

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO.,	)	
LTD., KYORIN PHARMACEUTICAL	)	
CO., LTD. AND ALLERGAN, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. No. 12-159-SLR
	)	
APOTEX, INC. AND	)	
APOTEX CORP.,	)	
	)	
Defendants.	)	

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**MEMORANDUM OPINION**

Dated: February 6, 2013  
Wilmington, Delaware

  
ROBINSON, District Judge

## I. INTRODUCTION

This action arises out of the filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) by defendants Apotex, Inc. and Apotex Corp. (collectively, “Apotex”). Allergan, Inc. (“Allergan”) is the holder of approved New Drug Application (“NDA”) No. 22-548 that covers Zymaxid®, a 0.5% ophthalmic solution of gatifloxacin. (D.I. 1 at ¶¶ 29) Senju Pharmaceutical Co., Ltd. (“Senju Pharma”), Kyorin Pharmaceutical Co., Ltd. (“Kyorin”), and Allergan (collectively, “Senju”) are the owners or licensees of U.S. Patent Nos. 6,333,045 (“the ‘045 patent”) and 5,880,283 (“the ‘283 patent”), which are listed in the FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as the “Orange Book”) for Zymaxid®.<sup>1</sup> (*Id.* at ¶¶ 15-16, 18-19, 30)

In a letter dated January 13, 2012, pursuant to 21 U.S.C. § 355(j)(2)(B), Apotex notified Senju that it had submitted ANDA No. 203523, for a generic 0.5% ophthalmic solution of gatifloxacin, with a Paragraph IV certification.<sup>2</sup> (*Id.* at ¶ 33) On February 10, 2012, Senju responded by filing a complaint against Apotex, alleging that ANDA No. 203523 infringes the ‘045 and ‘283 patents (collectively, “the patents-at-issue”). (*Id.*)

On March 16, 2012, Apotex filed its answer in the action and asserted counterclaims, including non-infringement, invalidity, and unenforceability of the patents-at-issue. (D.I. 9) Presently before the court is Senju’s motion for partial dismissal of Apotex’s counterclaims and to strike certain affirmative defenses, filed May

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<sup>1</sup>The Orange Book must list “each drug which has been approved for safety and effectiveness through an NDA.” See 21 U.S.C. § 355(j)(A)(ii).

<sup>2</sup>See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

9, 2012.<sup>3</sup> (D.I. 20) The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1400(b).

## II. BACKGROUND

### A. The Parties

Senju Pharma and Kyorin are corporations organized under the laws of Japan with principal places of business in Japan. (D.I. 1 at ¶¶ 2-3) Allergan is a Delaware corporation with a principal place of business in California. (*Id.* at ¶ 4) Apotex Corp. is a Delaware corporation with a place of business in Florida, and Apotex, Inc. is a corporation organized under the laws of Canada, with a place of business in Ontario, Canada. (*Id.* at ¶¶ 5, 7)

### B. Reexamination of the '045 Patent

The parties to this action were previously engaged in another lawsuit before this court, Civ. No. 07-779 (“the prior litigation”). In an opinion in that case dated June 14, 2010, the court found claims 1-3 and 6-9 of the '045 patent invalid as obvious.<sup>4</sup> *Senju Pharm. Co. v. Apotex Co.*, 717 F. Supp. 2d 404, 433 (D. Del. 2010).

On February 25, 2011, before final judgment was entered in the prior litigation,

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<sup>3</sup>Although Senju’s motion is also labeled as one for attorney fees, Senju states that it “will be filing a separate motion for attorney fees pursuant to Fed. R. Civ. P. 11(c).” (D.I. 20 at 20) Therefore, the court will not address the issue of attorney fees instantly. The court also declines to impose any of the parties’ requested sanctions at this time.

<sup>4</sup>On December 20, 2011, after reopening the judgment on claim 7 and reviewing additional evidence, the court issued a final judgment confirming the invalidity of claim 7. *Senju Pharm. Co. v. Apotex Co.*, 836 F. Supp. 2d 196, 201-11 (D. Del. 2011). Senju appealed the judgment on claim 7 and, on October 5, 2012, the Federal Circuit affirmed. *Senju Pharm. Co. v. Apotex, Inc.*, 485 F. App’x 433 (Fed. Cir. 2012).

Senju Pharma and Kyorin filed a request for reexamination of claims 1-3, 6, 8, and 9 of the '045 patent with the U.S. Patent and Trademark Office ("PTO"). (D.I. 1 at ¶ 26) The request was granted on April 28, 2011. (*Id.*) A reexamination certificate was issued for the '045 patent on October 25, 2011, cancelling claims 1-3 and 8-11, amending claim 6, and adding new claims 12-16. (*Id.* at ¶ 27)

### **C. Apotex's Counterclaims and Affirmative Defenses**

Apotex's second and fourth affirmative defenses aver that the asserted claims of the patents-at-issue "are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 101, 102, 103 and/or 112." (D.I. 9 at 13-14) Counts II and IV of Apotex's counterclaims repeat these allegations using the same language. (*Id.*, counterclaims at ¶¶ 11, 13) The counterclaims do not recite any factual allegations, except for party background and jurisdictional statements. (*Id.*, counterclaims at ¶¶ 1-9)

Apotex's fifth affirmative defense cross-references count V, which claims that the '045 patent is unenforceable due to inequitable conduct during reexamination of the '045 patent. (*Id.* at 14, counterclaims at ¶¶ 14-36) Apotex alleges that "but for" material omissions and misrepresentations made by "Senju [Pharma], Kyorin, the inventors, and/or those acting on their behalf"<sup>5</sup> with an intent to deceive the PTO, the reexamined

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<sup>5</sup>Several paragraphs of the counterclaims assert, more narrowly, that Senju Pharma and Kyorin were responsible for the omissions and misrepresentations before the PTO. (D.I. 9, counterclaims at ¶¶ 19-31, 34-35) In another paragraph, Apotex asserts that the material misrepresentations and omissions were committed by Senju [Pharma], Kyorin [], and/or their prosecuting attorneys." (*Id.*, counterclaims at ¶ 36) For purposes of a motion to dismiss, the court must view the allegations in the light most favorable to the nonmovant, so the court looks to Apotex's best-pled allegation against "Senju [Pharma], Kyorin, the inventors and/or those acting on their behalf." (*Id.*,

claims of the '045 patent would not have issued. (*Id.*, counterclaims at ¶¶ 14-36)

Specifically, the pleadings allege that the following materials were withheld: (1) portions of the trial record and expert reports from the prior litigation disclosing that Kyorin's researchers had been the first to make and test gatifloxacin ophthalmic formulations covered by the '045 patent claims (*id.*, counterclaims at ¶¶ 20, 22); (2) evidence showing that the formulations as claimed by the '045 patent did not exhibit unexpected results (*id.*, counterclaims at ¶¶ 20, 30, 33); and (3) deposition testimony of Senju's expert from the prior litigation allegedly conceding the obviousness of preparing aqueous liquid compositions containing 0.3 w/v% gatifloxacin and 0.01 w/v% of disodium edetate, based on the well-known use of disodium edetate to prevent coloration. (*Id.*, counterclaims at ¶¶ 21, 29) Apotex further alleges that "Senju [Pharma] and Kyorin . . . amended reexamination claim 6 knowing that the added limitations to the claimed methods were not supported by the written description of the '045 patent specification, and thus reexamined claim 6 was invalid." (*Id.*, counterclaims at ¶¶ 25-26)

### **III. STANDARD OF REVIEW**

#### **A. Motion to Dismiss**

In reviewing a motion filed under Federal Rule of Civil Procedure 12(b)(6), the court must accept all factual allegations in a complaint as true and take them in the light most favorable to the pleader. See *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). A court may consider the pleadings, public record, orders, exhibits attached to the complaint, and documents incorporated

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counterclaims at ¶ 17)

into the complaint by reference. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384-85 n.2 (3d Cir. 1994). A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation marks omitted) (interpreting Fed. R. Civ. P. 8(a)). A complaint does not need detailed factual allegations; however, “a [pleader’s] obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of a cause of action’s elements will not do.” *Id.* (alteration in original) (citation omitted). The “[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true . . . .” *Id.* (citations omitted) Furthermore, “[w]hen there are well-ple[d] factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1950 (2009). Such a determination is a context-specific task requiring the court “to draw on its judicial experience and common sense.” *Id.*

## **B. Motion to Strike**

Fed. R. Civ. P. 12(b)(6) does not offer a mechanism for dismissing affirmative defenses because it refers only to “claim[s].” See *Wyeth Holdings Corp. v. Sandoz, Inc.*, Civ. No. 0-955, 2012 WL 600715, at \*4 (D. Del. Feb. 3, 2012). However, Fed. R. Civ. P. 12(f) provides: “The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” “When ruling on a motion to strike, the [c]ourt must construe all facts in favor of the nonmoving party and

deny the motion if the defense is sufficient under law. Further, a court should not grant a motion to strike a defense unless the insufficiency of the defense is clearly apparent.” *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009) (alteration in original) (citations omitted) (internal quotation marks omitted). “As a general matter, motions to strike under Rule 12(f) are disfavored.” *Fesnak & Assocs., LLP v. U.S. Bank Nat’l Ass’n*, 722 F. Supp. 2d 496, 502 (D. Del. 2010).

#### **IV. DISCUSSION**

Senju moves to dismiss counts II, IV, and V of the counterclaims and to strike the second, fourth, and fifth affirmative defenses. (D.I. 20) Counts II and IV of the counterclaims, as well as the second and fourth affirmative defenses, allege that the patents-in-suit are invalid.<sup>6</sup> Count V of the counterclaims and the fifth affirmative defense assert unenforceability of the ‘045 patent for inequitable conduct.<sup>7</sup>

##### **A. Apotex’s Invalidity Defense**

Senju asserts that Apotex’s invalidity defense is deficient because the counterclaims and affirmative defenses recite legal conclusions without factual support and, as such, do not comply with Fed. R. Civ. P. 8, as interpreted by the Supreme Court in *Twombly* and *Iqbal*. (D.I. 20 at 2-4) Apotex does not attempt to argue that its invalidity defense lays out sufficient supporting facts. Rather, it avers that its invalidity defense is not subject to the heightened pleading standard of *Twombly* and *Iqbal*;

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<sup>6</sup>For ease of reference, counts II and IV of the counterclaims and the second and fourth affirmative defenses are collectively referred to as Apotex’s “invalidity defense.”

<sup>7</sup>For ease of reference, count V of the counterclaims and the fifth affirmative defense are collectively referred to as Apotex’s “inequitable conduct defense.”

complies with Fed. R. Civ. P. Form 18; is pled with the same level of detail as Senju's infringement complaint; and will become more detailed as the lawsuit progresses. (D.I. 24 at 6-7) In addition, Apotex contends that Senju cannot complain because "notice letters and the prior proceedings between the parties in this court provide Senju with abundant detail of the general bases of Apotex's invalidity contentions." (*Id.* at 6)

### **1. Counts II and IV of Apotex's counterclaims**

Apotex cites to *Bayer Cropscience AG v. Dow Agrosciences LLC*, Civ. No. 10-1045, 2011 WL 6934557 (D. Del. Dec. 30, 2011), to argue that the heightened pleading standard set forth in *Twombly* and *Iqbal* should not apply to invalidity counterclaims.<sup>8</sup> *Bayer Cropscience*, however, did not draw any conclusions in this regard; rather, it adopted the reasoning of other district courts regarding the pleading standard for invalidity counterclaims to decline imposing the rigors of *Twombly* and *Iqbal* to an unenforceability counterclaims. *Bayer Cropscience*, 2011 WL 6934557, at \*3 ("[T]he same logic that led other courts to conclude that invalidity counterclaims were not subject to heightened pleading under *Twombly/Iqbal* leads this [c]ourt to the same conclusion with respect to patent unenforceability counterclaims."). Generally, the courts that have declined to apply the rigors of *Twombly* and *Iqbal* to invalidity counterclaims have reasoned that doing so would: (1) render the courts' local patent rules on the pleading standard for invalidity counterclaims superfluous; and (2) be inequitable to defendants in that it would impose on them a higher pleading burden than the Form 18 pleading burden on patent plaintiffs. See *Elan Pharm. Int'l Ltd. v. Lupin*

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<sup>8</sup>*Bayer Cropscience* was decided by a judge sitting by designation on this court.



*Ltd.*, Civ. No. 09-1008, 2010 WL 1372316, at \*5 (D.N.J. Mar. 31, 2010); *Teirstein v. AGA Med. Corp.*, No. 6:08cv14, 2009 WL 704138, at \*5 (E.D. Tex. Mar. 16, 2009); *Microsoft Corp. v. Phoenix Solutions, Inc.*, 741 F. Supp. 2d 1156, 1159 (C.D. Cal. 2010); *Pfizer, Inc. v. Apotex, Inc.*, 726 F. Supp. 2d 921, 937-38 (N.D. Ill. 2010).

The court, however, finds the above reasoning unpersuasive. In the first instance, the District of Delaware has not adopted any local patent rules regarding the pleading standard for invalidity counterclaims or requiring that factual contentions be served promptly after a counterclaim of invalidity is advanced. Moreover, Form 18 still requires that some factual underpinning be presented, a factual underpinning absent from Apotex's pleading. Most significantly, the fact that Form 18 (rather than *Twombly* and *Iqbal*) remains the standard for pleading infringement claims is an insufficient justification for deviating from *Twombly* and *Iqbal* for pleading other causes of action. As explained in *In re Bill of Lading Transmission*, 681 F.3d 1323, 1336 (Fed. Cir. 2012), "Form 18 should be strictly construed as measuring only the sufficiency of allegations of direct infringement . . . ."

Therefore, the court concludes that the pleading standards set forth in *Twombly* and *Iqbal* apply to counterclaims of invalidity. See *Internet Media Corp. v. Hearst Newspapers, LLC*, Civ. No. 10-690, 2012 WL 3867165, at \*2 (D. Del. Sept. 6, 2012); accord *Tyco Fire Prods. LP v. Victaulic Co.*, 777 F. Supp. 2d 893, 898 (E.D. Pa. 2011) ("In the wake of *Twombly* and *Iqbal*, it is clear that a[] counterclaim must set forth sufficient facts to give rise to a plausible claim for relief."); *Xilinx, Inc. v. Invention Inv. Fund I LP*, No. C 11-0671, 2011 WL 3206686, at \*6 (N.D. Cal. July 27, 2011) (holding that the court "will not accept 'wholly conclusory allegations' in a claim alleging patent

invalidity, and that simply 'pleading the citation' to a section of the Patent Act is not sufficient"). Apotex does not contend that its invalidity counterclaims allege sufficient facts to pass muster under these pleading standards.

Apotex's averment that there are several other actions before the court involving the patents-in-suit is not a substitute for pleading sufficient facts.<sup>9</sup> Apotex provided no supporting case law regarding how other lawsuits may affect the pleading standard and made no indication why Senju should be able to infer from the other cases what the invalidity contentions might be in the instant case. Of the other actions in this court involving at least one of the patents-at-issue, Apotex and Senju are parties to the prior litigation and Civ. Nos. 11-1171 and 12-196. None of those cases involve the infringement or invalidity of the '283 patent. The prior litigation and Civ. No. 11-1171 relate to infringement and invalidity of the '045 patent; however, judgment in the former issued prior to the completion of reexamination, and the latter was dismissed on res judicata grounds.

Therefore, the court will not excuse Apotex's insufficient pleading. The court grants Senju's motion to dismiss with respect to counts II and IV of Apotex's counterclaims.

## **2. The second and fourth affirmative defenses**

Due to the "differences between Rules 8(a) and 8(c) in text and purpose, [] *Twombly* and *Iqbal* do not apply to affirmative defenses,' which 'need not be plausible to survive. [An affirmative defense] must merely provide fair notice of the issue involved."

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<sup>9</sup>The court gathers that Apotex is referring to the prior litigation and Civ. Nos. 11-271, 11-439, 11-926, 11-1059, 11-1171, and 12-196.

*Internet Media*, 2012 WL 3867165, at \*3 (quoting *Tyco Fire Prods.*, 777 F. Supp. 2d at 900); see also *Bayer Cropscience*, 2011 WL 6934557, at \*1-2 (articulating nine reasons utilized by courts recognizing a Rule 8(a)/Rule 8(c) distinction). The court has held that an allegation that states that the claims of a patent are invalid for “fail[ing] to meet the conditions for patentability within the meaning of the patent laws, Title 35 § 101 et seq., including, but not limited to, §§ 101, 102, 103 and/or 112” – while insufficient as a counterclaim to survive a motion to dismiss – is sufficient as an affirmative defense to survive a motion to strike. *Id.* at \*1, \*3. Apotex’s affirmative defense of invalidity is asserted almost identically to that permitted in *Internet Media*. As such, the court denies the motion to strike Apotex’s second and fourth affirmative defenses.

#### **B. Apotex’s Inequitable Conduct Defense**

“An individual associated with the filing and prosecution of a patent application commits inequitable conduct when he or she (1) makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information to the PTO; (2) with the specific intent to deceive the PTO.” *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 379 (D. Del. 2012) (internal quotation marks omitted). Senju asserts that Apotex’s inequitable conduct defense – count V of the counterclaims and the fifth affirmative defense – should be dismissed because they: (1) are self-evidently false under Third Circuit precedent; and (2) do not meet the minimal requirements for pleading inequitable conduct under Federal Circuit precedent. (D.I. 20 at 5-19)

##### **1. Whether Apotex’s allegations are self-evidently false**

On a motion to dismiss, the court is not obligated to accept as true “bald

assertions,” “unsupported conclusions and unwarranted inferences,” or allegations that are “self-evidently false” at the motion to dismiss stage. *Rader v. ShareBuilder Corp.*, 772 F. Supp. 2d 599, 603 (D. Del. Mar. 24, 2011) (internal quotation marks omitted). Senju contends that Apotex’s allegations of inequitable conduct are “self-evidently false from the public record of the reexamination.” (D.I. 20 at 5) In support, Senju attached to its opening brief exhibit A, which contains electronic versions of over 9000 pages of materials filed with the PTO during reexamination of the ‘045 patent. (*Id.*, ex. A) Citing portions of exhibit A, Senju argues that the documents that were submitted to the PTO during reexam were identical or substantively identical to the materials that were allegedly withheld. (*Id.* at 5-13; D.I. 25 at 3)

In reviewing a motion to dismiss, “[c]ourts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record.”<sup>10</sup> *Collins & Aikman Corp. v. Stockman*, Civ. No. 07–265, 2010 WL 184074, at \*3 (D. Del. Jan. 19, 2010) (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). Because exhibit A contains the reexamination file of the ‘045 patent, which is publicly available through the PTO’s Public Patent Application Information Retrieval (“PAIR”) database, it is a public document that the court may rely upon in deciding this motion to dismiss.<sup>11</sup> See, e.g.,

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<sup>10</sup>The Federal Circuit applies the rule of the regional circuit to purely procedural questions not pertaining to patent law. See *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1355-56 (Fed. Cir. 2007); *C&F Packing Co. v. IBP, Inc.*, 224 F.3d 1296, 1306 (Fed. Cir. 2000).

<sup>11</sup>The control number for retrieving the reexamination file of the ‘045 patent on PAIR is 90/011509.

*Benihana of Tokyo, Inc. v. Benihana Inc.*, Civ. No. 10-1051, 2011 WL 3861897, at \*2 & n.1 (D. Del. Sept. 1, 2011) (considering, on a motion to dismiss, a document that was submitted to the PTO and publicly available).

As summarized *supra*, Apotex alleges that the following material was withheld from the PTO during reexamination: (1) portions of the trial record and expert reports from the prior litigation disclosing that Kyorin's researchers had been the first to make and test gatifloxacin ophthalmic formulations covered by the '045 patent claims (D.I. 9, counterclaims at ¶¶ 20, 22); (2) evidence showing that the formulations as claimed by the '045 patent did not exhibit unexpected results (*id.*, counterclaims at ¶¶ 20, 30, 33); and (3) deposition testimony of Senju's expert from the prior litigation allegedly conceding the obviousness of preparing aqueous liquid compositions containing 0.3 w/v% gatifloxacin and 0.01 w/v% of disodium edetate, based on the well-known use of disodium edetate to prevent coloration. (*Id.*, counterclaims at ¶¶ 21, 29) Senju cites various documents in the reexamination file to argue that the allegedly withheld materials were disclosed in other forms, such that the factual allegations are self-evidently false.<sup>12</sup>

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<sup>12</sup>Regarding the first category of alleged omissions, Senju points to portions of the reexamination file disclosing the following materials from the prior litigation: this court's opinion (D.I. 20, ex. A at 673-74); Apotex's invalidity expert report (*id.*, ex. A at 3622-23); Apotex's expert's tutorial (*id.*, ex. A at 1990); Apotex's proposed findings of fact (*id.*, ex. A at 1208-09); Apotex's briefs (*id.*, ex. A at 966-67, 1153-54, 1176-77); and deposition excerpts of the Kyorin formulators. (*Id.*, ex. A at 1304-06, 1313-17). With respect to the second category of alleged omissions, Senju cites to materials in the reexamination file regarding freeze-thaw studies and corneal permeability testing that Senju conducted, corneal permeability and precipitation studies that Apotex conducted (*id.*, ex. A at 2039-47, 2253-60, 2462-2532, 2537-2657, 2659-2728, 2731-66, 2776-83, 2785-90, 3223-3384, 3385-3420, 2787-3102, 4080-4136, 4158-4612, 4634-96, 5477-7091, 7104-39, 7141-7392, 7574-7609, 7611-75, 7698-8257, 9301-75), a precipitation

Senju, however, does not dispute that the materials identified in the inequitable conduct allegations were withheld from the PTO. It instead argues that the materials that were submitted contained information that was either identical, or substantively identical, to the alleged omissions before the PTO.<sup>13</sup> Therefore, there is nothing in the reexamination files that renders Apotex's allegations that certain materials were withheld to be self-evidently false. Whether the information contained in the disclosed materials was identical, or substantively identical, to materials that were withheld raises a separate issue regarding the "but for materiality" of the withheld evidence.<sup>14</sup> See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291-92 (Fed. Cir. 2011) (clarifying that "but for" materiality – "whether the PTO would have allowed the claim if it had been aware of the undisclosed reference" – is generally required to establish the

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study that a third party conducted (*id.*, ex. A at 8984-8998), and Senju's briefs, proposed findings of fact, and expert's tutorial from the prior litigation. (*id.*, ex. A at 944-995, 1137-98, 1199-1227, 1870-2029, 5340-5403, 7445-52) Finally, for the third category of alleged omissions, Senju cites to trial testimony of Senju's expert, from the prior litigation, regarding the prevention of coloration (*id.*, ex. A at 2375), Apotex's brief quoting that trial testimony (*id.*, ex. A at 965, 1175), and this court's opinion quoting that trial testimony. (*id.*, ex. A at 265-66)

<sup>13</sup>Senju also contends that its expert in the prior litigation never conceded, as Apotex alleges, the obviousness of preparing an aqueous liquid composition containing 0.3 w/v% gatifloxacin and 0.01 w/v% disodium edetate. (D.I. 20 at 9) Because the court must take Apotex's allegations as true, Senju's denial is not enough. There is a factual dispute regarding the import of the expert's testimony, so it would be improper for the court to interpret the expert's testimony at this stage of the litigation.

<sup>14</sup>Senju also contends, in the alternative, that the information is cumulative and that cumulative information cannot be material for purposes of inequitable conduct. (D.I. 25 at 4) However, Senju's argument relies on *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1319 (Fed. Cir. 2006), a pre-*Therasense* case that addressed the standard for materiality under 37 C.F.R. § 1.56 rather than the "but for" materiality standard that the Federal Circuit adopted in *Therasense*.

materiality prong of inequitable conduct).

Having considered the reexamination files, the court cannot determine at this juncture whether the alleged omissions, in light of the documents that were submitted to the PTO, were “but for” material. “To survive a motion to dismiss, a complainant must allege facts that ‘raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).’” *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). “The [c]ourt does not decide the merits of the claim at this stage, only whether materiality has been properly alleged with sufficient particularity.” *Evonik Degussa GMBH v. Materia Inc.*, Civ. No. 09-636, 2012 WL 4503771, at \*6 (D. Del. Oct. 1, 2012). As a result, Apotex’s allegations are not self-evidently false and must be taken as true at the motion to dismiss stage of litigation.

## **2. Whether Apotex sufficiently pled inequitable conduct**

The court next reviews whether Apotex sufficiently pled inequitable conduct. A claim of patent unenforceability premised upon inequitable conduct is a claim sounding in fraud. Under Fed. R. Civ. P. 9(b), fraud is a clear exception to the otherwise broad notice-pleading standards. A party alleging unenforceability, therefore, must plead with particularity those facts which support the claim that the patent holder acted fraudulently before the PTO. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009).

“[T]o plead the circumstances of inequitable conduct with the requisite particularity under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the

PTO.” *Exergen*, 575 F.3d at 1328; see also *Evonik Degussa*, 2012 WL 4503771, at \*6 (discussing *Exergen* as the applicable heightened pleading standard for inequitable conduct).

[M]oreover, although ‘knowledge’ and ‘intent’ may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

*Exergen*, 575 F.3d at 1328-29.

Just as a claim for inequitable conduct must meet the heightened pleading requirements of Rule 9(b), a defendant is also “required to plead this affirmative defense with particularity under Rule 9(b).” See *Bayer Cropscience*, 2011 WL 6934557, at \*3. As a result, Apotex’s counterclaim and affirmative defense for inequitable conduct rise or fall together. See *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 379-83 (D. Del. 2012) (assessing the sufficiency of counterclaims and affirmative defenses of inequitable conduct together); *Southco, Inc. v. Penn Eng’g & Mfg. Corp.*, 768 F. Supp. 2d 715, 721-24 (D. Del. 2011) (same).

The pleadings at issue sufficiently plead the “how” (misleading the PTO regarding evidence of obviousness, secondary considerations, and the scope of the patent’s written description) and “where” (materials omitted in submissions to the PTO and teachings of the written description) standards. With respect to the alleged omissions before the PTO, the pleadings also meet the “what” (omission of material evidence and testimony) and “when” (during reexamination of the ‘045 patent) standards and plead the requisite state of mind. The court can reasonably infer, given the volume of



materials from the prior litigation that was submitted during reexamination, that the materials that were withheld were done so with knowledge and intent to deceive the PTO.

However, the court finds that Apotex has not met the *Exergen* pleading standard with respect to “who” deceived the PTO. The duty of candor and good faith in dealing with the PTO applies to individuals, not organizations. See *Exergen*, 575 F.3d at 1329 (citing 37 C.F.R. §1.56(a); Manual of Patent Examining Procedures § 2001.01 (8th ed., rev. 2, May 2004)). Apotex alleges that “Senju [Pharma], Kyorin, the inventors and/or those acting on their behalf” made the alleged misrepresentations and omissions before the PTO. (D.I. 9 at ¶ 17) In *Exergen*, the Federal Circuit found a similarly-worded allegation – only naming “Exergen, its agents and/or attorneys” – to be deficient because it failed to identify the specific individual or individuals who deceived the PTO. *Exergen*, 575 F.3d at 1329. Similarly, this court in *XpertUniverse* found that allegations of inequitable conduct against “Abraham Zelkin or one or more of the other individuals listed as an inventor” fell short of the pleading standard. *XpertUniverse*, 868 F. Supp. 2d at 381. The court characterized the pleadings as “scant allegations . . . further diluted by the qualifiers that either Zelkin, or ‘one or more’ of the other inventors, knew about the [withheld information] and their materiality – affording the possibility that Zelkin, the only specific individual named, did not know about them at all.” *Id.*

As in *Exergen*, Apotex’s inclusion of general entities, Senju Pharma and Kyorin, in the pleadings does not permit the court to reasonably infer that any specific individual was responsible. See *Exergen*, 575 F.3d at 1329-30. As in *XpertUniverse*, Apotex’s broadly cast net around the inventors and those acting on their behalf also does not

allow the court to reasonably infer that a specific individual both knew of the invalidating information and had a specific intent to deceive the PTO. Apotex's vague allegations could implicate all or none of the individuals who had dealings with the PTO during the reexamination. As such, the court finds that Apotex has insufficiently pled "who" deceived the PTO.

Aside from this factual deficiency, which is fatal under Rule 9(b), see *Exergen*, 575 F.3d at 1330, Apotex's allegation regarding misrepresentation of the written description also falls short of the pleading standard in other regards. In particular, Apotex fails to sufficiently plead the "what," "when," and requisite mental state. The allegation claims: "Senju [Pharma] and Kyorin also amended reexamination claim 6 knowing that the added limitations to the claimed methods were not supported by the written description of the '045 patent specification, and thus reexamined claim 6 was invalid." (D.I. 9, counterclaims at ¶¶ 25-26) Although the pleading identifies the claim and limitations to which the misrepresentation would be relevant (the additional limitations of reexamined claim 6), it does not identify what the misrepresentation was or when it was made. See *Wyeth Holdings*, 2012 WL 600715, at \*9 (finding that the "what" standard was met by alleged misrepresentations regarding the state of prior art, and that the "when" standard was met by implicating two dates on which the misrepresentations were allegedly made). The only alleged action related to the written description is that claim 6 was amended; amending a claim, on its face, does not constitute an affirmative misrepresentation before the PTO. Moreover, there are no facts from which the court can reasonably infer that any individual with knowledge of the written description also had knowledge of the falsity of any material misrepresentation

and that the same individual misrepresented the information with a specific intent to deceive the PTO.

Therefore, although Apotex's allegations of inequitable conduct are not self-evidently false, they do not meet the pleading requirements under *Exergen*.<sup>15</sup> The court grants the motion to dismiss Apotex's counterclaim of unenforceability for inequitable conduct and to strike the corresponding affirmative defense.

## V. CONCLUSION

For the foregoing reasons, Senju's motion for partial dismissal of Apotex's counterclaims and to strike certain affirmative defenses is granted in part and denied in part. The court grants Senju's motion with respect to counts II, IV, and V of the counterclaims, as well as the fifth affirmative defense, with leave to amend. The court denies the motion with respect to the second and fourth affirmative defenses. An appropriate order shall issue.

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<sup>15</sup>Apotex also alleges that the "material misrepresentations and omissions amounted to affirmative egregious misconduct . . . ." (D.I. 9, counterclaims at ¶ 36) Omissions, however, cannot constitute affirmative egregious misconduct. *Therasense*, 649 F.3d at 1292-1293 ("Because neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct, claims of inequitable conduct that are based on such omissions require proof of but-for materiality."). Insofar as Apotex pleads affirmative egregious misconduct based on omissions, the court grants the motion to dismiss the inequitable conduct counterclaim and affirmative defense in this regard as well.