

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MEDLINE INDUSTRIES, INC.,)	
)	
Plaintiff,)	
)	No. 17 C 7216
v.)	
)	Judge Sara L. Ellis
C.R. BARD, INC.,)	
)	
Defendant.)	

OPINION AND ORDER

Plaintiff Medline Industries, Inc. (“Medline”) alleges that Defendant C.R. Bard, Inc., (“Bard”) has infringed on Medline’s patents for a single-layer Foley urinary catheter tray. Bard answered the complaint and brought four counterclaims seeking to invalidate Medline’s patents alleging that Medline’s attorneys engaged in inequitable conduct during the prosecution of those patents. Bard also asserted the affirmative defense of inequitable conduct in its answer. Medline now moves to dismiss the counterclaims and to strike the inequitable conduct affirmative defense [69]. Because the Court finds that Bard has not adequately alleged materiality or intent with respect to Medline’s alleged inequitable conduct in the prosecution of U.S. Patent No. 9,808,400 (the “‘400 Patent”), the Court grants the motion to dismiss the ‘400 Patent counterclaim. Because the declarations Medline filed in support of U.S. Patent No. 9,808,596 (the “‘596 Patent”) were not false, Bard fails to allege inequitable conduct with respect to that patent and the Court grants Medline’s motion to dismiss that claim as well. Because the claims with respect to U.S. Patent Nos. 8,745,088 (the “‘088 Patent”) and 9,795,761 (the “‘761 patent”) are dependent upon the other two claims, the Court grants the motion to dismiss these claims as well. Finally, because Bard’s inequitable conduct affirmative defenses are materially identical to its

counterclaims, they fail for the same reasons discussed above and the Court strikes those affirmative defenses.

BACKGROUND¹

Medline sued Bard for violation of the ‘596 Patent², the ‘400 Patent³, the ‘088 Patent, and the ‘761 Patent. Each of these patents relates to a single tray design for a Foley or indwelling urinary catheter. A Foley catheter is a urinary catheter that is indwelling, meaning that it can reside in the bladder continuously for a period of time.

1. The ‘400 Patent

On January 10, 2017, the Patent Examiner issued Final Rejections of the claims for the ‘400 patent. In the Final Rejection notice, the Examiner stated that the rejection was because the drawings did not show a fluid bag, because the claim was anticipated by a prior patent, and because the patent was obvious. The examiner noted that Medline made several arguments against this rejection, but each argument was unpersuasive. Medline’s arguments related to the presence of a fluid bag.

On May 23, 2017, John Mills, outside counsel for Medline responsible for prosecuting the patents at issue, held a phone interview with the Examiner. During this interview, the

¹ The facts in the background section are taken from the Second Amended Answer to Second Amended Complaint for Patent Infringement (“SAA”) and exhibits attached to the Motion for Leave to Add Counterclaims for Inequitable Conduct and reference in the SAA and are presumed true for the purpose of resolving Medline’s motion to dismiss. See *Virnich v. Vorwald*, 664 F.3d 206, 212 (7th Cir. 2011); *Local 15, Int’l Bhd. of Elec. Workers, AFL-CIO v. Exelon Corp.*, 495 F.3d 779, 782 (7th Cir. 2007). A court normally cannot consider extrinsic evidence without converting a motion to dismiss into one for summary judgment. *Hecker v. Deere & Co.*, 556 F.3d 575, 582–83 (7th Cir. 2009). Where a document is referenced in the SAA and central to the counterclaims, however, the Court may consider it in ruling on the motion to dismiss. *Id.* The Court may also take judicial notice of matters of public record. *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080–81 (7th Cir. 1997).

² The ‘596 Patent followed from Patent Application No. 15/067/903. For simplicity’s sake, the Court will refer to this application as the ‘596 Patent Application.

³ The ‘400 Patent followed from Patent Application No. 14/265/909. For simplicity’s sake, the Court will refer to this application as the ‘400 Patent Application.

Examiner agreed with Mills that the prior art did not relate to a tray for an indwelling catheter, and that if the application were limited to indwelling catheters, that would overcome the obviousness rejections. However, the Examiner was not convinced that the original '400 Patent Application submission described an indwelling catheter. He stated that because the original submission did not describe an indwelling catheter, limiting the application to that construction would be treated as new material. The Examiner suggested providing a declaration or affidavit regarding the claimed indwelling catheter.

On July 10, 2017, Medline filed a Request for Continued Examination of the '400 Patent Application. In this Request, Medline provided amendments to the drawings, the specification, and claims in the '400 Patent Application. The amendments to the drawings replaced the sheets including Figures 7 and 8 with new versions that included "reference signs for the tube (720), the fluid receptacle (730), and portions of these components." Doc. 55-3 at 20. The revisions to the specification included updating the specification to include the numerical reference signs to correspond to the changes to the drawings. Further, the changes included the addition of sentences that state, "The catheter assembly 700 includes an indwelling (or Foley) catheter coupled to a fluid bag 730 by a tube 720. The first end portion 721 of the tube 720 is coupled to the indwelling catheter and the second end portion 722 of the tub 720 is coupled to the fluid bag 730 via an anti-reflux device 731." Doc. 55-3 at 22. Medline amended the claims to make several non-substantive changes as well as to specify that the catheter was indwelling. Medline also added new claims that stated that the tray related to an indwelling catheter to be used with a fluid receptacle, an anti-reflex device, and a coiled tube.

Medline supported its July 10 Request by an expert declaration from Barbara Weintraub (the "Weintraub Declaration"), a registered nurse. The purpose of the Weintraub Declaration

was for Weintraub to “provide an opinion related to how a healthcare service provider would have understood the term ‘catheter assembly’ as used in [a related patent].” Doc. 55-3 at 38. In the declaration, Weintraub states that a healthcare service provider would readily comprehend that several of the features of the catheter assembly described in the ‘400 Patent Application are components of a Foley or indwelling catheter and not components of some other type of catheter. Specifically, she states, “two syringes containing sterile water and lubricating jelly and a specimen container are . . . typically used with Foley catheters and not with intermittent catheters. Two syringes would never be necessary for inserting an intermittent catheter.” Doc. 55-3 at 40. She also states that the trays discussed in the patents “are not practical for intermittent catheters and would never be used by healthcare service providers for intermittent catheters.” *Id.* She goes on to state, “All of the Figures in the patents showing a catheter assembly are easily recognizable to a healthcare service provider as a Foley catheter with coiled tubing connected to a drainage bag. Because of the coiled tubing, no healthcare service provider would conclude the catheter assembly described in the patents includes an intermittent catheter.” *Id.* at 41.

Medline further supported its July 10 Request with a declaration from Richard Meyst, a mechanical engineer. Meyst stated that after having read through a different patent describing the same tray, he determined that the term “catheter assembly” in that context means “a medical device that includes a Foley catheter connected via coiled tubing to a drainage receptacle.” *Id.* at 48. He stated that the term catheter assembly has no independent accepted definition and that it must be viewed in context of the patent to be given a meaning to a person of ordinary skill in the art (“POSITA”).

On August 24, 2017, the Examiner withdrew his obviousness rejection based on the Meyst and Weintraub declarations. In so doing he wrote:

Furthermore, the affidavit filed 7/10/2017 states that the figures disclosed in the drawings of the catheter clearly show a Foley catheter with the recited structure as claimed and would be obvious to anyone in the field that the drawings depict such features. If the catheter is obvious to anyone in the field, then it would be considered prior art without the need for its description in the specification.

Doc. 55-3 at 71. The '400 patent subsequently issued with claims reciting an "indwelling" catheter.

2. The '596 Patent

On June 30, 2016, the Examiner issued Non-Final Rejections of claims for the '596 Patent. The Examiner objected to the drawings included in the patent application for failing to show a "fluid bag attached to the catheter and disposed in the second compartment" and a "coiled medical device comprising catheter, tubing and fluid bag" as recited in the proposed claims. Doc. 55-4 at 4. The Examiner stated that the drawings must show every feature of the invention specified in the claims.

On September 26, 2016, Medline filed an amendment to the '596 Patent Application requesting reconsideration of the June 30 Non-Final Rejections. In the amendment, Medline stated that Figure 14 of the '596 Patent Application "illustrates a catheterization procedure system. The catheter, tubing, and fluid bag are all shown." Doc. 55-4 at 27. Medline also pointed out that Figure 14 shows the catheter coupled to tubing, coupled to a fluid bag.

On January 13, 2017, the Examiner issued Final Rejections of the '596 Patent Application. The Examiner found Medline's arguments in its September 26 submission to be unpersuasive. The Examiner stated that Figure 14 is "printed instructions," and that the "fluid bag is not shown." Doc. 55-4 at 57.

On May 23, 2017, the Examiner had a telephone interview with Mills regarding the ‘596 Patent Application. During the conversation, Mills and the Examiner agreed that Medline could overcome the Examiner’s obviousness objections by amending the claims to limit them to indwelling Foley catheters, but they did not come to an agreement on whether the original disclosure described such a catheter. The Examiner did agree, however, to consider arguments and amendments that the claims are fully supported by the specification, and that “given the disclosure of the originally-filed figures (e.g., FIG. 14), additional evidence would not be necessary.” Doc. 55-4 at 63.

On July 10, 2017, Medline submitted proposed amendments. In the summary of those proposed amendments, Medline stated, “FIGS. 7, 8, and 14 have been amended to include reference signs for the Foley catheter (710), the tube (720), the fluid receptacle (730), and portions of these components.” Doc 55-4 at 79. The amendment also included the amended drawings. In amended Figures 7 and 8, there is no Foley catheter actually shown and no 710 number reference, but the number references for the tube and fluid receptacle, which were not previously in Figures 7 and 8, are included. In amended Figure 14, all three number references are included as well as their relevant components. The Examiner subsequently withdrew his objections and the ‘596 Patent issued.

3. The ‘088 and ‘761 Patents

Medline prosecuted the ‘088 and ‘761 Patents around the same time as the other two patents. Medline amended these patents to include a Foley catheter. Bard alleges that the same alleged inequitable conduct in which Medline engaged with respect to the ‘400 and ‘569 patents infected the prosecution of these patents rendering them unenforceable.

ANALYSIS

Bard's counterclaims and affirmative defenses based on Medline's alleged inequitable conduct boil down to two actions Medline's attorneys took during the prosecution of those two patents. With respect to the '400 patent, Bard asserts that Medline submitted two false expert declarations—the Weintraub and Meyst Declarations—that Figures 7 and 8 of the '400 Patent in fact show Foley catheters when they do not, and that these false declarations caused the Examiner to withdraw his objections to the '400 Patent. With respect to the '596 Patent, Bard asserts that in its brief describing proposed amendments to the '596 Patent, Medline grouped together revisions to Figures 7, 8, and 14 to improperly suggest that Medline had revised all three figures to include numerical references to the Foley catheter, when in fact Medline made no such edit to Figures 7 and 8, those figures do not show a Foley catheter, and that this presumably misled the Examiner to believe incorrectly that those figures did show a Foley catheter.

To survive a motion to dismiss, a counterclaim for inequitable conduct must set forth “the particularized factual bases for the allegation.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). “The substantive elements of inequitable conduct are: (1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the [Patent and Trademark Office].” *Id.* at 1327 n.3. Particularity “requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Id.* at 1327. Additionally, knowledge and intent may be averred generally, however, the pleading must contain “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.

The Court finds that the allegations of the counterclaim fail to satisfy Rule 9(b) for several reasons. First, with respect to the alleged misstatements regarding the ‘596 Patent, Bard asserts that after Medline made the statement that “FIGS. 7, 8, and 14 have been amended to include reference signs for the Foley catheter (710), the tube (720), the fluid receptacle (730), and portions of these components,” Doc 55-4 at 79, the Examiner took this assertion to mean that all three figures had been amended to include all three of these changes and then the Examiner failed to do the slightest bit of additional work, such as look at the patent to see if the reference to the Foley catheter had been added to Figures 7 and 8, where there had not previously been an image of a Foley catheter. The statement in question did not form part of the proposed patent, it was from a brief summarizing proposed changes to the ‘596 Patent to address objections the Examiner had raised. If including images and labels for the Foley catheter were so important to approval of the patent that their absence would doom the patent application to failure, it defies reason to believe that the Examiner would take a poorly written paragraph as sufficient evidence of that change without confirming the change in the patent itself. And absent some indication to the contrary, the Examiner is “presumed to have properly done [his] job.” *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008) (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)). It is plain on the face of the patent that Figures 7 and 8 do not include the reference number 710 nor do they depict a Foley catheter. It is clear from the face of the prosecution history that the Examiner went through numerous detailed reviews of the patent applications and did not simply rubberstamp assertions of Medline’s prosecution counsel. In this case, the Examiner was diligent throughout the entire

process and there is no reason to conclude he abandoned that diligence at the very end of the process.

For similar reasons, the allegations do not support an inference that Medline or its attorneys had an intent to deceive the PTO. To support such an inference, the defendant must show that an individual knew of and withheld material information or knew of the falsity of the material misrepresentation. Plainly, Medline did not do so here. Bard argues that by failing to correct the Examiner's misconception that Figures 7 and 8 included a Foley catheter and numeric references to the Foley catheter, Medline's attorneys satisfied this prong. But it is impossible to conclude that Medline withheld the contents of Figures 7 and 8 when they affirmatively provided those Figures to the Examiner and the Figures clearly do not include an image of a Foley catheter or the numeric reference. Therefore, Bard cannot show an intent to deceive.

With respect to the '400 patent, the story is much the same. Bard asserts that the statement in the Weintraub Declaration that, "All of the figures in the patents showing a catheter assembly are easily recognizable to a healthcare provider as a Foley catheter with coiled tubing connected to a drainage bag," Doc. 55-3 at 41, is false because none of the Figures in the '400 patent actually depict a Foley catheter. However, when read in context of the entire declaration, it becomes clear that Weintraub is trying to state that the catheter assembly that is visible in the figures is one that healthcare providers associate with Foley catheters. First, the declaration's stated purpose is to provide an opinion on how healthcare providers would understand the term "catheter assembly" as it is used in the patent. Next, Weintraub explains how various urinary catheters differ in key, obvious respects. She notes that only Foley catheter assemblies would use a drainage bag connected to the catheter via long coiled tubing. Next, she notes that only Foley catheter assemblies would come with two syringes, one for lubrication and one for

inflating the balloon with sterile water. She then notes that the instructions with the assembly state that one should not leave the catheter in for more than 48 hours, a warning that would only be needed with a Foley catheter. It is only after going through all of the reasons the complete assembly and corresponding medical devices would indicate to a healthcare provider that “catheter assembly” in this context refers to a Foley catheter assembly, does Weintraub state, “All of the figures in the patents showing a catheter assembly are easily recognizable to a healthcare provider as a Foley catheter with coiled tubing connected to a drainage bag.” Doc. 55-3 at 41. It is clear in reading the entire declaration that what she is trying to express is that a healthcare provider viewing those figures would immediately recognize the assembly as one associated with Foley catheters based on the reasons she provided in the preceding paragraphs. If she were trying to say that the picture in fact depicts a Foley catheter she would have omitted the phrase “easily recognizable to a healthcare provider” and simply stated that the figures show a Foley catheter. The inclusion of the “easily recognizable to a healthcare provider” clause demonstrates that it is recognizable not because of the presence of the Foley catheter itself, but because of the numerous other indicia of a Foley catheter present in the figures and specification.

As for the Meyst Declaration, it is even more obvious that he is not attempting to say that the figures actually depict a Foley catheter. Medline retained Meyst to provide an opinion on how a POSITA would have understood the term “catheter assembly” in related patents. After going through a similar exegesis of the patent as Weintraub, Meyst concluded that “A POSITA, having read the entire patent, would have understood the catheter assembly to include a Foley catheter.” Doc. 55-3 at 53. Bard also directs the Court to paragraph 30 of the Meyst Declaration, which states, “All disclosed embodiments of ‘catheter assembly’ in the specification include a catheter with coiled tubing.” Doc. 55-3 at 51. Bard then states that Meyst “specifically

cited Figures 7 and 8.” Doc. 77 at 3. This misstates Meyst’s declaration. He does not cite Figures 7 and 8 to support his statement that “[a]ll disclosed embodiments . . . include a catheter,” rather the declaration cites the Figures as examples of the catheter assembly including just coiled tubing. *See* Doc. 55-3 at 51 (“Figures 7, 8, and 10 of [the patent] identify the catheter assembly 700 that includes coiled tubing.”).

Viewing both declarations in their proper contexts, one can see that they are not advancing the plainly false idea that Figures 7 and 8 actually depict a Foley catheter, but rather that both healthcare providers and POSITAs would understand the catheter assemblies depicted in those Figures and described in the patents as being Foley catheter assemblies.

Therefore, based on the facts alleged in the counterclaim along with the documents Bard cites and relies on in its counterclaim, Bard’s counterclaims for inequitable conduct in the prosecution of the ‘400 and ‘596 Patents fail. The Weintraub and Meyst Declarations are not false; thus, they do not support a claim for inequitable conduct with respect to the ‘400 patent. And Bard cannot show that Medline or its attorneys acted with intent to deceive the PTO regarding the ‘596 Patent when they provided truthful evidence directly contradicting their alleged misstatement, and Bard cannot show that the alleged misstatement was material to the patent review process. Thus, the Court grants the motion to dismiss the inequitable conduct counterclaims for the ‘400 and ‘596 Patents.

Because the counterclaims for the ‘088 and ‘761 patents are premised on the unenforceability of the ‘400 and ‘596 Patents due to inequitable conduct, the Court also grants the motion to dismiss Bard’s counterclaims for the ‘088 and ‘761 Patents.

Finally, because the Court grants the motion to dismiss the counterclaims, and the affirmative defenses are simply an alternative pleading of its counterclaims and incorporates the

content of those counterclaims, they “rise or fall together.” *Medline Indus., Inc. v. C.R. Bard, Inc.*, No. 16-CV-3529, 2016 WL 5871501, at *3 (N.D. Ill. Oct. 7, 2016) (citing *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013)). Thus, the Court grants the motion to strike the inequitable conduct affirmative defense.

CONCLUSION

For the foregoing reasons, the Court grants Medline’s motion to dismiss the counterclaims and to strike the inequitable conduct affirmative defense [69].

Dated: September 11, 2018

A handwritten signature in black ink, appearing to read 'S. L. Ellis', written over a horizontal line.

SARA L. ELLIS
United States District Judge