

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF KENTUCKY  
SOUTHERN DIVISION  
(at London)

NAOMA SLONE, et al.,	)	
	)	
Plaintiffs,	)	Civil Action No. 6: 13-215-DCR
	)	
V.	)	
	)	
CL MEDICAL, INC., et al.,	)	<b>MEMORANDUM OPINION</b>
	)	<b>AND ORDER</b>
Defendants.	)	

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This civil action involves claims that a medical device which was developed, marketed and distributed by the defendants injured Plaintiff Naoma Slone. Slone and her husband, Tommy Slone, filed a Complaint in the Jackson Circuit Court on September 19, 2013. [Record No. 1-1] Thereafter, the matter was removed to this Court based on diversity jurisdiction.

Following removal, Defendant CL Medical, Inc. moved the Court to dismiss Count 5 of the plaintiffs' Complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. [Record No. 5] Defendant CL Medical, Inc.'s motion was filed on November 12, 2013. However, the plaintiffs have not responded within the time provided by the Local Rules. See Local Rule 7.1.<sup>1</sup> As a result, the Court will evaluate the merits of the defendant's motion without the benefit of a response.

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<sup>1</sup> Local Rule 7.1(c) provides that "[a] party opposing a motion must file a response memorandum within twenty-one (21) days of service of the motion. Failure to timely respond to a motion may be grounds for granting the motion. . . ." Notwithstanding this language, the Court will proceed to consider the merits of the defendant's motion to dismiss.

## I.

The plaintiffs' Complaint contains a lengthy recitation of alleged facts relating to the manufacture and distribution of the medical device "I-STOP" which is used to treat female urinary incontinence. [See Record No. 1-1, pp. 4-24.] Following their factual assertions, the plaintiffs make the following claims for relief: (i) Count One – Products Liability, Defective Design; (ii) Count Two – Products Liability, Failure to Warn; (iii) Count Three – Products Liability, Breach of Implied Warranty; (iv) Count Four – Products Liability, Breach of Express Warranty; (v) Count Five – Negligence; and (vi) Count Six – Loss of Consortium.

Defendant CL Medical, Inc.'s motion relates only to Count Five, which contains the following allegations:

### **COUNT FIVE NEGLIGENCE**

125. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

126. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that I-STOP had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by the Defendants, in fact, were false.

127. Defendants failed to exercise ordinary care in the representations concerning I-STOP while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented I-STOP's high risk of unreasonable, dangerous and adverse side effects.

128. Defendants breached their duty in representing that I-STOP had no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical healthcare community.

129. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants know, and had reason to know, that I-STOP had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

130. As a direct and proximate result of the Defendants' conduct, Plaintiff has Suffered [sic] the herein described injuries and damages.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, in an amount exceeding the minimum jurisdictional requirements of this court sufficient to compensate Plaintiff for her damages; for costs expended herein; and for all other relief to which plaintiff may be entitled.

[Record No. 1-1, pp. 32-33]

The plaintiffs claim that CL Medical, Inc., a Delaware corporation, was involved in the design, manufacture, development, labeling, marketing, distribution and sale of I-STOP. Additionally, they assert that this defendant is the exclusive importer of the device from a related entity, Defendant CL Medical<sup>2</sup>. According to the plaintiffs, Defendant CL Medical was also responsible for designing, manufacturing, developing, labeling, marketing, distributing and selling the product. [See Record No. 1-1, pp. 4-5.] After identifying the defendants as being jointly responsible for placing the I-STOP device into the stream of commerce, the plaintiff makes allegations against them jointly. [Id. at ¶ 7]

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<sup>2</sup> The plaintiffs allege that Defendant CL Medical is a foreign business entity whose address is 28, Avenue General deGaulle, F 69110, Sainte Foy Les Lyon, France. [Record No. 1-1, p. 4] Defendant CL Medical, Inc. refers to the co-defendant as "CL Medical SARL." It states that CL Medical SARL has not yet been served. [Record No. 5]

Defendant CL Medical, Inc. asserts that the claim of negligent misrepresentation should be dismissed because it is not adequately plead and does not state a claim for relief under *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atl. Corp. v. Twombly*, 550 U.S. 554 (2007). More specifically, it argues that, while the plaintiffs' Complaint contains boilerplate allegations of purported misrepresentations related to the product in issue in paragraphs 86, 87, 90, 91, 92, 93, and 96, the plaintiffs fail to identify any *specific* misrepresentation, communication, labeling or other material that it transmitted or authored. Further, CL Medical, Inc. correctly asserts that the plaintiffs make no effort to distinguish the two defendants in their allegations.

## II.

When evaluating a motion to dismiss under Rule 12(b)(6), the Court must determine whether the complaint alleges “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The plausibility standard is met “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). Although the complaint need not contain “detailed factual allegations” to survive a motion to dismiss, “a plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (internal quotation marks and alteration omitted).

Under the foregoing standard, the Court is required to “accept all of plaintiff’s factual allegations as true and determine whether any set of facts consistent with the allegations would

entitle the plaintiff to relief.” *G.M. Eng’rs & Assoc., Inc. v. West Bloomfield Twp.*, 922 F.2d 328, 330 (6th Cir. 1990) (citation omitted). However, the Court need not accept as true legal conclusions cast in the form of factual allegations if those conclusions cannot be plausibly drawn from the facts, as alleged. *See Iqbal*, 556 U.S. at 678 (“[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.”); *see also Papasan v. Allain*, 478 U.S. 265, 286 (1986) (noting that in reviewing a motion to dismiss, the district court “must take all the factual allegations in the complaint as true,” but that the court is “not bound to accept as true a legal conclusion couched as a factual allegation.”).

In the present case, neither Count Five nor the paragraphs which it incorporates contain sufficient factual assertions to overcome the defendant’s motion to dismiss. Under Kentucky law, the plaintiff must identify the false or misleading information provided by the specific defendant. *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 746 (Ky. 2011). Additionally, he or she must demonstrate that: the plaintiff was a reasonably foreseeable recipient of the information; the plaintiff justifiably relied on the information; the plaintiff exercised reasonable care in relying on the information; and the false statements allegedly made by the defendant were a proximate cause of the plaintiff’s damage. *Presnell Const. Managers, Inc. v. EH Const., LLC*, 134 S.W.3d 575, 580 (Ky. 2004). The defendant also correctly asserts that claims of negligent misrepresentation in this jurisdiction must be plead with particularity. *Republic Bank & Trust Co. v. Bear Stearns & Co., Inc.*, 683 F.3d 239, 260 (6th Cir. 2012) (holding that the heightened pleading standard of Rule 9(b), Fed. R. Civ. P., applies to claims

of negligent misrepresentation).<sup>3</sup> The plaintiffs have failed to meet this standard with regard to any alleged misrepresentations of Defendant CL Medical, Inc.

### III.

Based on the foregoing analysis and discussion, it is hereby

**ORDERED** as follows:

1. Defendant CL Medical, Inc.'s Motion to Dismiss [Record No. 5] is **GRANTED**. Count Five of the plaintiffs' Complaint is **DISMISSED**, with prejudice, with regard to Defendant CL Medical, Inc.
2. The claim contained in Count Five of the plaintiffs' Complaint remains pending with respect to Defendant CL Medical.

This 13<sup>th</sup> day of December, 2013.



**Signed By:**

**Danny C. Reeves** DCR

**United States District Judge**

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<sup>3</sup> The plaintiffs have not sought to amend their Complaint following removal of the action to this Court for the purpose of meeting the requirement of Rule 9(b) of the Federal Rules of Civil Procedure. By failing to respond to the defendant's motion to dismiss, the Court assumes that the plaintiffs have identified all information available to them regarding their claim of negligent misrepresentation.