

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

MEDLINE INDUSTRIES, INC.,)	
)	
Plaintiff,)	Case No. 16-cv-3529
)	
v.)	Judge Sharon Johnson Coleman
)	
C.R. BARD, INC.,)	
)	
Defendant.)	
)	

MEMORANDUM OPINION AND ORDER

The Plaintiff, Medline Industries, Inc., brought this patent infringement action against C.R. Bard, Inc., alleging that Bard infringed its patents – Nos. 8,746,452 (“the 452 patent”) and 9,283,352 (“the 352 patent”)—protecting the design of a tray for urinary catheters. Bard’s answer to Medline’s complaint asserted the affirmative defense of inequitable conduct and alleged a counterclaim seeking a declaratory judgment of unenforceability as to the ‘452 patent based on the alleged inequitable conduct. Medline promptly filed a motion to dismiss the counterclaim and to strike the inequitable conduct affirmative defense [28]. For the reasons set forth herein, that motion is granted.

Background

The following facts are alleged in the defendant’s counterclaim, and are taken as true for the purpose of the present motion. The initial application relevant to this motion was patent application 12/495,148 (“the 148 application”), which subsequently yielded patent number 8,631,935 (“the 935 patent”). The patent examiner issued a restriction requirement, resulting in the severance of claims 1–18 from the 148 application and their refiling as divisional application No. 12/846,675 (“the 675 application”), which yielded the 452 patent.

In a December 22, 2011 office action, the Examiner rejected the pending claims in the 675 application as obvious. Medline’s attorney, Phillip Burrus, filed a response asserting secondary

considerations of non-obviousness. Specifically, the response included articles from *Infection Control Today* and *iStockAnalyst.com* which were characterized as evidence of secondary considerations of non-obviousness. The examiner subsequently issued an office action again rejecting all pending claims as obvious. With respect to the articles submitted, the office action noted that “Applicant submits secondary considerations in the arguments; however, this is not a proper affidavit under 37 CFR 1.132” and that the examiner accordingly had not considered that evidence. On March 25, 2013, Burrus filed a response challenging the rejection of the claims as obvious based on the purported secondary considerations of non-obviousness.

During the prosecution of the 148 application, the examiner similarly rejected all pending claims as obvious. Burrus submitted a response containing an article from *Infection Control Today*, which was characterized as evidence of secondary considerations of non-obviousness. Burrus subsequently filed a request for continued examination discussing the previously submitted *Infection Control Today* article and an *iStockAnalyst* article. Attached to that request was a *Medical News Today* article with the same content as the *iStockAnalyst* article and an article published by *Morningstar*. The examiner issued an office action rejecting the pending claims, again noting that “Applicant submits secondary considerations in arguments; however, this is not a proper affidavit under 37 CFR 1.132.” On April 3, 2013, Burrus filed a response challenging the rejection of the claims as obvious based on the purported secondary considerations of non-obviousness. Both Burrus’ March 25 response in the 675 application and his April 3 response in the 148 application asserted that the previously attached articles constituted objective evidence of secondary considerations because they extolled the virtues of the claimed invention and demonstrated an immediate and favorable response. Of particular note, both the March 25, 2013 and April 3, 2013 responses filed by Burrus contained seven pages of identical argument under the heading “Secondary Considerations Demonstrate Applicant's Invention is Non-obvious over Prior Art.”

That section of the responses addressed three articles, from *Infection Control Today*, *iStockAnalyst*, and *Morningstar*, that Burrus characterized as objective evidence of secondary considerations of non-obviousness. Burrus specifically argued, among other things, that the articles constituted objective evidence of non-obviousness because they illustrated an immediate and favorable response to the invention.

Burrus contended that the *Infection Control Today* article, titled “Medical Center Cuts Catheterizations by 21 Percent With Foley Catheter Management System,” demonstrated that Medline’s invention had been used to lead to a 21 percent decrease in catheter-based infections and that this reduction was directly attributable to the design of Medline’s tray. Burrus asserted that the *iStockAnalyst* article, titled “‘Getting to Zero!’ Medline’s ERASE CAUTI Program Helps Hospitals Reduce Catheter Use by 20 Percent,” indicated that Medline’s invention helped hospitals reduce the cost of catheter procedures and the risk of infections or other complications. Burrus, however, did not file the *iStockAnalyst* article but instead filed an identical article published a day later in *Medical News Today*. Finally, Burrus referenced a *Morningstar* article titled “Floyd Medical Center Reduces Catheter-Associated Urinary Tract Infections 83 Percent and Catheter Use by 23 Percent,” which Burrus characterized as directly crediting Medline’s tray with reducing the incidence of urinary infections.

In his responses, Burrus stated that these articles “are objective in that they were not written by the inventors or assignee of record, but were written instead by third parties.” Burrus further asserted that the articles “are evidence in that they are not merely ‘conclusory statements,’ but rather articles published in national publications that extoll the virtues of the claimed invention and demonstrate an immediate and favorable response.”

All three articles, however, are republished Medline press releases. The *Infection Control Today* article contains the same text as a September 2010 Medline press release titled “Arkansas Methodist

Medical Center Cuts Catheterizations by 21 Percent with Innovative Foley Catheter Management System.” The January 2011 *Morningstar* article is identical to a January 2011 Medline press release of the same title. And the *Medical News Today* and *iStockAnalyst* articles are republished copies of an April 2011 Medline press release of the same title. All of these press releases were authored by Medline employees. The defendant alleges, on information and belief, that Burrus knew that these articles were republished Medline press releases. The defendant further alleges that the case studies and white papers described in the press releases were themselves ghost-written by Medline employees.

Jennifer E. Tomes is listed as an inventor on the ‘935 and ‘452 patents. On the same dates that Burrus filed his responses in the ‘675 and ‘148 applications, Medline filed substantially similar declarations by Tomes in support of those applications. Both declarations quote from the *Infection Control Today*, *iStockAnalyst*, and *Morningstar* articles, as well as an article in the *Journal of Healthcare Contracting* and a Medline publication. The declarations point to these articles as evincing secondary considerations, especially commercial success and unexpected results. Neither declaration, however, is alleged to assert that the articles are evidence of an immediate and favorable secondary response. The declaration identified these articles as providing evidence of secondary considerations but did not disclose that the articles were Medline press releases. Tomes was Medline’s Director of Marketing at the time of her declaration. As such, the defendants allege on information and belief that she was aware of the contents of Medline’s press releases and that the articles she had identified were republished press releases.

The examiner in the ‘148 application entered a final office action on July 31, 2013, holding that the bulk of the claims in that application avoided the prior art of record. The examiner specifically rejected the arguments concerning the unexpected benefits of the invention contained in Tomes’ declaration and noted that the ruling was based on the persuasive nature of Medline’s

arguments on page 22 of its reply (which concerned secondary considerations demonstrating an immediate and favorable response). In a subsequent office action, the examiner withdrew the obviousness rejections of claims 1–13 of the ‘675 Application without comment.

The defendants contend that, by failing to disclose that the articles were republished press releases, Burrus and Tomes violated their duty of candor and good faith, made material misrepresentations with intent to deceive the PTO, and thereby engaged in inequitable conduct rendering the ‘452 patent unenforceable.

Legal Standard

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the complaint, not the merits of the allegations. The allegations must contain sufficient factual material to raise a plausible right to relief. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 569 n.14, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). Although Rule 8 does not require a plaintiff to plead particularized facts, the complaint must allege factual “allegations that raise a right to relief above the speculative level.” *Arnett v. Webster*, 658 F.3d 742, 751–52 (7th Cir. 2011). Put differently, Rule 8 “does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), *see also* Fed. R. Civ. P. 8(a). When ruling on a motion to dismiss, the Court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff’s favor. *Park v. Ind. Univ. Sch. of Dentistry*, 692 F.3d 828, 830 (7th Cir. 2012).

Although motions to strike affirmative defenses are generally disfavored, affirmative defenses are pleadings subject to the requirements of Federal Rules of Civil Procedure 8 and 9. *Heller Fin., Inc. v. Midway Powder Co., Inc.*, 883 F.2d 1286, 1294 (7th Cir. 1989). Thus, in order to survive a motion to strike an affirmative defense must (1) be properly pleaded as an affirmative

defense; (2) be adequately pleaded under the Federal Rules of Civil Procedure; and (3) be able to withstand a Rule 12(b)(6) challenge. *Renalds v. S.R.G. Restaurant Group*, 119 F. Supp. 2d 800, 802 (N.D. Ill. 2000) (citing *Heller*, 883 F.2d at 1294). Accordingly, inequitable conduct counterclaims and affirmative defenses of inequitable conduct rise or fall together. *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013). This is especially so in this case, because Bard's inequitable conduct affirmative defense consists of a single paragraph incorporating by reference the contents of Bard's inequitable conduct counterclaim.

In order to allege a counterclaim for inequitable conduct, a defendant must allege (1) that 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) that 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). Inequitable conduct must be pleaded with particularity under Federal Rule of Civil Procedure 9(b). *Id.* at 1326–27. “A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual basis for the allegation, does not satisfy Rule 9(b).” *Id.* Instead, Rule 9(b) requires the identification of the specific “who, what, when, where, and how” of the material misrepresentation or omission committed before the PTO. *Id.* at 1327. Moreover, “although ‘knowledge’ and ‘intent’ may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation or (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.* at 1328–29.

Discussion

Medline contends that Bard has not adequately alleged how or why Burrus' alleged misrepresentations were material. Yet Medline's own filings in support of its patent applications, as excerpted in the counterclaim, show the materiality of the alleged misrepresentation. Burrus, for instance, asserted in the responses that secondary considerations could be set forth in the form of "any objective evidence" and that "any objective evidence of nonobviousness" must be considered by the examiner. Burrus further asserted that the articles in question were "objective evidence" because "they were not written by the inventors or assignee of record, but were written instead by third parties." Thus, by Burrus' own reasoning, if Medline had authored the articles they would not have constituted objective evidence and would not have been worthy of consideration.¹ Instead, Burrus asserted that the articles were objective evidence that the examiner was required to consider, and the examiner subsequently stated that it was this objective evidence of an immediate and favorable response by third parties that he found to be persuasive.²

Medline also contends that Bard has not alleged facts from which a court could reasonably infer that Burrus knew of the falsity of his misrepresentation. Here, Bard has not alleged that the articles that Burrus cited provided any indication that they were republished Medline press releases. Nor has Bard alleged that Burrus had previously received the Medline drafted press releases or that he had some other reason to know of their existence. Even if, as Bard alleges, Tomes was aware that the articles were merely republished press releases, Bard has alleged nothing to suggest that Burrus was privy to that knowledge. Instead, Bard has alleged "on information and belief" that Burrus knew the articles were republished Medline press releases. Information and belief, however,

¹ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 744 (Fed. Cir. 2002) is inapposite, because in that case the identity of the declaration's author was unrelated to the legal significance of its contents, whereas here the articles' purported third-party authorship gave rise to their legal significance.

² No similar statement is alleged with respect to the '675 application. This Court assumes, without deciding, that the examiner's basis for finding non-obviousness with respect to the '675 application was the same as that described with respect to the '148 application.

is insufficient to plead allegations of inequitable conduct unless the allegations set forth the specific facts on which the belief is based, which Bard has not done here. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1330 (Fed. Cir. 2009).

Bard instead argues that scienter can be inferred based on *Merck & Co., Inc. v. Reynolds*, 559 U.S. 633, 649–50, 130 S.Ct. 1784, 176 L.Ed.2d 582 (2010). In *Merck*, the Supreme Court recognized that certain statements inherently demonstrate scienter when they are shown to be false. The Court explained, for instance, that it is unlikely that someone would falsely say “I am not married” without being aware that his statement was false. *Id.* Burrus’ representations regarding the articles’ authorship, however, are entirely dissimilar to the scenario envisioned in *Merck*, and Bard offers no plausible argument for why an article’s authorship should be treated comparably to an inherently known fact such as the speaker’s marital status. Accordingly, Bard has not alleged facts from which a reasonable court could infer scienter with respect to Burrus.

Medline also contends that Bard has not alleged facts establishing the materiality of the Tomes declaration. In her declarations, Tomes does not make any claim as to who authored the articles in question, although she repeatedly attributed statements to the articles’ authors when, according to the allegations, she was aware that Medline staff had written the articles and ghost-written the underlying white-papers. Unlike Burrus, however, Tomes’ arguments to the examiner were based on the unexpected results described within the articles and not upon their role as immediate and favorable reactions to the invention by third-party observers. The authorship of the articles thus was not directly material. *See Juicy Whip, Inc.*, 292 F.3d at 744. The examiner, moreover, expressly rejected Tomes’ arguments because the results that the articles described did not demonstrate obviousness. In light of this express disclaimer of materiality by the examiner, Bard has not alleged facts sufficient to support an inference of materiality with respect to Tomes’ declaration. This Court is not convinced otherwise by Bard’s assertion that Tomes’ declarations were

unmistakably false and therefore intrinsically material. *Cf. Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012) (recognizing that affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, are material). Although Tomes' declarations failed to disclose the articles' authorship and thus may have been materially misleading, Tomes is not alleged to have made any affirmative assertions about the author's identity. Her statements were therefore not unmistakably false, even if they were potentially misleading. Bard, moreover, has not alleged any facts supporting an inference that Tomes acted with the specific intention to deceive the PTO.

Conclusion

For the foregoing reasons, this Court holds that Bard's allegations are insufficient to state a counterclaim for inequitable conduct or an affirmative defense of inequitable conduct. Accordingly, Medline's motion to dismiss the counterclaim and strike the inequitable conduct affirmative defense [28] is granted, Bard's declaratory judgment counterclaim is dismissed without prejudice, and Bard's inequitable conduct affirmative defense is stricken without prejudice.

IT IS SO ORDERED.

Date: October 7, 2016

Entered: 
SHARON JOHNSON COLEMAN
United States District Court Judge