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

BAXTER INTERNATIONAL, INC.,	)	
	)	
Plaintiff,	)	
	)	No. 15-cv-9986
v.	)	
	)	Hon. Amy J. St. Eve
CAREFUSION CORPORATION and BECTON, DICKINSON AND COMPANY,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, United States District Court Judge:

Defendants CareFusion Corporation and Becton, Dickinson and Company (collectively, "Defendants") have moved for leave to amend their answer and counterclaims to assert inequitable conduct pursuant to Federal Rule of Civil Procedure 15. (R. 79.) Plaintiff Baxter International, Inc. ("Baxter") opposes Defendants' motion on the grounds that amendment is futile and that Defendants failed to act diligently in seeking leave to amend. (R. 94.) For the following reasons, the Court grants Defendants' motion.

BACKGROUND

I. Baxter's Allegations and the Patents at Issue

In its First Amended Complaint, Baxter alleges that Defendants' Alaris System—an infusion pump system that enables the delivery of intravenous ("IV") fluids and drugs—infringes three of Baxter's patents, U.S. Patent Nos. 5,764,034 ('034 Patent); 5,782,805 ('805 Patent); and 6,321,560 ('560 Patent). (R. 29 at ¶¶ 9, 11, 25–45.)[1]

[1] Defendants assert that only the '034 Patent and the '805 Patent are unenforceable based on inequitable conduct. (R. 77-1, 24, ¶¶ 26–44.) Thus, the '560 Patent is not pertinent to the current motion.

The ‘034 Patent, entitled “Battery Gauge For A Battery Operated Infusion Pump” was filed on April 10, 1996. (R.29-1, ‘034 Patent, 1). The ‘034 Patent lists two inventors, George Bowman and Grace Esche, and is assigned to Baxter. (*Id.*). The ‘034 Patent is directed to an infusion pump capable of estimating the amount of time left on a battery by monitoring both the voltage available from the battery and the amount of current flowing from the battery. (*Id.*, col. 2: 14-16, 20-23). The summary of the ‘034 Patent recites: “[t]he present invention provides a medical infusion pump which incorporates cost-effective, sensitive battery monitoring.” (*Id.*, col. 2: 11-13). The summary further discloses an electric circuit which enables a “sampling technique [that] alternates between sampling battery voltage and sampling current drain.” (*Id.*, col. 2: 25-28). “A method is then applied to the sampling signals by a microprocessor which determines the amount of time left under battery power.” (*Id.*, col. 2: 28-30). The specification recites that the “invention also provides several troubleshooting alert, alarm and failure messages” to health care providers. (*Id.*, col. 8: 15-16). The alert condition includes “a battery low alert, which indicates that the auxiliary battery has less than a predetermined amount of infusion time left.” (*Id.*, col. 8: 29-32). The alarm condition “indicates that the auxiliary battery charge has diminished below the level necessary to continue infusion.” (*Id.*, col. 8: 34-35).

The ’805 Patent, entitled “Medical Infusion Pump,” was also filed on April 10, 1996. (R. 29-2, ’805 Patent, 1.) It lists the following inventors: Randolph Meinzer, Grace Esche, Eric Michael, Kimball Knowlton, Cynthia Bennett, Eric Linner, Kenneth Lynn, Joseph Kruft, Eileen Hirotsuka, Daniel Kusswurm, Jane Zeisloft, Janice Stewart, Debra Gelhar, and Gilbert Rivas. (*Id.*) The summary of the ’805 Patent indicates that “[t]he present invention provides a medical infusion pump which is readily adaptable to use in multiple clinical settings without unduly burdening the user with programming parameters for such a variety of uses.” (*Id.* col. 1:65–67,

col. 2:1–3.) The invention "allows the user to select the number of flow channels available or to allow for existing pumps to add flow channels as needed." (*Id.*, col. 2:2–5.) The pump contains "a display area for displaying user interface information" on the main body portion as well as "an auxiliary display area for displaying supplemental user interface information." (*Id.* col. 2:12–14.)

II. Defendants' Inequitable Conduct Allegations

Defendants seek to amend their answer and counterclaims to assert inequitable conduct based on Baxter's prosecution of the applications that led to the issuance of the '034 and '805 Patents. (R. 77-1, Defs.' Proposed Am. Answer & Counterclaims, 21, 24–29.) In short, Defendants claim that Baxter omitted material information during the course of prosecuting the two patents—specifically, the existence of two infusion pumps that anticipated and/or rendered obvious Baxter's patent claims—that would have caused the PTO not to issue the '034 and '805 Patents.

Defendants allege that the '034 and '805 Patents are "based on a Baxter product alternatively called the 'Colleague' or 'Odyssey' infusion pump." (*Id.* at 24, ¶ 27.) When Baxter was developing the Colleague/Odyssey infusion pump, "its primary competitors in the infusion pump market included CareFusion's predecessors IVAC Corporation ('IVAC') and IMED Corporation ('IMED')." (*Id.* at 25, ¶ 28.) At that time, IVEC marketed the Signature Edition ("SE") infusion pumps, which were available in single-channel ("model 7100" or "SE I") and dual-channel ("model 7200" or "SE II") configurations. (*Id.* at 25, ¶ 29.) "The only material difference between the [two SE] pumps was the number of pumping channels. The other relevant aspects of the pumps, including the battery monitoring user interface features, were the

same." (*Id.*) Also at that time, IMED marketed the Gemini line of infusion pumps, "including the four-channel Gemini PC-4 infusion pump." (*Id.* at 25, ¶ 30.)

On approximately June 30, 1995—about nine months before Baxter filed its applications for what became the '034 and '805 Patents—Baxter filed an application with the U.S. Food and Drug Administration ("FDA") for clearance to market the Odyssey Volumetric Infusion Pump. (*Id.* at 25, ¶¶ 31, 36.) In this application, Baxter identified three infusion pumps that the FDA had already approved as being "substantially equivalent" to the Odyssey pump: (1) IMED's Gemini PC-4 Volumetric Infusion Pump/Controller, cleared on June 9, 1992; (2) Abbott Laboratories' LifeCare 175 Breeze Volumetric Infusion System, cleared on April 7, 1993; and (3) IVAC's Signature Edition I Volumetric Infusion Pump, Model 7100, cleared on August 19, 1993. (*Id.* at 25, ¶ 32.) In its FDA submission, Baxter included manuals for the three predicate devices it identified as well as a "feature comparison chart" comparing the Odyssey pump to the three predicate pumps. (*Id.* at 26, ¶ 33.) Based on its comparison of the predicate devices and the Odyssey pump, Baxter represented that "'the indication statement for the Odyssey Volumetric Infusion Pump is almost identical to the indication statement for IVAC's Signature Edition™ Volumetric Infusion Pump, Model[] 7100'"[2] and that "the Colleague pump 'does not have any unique technological features as compared to currently marketed pumps.'" (*Id.* at 27, ¶ 34.) According to Defendants, Baxter's FDA submission amounts to an admission that "the Signature Edition and Gemini PC-4 pumps were known prior art." (*Id.* at 25–26, ¶ 32.)

Defendants allege that the PTO would not have issued the '034 and '805 Patents if Baxter "had disclosed the existence of the Gemini PC-4 infusion pump and the Gemini PC-4 manual" or the "Signature Edition pumps and the Signature Edition I manual," as it had in its FDA

[2] By "indication statement," Baxter is referring to Indications for Use Statements. *See Indications for Use Statement*, FDA, https://www.fda.gov/RegulatoryInformation/Guidances/ucm080275.htm.

application. (*See id.* at 27–28, ¶ 39–40.) Specifically, Defendants claim that the SE II (model 7200) pump—which Defendants allege is materially the same as the SE I (model 7100) pump—"anticipates and/or renders obvious at least asserted claims 1–2, 5, 8–10, 24–26, 28–30, and 35 of the '805 Patent and asserted claims 1–3 and 9–12 of the '034 Patent." (*Id.* at 27–28, ¶ 39.) Additionally, Defendants claim that the Gemini PC-4 infusion pump anticipates and/or renders obvious at least asserted claims 1, 3, 5, 8–10, 24–26, 28–29, 31, and 35 of the '805 Patent and claims 1–3 and 9–12 of the '034 Patent. (*Id.* at 28, ¶ 40.) To support these contentions, Defendants rely on charts of the "invalidity of asserted claims," which Defendants attach to their proposed amended answer and counterclaims. (*Id.* at 27–28, ¶¶ 39–40; Exs. A–D.)

Defendants allege that "many of the named inventors of the '034 and '805 Patents were also actively involved in Baxter's [FDA] submission for the Colleague/Odyssey pump, including at least Randolph Meinzer, Grace Esche, Eric Michael, Kimball Knowlton, Cynthia Bennett, Eric Linner, Kenneth Lynn, Joseph Kruft, Eileen Hirotsuka, Daniel Kusswurm, Jane Zeisloft, Janice Stewart, Debra Gelhar, and Gilbert Rivas." (*Id.* at 27, ¶ 37.) Ms. Esche testified at her deposition that she was aware that IVAC, IMED, and Abbott marketed pumps that were in direct competition with the Odyssey/Colleague pump, and Mr. Bowman similarly testified that he knew IVAC was a direct competitor of Baxter. (*Id.* at 27, ¶ 38.) Both Esche and Bowman did not provide an explanation of why the documents related to the predicate devices in Baxter's FDA application were not submitted to the PTO. (*Id.* at 28–29, ¶ 42.) Defendants claim that "[g]iven the involvement of the named inventors of the '034 and '805 Patents in Baxter's [FDA] application for the Odyssey/Colleague infusion pump (the commercial embodiment of both patents) and Baxter's identification of the Signature Edition and Gemini PC-4 infusion pumps as two of the three most relevant predicate devices to the FDA, the most reasonable inference is that

Baxter's named inventors deliberately withheld this prior art from the [PTO] in order to obtain patent claims that would not otherwise have been allowed." (*Id.* at 29, ¶ 43.)

III. Procedural History

Pursuant to Local Patent Rule 2.3, Defendants served Baxter with their Initial Non-Infringement, Unenforceability, and Invalidity Contentions in July 2016. (R. 81-3.) In those contentions, Defendants asserted that the Gemini PC-4 pump and the SE II (model 7200) pump anticipated or rendered obvious many of the claims in the '034 and '805 Patents. (*Id.* at 5, 8–9.)[3] Defendants included detailed claim charts explaining where the elements of Baxter's asserted patent claims are found in the prior art. (*Id.*, D-4, D-6, E-1, E-2.) Defendants also noted that they "reserve[d] the right to amend or supplement [their] contentions if discovery or further investigation reveals evidence of inequitable conduct or other bases of unenforceability, such as the failure to disclose knowledge of a competitor's on-sale, directly competing products during prosecution of the '034 patent[and the] '805 patent." (*Id.* at 23.)

At a December 13, 2016 status conference, Defendants noted that the deposition testimony of Bowman might reveal additional information related to its invalidity and unenforceability contentions, but the parties could not schedule his deposition before Defendants' final contention deadline. (R. 81-4 at 9–10.) The Court instructed the parties "come back in shortly after the deposition, and you can let me know at that point orally if there is something that was brought up that [would warrant amendment]." (*Id.* at 10.) On December 20, 2016, Defendants took Esche's deposition. (R. 77-3.) Two days later, Defendants served their Final Unenforceability and Invalidity Contentions, in which, among other things, Defendants asserted in a section regarding unenforceability that Baxter was aware of the Gemini PC-4 and

[3] The claims Defendants contended were obvious or lacking novelty are the same as those Defendants contend the PTO would not have allowed if Baxter had disclosed the Gemini PC-4 and SE pumps. (*See* R. 81-3 at 5, 8–9; R. 77-1 at 27–28, ¶¶ 39–40.)

the SE I pump but "failed to provide prior art documents in its possession for such infusion pumps to the [PTO] during the prosecution of the asserted patents." (R. 77-4 at 28.) On January 18, 2017, Defendants took Bowman's deposition in which he testified that he was aware of IVAC as a competing pump manufacturer and did not know why the Gemini PC-4 or the SE pumps were excluded from the patent applications. (R. 77-5 at 70, 81–82, 84.) On January 23, 2017, Defendants filed the motion now before the Court.

LEGAL STANDARD

Even in patent cases, regional circuit law governs procedural issues that are not specific to patent law, including the standards of Rule 15(a)(2). *See Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1318 (Fed. Cir. 2009); *Waters Indus., Inc. v. JJI Int'l, Inc.*, No. 11 C 3791, 2012 WL 5966534, at *1 (N.D. Ill. Nov. 28, 2012); *see also SunPower Corp v. PaneClaw, Inc.*, No. 12-1633-MPT, 2016 WL 5107029, at *4, n.65 (D. Del. Sept. 19, 2016). Under Rule 15(a)(2), "a party may amend its pleading only with the opposing party's written consent or the court's leave." Here, Baxter does not consent. (R. 94.) While the Rule further provides that "[t]he court should freely give leave when justice so requires," Fed. R. Civ. P. 15(a)(2), "district courts have broad discretion to deny leave to amend where there is undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice to the defendants, or where the amendment would be futile." *Arreola v. Godinez*, 546 F.3d 788, 796 (7th Cir. 2008); *see also Heng v. Heavner, Beyers & Mihlar, LLC*, 849 F.3d 348, 354 (7th Cir. 2017). "A motion to amend should state with particularity the grounds for the motion and should be accompanied by the proposed amendment." *Gonzalez-Koeneke v. West*, 791 F.3d 801, 806 (7th Cir. 2015) (quoting *Otto v. Variable Annuity Life Ins. Co.*, 814 F.2d 1127, 1139 (7th Cir. 1986)). An amendment is futile if the amended claims could not survive a motion to dismiss under Rule

12(b)(6). *See Runnion ex rel. Runnion v. Girl Scouts of Greater Chi. & Nw. Ind.*, 786 F.3d 510, 524 (7th Cir. 2015); *Naperville Smart Meter Awareness v. City of Naperville*, 114 F. Supp. 3d 606, 611 (N.D. Ill. 2015); *Waters*, 2012 WL 5966534, at *1. When considering a Rule 12(b)(6) motion, the Court assumes the truth of the counterclaim's factual allegations. *See Roberts v. City of Chicago*, 817 F.3d 561, 564 (7th Cir. 2016); *DS Smith*, 2016 WL 69632, at *1.

ANALYSIS

Baxter argues that the Court should deny Defendants' motion because their amendment is futile and because they failed to act diligently in bringing the current motion. (R. 94 at i.) The Court addresses these contentions in turn.

I. Futility

A. Inequitable Conduct Pleading Standard

"Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [Patent and Trademark Office ('PTO')], which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability . . . ." 37 C.F.R. § 1.56(a); *see also Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007); *DS Smith Plastics Ltd. v. Plascon Packaging, Inc.*, 2016 WL 69632, at *3 (N.D. Ill. Jan. 6, 2016). "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; *see also TransWeb, LLC v. 3M Innovative Properties Co.*, 812 F.3d 1295, 1303–04 (Fed. Cir. 2016) ("A judgment of inequitable conduct requires clear and convincing evidence of materiality, knowledge of materiality, and a deliberate decision to deceive."); *Weber-Stephen Prods. LLC v. Sears Holding Corp.*, No. 1:13-cv-01686, 2014 WL

656753, at *2 (N.D. Ill. Feb. 20, 2014). Inequitable conduct is "the 'atomic bomb' of patent law," because unlike claim-specific validity defenses, it "renders the entire patent unenforceable." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc) (quoting *Aventis Pharm. S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting)).

There are two elements in an equitable conduct claim: "(1) an individual associated with the filing and prosecution of a patent application . . . failed to disclose material information" to the PTO, and (2) "the individual did so with a specific intent to deceive the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009); *DS Smith*, 2016 WL 69632, at *3. While inequitable conduct is a "broader concept than fraud," a party must plead inequitable conduct with particularity pursuant to Federal Rule of Civil Procedure 9(b). *Exergen*, 575 F.3d at 1326–27; *DS Smith*, 2016 WL 69632, at *3. "Whether inequitable conduct has been pleaded with particularity under Rule 9(b) is a question governed by Federal Circuit law." *Exergen*, 575 F.3d at 1318; *Weber-Stephen*, 2014 WL 656753, at *2. Under Federal Circuit law, a party pleading inequitable conduct must set forth the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1327 (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)); *DS Smith*, 2016 WL 69632, at *3. Rule 9(b) permits a party to allege a states of mind "generally."[4]

[4] Even where Rule 9's heightened pleading standards do not apply, Defendants must still plead in accordance with Rule 8. *See Ashcroft v. Iqbal*, 556 U.S. 662, 686–87 (2009). Under Rule 8, a pleading must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The short and plain statement under Rule 8(a)(2) must "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) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). A plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* Put differently, a pleading "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). In determining a pleading under the plausibility standard, courts must "accept all well-pleaded facts as true and draw reasonable inferences in [a plaintiff's] favor." *Roberts v. City of Chicago*, 817 F.3d 561, 564 (7th Cir. 2016).

Nevertheless, 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." *Exergen*, 575 F.3d at 1328–29; *see also Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011); *DS Smith*, 2016 WL 69632, *6. "A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith." *Id.* at 1329 n.5; *Waters*, 2012 WL 5966534, at *4.[5]

B. Materiality

In a case like the one before the court alleging inequitable conduct based on an alleged failure to disclose a prior art reference, *Therasense* makes clear that the materiality the proponent of an inequitable conduct claim must prove is "but-for material[ity]"—meaning, the party must show that the "PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Therasense*, 649 F.3d at 1291; *see also TransWeb*, 812 F.3d at 1304; *Weber-Stephen*, 2014 WL 656753, at *2. As previously noted, a party pleading inequitable conduct must set forth the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1327 (quoting *DiLeo*, 901 F.2d at 627)).

1. The "who" of the material omissions

To plead the "who" aspect of materiality, Defendants must identify "the specific individual associated with the filing or prosecution of the [patent] application . . ., who both knew of the material information and deliberately withheld or misrepresented it." *Exergen*, 575

[5] In 2011, the Federal Circuit, sitting en banc, tightened the proof requirements of inequitable conduct with respect to the elements of materiality and intent. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285, 1290–95 (Fed. Cir. 2011) (en banc); *Waters*, 2012 WL 5966534, at *4. It did not, however, "override *Exergen*'s pleading requirements." *See Delano Farms*, 655 F.3d at 1350, *Waters*, 2012 WL 5966534, at *4; *accord Weber-Stephen*, 2014 WL 656753, at *3 n.3.

F.3d at 1329. It is not enough to refer generally to "[Baxter], its agents and/or attorneys." *Id.*; *see also DS Smith*, 2016 WL 69632, at *3. Defendants argue that they adequately plead the "who" of inequitable conduct by "expressly identif[ying] Baxter's named inventors Randolph Meinzer, Grace Esche, Eric Michael, Kimball Knowlton, Cynthia Bennett, Eric Linner, Kenneth Lynn, Joseph Kruft, Eileen Hirotsuka, Daniel Kusswurm, Jane Zeisloft, Janice Stewart, Debra Gelhar, and Gilbert Rivas." (R. 77 at 11.) Baxter does not dispute this. The Court therefore accepts that Defendants have adequately pled the "who" component of materiality.

2. The "what" and "where" of the material omissions

With respect to the "what" and "where" of the material omissions, Defendants must identify "which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found." *Exergen*, 575 F.3d at 1329; *see also Weber-Stephen*, 2014 WL 656753, at *3. Defendants contend that their counterclaim meets these requirements as it (1) identifies the patent claims that the prior art anticipates and/or render obvious, and (2) includes detailed claim charts "comparing the limitations of those claims to the withheld prior art." (R. 77 at 12.) Baxter argues that Defendants have failed to plead the "what" and "where" of the allegedly material omissions for two reasons. (R. 94 at 6–10.) Baxter's arguments fall short.

First, Baxter contends that "not having submitted the same materials [it gave to the FDA] . . . does not support any claim of inequitable conduct because there is no relationship between 'predicate device' similarity and the claim element invalidity analysis required to show but-for materiality." (R. 94 at 10.) Baxter is correct to the extent that it argues that the substantial similarity of medical devices for the purposes of FDA approval is irrelevant to the question of patent infringement. *See Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342,

1349 n.3 (Fed. Cir. 2008) (explaining that FDA equivalence is not relevant to whether patent infringement occurred); *see also Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) ("As we have repeatedly said, it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent."). FDA proceedings, however, are not necessarily entirely irrelevant in patent cases. Indeed, one of the cases Baxter cites, *Abbott Point of Care, Inc. v. Epocal, Inc.*, CV-08-S-543-NE, 2012 U.S. Dist. LEXIS 54435, at *7–15 (D. Ala. Apr. 18, 2012), notes that evidence of substantial similarity for FDA purposes may be relevant for purposes other than proving infringement. While the *Epocal* court excluded such evidence because of the risk of prejudice and jury confusion, this Court need not make evidentiary rulings at this juncture. 2012 U.S. Dist. LEXIS 54435, at *14.[6]

Defendants respond, however, that Baxter's "inconsistent submissions to the FDA and [PTO] are evidence of its knowledge and deceptive intent," rather than evidence supporting the "what" or "where" of materiality. The Court agrees. Thus, Baxter's argument regarding FDA equivalence is inapposite to the matter now under consideration. Furthermore, Defendants are correct that an individual's submission to the FDA may be relevant to show knowledge and deceptive intent. *See Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d

[6] The other cases Baxter cites are not on point. Two deal with similarity or equivalence for FDA purposes being irrelevant to the question of patent infringement. *See Ethicon Endo-Surgery, Inc. v. Hologic, Inc.*, 689 F. Supp. 2d 929, 936 (S.D. Ohio 2010); *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, No. 2:7-cv-250, 2009 WL 8725107, at *5 (E.D. Tex. Oct. 8, 2009). The other case Baxter cites concerns trade secret misappropriation. *See Cardiovention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007). In that case, the court drew on other courts having refused to allow FDA substantial equivalence evidence as an admission of infringement. *See id.* Additionally, the court cited concerns related to unfair prejudice, delay, and time waste. *See id.* The court further noted that FDA substantial equivalence "means that the proposed device has the same intended use as the predicate device and that it either has the same technological characteristics as the predicate device or is as safe and effective as the predicate device." *Id.* The Court concluded that these issues were not relevant to the issue of whether two devices were similar for purposes of the trade secret misappropriation claim. *Id.* at 840–41.

1348, 1354 (Fed. Cir. 2005) ("The fact that an official of Bruno, who was involved in both the FDA and PTO submissions, chose to disclose the Wecolator to the FDA, but not to the PTO, certainly supports a finding of deceptive intent to withhold the disclosure from the PTO."); *see also Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989); *Dura Operating Corp. v. Magna Int'l*, No. 10-11566, 2011 WL 869372, at *12 (E.D. Mich. Mar. 10, 2011). Accordingly, Baxter's first argument fails.

Second, Baxter argues Defendants' claim charts do not show the "what" or "where" of materiality because they "are largely based on other information about [the IMED and IVAC] pumps—patents, technical documents, and different manuals—and not the manuals that Baxter had in its possession, gave to the FDA but purportedly 'withheld' from the PTO." (R. 94 at 7–8.) Baxter's argument is unavailing. Its argument is directed toward whether Defendants have adequately pled that the individuals Defendants have identified knew of the materially withheld information—a question that the Court takes up later in this opinion—rather than the question at hand.

The claim charts are specific about which claims and limitations the prior art references cover as well as where in the prior art there is material information going to the obviousness or the lack of novelty of the relevant claims. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, No. CIV. 08-309-JJF-LPS, 2009 WL 4928024, at *8 (D. Del. Dec. 18, 2009) ("The claim charts Power appended to the Counterclaims clearly identify 'where' in the alleged prior art the material references can be found, and further identify the limitations in the '972 patent to which they correspond."), *report and recommendation adopted*, No. CIV. 08-309-JJF-LPS, 2010 WL 2990039 (D. Del. July 22, 2010); *Konami Dig. Entm't Co. v. Harmonix Music Sys.*, No. 6:08cv286-JDL, 2009 WL 5061812, at *2 (E.D. Tex. Dec. 14, 2009) ("The

Court is similarly persuaded that Viacom has met the 'what' and 'where' requirements with pleadings that identify charts of potentially invalidating Konami prior art games—on a claim-by-claim and limitation-by-limitation basis."). Accordingly, Defendants have satisfied the "what" and "where" elements of materiality.[7]

3. The "why" and "how" of the material omissions

To plead the "why" and "how" aspects of materiality, Defendants must plead facts indicating 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." *Exergen*, 575 F.3d at 1329–30; *Weber-Stephen*, 2014 WL 656753, at *3. Additionally, given *Therasense*'s but-for materiality standard, "the court must determine whether there are sufficient allegations from which a court may reasonably infer that 'the PTO would not have allowed the claim if it had been aware of the undisclosed prior art.'" *Sloan Valve Co. v. Zurn Indus., Inc.*, No. 10-cv-204, 2012 WL 1108129, at *5 (N.D. Ill. Apr. 1, 2012) (quoting *Therasense*, 649 F.3d at 1291–94); *accord DS Smith*, 2016 WL 69632, at *4.

Baxter argues that Defendants fail to plead the "how" and "why" components of materiality because they "fail[] to plead the non-cumulativeness of the allegedly withheld information, and provide[] no explanation of how the allegedly withheld information would have

[7] Baxter also argues that Defendants' counterclaim fails because they do not "show details explaining the alleged similarity" between the SE I (the pump Baxter submitted to the FDA) and the SE II (the pump Defendants discuss in their claim charts). (R. 94 at 8–9.) This presents a question of knowledge—whether Baxter knew about the relevant aspects of the SE II pump—rather than the question at hand. Moreover, Defendants plead that the SE I and SE II are materially the same except for the number of pumping channels. (R. 77-1 at 25, ¶ 29.) Defendants need not *prove* that this is true at this stage of the litigation.

Baxter also presents an argument in a footnote that omitted portions of a "feature comparison chart" it submitted to the FDA, which Defendants depict in part in its counterclaim, "appear to refute [Defendants' materiality] arguments." (R. 94 at 9 n.2.) This insufficiently developed argument is waived. *See Harmon v. Gordon*, 712 F.3d 1044, 1053 (7th Cir. 2013); *Long v. Teachers' Ret. Sys. of Ill.*, 585 F.3d 344, 349 (7th Cir. 2009); *Keith v. Ferring Pharma., Inc.*, No. 15 FC 10381, 2016 WL 5391224, at *13 (N.D. Ill. Sept. 27, 2016). Moreover, this argument fails because it does not explain how the feature comparison chart—which does not address patent claims and makes comparisons of pumps at a high level of generality—rebuts Defendants' detailed claim charts.

been used." Defendants' counterclaim, however, includes detailed claim charts explaining how the Gemini PC-4 pump and the SE II pump anticipate and/or render obvious each element of a number of claims in the '805 and '034 Patents. Additionally, Defendants allege that Baxter did not submit any information regarding the Gemini PC-4 or SE II pumps to the PTO and that the failure to do so resulted in the allowance of claims that the PTO would have otherwise denied. In similar circumstances, courts, including some within this district, have found that parties have adequately pled the "how" and "why" aspects of materiality. In *Cumberland Pharmaceuticals v. Mylan Institutional LLC*, for example, the court rejected the counter-defendant's argument that the counter-plaintiff "failed to explain how or why the withheld information would have affected the PTO's allowance of the '356 patent, and why the withheld information is not cumulative." No. 12 C 3846, 2012 WL 6567922, at *6 (N.D. Ill. Dec. 14, 2012) (Pallmeyer, J.) (citation omitted). The court explained that "[b]y asserting that the withheld information would anticipate and/or render obvious each and every claim of the '356 patent, [the counter-plaintiff] is clearly alleging that the patent application would not have been granted had that information been disclosed." *Id.* Furthermore, based on these allegations, "the court [could] reasonably infer that the undisclosed information was not cumulative of the information before the PTO." *Id.*; *see also, e.g.*, *Ameranth, Inc. v. GrubHub, Inc.*, No. 12-CV-739 JLS (NLS), 2012 WL 12847584, at *4 (S.D. Cal. Oct. 4, 2012) ("[T]o the extent that GrubHub has alleged that Ameranth failed to disclose an anticipatory reference to the patent examiner and charted how the reference anticipates the asserted claims of the '850 and '325 patents, GrubHub has adequately alleged why the withheld reference is material and not cumulative. To require GrubHub to further state that the anticipatory reference is material and not-cumulative because it anticipates the asserted claims of the patents, thereby restating the definition of an anticipatory reference, would be

redundant."); *Eon Corp. IP Holdings, LLC v. T-Mobile USA, Inc.*, No. 6:10-CV-379-LED-JDL, 2011 WL 13134896, at *4 (E.D. Tex. Dec. 13, 2011), *report and recommendation adopted*, No. 6:10-CV-379-LED-JDL, 2012 WL 12893881 (E.D. Tex. Jan. 18, 2012); *Pollin Patent Licensing v. Capital One Auto Fin., Inc.*, No. 1:10-CV-07420, 2011 WL 5118891, at *3 (N.D. Ill. Oct. 25, 2011) (Hibbler, J.); *Bone Care Int'l, LLC v. Pentech Pharm., Inc.*, No. 08-CV-1083, 2010 WL 1655455, at *5–7 (N.D. Ill. Apr. 23, 2010) (Dow, J.) (emphasizing that Rule 9(b) "does not require adherence to blind formalism" and concluding that the defendants sufficiently had alleged non-cumulativeness by identifying withheld references that allegedly anticipated or rendered obvious patent claims, thereby implicitly alleging that those references were "not merely repetitive of other prior art references"). The sound reasoning of these cases applies here. Accordingly, Baxter's argument fails.

C. Intent

Therasense made clear that courts "may not infer intent solely from materiality." 649 F.3d at 1290. In other words, "[i]ntent and materiality are separate requirements," and "[a] district court should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa." *Id.* As previously noted, 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." *Exergen*, 575 F.3d at 1328–29; *see also Delano Farms*, 655 F.3d at 1350. The inference "need not be probable, only plausible." *Indep Trust Corp. v. Stewart Info. Servs. Corp.*, 665 F.3d 930, 935 (7th Cir. 2012).

Baxter primarily argues that Defendants have failed to allege facts from which the Court can draw any reasonable inference of a specific intent to deceive the PTO. (R. 94 at 11–14.) Baxter, however, also somewhat obliquely argues that Defendants have failed to allege that a specific individual knew of withheld material information because Defendants' claim invalidity charts "are largely based on other information about [the IMED and IVAC] pumps—patents, technical documents, and different manuals—and not the manuals that Baxter had in its possession, gave to the FDA but purportedly 'withheld' from the PTO." (R. 94 at 7–8.) As Defendants point out, the counterclaim "expressly identif[ies] the undisclosed Signature Edition and Gemini PC-4 *infusion pumps*, not just a particular version of their user manuals, as the material prior art that Baxter intentionally failed to disclose." (R. 101, Defs.' Reply, 4 (emphasis added) (quoting R. 77-1 at 27–28, ¶¶ 39–40; 25, ¶ 32.).) Moreover, it is reasonable to infer from Defendants' allegations that the Baxter employees who submitted the FDA application were intimately familiar with the two competitor pumps at issue as well as their features and how they functioned. Accordingly, drawing all reasonable inferences in Defendants' favor, the Court can plausibly make an inference that the Baxter employees identified in the counterclaim had more than general familiarity with the two pumps and knew of the withheld material information. *Cf. Exergen Corp.*, 575 F.3d at 1330 (explaining that a pleading failed to sufficiently allege the requisite knowledge based on mere general awareness that a reference existed); *see also DS Smith*, 2016 WL 69632, at *6 (distinguishing *Exergen*); *Cumberland Pharm.*, 2012 WL 6567922, at *11.

The Court turns to the last question—do Defendants adequately plead a specific intent to deceive the PTO? Baxter argues that they do not, contending that the FDA disclosure upon which Defendants rely is irrelevant and that Defendants are asking the Court to infer intent

"solely from some level of knowledge of a prior art reference." (R. 94 at 13 (quoting *Zvelo, Inc. v. SonicWall, Inc.*, No. 06-cv-0045-PAB-KLM, 2013 WL 5443858, at *5 (D. Colo. Sept. 30, 2013) (citing *Exergen*, 575 F.3d at 1331)).) Defendants first point to Federal Circuit precedent—which Baxter does not cite—that contradicts Baxter's argument that disclosing prior art to the FDA is irrelevant to the question before the Court. As noted above, *Bruno* states that "[t]he fact that an official of Bruno, who was involved in both the FDA and PTO submissions, chose to disclose the Wecolator to the FDA, but not to the PTO, *certainly supports a finding of deceptive intent* to withhold the disclosure from the PTO." 394 F.3d at 1334 (emphasis added). While *Bruno* predates *Exergen* and *Therasense*, its conclusion that including prior art in an FDA submission but withholding it from the PTO can constitute circumstantial evidence supporting a finding of deceptive intent remains authoritative. Consequently, Baxter's argument that Defendants are asking the Court to infer intent solely from materiality falls flat. Moreover, the current case is distinguishable from *Exergen*, where the proponent of the inequitable conduct claim relied on the fact that "an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application." 575 F.3d at 1331. In *Exergen*-, the pleading "d[id] not contain specific factual allegations to show that the individual who had previously cited the [prior art] knew of the specific information that is alleged to be material to the [patent at the center of the inequitable conduct claim] and then decided to deliberately withhold it from the relevant examiner." *Id.* As previously discussed, Defendants properly allege knowledge of specific material information. Given these distinctions from *Exergen* and the forgiving pleading standards under Rule 8 (recall, Rule 9 does not apply to pleading state of mind), the Court can properly make the reasonable inferences necessary to

support Defendants' claim. *See DS Smith*, 2016 WL 69632, at *7 (distinguishing *Exergen*); *Cumberland Pharm.*, 2012 WL 6567922, at *11.

II. Diligence

Baxter argues that Defendants failed to act diligently in bringing the current motion, pointing out that Defendants filed their motion five months after an August 2016 deadline for amendment and six months after receiving the FDA documents relevant to their motion. (R. 94 at 14–15.) Defendants, however, provide a satisfactory explanation for any delay. Defendants filed their motion just days after Bowman's deposition and about one month after Esche's. While Baxter argues that this does not justify any delay because their depositions did not "provide[] any material support for the proposed amendment," even if that were the case, it was prudent for Defendants to depose those inventors before moving to amend their counterclaims.

Additionally, Baxter does not explain how it suffers prejudice based on any delay. *See Life Plans, Inc. v. Sec. Life of Denver Ins. Co.*, 800 F.3d 343, 358 (7th Cir. 2015) (explaining that delay must usually be coupled with prejudice to the nonmoving party to justify denying leave to amend); *see also Nolan v. City of Chicago*, No. 15-CV-11645, 2017 WL 569154, at *7 (N.D. Ill. Feb. 13, 2017). At a December 2016 status hearing, Defendants put both Baxter and the Court on notice that they may seek amendment after Bowman's deposition. Additionally, much of Defendants' inequitable conduct claim is intertwined with their invalidity contentions, which Defendants disclosed to Baxter prior to filing the current motion. Finally, when Defendants served their Initial Non-Infringement, Unenforceability, and Invalidity Contentions in the summer of 2016, they "reserve[d] the right to amend or supplement [their] contentions if discovery or further investigation reveals evidence of inequitable conduct or other bases of unenforceability, such as the failure to disclose knowledge of a competitor's on-sale, directly

competing products during prosecution of the '034 patent[and the] '805 patent." (R. 81-3 at 23.) Thus, Baxter could have anticipated the current motion, which relies in large part on information Baxter already possessed. Accordingly, Defendants did not fail to act diligently as Baxter contends.

CONCLUSION

For the foregoing reasons, the Court grants Defendants' motion.

DATED: March 20, 2017

ENTERED

AMY J. ST. EVE
United States District Court Judge