

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

BONE CARE INTERNATIONAL, LLC)	
and GENZYME CORPORATION,)	
)	
Plaintiffs,)	
)	Case No. 08-cv-1083
v.)	
)	Judge Robert M. Dow, Jr.
PENTECH PHARMACEUTICALS, INC.,)	
and COBREK PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Bone Care International, LLC and Genzyme Corporation (collectively “Plaintiffs”) brought this patent infringement suit against Defendants Pentech Pharmaceuticals, Inc. and Cobrek Pharmaceuticals, Inc. (collectively “Defendants”) for infringement of United States Patent Nos. 5,602,116 (the “‘116 patent”) and 6,903,083 (the “‘083 patent”). Defendants have asserted affirmative defenses and counterclaims [227] alleging, *inter alia*, that the ‘116 patent is unenforceable because of Plaintiffs’ inequitable conduct before the United States Patent and Trademark Office. Currently before the Court is Plaintiffs’ motion to dismiss [241] Defendants’ ‘116 patent inequitable conduct defenses and counterclaims, which seeks dismissal of affirmative defense ¶ 8 and counterclaims ¶ 38 and ¶ 135 pursuant to Federal Rule of Civil Procedure 9(b). For the reasons stated below, Plaintiffs’ motion to dismiss [241] is granted in part and denied in part.

I. Background

On February 11, 1997, the ‘116 patent issued from Application no. 415,488 (“‘488 patent application”), which was filed on April 3, 1995. The ‘116 patent claims a method for treating

patients suffering from hyperparathyroidism secondary to end-stage renal disease with 1α -OH-vitamin D₂. The ‘116 patent issued from a chain of five patent applications:

1. Application no. 415,488 (“488 patent application”), filed on April 3, 1995 and issued as the ‘116 patent on February 11, 1997;
2. Application no. 119,895 (“895 patent application”), filed on September 10, 1993 and issued as U.S. Patent No. 5,403,831 (“831 patent”) on April 4, 1995;
3. Application no. 812,056 (“056 patent application”), filed on December 17, 1991;
4. Application no. 569,412 (“412 patent application”), filed on August 17, 1990 and issued as U.S. Patent No. 5,104,864 (“864 patent”) on April 14, 1992; and
5. Application no. 227,371 (“371 patent application”), filed on August 2, 1988.

Dr. Charles W. Bishop, Ph.D. is a named inventor on each application in the above-referenced chain of patent applications.

II. Analysis

Patent applicants have a duty to prosecute patent applications in the United State Patent and Trademark Office (“PTO”) with candor, good faith, and honesty. *Honeywell Intern. Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007); see also 37 C.F.R. § 1.56. “A breach of this duty – including affirmative misrepresentations of material facts, failure to disclose material information, or submission of false material information – coupled with an intent to deceive, constitutes inequitable conduct.” *Honeywell*, 488 F.3d at 999. Thus, there are two substantive elements to a claim of inequitable conduct – materiality and intent to deceive. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). With respect to intent, an accused infringer must show that “an applicant had the *specific intent* to * * * mislead[] or deceiv[e] the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a

known material reference.” *Id.* at 1366 (emphasis in original) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

Inequitable conduct must be pled with particularity under Rule 9(b). *Exergen Corporation v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009). The Federal Circuit recently held that, “in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Id.* at 1327.¹ Furthermore, the court held that while “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct “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.” *Id.* at 1328-29.

In their Amended Answer, Affirmative Defenses and Counterclaims [227], Defendants allege seven instances of inequitable conduct, which are pleaded both as affirmative defenses and as counterclaims. Consistent with the parties’ briefs, the Court will refer to those seven instances as allegations A through G. Plaintiffs argue in their motion to dismiss that Defendants’ inequitable conduct defenses and counterclaims are deficient for failing to plead the elements of inequitable conduct with particularity as required under Rule 9(b) and *Exergen*. The Court addresses each of Defendants’ inequitable conduct allegations in turn below.

¹ In so doing, the Federal Circuit expressly stated that it was “following the lead of the Seventh Circuit in fraud cases,” and quoted from the Seventh Circuit’s articulation of the standard in *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990). See *Exergen*, 575 F.3d at 1327. That standard of course is a familiar one to attorneys and judges in this district.

A. Inequitable Conduct Allegations Related To Earlier Patent Applications

Defendants' first three inequitable conduct allegations – allegations A, B, and C – concern alleged inequitable conduct committed during the prosecution of patent applications that preceded the '488 application. Allegation A relates to alleged misrepresentations and omissions made during the prosecution of the '371 patent application, which involved a method of preventing or treating bone loss in mammals with or predisposed to bone-depletive disorders using 1α -OHD₂. Allegation B concerns alleged misrepresentations and omissions made during the prosecution of the '412 patent application, which involved the treatment of osteoporosis with 1α -OHD₂. Allegation C concerns alleged misrepresentations made during the prosecution of the '056 patent application, which involved a method for preventing loss of bone mass using 1α -OHD₂. Defendants contend that these instances of inequitable conduct render the '116 patent unenforceable under the doctrine of infectious unenforceability.

Under the doctrine of infectious inequitable conduct or infectious unenforceability, a finding of inequitable conduct with regard to an earlier patent application may render the claims of a later related patent unenforceable under certain circumstances. See *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007). Specifically, infectious unenforceability applies “where (1) the applicant engaged in inequitable conduct with respect to the prosecution of an earlier related application in the chain leading to the challenged patent and (2) the inequitable conduct relates to the asserted claims of the patent.” *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 900 (N.D. Ill. 2006). By contrast, “where the claims [at issue] are subsequently separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to inequitable conduct committed in the parent application.” *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1331-32

(Fed. Cir. 1998). The relevant inquiry is whether the “inequitable conduct in prosecuting the [earlier] patent had immediate and necessary relation to the * * * enforcement of the [later related] patents.” *Consol. Aluminum Corp. v. Foseco Int’l, Ltd.*, 910 F.2d 804, 810-11 (Fed. Cir. 1990).

Plaintiffs argue that Defendants have not properly pled infectious inequitable conduct because they have failed to allege the existence of an immediate and necessary relation between the ‘116 patent and the purported inequitable conduct committed during prosecution of the earlier patent applications. Defendants respond that they are required to show only a substantial relationship between the ‘116 patent and the earlier applications. Defendants misapprehend the governing law. As explained above, the Federal Circuit has held that inequitable conduct in the prosecution of a patent infects a later-issued related patent only where there is an “immediate and necessary relation” between the inequitable conduct and the enforcement of the patent-in-suit, here the ‘116 patent. *Id.* The mere fact that the ‘116 patent is related to the earlier applications is not sufficient to invoke the infectious unenforceability doctrine. See *Cordis Corp. v. Boston Scientific Corp.*, 188 Fed.Appx. 984, 989 n.2 (Fed. Cir. 2006) (unpublished) (“related patents do not necessarily rise and fall together”); *Pharmacia Corp. v. Par Pharmaceutical, Inc.*, 417 F.3d 1369, 1375 (Fed. Cir. 2005) (“this court’s inequitable conduct cases do not extend inequitable conduct in one patent to another patent that was not acquired through culpable conduct”); *Abbott Laboratories v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 819 (N.D. Ill. 2007) (“unenforceability of a parent patent for inequitable conduct does not automatically render the later-issued descendants of that patent unenforceable”).

It is clear from Defendants’ pleading that the ‘116 patent and the earlier applications – all of which involve the use of 1α -OHD₂ – are closely related. Indeed, as Defendants note,

Plaintiffs claim that the ‘116 patent is entitled to priority to the ‘371 application, which indicates a close relationship between the two. However, Defendants must allege more than a relationship between the patents. See *Power Integrations, Inc. v. Fairchild Semiconductor Intern., Inc.*, 2009 WL 4928024, at *9 (D. Del. Dec. 18, 2009) (magistrate judge recommending that allegations of infectious inequitable conduct be stricken where pleading merely “asserted connections among the three patents,” reasoning that such connections “are not sufficient to establish the required ‘immediate and necessary relation’”). In order to plead inequitable conduct with particularity under Rule 9(b), Defendants must allege an immediate and necessary relation between the ‘116 patent and the specific inequitable conduct alleged. Defendants’ failure to do so means that their first three inequitable conduct allegations cannot stand, and Plaintiffs’ motion to dismiss must be granted with respect to allegations A, B, and C.

B. Alleged Failure by Welch, Gulbrandsen, and Bishop to Disclose Previously Cited Prior Art During the Prosecution of the ‘116 Patent

In allegation D, Defendants allege that Dr. Bishop and two patent attorneys involved in the prosecution of the ‘116 patent – Teresa Welch and Carl Gulbrandsen – intentionally failed to disclose material information during the prosecution of the ‘116 patent. Specifically, Defendants point to the omission of eight prior art references that had been disclosed to the PTO during the prosecution of the ‘371, ‘412, and ‘056 applications. Five of the eight references had been relied upon by patent examiners to make rejections in the prosecution of those earlier applications. Plaintiffs move to dismiss Defendants’ inequitable conduct counterclaim and affirmative defense related to the non-disclosure of the prior art references on two grounds: that Defendants (i) have failed to adequately plead deceptive intent, and (ii) do not allege why the omitted references are not cumulative of any other prior art.

1. Deceptive Intent

With respect to deceptive intent, Defendants allege that Bishop was a named inventor for all of the applications at issue. Defendants further allege that Bishop routinely was advised of the Examiner's Official Actions, and therefore would have known that rejections were made during the prosecution of the '371, '412, and '056 applications based on five of the omitted references. Defendants allege that Gulbrandsen was involved in the prosecution of the '371, '412, and '056 applications, and that he had cited all eight prior art references in connection with those applications. Defendants also allege that, in connection with the '056 application, Welch submitted an Information Disclosure Statement referencing all eight prior art references. Based on these allegations, the Court reasonably can conclude that Bishop, Welch, and Gulbrandsen were aware of the eight omitted references.

Defendants also make specific allegations regarding the materiality of each of the eight references, including identifying the claims in the '488 application to which each withheld reference allegedly is relevant. These allegations are sufficient to give rise to an inference that the references were withheld deliberately in order to deceive the PTO. See *Lincoln Nat. Life v. Transamerica Financial Life Ins. Co.*, 2009 WL 4547131, at *4 (N.D. Ind. Nov. 25, 2009) (defendant sufficiently alleged intent to deceive where defendant alleged that "at least two individuals knew of the withheld references," "that each of these references was highly material to the '608 Patent, yet was not disclosed to the examiner"); *Synventive Molding Solutions, Inc. v. Husky Injection Molding Systems, Inc.*, 2009 WL 3172740, at *3 (D. Vt. Oct. 1, 2009) (finding a reasonable inference of scienter after defendant "specifically alleged the individuals involved, the information withheld and why it was material"); *The Braun Corp. v. Vantage Mobility Intern., LLC*, 2010 WL 403749, at *7 (N.D. Ind. Jan. 27, 2010) (defendant sufficiently pled

scienter where defendant alleged that “specific individuals knew of the withheld references, these references were highly material, and, yet, were not disclosed to the Examiner”).

In support of their contention that Defendants have not adequately pled scienter, Plaintiffs rely on the Federal Circuit’s statement in *Exergen* that “[t]he mere fact that an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application, is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct.” 575 F.3d at 1331. The defective pleading in *Exergen* pled deceptive intent “solely on ‘inform[ation] and belie[f],’” and did “not contain specific factual allegations to show that the individual who had previously cited the [omitted reference in connection with a related patent] knew of the specific information that [was] alleged to be material to the * * * patent [at issue] and then decided to deliberately withhold it from the relevant examiner.” *Id.* at 1330-31. The *Exergen* court concluded that the pleading did not give rise to an inference of deceptive intent because it “mere[ly] show[ed] that art or information having some degree of materiality was not disclosed.” *Id.* at 1331 (quoting *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)).

Here, by contrast, Defendants allege that Welch and Gulbrandsen previously had cited the specific omitted material in connection with the earlier patent applications, on which Bishop was a named inventor. Defendants also identify the claims in the ‘488 application to which each reference allegedly is relevant, allege that five of the omitted references were the basis for prior rejections of claims similar to those asserted in the ‘488 application, and further allege that at least Bishop and Gulbrandsen were aware of those previous rejections. Based on these factual allegations, Defendants’ claims as to allegation D survive the motion to dismiss because the Court reasonably can infer that Welch, Gulbrandsen, and Bishop knew of the omitted references

and withheld the allegedly material information with a specific intent to deceive the PTO in order to avoid rejections like those they faced in the prosecution of prior patents.

Plaintiffs also contend that the fact that the prior art references previously were cited in connection with the earlier applications is evidence of good faith with respect to the prosecution of the '116 patent because the same PTO examiner was responsible for examining all of the applications. According to Plaintiffs, Bishop, Welch, and Gulbrandsen could not have intended to mislead the examiner by failing to disclose information of which they previously had made him aware. But, as Bishop, Welch, and Gulbrandsen likely understood, patent examiners cannot be expected to recall the details of previously examined patent applications. See *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779 (7th Cir. 1972) (“it is unfair to the busy examiner, no matter how diligent and well informed he may be, to assume that he retains details of every pending file in his mind when he is reviewing a particular application * * * the applicant has the burden of presenting the examiner with a complete and accurate record to support the allowance of letters patent”). Therefore, the fact that the examiner previously had seen the omitted references does not refute the inference of deceptive intent at the pleading stage.

2. Pleading Non-Cumulativeness

Plaintiffs also argue that the affirmative defense and counterclaim based on allegation D merit dismissal because Defendants do not allege why the omitted references in allegation D are not cumulative of any other prior art, as required by *Exergen*.² In *Exergen*, the defendant

² Plaintiffs raise this argument for the first time with respect to allegation D in their reply brief. Normally, arguments raised for the first time in a reply brief are waived and cannot be considered at the motion to dismiss stage. *United States v. Adamson*, 441 F.3d 513, 521 n.2 (7th Cir. 2006). However, here Defendants had the opportunity to respond to that argument in a surreply, which dispels any prejudice that Defendants might suffer as a result of the Court’s consideration of Plaintiffs’ argument. Furthermore, Defendants certainly suffer no prejudice here, as the Court rejects Plaintiffs’ argument that allegation D fails to satisfy the pleading requirements set forth by *Exergen*.

generally alleged that the withheld prior art references were “material” and “not cumulative to the information already of record.” 575 F.3d at 1329. The Federal Circuit found the defendant’s pleading deficient, in part because the defendant did not identify the particular claim limitations “that are supposedly absent from the information of record,” which were “necessary to explain both ‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.” *Id.* at 1329-30.

Whether a withheld reference is cumulative of other information before the examiner is relevant to an inequitable conduct claim because “information is material to patentability when it is not cumulative to information already of record or being made of record in the application.” 37 C.F.R. § 1.56(b). If an allegedly withheld reference is cumulative, it is not material and cannot form the basis for an inequitable conduct claim. According to Plaintiffs, allegation D fails because Defendants do not specifically allege that the omitted references are not cumulative of other information before the patent examiner. Defendants counter that it would be redundant to plead both materiality and non-cumulativeness. According to Defendants, the *Exergen* court mentioned both materiality and non-cumulativeness only because the defendant in that case had pled both, and did not intend to require a defendant to plead both materiality and non-cumulativeness in order to survive a motion to dismiss.

This Court does not read *Exergen* as imposing a strict requirement that pleadings include the word “non-cumulative” in order to plead inequitable conduct with the requisite particularity. Courts – including those in this district – have recognized that “the heightened pleading standard of Rule 9(b) does not require adherence to blind formalism.” *Prince-Servance v. BankUnited, FSB*, 2007 WL 3254432, at *6 (N.D. Ill. Nov. 1, 2007); see also *United States v. Ford Motor Co.*, 532 F.3d 496, 503 (6th Cir. 2008) (Rule 9(b) “should not be read as a mere formalism,

decoupled from the general rule that a pleading must only be so detailed as is necessary to provide a defendant with sufficient notice to defend against the pleading's claims"). Instead, Rule 9(b) should be applied with an eye towards its "three main purposes: (1) protecting a defendant's reputation from harm; (2) minimizing 'strike suits' and 'fishing expeditions'; and (3) providing notice of the claim to the adverse party." *Vicom, Inc. v. Harbridge Merchant Services, Inc.*, 20 F.3d 771, 777 (7th Cir. 1994).

In light of Rule 9(b)'s goals, the pertinent inquiry on Plaintiffs' motion to dismiss is not whether Defendants used certain magic words, but whether Defendants pled the who, what, when, where, why, and how of the allegedly material omissions in sufficient detail to give Plaintiffs fair notice of the basis for their inequitable conduct claims. With respect to materiality and non-cumulativeness, the pleading must put Plaintiffs on notice as to what information Defendants contend should have been before the examiner but wasn't and how that information would have changed the examiner's decision regarding the patentability of the claims in the '116 patent.

In allegation D, Defendants allege that examiners relied on five of the omitted references in prior related patent applications to make rejections of substantially similar claims to those presented in the '488 application.³ Defendants also specify the claims of the '488 application to which each omitted reference is relevant. With respect to the five references, the clear implication is that if the references had been before the examiner on the '488 application, the substantially similar claims would have been rejected. That those claims were not rejected

³ The five references previously relied upon by for rejections include: (1) U.S. Patent 4,225,596 to DeLuca (1980) ("DeLuca '596 patent"); (2) U.S. Patent 4,508,651 to Baggiolini et al. (1985) ("Baggiolini '651 patent"); (3) Sjoden, et al., Effects of 1α -OHD₂ on Bone Tissue, *Acta Endocrinol. (Copenh.)*, vol. 16, Nr. 4, Aug. 1984, pp. 564-568 ("Sjoden (Acta Endocrinol.)"); (4) U.S. Patent 4,588,716 to DeLuca (1986) ("DeLuca '716 patent"); (5) EP A 197,514 to Potts, Jr. et al., The General Hospital Corporation (1986) ("EP A 197,514" or "Potts et al.").

implies that no other information before the examiner compelled rejection, and thus that the five omitted references are not cumulative.

Defendants also sufficiently allege non-cumulativeness with respect to the three other allegedly withheld references. As to Reeve,⁴ Defendants allege that this article teaches the skilled person that $1\alpha\text{OHD}_2$ could be of use in the treatment of renal osteodystrophy. That allegation suggests that the other prior art disclosed to the examiner did not repeat this teaching. Defendants allege that PDR 43rd Ed,⁵ “in combination with other art such as DeLuca ‘596 * * *, suggests to the skilled person the inventions claimed in the ‘488 application. Similarly, the PDR in combination with other art such as the Baggiolini ‘651 patent or the DeLuca ‘716 patent, makes at least claims 1, 2, 15 and 17 and of the ‘488 application obvious.” Implicit in those allegations is the assertion that PDR 43rd Ed. is not merely repetitive of other prior art references, but teaches something additional. Finally, Defendants allege that Brautbar⁶ teaches the skilled person that vitamin D metabolites are effective in lowering serum PTH, especially in persons with diminished kidney function. That allegation is sufficient to put Plaintiffs on notice that Defendants contend that no other prior art before the examiner repeated this teaching. For these reasons, Plaintiffs’ motion to dismiss is denied as it relates to the non-disclosure of the eight prior art references discussed in allegation D.

⁴ Reeve, L.E., Schnoes, H.K, DeLuca, H.F., Biological Activity of 1α -Hydroxyvitamin D₂ in the Rat, Arch. Biochem. Biophys. 186 (No. 1):164-167 (1978) (“Reeve”).

⁵ Physicians Desk Reference, 43d Ed., pp. 1746-1748 (1988) (“PDR 43rd Ed.”).

⁶ Brautbar, N., Osteoporosis: Is 1,25-DihydroxyVitamin D₃ of Value in Treatment?, Nephron. 44:161-168 (1986) (see pp. 162-164) (“Brautbar”).

C. Bishop's Alleged Failure to Disclose Prior Art During the Prosecution of the '116 Patent That was Inconsistent with Statements Made in the Specification

In allegation E, Defendants assert that the '488 application contained a false statement regarding the medical community's understanding of vitamin D₂ and D₃ compounds, which Bishop knew to be false at the time, and that Bishop withheld eight prior art references contradicting the statement. Specifically, Defendants point to the following statement in the specification of the '116 patent:

It is noted that the medical community currently views vitamin D₃ compounds as biologically indistinguishable from the corresponding vitamin D₂ compounds. This is evident from the indiscriminate inclusion of either vitamin D₂ or D₃ in vitamin supplements prepared for human use, and from the interchangeable use of either vitamin in treating bone diseases caused by vitamin D deficiency. Curiously, medical experts consider the hormonally active forms of the two vitamins to be equivalent despite lack of confirmation from a single human study.

According to Defendants, Bishop was aware of literature in the medical community (eight prior art references in particular) demonstrating differences in vitamin D₂ and vitamin D₃ compounds in humans and other mammals, and thus knew the statement to be false. In support of their motion to dismiss, Plaintiffs contend that Defendants have failed to include sufficient factual allegations from which the Court reasonably could infer deceptive intent. The Court agrees.

In support of the allegation that Bishop was aware of the eight omitted references, Defendants point to a March 1989 letter from Bishop to Dr. Donald Buyske, Ph.D., a potential investor, in which Bishop discussed the eight studies. Defendants contend that, in that letter, Bishop concluded that the studies showed that vitamin D₂ is less toxic in mammalian species than vitamin D₃. According to Defendants, that conclusion renders the statement above false, and provides a reasonable factual basis from which the Court can infer that Bishop knowingly misrepresented the views of the medical community with a specific intent to deceive the PTO.

In determining whether the facts alleged give rise to a reasonable inference of an intent to deceive, courts must consider “any objective indications of candor and good faith.” *Exergen*, 575 F.3d at 1329 n.5. Here, taken as a whole, the facts do not suggest that Bishop believed the statement regarding the medical community’s understanding of the two vitamins to be false. Bishop expressly states in the Buyske letter that “[a] review of the medical literature shows that vitamin D₂ compounds are generally regarded as equivalent to corresponding vitamin D₃ compounds.”⁷ This statement is entirely consistent with the allegedly false statement, and indicates that Bishop did not interpret the eight references as undermining that statement, as Defendants contend. Furthermore, the Buyske letter contains a statement that is almost identical to the one Defendants contend is rendered false by the eight references discussed in the letter.⁸ In light of the fact that the Buyske letter itself contains statements that are consistent with the allegedly misleading statement in the ‘116 patent, the Court finds no basis for inferring that Bishop knowingly acted with intent to deceive the PTO. Therefore, Plaintiffs’ motion to dismiss is granted as to allegation E.

⁷ This portion of the Buyske letter is excerpted in Defendants’ Expert Affidavit and Report of John F. W. Keana. Ph.D. at ¶ 149, which Defendants incorporated by reference in their answer and attach as Exhibit D to their response in opposition to Plaintiffs’ motion to dismiss [254].

⁸ The statement at issue appears in a portion of the letter that Plaintiffs have attached under seal as exhibit A to the Declaration of Fiona E. Darkin [242], which they submitted with their motion to dismiss. See [244]. Generally on a motion to dismiss the Court must confine its inquiry to the factual allegations set forth within the four corners of the operative complaint. See *Rosenblum v. Travelbyus.com*, 299 F.3d 657, 661 (7th Cir. 2002). In the usual case, therefore, if a party moving for dismissal submits documents with its motion to dismiss, the Court either must ignore the documents or convert the motion to one for summary judgment. *Venture Assoc. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir. 1993). However, “[d]ocuments that a [party] attaches to a motion to dismiss are considered part of the pleadings,” and may be considered on a motion to dismiss, “if they are referred to in the [pleading] and are central to” the relevant claims. *Venture*, 987 F.2d at 431. Documents that fall within this “narrow” exception must be “concededly authentic.” *Tierney v. Vahle*, 304 F.3d 734, 738 (7th Cir. 2002). Here, Bishop’s letter to Buyske is referred to in Defendants’ counterclaims and is central to Defendants’ inequitable conduct counterclaims and affirmative defenses. Therefore, the Court properly can consider the portion of the Buyske letter submitted with Plaintiffs’ motion to dismiss.

D. Bishop's Alleged Failure to Disclose Six Abstracts and Posters He Authored With J.C. Gallagher

With respect to allegation F – in which Defendants allege that, during the prosecution of the '116 patent, Bishop failed to disclose abstracts and posters that he co-authored – Plaintiffs contend that Defendants do not explain why the references are not cumulative of any other prior art, as required by *Exergen*. As explained above, the pleading simply must put Plaintiffs on notice as to what information Defendants contend should have been before the examiner but wasn't and how that information would have changed the examiner's patentability determination.

Here, Defendants allege that the abstracts “were the first reported studies with $1\alpha(\text{OH})\text{D}_2$ in humans, and the first to report a decrease in PTH levels with this analog; such a finding is material for therapeutic consideration in hyperparathyroidism secondary to end stage renal disease, and is of special relevance to the claims set forth in the '488 application.” Defendants further allege that the abstracts, “in combination with other prior art, render obvious the claims of the '488 application.” Finally, Defendants allege that an argument Plaintiffs' attorneys made in an amendment “would have been belied by the [abstracts], which showed the capability of $1\alpha\text{OHD}_2$ in lowering serum PTH in osteoporotic patients.” Implicit in these allegations is the assertion that no other information before the examiner compelled the same conclusions – *i.e.*, that the abstracts and posters are not cumulative. The Court concludes that Defendants adequately put Plaintiffs on notice as to the basis for the inequitable conduct claim set forth in allegation F, and thus have satisfied the requirements of Rule 9(b).

The parties also debate whether the abstracts and posters in fact were cumulative of other information already in the record. According to Plaintiffs, the abstracts and posters are

cumulative to the JBMR article, which was cited in the prosecution of the ‘116 patent.⁹ Defendants respond that the abstracts are not cumulative because the JBMR article is not prior art under 35 U.S.C. § 102(a). Plaintiffs reply that the JBMR article is prior art.

Section 102(a) provides that: “A person shall be entitled to a patent unless – (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.” 35 U.S.C. § 102(a). However, there is an exception to this rule for the inventor’s own work that is published within one year of the date of the patent application. *In re Katz*, 687 F.2d 450, 454-55 (C.C.P.A. 1982). Here, it is undisputed that the JBMR article was published less than a year prior to the filing of the ‘488 application. The parties dispute whether the JBMR article constitutes Bishop’s own work, such that it is not prior art for purposes of § 102(a). See *Katz*, 687 F.2d at 455 (“Since the publication in this case occurred less than one year before appellant’s application, the disclosure comes within the scope of § 102(a) only if the description is not of appellant’s own work”).

It is not necessary to determine at this time whether or not the JBMR article fits within the *Katz* exception, because even if it does not (such that it could be prior art), the Court nevertheless cannot determine whether the JBMR article constitutes prior art under § 102(a) on the current record. “Section 102(a) explicitly refers to invention dates[; therefore,] * * * a document is prior art only when published before the invention date.” *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996). Defendants argue that the invention date was in February 1994 – before the article was published. See [254, at 23]. If Defendants are correct,

⁹ The “JBMR article” is an article entitled “Effects of Increasing Doses of 1 α -Hydroxyvitamin D₂ on Calcium Homeostasis in Postmenopausal Osteoporotic Women” that appeared in the *Journal of Bone and Mineral Research*, and was authored by J.C. Gallagher, C.W. Bishop, J.C. Knutson, R.B. Mazess, and H.F. DeLuca. The article was published in May 1994.

then the JBMR article is not prior art regardless of whether it is Bishop's work. Plaintiffs assume an invention date of April 1995 for purposes of the motion to dismiss, see [241, at 18], and do not address Defendants' contention that the invention date predates that publication of the article. Based on the pleadings, the Court cannot determine the invention date, and therefore cannot establish whether the JBMR article is prior art under 35 U.S.C. § 102(a) and the *Katz* exception.

Plaintiffs also contend – for the first time in their reply brief – that Defendants have not alleged sufficient facts to give rise to an inference of scienter with respect to the non-disclosure of the abstracts. The Court disagrees. Defendants allege that Bishop knew of the withheld references, and failed to disclose them despite the fact that the references were material to the '116 patent and would have rendered its claims obvious. These allegations are sufficient to give rise to an inference that the references were withheld deliberately in order to deceive the PTO. Therefore, Plaintiffs' motion to dismiss is denied with respect to allegation F.

E. Alleged Misstatement of Fact in Abstract to Article Co-Authored By Bishop That Was Submitted During The Prosecution of the '116 Patent

In allegation G, Defendants contend that Bishop engaged in inequitable conduct by submitting the JMBR article in connection with the '488 patent application and signing the inventors' declaration attesting to the accuracy of the application, because, Defendants allege, the article contained a misleading statement of which Bishop was aware. The first sentence of the JMBR article states: "This study is the first reported administration of α -hydroxyvitamin D₂ (α -OHD₂) to human subjects." Defendants claim that that sentence is inaccurate because the study referenced had been described in previous publications, including ones that Bishop co-authored. According to Defendants, the sentence is misleading because it would have suggested to the patent examiner that there were no prior publications regarding the clinical trials with

1 α OHD₂ that constituted prior art. Defendants further allege that Bishop's failure to submit the previous publications referencing the study – specifically the 1989 and 1993 Gallagher Abstracts – constituted a material omission.

Plaintiffs move to dismiss the inequitable conduct claim set forth in allegation G on multiple grounds. First, Plaintiffs argue that the sentence is not misleading. However, the falsity of the statement is a question of fact that cannot be resolved on this motion to dismiss.

Second, Plaintiffs contend that Defendants fail to sufficiently allege deceptive intent. According to Plaintiffs, when Bishop published the allegedly misleading statement in 1992, he could not have intended to deceive the PTO years later during the 1995 prosecution of the '488 application. But Plaintiffs misconstrue Defendants' claim in making this argument. The inequitable conduct at issue is not the 1992 publication, but Bishop's decision to include the citation to the JBMR article in the '488 application despite his knowledge that it contained a false and misleading statement.

Defendants allege that Bishop knew of the withheld references and the fact that they rendered the statement misleading, but that he nevertheless failed to correct the statement or to submit references that would have demonstrated its falsity. As discussed above, Defendants contend that the JBMR article was not prior art because it was published within a year of the filing of the '488 application, whereas the withheld references would have been considered prior art. Defendants allege that the existence of prior art concerning the study described in the JBMR article would have influenced the examiner's decision regarding whether to allow claim 1. See Defendants' Expert Affidavit and Report of Leonard J. Deftos, M.D. at ¶ 257. These allegations are sufficient to give rise to an inference of intent to deceive at the pleading stage.

Finally, in their reply brief, Plaintiffs raise Defendants' failure to expressly allege non-cumulativeness with respect to the omissions described in allegation G. Defendants allege that disclosure of the omitted references "would have corrected the misstatement [in the JMBR article] during the prosecution of the '488 application that became the '116 patent." Implicit in that allegation is the assertion that nothing else that the examiner considered demonstrated the alleged falsity of the statement at issue. Thus, Defendants adequately have pled non-cumulativeness with respect to allegation G.

IV. Conclusion

For the reasons stated above, Plaintiffs' motion to dismiss [241] granted in part and denied in part. Plaintiffs' motion to dismiss is granted with respect to allegations A, B, C, and E, and is denied as to allegations D, F, and G.



Dated: April 23, 2010

Robert M. Dow, Jr.
United States District Judge