NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WARNER CHILCOTT CO., LLC, et al., **Plaintiffs,** **v.** **AMNEAL PHARMACEUTICALS, LLC, et al.,** **Defendants.**	**Civil Action No. 11-5989 (FSH)**
WARNER CHILCOTT CO., LLC, et al., **Plaintiffs,** **v.** **TEVA PHARMACEUTICALS USA, INC.,** **Defendant.**	**Civil Action No. 11-6936 (FSH)**
WARNER CHILCOTT CO., LLC, et al., **Plaintiffs,** **v.** **RANBAXY INC. et al.,** **Defendants.**	**Civil Action No. 12-2474 (FSH)** **OPINION DENYING MOTION TO AMEND**

PRESENTLY BEFORE THE COURT are joint motions to amend Defendants' Answers and Counterclaims, made in three actions consolidated for pretrial purposes. Defendants Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (hereinafter "Amneal") in Civil Action No. 11-5989 filed the motion at Docket Entry No. 131.[1]

[1] This motion was originally brought by Watson Laboratories, Inc., - Florida. Plaintiffs filed the action against Watson after Watson filed its Abbreviated New drug Application ("ANDA") No. 203090. Prior to the Court's

Defendant Teva Pharmaceuticals USA, Inc., in Civil Action No. 11-6936 filed the motion at Docket Entry No. 135. Defendants Ranbaxy Inc., and Ranbaxy Laboratories Limited (hereinafter "Ranbaxy"), in Civil Action No. 12-2474, filed the motion at Docket Entry No. 95. Amneal, Teva, and Ranbaxy, ("Defendants") seek to add a claim for inequitable conduct before the Patent and Trademark Office ("PTO") relating to the applications of the patents-in-suit. *See* Amneal's Motion to Amend/Correct Answer and Counter Claims to the Amended Complaint, Docket Entry No. 139 on Docket 11-5989.[2] Plaintiffs, Warner Chilcott Co., LLC, and Warner Chilcott (US), LLC, ("Plaintiffs") oppose the motion, arguing that Defendants fail to plead the elements of inequitable conduct. *See* Plaintiffs' Opposition Brief at Docket Entry No. 134 ("Pls.' Opp."). For the reasons stated below, Defendants' Motions to Amend are denied.

I. Procedural History

The underlying actions are patent infringement suits triggered by the filing of Defendants' ANDAs with the United States Food and Drug Administration ("FDA") for the sale of generic versions of Plaintiffs' osteoporosis drug, Atelvia. Atelvia is a delayed-release formulation of the drug risedronate. *See* Amended Complaint ¶ 13 at Docket Entry No. 71 ("Am. Compl."). Atelvia encompasses the three patents-in-suit: 7,645,459 ("'459"), entitled "Dosage Forms of Bisphosphonates," 7,645,460 ("'460"), entitled "Dosage forms of Risedronate," and 8,246,989 ("989"), entitled "Dosage Forms of Risedronate." *See* Am. Compl. ¶¶ 14-16 & Exhibits A-C. The '459 and '460 patents were prosecuted by The Proctor & Gamble

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decision on the motion, Watson sold certain assets, including ANDA No. 203090, to Amneal. Amneal filed an Order of Substitution as the real party in interest, which was so ordered by the Hon. Faith S. Hochberg, U.S.D.J. *See* Docket Entry No. 172.

[2] As Defendants' motions are identical, the Court will refer to the motion papers filed on Docket 11-5989, Warner Chilcott, et al. v. Amneal Pharmaceuticals, et al. For reference, the corresponding papers may be found at the following locations: for 11-5989, Defendants' Motion is at Docket Entry No. 131, and brief in support at No. 132; Plaintiffs' Opposition at Docket Entry No. 134; and Defendants' Reply at No. 139. For Docket 11-6936, Motion papers are at Docket Entry No. 135, and brief in support at No. 137; Opposition is at No. 138; Reply is at No. 143. For Docket 12-2474, Defendants' Motion papers are at Docket Entry No. 95, and brief in support at No. 96; Opposition is at No. 98, and Reply is at No. 103.

Company ("P&G" or the "Applicants"), from whom Plaintiffs acquired their pharmaceutical business and intellectual property. Pls.' Opp. at 7, n.2. [3] The '989 patent is a continuation in part of the '459 patent. *See* Exhibit C, Am. Compl..

On October 12, 2011, November 22, 2011, and April 26, 2012, Plaintiffs initiated patent infringement actions against Defendants for the infringement of the '459 and '460 patents as triggered by Defendants' ANDAs. Plaintiffs filed an Amended Complaint with the later-granted '989 patent in September 2012. On September 28, 2012 and October 2, 2012, Defendants filed their respective Answers and Counterclaims, including claims for non-infringement and invalidity of the patents-at-issue. The three actions were consolidated for pretrial purposes. *See* Docket Entry No. 64.

On March 8, 2013, Defendants filed their respective motions to amend to add inequitable conduct. *See* Docket Entry Nos. 122 & 123. As the motions included information designated confidential, Defendants filed their papers under seal, including the proposed Amended Answers and Counterclaims. *See* Docket Entry No. 126. Judge Shwartz, the then-assigned magistrate judge, terminated the motions and directed the parties to confer on pleadings that could be fully made public. *See* Docket Entry No. 127. Judge Shwartz also encouraged the parties to consent to the amendments without prejudice to Plaintiffs' right to move to dismiss. *Id.*

Defendants renewed their motions on publically accessible pleadings on April 12, 2013. *See* Docket Entry No. 131. Plaintiffs, however, chose to challenge the motion on substantive grounds and refused to consent to the amendments. Thus, to address any substantive arguments made, the parties argue the motion on the publically accessible pleadings and confidential

[3] Due to inconsistencies between the pagination of the parties briefs and the Court's electronic filing system ("ECF"), the Court will refer to the pagination of ECF.

information, and their motion papers are filed under seal. *See* Defendants' Brief in Support of the Motions to Amend ("Defs.' Br.") at 8-9.

II. Standard

A. Motion to Amend

Pursuant to Fed.R.Civ.P. 15(a)(2), leave to amend the pleadings is generally freely granted. *See Foman v. Davis,* 371 U.S. 178, 182 (1962); *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). Nevertheless, the Court may deny a motion to amend where there is "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment." *Foman,* 371 U.S. at 182.

An amendment is futile if it "is frivolous or advances a claim or defense that is legally insufficient on its face." *Harrison Beverage Co. v. Dribeck Imp., Inc.,* 133 F.R.D. 463, 468 (D.N.J. 1990) (internal quotation marks and citations omitted). The court uses "the same standard of legal sufficiency" as a motion to dismiss under Rule 12(b)(6). *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000).

When faced with a motion to dismiss for failure to state a claim, the court conducts a two-step analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual elements from the legal elements of the claim. *Id.* at 210-11. The court must accept the factual elements alleged in the well-pleaded complaint as true, but may disregard any legal conclusions. *Id.*

Second, the court must decide if the facts alleged are sufficient to show a "plausible claim for relief." *Fowler*, 578 F.3d at 210 (quoting *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1955 (2009)). A plausible claim is one which "allows the court to draw the reasonable inference that the

defendant is liable for the misconduct alleged." *Id.* (quoting *Iqbal*, 129 S.Ct. at 1948). "Ultimately, this two-part analysis is 'context specific' and requires the court to draw on 'its judicial experience and common sense' to determine if the facts pled in the complaint have 'nudged [plaintiff's] claims' over the line from '[merely] conceivable or [possible] to plausible.'" *Hobson v St. Luke's Hospital and Health Network*, 735 F. Supp. 2d 206, 211 (E.D. Pa. 2010) (quoting *Fowler*, 578 F.3d at 211).

B. Inequitable Conduct

A patent applicant has a duty of good faith and candor in dealing with the PTO, "which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability." *McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007); 37 C.F.R. § 1.56. A breach of this duty gives rise to the defense of inequitable conduct, an equitable remedy that may nullify the patent at issue. *See Sepracor Inc. v. Teva Pharmaceuticals USA, Inc.*, 2010 WL 2326262 at *3 (D.N.J. Jun. 7, 2010). A party may plead the defense by alleging "affirmative misrepresentation of material fact, failure to disclose material information, or submission of false information, coupled with an intent to deceive." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

Where a party alleges misrepresentations, courts look to distinguish between misrepresentations of material facts and permissible attorney argument. *See Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007). Attorney argument is a permissible method for applicants to distinguish or present their interpretations of the prior art. *Id.* Often where the examiner is provided the prior art, courts find an applicant's statements is only argument. *Id.*; *WesternGeco LLC v. ION Geophysical Corp.*, 2012 WL 567430 at *19 (S.D. Tex. Feb. 21, 2012). Misrepresentations are found where applicants exceed the boundaries of argument, by

presenting false information or withholding information necessary to understand other references before the PTO. *See, e.g., Wyeth Holdings Corp. v. Sandoz, Inc.*, 2012 WL 600715 at *12 (D. Del. Feb 3. 2005) (finding misrepresentations where the applicant failed to accurately describe industry knowledge, internal testing and protocol and failed to provide significant error rates); *Therasense, Inc. v. Becton, Dickinson and Co.*, 864 F. Supp. 2d 856 (N.D. Cal. 2012) (finding inequitable conduct where the applicant withheld briefs submitted to foreign patent office that contradicted the applicant's main point being made to the PTO).

Inequitable conduct is subject to the higher pleading standards of Fed.R.Civ.P. 9(b). *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009). A party alleging inequitable conduct must plead "the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* at 1327. To prove inequitable conduct, the alleging party must establish by clear and convincing evidence that the applicant "misrepresented or omitted material information with the specific intent to deceive the PTO." *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011). At the pleading stage, the moving party must provide sufficient facts for the court to "reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with specific intent to deceive the PTO." *Delano Farms Co., v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011).

Materiality and intent are independent factors. *Therasense*, 649 F.3d at 1287. Materiality is a "but-for" standard. *Id.* Information is material if the examiner would not have allowed a claim had it been aware of the undisclosed prior art. *Id.* at 1291.

Intent cannot be merely inferred from the materiality of the reference. *See Therasense* at 1290 (citing *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir.

2008)) ("Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive."). Since deceit is rarely explicit, courts may infer intent from indirect and circumstantial evidence. *Id.* "[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Therasense*, 649 F.3d at 1290 (quoting *Star*, 537 F.3d at 1366). While conditions of the mind may be averred generally, the pleadings must contain "sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." *Exergen*, 575 F.3d at 1327.

III. Background[4]

A. Atelvia and the Patents-in-Suit

Atelvia is a member of the bisphosphonate class of drugs for the treatment of osteoporosis. *See* Pls.' Opp. at 7. Prior to Atelvia, bisphosphonate products on the market were immediate release formulations. *Id.* Eating too soon after taking the drug or at the same time as taking the drug resulted in reduced absorption of the medication, an event called "food effect." *Id.* Patients had to take the medication in a fasted state to maintain efficacy. *Id.* This restriction, however, "posed a major inconvenience to patients, resulting in a high degree of non-compliance." *Id.* at 7. P&G developed Atelvia to overcome the problem through a delayed release formulation that allowed patients to take the drug with or without food without compromising the medication's efficacy. *See id.* at 8.

The patents-in-suit "cover the use of Atelvia in accordance with the labeling approved by the FDA." Am. Compl. ¶ 18. Each patent shares three features: a delayed release mechanism, the active ingredient risedronate, and an additive ingredient ethylenediaminetetraacetic acid,

[4] The facts and history have been taken from the proposed First Amended Answer and Counterclaims as well as the parties' motion papers.

commonly referred to as EDTA. In Atelvia, EDTA is added to "chelate metal ions such as calcium" and has the effect of preventing calcium and other metals in food ingested by patients from interacting with the risedronate, which would otherwise cause a decreased absorption, or "food effect." Defs.' Br. at 6. Each of the asserted claims of the patents is "directed to an oral dosage form and includes a limitation to an amount of EDTA, with amounts in different claims ranging from 1 mg to 500 mg." *See* Defendants' proposed First Amended Answer ("FAA"), Fourth Affirmative Defense, ¶ 2, Docket Entry No. 131 at 39.

B. Statements to regulatory agencies

In 2005, P&G raised its proposed Atelvia drug with the regulatory agencies. Confidential FAA ¶ 4.[5] In particular, P&G sought guidance on the use of EDTA prior to seeking permission to pursue clinical trials. *See* Defs.' Br. at 12. Defendants allege that during these discussions, P&G "told regulatory authorities that the prior art established the safety of disodium EDTA in humans in the claimed amounts." FAA ¶ 4. In particular, P&G cited references which established an acceptable daily intake amount ("ADI") of EDTA at 2.5 mg per kg body weight per day. P&G then used that figure to argue for the safety of EDTA in its proposed drug because the amounts it intended on using were below the ADI. FAA ¶ 5; Confidential FAA ¶ 7. While the FDA accepted P&G's claims of the safety of the limited doses of EDTA, it further questioned P&G about EDTA's effect on the absorption rates of other drugs and cited to prior art references *Ezra* and *Janner*. Confidential FAA ¶ 9. P&G distinguished *Ezra* and *Janner*, arguing the references involved instances of substantially higher doses of EDTA than P&G intended to use. Confidential FAA at ¶10. P&G believed the "increase in absorption was due at

[5] The Court has included certain information only found in the Defendants' original First Amended Answers and Counterclaims which were filed under seal. Docket Entry No. 123-1. References to the confidential and sealed First Amended Answer and Counterclaims will be cited as "Confidential FAA."

least in part to known effects high doses of edetate [EDTA] on mucosal permeability," which P&G believed would not occur with the lower doses. Confidential FAA, ¶ 10.

C. Prosecution of the Patents

In 2005, P&G submitted the '459 and '460 patent applications to the PTO. *See* Pls.' Opp. at 8. As part of the applications, P&G listed various prior art references, including the three at issue here: *Lin*, *Janner*, and *Ezra*. *Id.* The patent examiner rejected the claims for obviousness based on several existing United States patents and other prior art, including *Lin*. FAA ¶ 9; Pls.' Opp. at 9. The examiner reasoned, "[t]he person of ordinary skill in the art would have been motivated to make those modifications, because the disodium EDTA would increase the absorption of bisphosphonate drugs, and reasonably would have expected success because all references dealt with drug absorptions." FAA ¶ 9.

In response, P&G argued that "the prior art 'taught away' from the clinical use of EDTA in humans" due to its effect on mucosal integrity. FAA ¶10. In particular, P&G used *Lin, Janner* and *Ezra* to demonstrate the teachings of the prior art:

> Lin reports that EDTA results in a 12-fold increase in alendronate absorptions (see Lin, p. 1745)...Notably, Lin actually teaches away from the use of EDTA by stating that "clinical use of EDTA is limited" (see Lin, p. 1745, last paragraph). Of importance in this context, in addition to Lin, other references in the art teach away from EDTA used with bisphosphonates, for example:
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> --Ezra et al., (2000), p. 185: "the applicability of this agent [EDTA] in human pharmacology is impossible" in light of damaging effects on mucosal integrity... "absorption still remains variable and occurs at EDTA concentrations that make this chelator unsuitable for clinical use."
>
> --Janner et al., Calif. Tissue Int. (1991), p. 280: "EDTA can . . . increase the intestinal absorption of bisphosphonates. The mechanism might involve an increase in available

> bisphosphonate… The amount of EDTA required is, however, too high for use clinically."

FAA ¶ 10 (emphasis in original).

In further support, Dr. David Burgio, a named inventor, submitted a sworn declaration in which he argued that the prior art taught away from using EDTA with bisphosphonates "because its effect on the gastrointestinal tract caused too large an increase in absorption of bisphosphonates when taken with food." FAA ¶¶ 11-12. He claimed in contrast to *Lin*, which reported a 12-fold increase in alendronate absorption, results from his study showed only a 1.4 times greater absorption rate from the delayed release with EDTA and immediate release without EDTA formulations. FAA ¶ 11. Dr. Burgio argued that "[in his] opinion, *Lin* teaches away from the unexpected results demonstrated in this Study." FAA ¶ 11.

The examiner found these arguments persuasive and cited them in his statement that withdrew his objections and allowed the '459 and '460 patents:

> Applicants' argument that the use of EDTA has been taught away by the prior art is persuasive. Note, the ZAKELJ et al reference (published in 2005) cited in the IDA filed on 03/06/09 also disclosed "the implementations of …EDTA in any kind of clinical study on humans would be inappropriate."

FAA ¶ 14. He made similar comments in the statement allowing the '989 patent. FAA ¶ 15.

D. Defendants' Inequitable Conduct Defense Based on P&G's Inconsistent Statements and Omission of a Foreign Patent Application

Defendants allege "[t]he '459, '460, and '989 patents are unenforceable due to inequitable conduct because the Applicants, through at least the named inventors David E. Burgio and Richard Dansereau, intentionally deceived the United States Patent and Trademark Office ("PTO") during patent prosecution by misrepresenting and failing to disclose information regarding the safety of using EDTA in humans." FAA ¶ 1. Defendants allege that

misrepresentations were made via statements to the PTO that were inconsistent with the positions P&G took with other regulatory agencies and that P&G withheld a foreign patent application that demonstrated other scientists' knowledge of the safety of EDTA. FAA ¶¶ 3, 7-8, 13, 18-19, & 24.

In regard to the statements made to the PTO, Defendants allege that the contrast between P&G's statements before the regulatory agencies and the PTO demonstrate "that the applicants misrepresented to the examiner how a person or ordinary skill in the art would have understood the teachings of *Lin, Janner,* and *Ezra* in light of the other prior art concerning the use of EDTA in human pharmacotherapy." FAA ¶ 18. Furthermore, "[h]ad the applicant been candid with the PTO, it would have informed the examiner that, far from teaching away, the prior art would have led a person or ordinary skill in the art to use the claimed amounts of EDTA in combination with delayed-release bisphosphonates because the prior art taught those amounts were safe for use in human pharmacotherapy." FAA ¶ 19. In making such statements, Defendants allege that P&G "intentionally deceived the PTO [as] is evident from the statements [P&G] previously made concerning the safety of EDTA." FAA ¶ 17.

Defendants specifically name Dr. Burgio and Dr. Dansereau as having violated their duty of candor to the PTO. *See* FAA ¶¶ 1, 8, 11, 12, 13, & 21-24; Defs.' Reply at 9. Defendants allege that both individuals participated in the regulatory discussions regarding the safety of EDTA. FAA ¶ 21. Dr. Burgio, despite his knowledge of the regulatory discussions, signed a declaration arguing contradictory terms "to overcome a rejection from the PTO." FAA ¶ 22. Dr. Dansereau "was responsible for formulating these statements regarding the safety of EDTA (citations omitted), but knew of and allowed the misleading statements regarding the teachings in *Lin*, *Janner*, and *Ezra* to be filed with the PTO." FAA ¶ 23.

In terms of the foreign patent application, Defendants allege that P&G, including at least Dr. Burgio and Dr. Dansereau, knew of a foreign patent application that "disclosed the same pharmaceutical compositions" and not only failed to disclose it to the PTO, but "actively concealed it during the prosecution of the claims." FAA ¶8. Defendants claim that if P&G had disclosed the application, "it would have had to abandon its argument that a person of ordinary skill would have understood from the prior art that EDTA was unsafe for human clinical use." FAA ¶ 8. In support, Defendants cite to emails filed under seal that discuss the foreign patent and also show that P&G was involved in the withdrawal of the foreign patent. *Id.,* citing exhibits at Docket Entry No. 133. Some of the emails are to or from Dr. Burgio and Dr. Dansereau. *Id.*

Additionally, Defendants allege that "Dr. Burgio's and Dr. Dansereau's specific intent to deceive the PTO is further evidenced by their knowledge that other formulation scientists, including the inventors of the foreign patent application, were not dissuaded by *Lin, Janner,* or *Ezra* from using EDTA in pharmaceutical compositions." FAA ¶ 24.

IV. Analysis

A. Inconsistent Statements to the PTO

Plaintiffs oppose the motion on the grounds of futility. Plaintiffs argue that no misrepresentation occurred because the examiner had the *Lin*, *Janner*, and *Ezra* references. *See* Pls.' Opp. at 18-19. P&G only summarized, quoted, or cited the prior art references, and thus its statements were only attorney arguments, not misrepresentations. *See id.*, citing *Young* at 1349. Furthermore, Plaintiffs argue that Defendants' motions must be denied because Defendants fail to "point out anything incorrect in what the Applicants actually told the PTO." *Id.* at 15-18.

Defendants counter that Plaintiffs overstate the law. Under 37 C.F.R. § 1.56, all applicants owe a duty of candor to the examiner regardless of what is submitted, including any

argument made. *See* Defendants' Reply ("Defs.' Reply") at 12. Providing references does not give the applicant license to make whatever representations he or she may like under the guise of "attorney argument." *Id.* at 12-13. Here, the applicants did just that by "mischaracterize[ing] *Lin, Janner,* and *Ezra* as teaching that *any amount* of EDTA was unsuitable for clinical use in humans, instead of being candid with the examiner and explaining – as it did to the FDA – that those references did not teach away from, or even address, use of the *claimed amounts* of EDTA." *Id.* at 8.

Accordingly, the threshold question before the Court is whether the statements made to the PTO by the Applicants are misrepresentations or attorney argument. The Federal Circuit delineated the two concepts in *Young*. There, the lower court found misrepresentations in the applicant's statements about the teachings of a certain prior art reference, the Fossum Reference, regarding where to make an incision in a patent application for a method of declawing cats. *Id.* The Federal Circuit overturned the finding, stating,

> Those statements are attorney argument, attempting to distinguish the claims from the prior art, not gross mischaracterizations or unreasonable interpretation of the Fossum Reference. They describe Young's interpretation of what the Fossum Reference teaches and why the incision disclosed in that reference is different from the claimed incision....Based on [the figure in the reference], that statement does not appear to be demonstrably false and, instead, represents Young's interpretation of what the Fossum Reference teaches.
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> The examiner had the Fossum reference to refer to during the reexamination proceeding and initially rejected claim 1 based on that reference. Young argued against the rejection, and the examiner was free to reach his own conclusions and accept or reject Young's arguments.

Young, 492 F.3d 1336, 1349.

Two important points arise from the Federal Circuit's finding. First, the Federal Circuit drew a line between a reasonable attempt to distinguish the art and statements that evidence a certain level of culpability: statements that are demonstrably false, gross mischaracterization, or unreasonable interpretations. Second, where the examiner has the prior art references, he is free to reject the statements made by an applicant as argument.

These points can be found in several of the cases cited by the parties. *See, e.g., Wyeth,* 2012 WL 600715. In *Wyeth*, the defendant argued that the applicant's conduct "'was not just zealous advocacy; it was a misleading characterization of a key reference'" and that the applicant withheld information material to data before the examiner. *Id.* at *11. The court found that the defendants had sufficiently pled misrepresentations to survive the motion to dismiss. Specifically, the court found that the applicant's statements about industry-specific information and internal procedures was information that the applicant "uniquely qualified to characterize and explain, which is what allegedly allowed him to 'deceive' the Examiner by failing to do so accurately." *Id.* at *12. Furthermore, the same individual withheld material information "which would have required the Examiner to rely even more significantly on [the applicant]'s representations." *Id.*

This Court notes that these cases provide a focus for examination: whether a party made statements or withheld information that would have prevented the examiner from accurately judging the prior art provided.

Here, Defendants have not alleged Plaintiffs thwarted the examiner in any way. Defendants recite the right words, that the Applicants "incorrectly asserted that the prior art 'taught away'" and that "the applicant misrepresented the prior art," but these phrases alone are conclusory. *See* FAA ¶ 10. Defendants do not support the allegations with facts that

demonstrate that misstatements were made. The examiner had the *Lin*, *Janner*, and *Ezra* references, and Plaintiffs listed them in the original patent application. The examiner rejected the claims, in part based on *Lin*. P&G responded by summarizing and quoting *Lin*, *Ezra*, and *Janner* and cited specific pages. Missing are allegations that the Applicants withheld information relating to the references, submitted false information, or misrepresented material facts that would hamper the examiner's ability to accept or reject the Applicants' arguments.

In fact, Defendants allege only that "a person of ordinary skill in the art would not have interpreted the prior art in the way the applicants portrayed it to the examiner." FAA ¶ 13. This fits squarely within the type of statements recognized by *Young*: an attempt to distinguish the prior art. Without more, P&G's statements rise only to the level of attorney argument and are not misrepresentations that evoke the defense of inequitable conduct. Consequently, the Court denies Defendants' motions to amend to add inequitable conduct claims relating to misrepresentations of the prior art references *Lin, Janner,* and *Ezra*.

B. Foreign Patent Application

Plaintiffs also contest Defendants' allegations relating to the foreign patent application as futile. Both parties argue the materiality of the application. Plaintiffs argue the application does not include EDTA safety data or examples of EDTA based formulations, and thus is not material. Pls.' Opp. at 23. Defendants claims the application reveals the primary components of the formulation: delayed release, using a chelating agent, and EDTA, and thus is material. Defs.' Reply at 14.

The Court, however, will not reach the contents of the application as Defendants fail to allege several of the factors required by *Therasense, Exergen*, and Rule 9(b) for pleading inequitable conduct. As set forth in *Exergen*, allegations cannot be directed towards an organization as the duty of candor to the PTO lies with individuals. *Id.* at 1329. Allegations of

"who" must "name the specific individual associated with the filing or prosecution of the application ..., who both knew of the material information and deliberately withheld or misrepresented it." *Id.* Dr. Dansereau and Dr. Burgio are the only named individuals in the FAA. Defendants allege Dr. Dansereau only knew of the application and allowed others to make statements to the PTO. FAA ¶ 23-24. Defendants do not allege facts pertaining to his role in the application, how his duty arises, when or how he made any misrepresentations or omissions. Additionally, Defendants allege no facts that establish he any deliberate intent to do anything. Merely being aware of a potentially material reference is insufficient to allege inequitable conduct. *See, e.g., Exergen*, 575 F.3d at 1327 (finding the relevant conditions of the mind include "knowledge of the withheld material information" and the "specific intent to deceive the PTO.")

Dr. Burgio is named in six paragraphs of the FAA. *See* ¶¶ 8, 11-13, 22-24. Of those paragraphs, only ¶ 8 and ¶ 24 relate to the foreign patent application.[6] In ¶ 8, Defendants allege Dr. Burgio and Dr. Dansereau knew of the foreign patent and did not disclose it. Paragraph 24 draws Dr. Burgio's intent from his "knowledge of other formulation scientists, including the inventors of the foreign patent application, were not dissuaded by *Lin*, *Janner* or *Ezra* from using EDTA in pharmaceutical composition." *Id.* at ¶ 24.

This allegation of intent, however, falls short as it is based only on the alleged materiality of the patent application. The Federal Circuit cautions against using the knowledge of materiality to impose intent. *See Star* at 1366 ("Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.") Instead, intent is a separate factor. *Therasense* at 1290. The

[6] The Court has also reviewed the pleadings filed under seal. While the sealed pleadings provide more detail, the allegations suffer from the same defects. Therefore, while the Court here references the publically accessible pleadings, the analysis equally applies to the pleadings filed under seal.

moving party must allege facts from which the court may reasonably infer the party acted with the requisite state of mind. *Exergen*, 575 F.3d at 1327. Defendants allege sufficient facts to show that Dr. Burgio had a duty to the PTO arising from his certification on the *Lin* prior art. Defendants also allege sufficient facts to show that Dr. Burgio knew of the foreign patent application. However, Defendants do not allege facts from which the Court may infer that Dr. Burgio was aware of the patent application's materiality or that he had the opportunity to disclose it and deliberately decided against it. Considering the draconian nature of an inequitable conduct claim, the Court is hesitant to permit the requested amendment where Defendants themselves fall silent on the relationship between knowing of the application and any intent to hide it from the PTO. Therefore, as Defendants have failed to sufficiently allege the necessary factors under *Exergen* and R. 9(b), the Court denies Defendants' motions to amend to add an inequitable conduct claim relating to the foreign patent application.

V. Conclusion

For the reasons stated above, Defendants' Motions to Amend are DENIED. A separate order will follow.

s/ James B. Clark, III
JAMES B. CLARK, III
United States Magistrate Judge

Date: November 19, 2013