at the summary judgment stage, concluding that "the record reveals a genuine factual dispute of whether Astra had an intent to deceive" the USPTO, and "[t]he district court

improperly resolved this factual dispute on summary judgment." *Id.* The Federal Circuit did not hold that identifying an incentive to deceive the USPTO was inadequate to plead specific intent at the initial stages of the litigation. To the contrary, the existence of an incentive to deceive the USPTO in *In re Metoprolol* was sufficient to create an issue of fact on summary judgment. In so ruling, the Federal Circuit acknowledged that intent to deceive "need not, and rarely can, be proven by direct evidence," but instead "is generally inferred from the facts and circumstances surrounding the applicant's overall conduct." *Id.* at 1020 (internal citations and quotation marks omitted).

At oral argument, Plaintiffs also suggested that Dr. Harris' incentive was to maximize his own financial interests, and he had no particular incentive to deceive the USPTO. (3/11/2020 Tr. at 19:10-25) But the pleaded allegations suggest that Dr. Harris' financial incentive not to disclose the inventions to UAH led him to knowingly mislead the USPTO regarding his role as an inventor of the claimed inventions by omitting his name from the Bentley and Bossard Patents. (D.I. 333 at ¶¶ 123, 127) That these alleged misrepresentations of inventorship to the USPTO were a side effect of Dr. Harris' desire to deprive UAH of benefitting financially from the inventions does not alter the fact that the pleading alleges Dr. Harris specifically intended to deceive the USPTO by disclaiming inventorship of the Bentley and Bossard Patents. In this regard, Dr. Harris' alleged financial incentive cannot be so easily detached from his intentions before the USPTO.

4. Infectious Unenforceability

Plaintiffs argue that Bayer's failure to adequately plead inequitable conduct with respect to the '440 and '223 patents precludes a finding of infectious unenforceability of the remaining

Bentley and Bossard Patents. (D.I. 385 at 14) Plaintiffs further contend that, even if Bayer's pleadings adequately allege inequitable conduct regarding the '223 and '440 patents, there is no "immediate and necessary relation" between the alleged inequitable conduct regarding the '223 and '440 patents and enforcement of the follow-on Bentley and Bossard Patents. (*Id.*) In response, Bayer contends that inequitable conduct occurring early in the prosecution may render unenforceable all claims eventually issuing from the same or a related application where, as here, the omitted prior art is material to those applications. (D.I. 396 at 15)

"[I]nfectious unenforceability occurs when inequitable conduct renders unenforceable claims in a related application" having an immediate and necessary relation to the inequitable conduct. *Robocast, Inc. v. Apple Inc.*, 39 F. Supp. 3d 552, 570 (D. Del. 2014) (citing *Agfa Corp. v. Creo Prods., Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006); *Truth Hardware Corp. v. Ashland Prods., Inc.*, 2003 WL 22005839, at *1 (D. Del. Aug. 19, 2003)). An "immediate and necessary relation" requires a relation between "the inequitable conduct that occurred earlier in the chain" of the issued patents and the "targeted claims of the ultimately-issued patent or patents sought to be enforced." *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580, 595 (D. Del. 2006) (internal citations and quotation marks omitted). Sharing a parent application, sharing similarities in subject matter, and containing a citation to an unenforceable patent are not sufficient to automatically suggest infectious unenforceability. *See IBM v. Priceline Grp., Inc.*, C.A. No. 15-137-LPS-CJB, 2017 WL 1349175, at *20 (D. Del. Apr. 10, 2017); *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 900 (N.D. Ill. 2006)

As a preliminary matter, the aforementioned deficiencies in Bayer's inequitable conduct counterclaims regarding the '440 and '223 patents preclude a determination at this stage that

Bayer adequately pleaded infectious unenforceability with respect to the balance of the Bentley and Bossard Patents. A claim for infectious unenforceability cannot survive in the absence of a viable allegation of inequitable conduct. *See Robocast*, 39 F. Supp. 3d at 570 (observing that "infectious unenforceability occurs when inequitable conduct renders unenforceable claims in a related application."); *IBM*, 2017 WL 1349175 at *21 (turning to "remaining question" of infectious unenforceability only after determining defendants had adequately alleged inequitable conduct).

Moreover, the fact that the '440 patent was separated from the follow-on Bentley Patents by the filing of a divisional application renders Bayer's allegations of infectious unenforceability unavailing with respect to the follow-on Bentley Patents. *See Robocast*, 39 F. Supp. 3d at 571. In *Robocast, Inc. v. Apple Inc.*, the court clarified that "[a] divisional application is drawn to a different invention, and different inventions do not share an 'immediate and necessary' relation to each other." *Id.* (discussing *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1332 (Fed. Cir. 1998)). The parties in the present case do not dispute the basic fact that the follow-on Bentley Patents were separated from the '440 patent by a divisional application. (D.I. 385 at 15-16; D.I. 396 at 16-17) Thus, Bayer has failed to adequately plead infectious unenforceability regarding the Bentley Patents.

Bayer's pleading regarding the Bossard Patents otherwise adequately pleads that the follow-on Bossard Patents are subject to infectious unenforceability regarding the concealed references and false statements. Beyond identifying similar subject matter and a shared patent family, (D.I. 333 at ¶ 87), the pleading also alleges that the applicants concealed the same material references during prosecution of the '223 patent and the follow-on Bossard Patents, (*id.*

at ¶¶ 74-78). Remaining disputes between the parties on this issue are factual in nature and are not properly resolved at this stage of the proceedings.

5. Duty of candor

Plaintiffs contend that Bayer's inequitable conduct counterclaims fail to adequately plead Dr. Harris and Dr. Charles owed a duty of candor to the USPTO. (D.I. 385 at 16) According to Plaintiffs, Dr. Harris and Dr. Charles were not inventors or prosecuting attorneys for the Bentley and Bossard Patents in accordance with 37 C.F.R. § 1.56(c), nor were they substantively involved in the prosecution of those patents. (*Id.* at 17)

Bayer does not dispute that Dr. Harris and Dr. Charles were not named inventors of the Bentley and/or Bossard Patents, nor did they act as prosecuting attorneys for those patents. Moreover, Bayer concedes that Dr. Charles does not owe a duty of candor to the USPTO. (D.I. 396 at 18) Instead, Bayer contends that the counterclaims allege Dr. Harris should have been a named inventor, and he had a duty of candor stemming from his knowledge and awareness of the Bentley and Bossard Patents. (*Id.* at 18-19) Bayer emphasizes that Dr. Harris authored an undisclosed prior art reference setting forth the limitations of the '440 patent, and he was directly involved in communications with prosecution counsel during prosecution of the '440 patent. (*Id.* at 19-20)

Bayer's pleadings adequately allege that Dr. Harris had a duty of candor because he was "substantively involved in the preparation or prosecution" of the applications leading to the Bentley and Bossard Patents. 37 C.F.R. § 1.56(c)(3). The Federal Circuit has defined "'substantively involved' to mean that the involvement relates to the content of the application or decisions related thereto, and that the involvement is not wholly administrative or secretarial in

nature." *Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 974 (Fed. Cir. 2010) (citing Manual of Patent Examining Procedures § 2001.01 (8th ed., rev.2, May 2004)). (D.I. 381 at ¶ 98; D.I. 333 at ¶ 91) The pleadings at issue in this case adequately establish that Dr. Harris obtained confidential information from Bayer and improperly disclosed that information to the inventors of the Bentley and Bossard Patents, omitting his own name from those patent applications to avoid exposing his role in misappropriating Bayer's confidential information. (D.I. 381 at ¶¶ 93, 96-105, 134-150; D.I. 333 at ¶¶ 86, 89-94, 120-138)

For instance, the pleadings allege that "it was Bayer that first discovered the use of that PEG structure with factor VIII in the 1990's and early 2000's," (D.I. 381 at ¶ 93; *see also* D.I. 333 at ¶ 86), at a time when "Dr. Harris and Bayer scientists regularly spoke by phone and in person" regarding "the details of its pegylated factor VIII research and discoveries" pursuant to Bayer's consulting agreement with Dr. Harris, (D.I. 333 at ¶¶ 19-21; D.I. 381 at ¶¶ 19-22). The pleadings further allege that Dr. Harris "knew that he had disclosed the use of fewer, large PEGs with factor VIII he learned from Bayer to the named inventors which subject matter was used in the Asserted [Bentley and] Bossard Patents." (D.I. 333 at ¶ 91; D.I. 381 at ¶ 99) The pleadings disclose that "Dr. Harris had a strong financial incentive to omit his name as a named inventor from the Applications for the Asserted [Bentley and] Bossard Patents to avoid the discovery by Bayer of his improper disclosure" of Bayer's confidential research. (D.I. 333 at ¶ 122; D.I. 381 at ¶ 134) These allegations support a reasonable inference that Dr. Harris was substantively involved in the prosecution of applications leading to the issuance of the Bentley and Bossard Patents, and he should have been listed as an inventor on those applications. Accordingly, Bayer's pleadings adequately allege that Dr. Harris owed a duty of candor to the USPTO.

B. *Walker Process* Antitrust Claim

Pursuant to the Supreme Court's ruling in *Walker Process*, "maintenance and enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under § 2 of the Sherman Act." *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 173 (1965). The party asserting the *Walker Process* claim must show that "the patentee committed fraud before the PTO, that the fraud caused the patent to issue, and that the patentee enforced the fraudulently procured patent." *In re Lipitor Antitrust Litig.*, 855 F.3d 126, 145 (3d Cir. 2017) (internal citation omitted); *see also TransWeb, LLC v. 3M Innovative Properties Co.*, 812 F.3d 1295, 1306 (Fed. Cir. 2016). The party asserting the *Walker Process* claim must also establish the other elements of a Sherman Act monopolization claim: (1) engagement in predatory or anticompetitive conduct, (2) specific intent to monopolize, and (3) "a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993).

1. Format

Plaintiffs argue that Bayer's counterclaims lack a separate count asserting a *Walker Process* antitrust violation, and the four paragraphs in the background section of the counterclaims pertaining to *Walker Process* violations are conclusory. (D.I. 385 at 17-18) Plaintiffs' effort to police the formatting of Bayer's pleadings is unavailing. Bayer's counterclaims specifically identify the *Walker Process* counterclaim: "The '440 patent is void, unenforceable, and of no legal effect by reason of derivation, inequitable conduct, *Walker Process* fraud, and/or unclean hands as to Bayer." (D.I. 381 at ¶ 183; *see also* D.I. 333 at ¶ 173) As Plaintiffs acknowledge, the Background section of the counterclaims contains a subsection

specific to *Walker Process* antitrust allegations comprising multiple pages of allegations. (D.I. 381 at ¶¶ 165-180; D.I. 333 at ¶¶ 155-170) Moreover, these allegations refer back to previous paragraphs relating to inequitable conduct and unclean hands because there is significant overlap among the three causes of action. (D.I. 381 at ¶ 165; D.I. 333 at ¶ 155)

2. Fraud on the USPTO

Plaintiffs further contend that Bayer has not alleged fraud on the USPTO, and because Bayer's inequitable conduct allegations are deficient, Bayer cannot rely on its inequitable conduct allegations in support of its *Walker Process* claims. (D.I. 385 at 19-20) In response, Bayer relies on the alleged sufficiency of its inequitable conduct allegations. (D.I. 396 at 21) For the reasons previously stated at § IV.A, *supra*, I recommend that the court grant the motion to dismiss the *Walker Process* claim for failure to plead fraud on the USPTO with the requisite specificity. *See TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016) (concluding that "the showing required for proving inequitable conduct and the showing required for proving the fraud component of *Walker Process* liability may be nearly identical.").

3. Entity-specific arguments

Next, Plaintiffs argue that Bayer's *Walker Process* allegations fail to plead knowledge of the patents' infirmity by Baxalta, an entity that did not itself engage in the fraud. (D.I. 385 at 20-21) In addition, Plaintiffs contend that Bayer's pleadings fail to identify Nektar as a market participant responsible for selling the products covered by the Bentley and Bossard Patents. (*Id.* at 26-27) Bayer responds that Plaintiffs should not be permitted to avoid antitrust liability by parsing out the roles of two entities working in concert to obtain and enforce the Bentley and Bossard Patents. (D.I. 396 at 25-26)

Bayer's *Walker Process* claims fail to adequately plead that Baxalta knew the Bentley and Bossard Patents were procured by fraud when it sought to enforce those patents in these lawsuits. The sole basis for Baxalta's knowledge, as alleged by Bayer, is that Baxalta waived its initial assertion of the '440 patent in its infringement case due to the alleged inequitable conduct, and "[t]he act of dropping the '440 Patent is intended to mask the ongoing scheme by Nektar and Baxalta to assert unenforceable patents against Bayer." (D.I. 381 at ¶¶ 75, 164, 172; D.I. 333 at ¶¶ 162-63) As an initial matter, Bayer's pleadings acknowledge that Baxalta did not drop the '440 patent from the litigation until after the suit was initially brought: "The Baxalta Litigants initially asserted five patents from the Bentley patent family in the related case . . . but waived its assertion of the Bentley '440 patent after the deposition of Dr. Bentley revealed his knowledge of material prior art that he knowingly did not disclose to the USPTO." (D.I. 333 at ¶ 162) Nothing in these allegations establishes whether, or how, Baxalta knew the Bentley and Bossard Patents were procured by fraud at the time the lawsuit was first filed. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998) (noting that the plaintiff "must also have been aware of the fraud when bringing suit"); *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338 (Fed. Cir. 2014) (assessing whether plaintiff "knew at the time it initiated this suit that it was 'seeking to enforce patents which had been procured by knowing and willful fraud.'").

In its answering brief, Bayer relies on Nektar's fourth amended privilege log, which allegedly shows 57 communications between Nektar and Baxalta, to support its position that Baxalta had knowledge of the infirmities of the Bentley and Bossard Patents. (D.I. 396 at 25) Although an earlier version of the privilege log is discussed in the pleading and appears to be

attached to the pleading itself, (D.I. 381 at ¶ 98; Ex. V), this is not the same document identified by Bayer in support of its position, (D.I. 396, Ex. 3). Also, the pleading refers to the privilege log to establish Dr. Harris' involvement in the prosecution of the Bentley Patents, not to show collaboration between Nektar and Baxalta. (D.I. 381 at ¶ 98) Bayer itself has emphasized the substantive differences among various versions of Plaintiffs' privilege logs, (D.I. 396 at 6), and Bayer acknowledges that the fourth amended privilege log was not produced until "long after the deadline to amend pleadings," (*id.* at 25). Bayer has not provided any authority supporting the court's consideration of a privilege log that is not incorporated by reference into the pleadings on a Rule 12(b)(6) motion. Nor does Bayer direct the court to any portion of the pleadings suggesting that Baxalta and Nektar collaborated to procure the Bossard Patents.

Moreover, Bayer's *Walker Process* counterclaims cannot survive as they pertain to Nektar because Nektar does not sell the products covered by the Bentley and Bossard Patents. (D.I. 381 at ¶ 73; D.I. 333 at ¶ 70) Bayer relies on *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* for the proposition that Nektar and Baxalta are jointly responsible for the *Walker Process* violations. (D.I. 396 at 26) But the decision in *Abbott* was based on pleaded allegations showing that "Abbott and Fournier worked together in the alleged scheme . . ., obtaining patents covering those products, enforcing those patents against [defendants], and ensuring that old formulations were no longer available for generic substitution." 432 F. Supp. 2d 408, 433 (D. Del. 2006). Bayer's pleadings fail to allege such collaboration between Nektar and Baxalta. Because Bayer does not plead that Nektar is a participant in a relevant product market, Bayer cannot satisfy the attempted monopolization requirement of a *Walker Process* claim as to Nektar. *See Allflex USA, Inc. v. Avid Identification Sys., Inc.*, 2010 WL 11405130, at *10 (C.D. Cal. Feb.

16, 2010) ("In other words, the plaintiff must be an actual market participant or be prepared to enter the market."). Bayer acknowledged the deficiencies in the pleaded allegations on these points. (3/11/2020 Tr. at 59:17-24)

4. Definition of relevant market

The aforementioned deficiencies in the *Walker Process* allegations warrant dismissal of the *Walker Process* counterclaims, and the court need not reach the additional bases for dismissal of the *Walker Process* claims at this stage. Nonetheless, Bayer's pleaded allegations do not reflect a consistent definition of the relevant market. The pleadings identify the relevant market as the "market for extended half-life products and products with comparable or even less frequent dosing." (D.I. 381 at ¶ 169; D.I. 333 at ¶ 159) The pleadings also allude to "the plasma product market." (D.I. 381 at ¶¶ 170, 178; D.I. 333 at ¶¶ 160, 169) However, a highly specific definition of the market is not required until a later stage of the proceedings "after a factual inquiry into the commercial realities faced by consumers." *Lifewatch Servs. Inc. v. Highmark Inc.*, 902 F.3d 323, 337 (3d Cir. 2018).

C. Unclean Hands

Bayer's unclean hands counterclaims rest on the same allegations as its counterclaims for inequitable conduct. The affirmative defenses regarding these two causes of action refer to the same range of paragraphs in the counterclaims in support. (D.I. 333 at 28 (citing ¶¶ 15-152 and ¶¶ 15-154); D.I. 381 at 17 (citing ¶¶ 15-162 and ¶¶ 15-180)) "Where an accused infringer's unclean hands defense is based on alleged acts of inequitable conduct, it rises and falls based on those allegations." *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 2017 WL 1101092, at *16 (N.D. Ill. Mar. 22, 2017). Therefore, I recommend that the court dismiss Bayer's unclean hands counterclaims, in accordance with the recommendation at § IV.A, *supra*.

D. Affirmative Defenses

I recommend that the court grant Plaintiffs' motion to strike Bayer's affirmative defenses for the same reasons and to the same extent as set forth at § IV.A-C, *supra*. Plaintiffs move to strike Bayer's affirmative defenses for inequitable conduct, unclean hands, and *Walker Process* fraud based on the same allegations made in support of their counterclaims. The sufficiency of the affirmative defenses is evaluated under Rule 12(f), which provides that the court "may strike from a pleading any insufficient defense." Fed. R. Civ. P. 12(f). When a party fails to state a corresponding claim under Rule 12(b)(6), the court may strike the associated affirmative defense under Rule 12(f). *See Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *4 (D. Del. Feb. 3, 2012) (citing *Power Integrations, Inc. v. Fairchild Semiconductor Int'l Inc.*, C.A. No. 08-309-JJF-LPS, 2009 WL 4928024, at *8-10 (D. Del. Dec. 18, 2009)).

E. Bifurcation

Having recommended that the court grant Bayer's motion to dismiss, Plaintiffs' request to bifurcate issues of inequitable conduct, *Walker Process*, and unclean hands is moot. Should the District Judge permit amendment of the counterclaims in the future, the inequitable conduct counterclaims would be subject to a bench trial. The unclean hands and *Walker Process* counterclaims rise or fall with the inequitable conduct counterclaims. *See Chamberlain Grp.*, 2017 WL 1101092, at *16. Because of the late addition of the inequitable conduct, *Walker Process*, and unclean hands counterclaims and affirmative defenses, additional discovery would be necessary.

V. CONCLUSION

For the foregoing reasons, I recommend that the court GRANT Plaintiffs' motion to dismiss Bayer's inequitable conduct, unclean hands, and *Walker Process* fraud counterclaims, and GRANT Plaintiffs' corresponding motion to strike Bayer's affirmative defenses.

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties shall jointly submit a proposed redacted version by no later than **July 20, 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 Report and Recommendation issued.

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: July 13, 2020

Sherry R. Fallon
United States Magistrate Judge