

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF KENTUCKY  
PADUCAH DIVISION  
CIVIL ACTION NO. 5:14-CV-00101-TBR**

ASHLEY BABICH-ZACHARIAS

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC.,  
BAYER PHARMA AG, and BAYER OY

Defendants.

**MEMORANDUM OPINION AND ORDER**

This matter comes before the Court upon the motion to dismiss filed by Defendant Bayer Healthcare Pharmaceuticals, Inc. (“Bayer”). (Docket No. 42.) Plaintiff Ashley Babich-Zacharias has responded, (Docket No. 44), and Bayer has replied, (Docket No. 46). Fully briefed, this matter stands ripe for adjudication. For the reasons set forth below, the Court will GRANT IN PART and DENY IN PART Bayer’s motion to dismiss.

**Factual Background**

Babich-Zacharias raises product liability claims arising from her use of Mirena, an intrauterine contraceptive system produced by Bayer. The device consists of a T-shaped polyethylene frame with a steroid reservoir that releases levonorgesterel, a synthetic hormone that acts as a contraceptive, into the uterus each day. A healthcare provider inserts the device into the uterus during an office visit, after which it may remain in use for up to five years.

The Amended Complaint alleges that in January 2010, Babich-Zacharias’s Mirena was inserted by Dr. Tasheema Fair at the Baynes-Jones Army Community Hospital in Fort Polk, Louisiana. Babich-Zacharias claims that in April 2011, she developed severe headaches and vision problems. When her symptoms worsened in August 2011, she sought additional treatment. She was ultimately diagnosed with bilateral optic nerve swelling, most likely attributable to pseudotumor cerebri. According to Plaintiffs,

pseudotumor cerebri, also known as idiopathic intracranial hypertension (“PTC/IIH”), occurs when fluid builds up in the skull, triggering “severe migraines or migraine-like headaches with blurred vision, diplopia (double vision), temporary blindness, blind spots, or other visual deficiencies” due to increased pressure on the optic nerve. (Docket No. 40 at ¶¶ 43-44.) If not correctly diagnosed and treated, PTC/IIH may cause permanent vision loss and blindness. (Docket No. 40 at ¶ 50.) Although the condition is treatable, positive outcomes are not assured.

In August 2011, Babich-Zacharias underwent surgery to prevent permanent damage to her optic nerve. On June 20, 2013, her Mirena was removed. She maintains that although the removal alleviated the severity of her symptoms, it did not cure them; she alleges continued vision problems and migraine-like headaches. (Docket No. 40 at ¶ 188.) She submits that her injuries were caused or triggered by her Mirena.

On March 10, 2015, Babich-Zacharias filed her Amended Complaint, asserting claims against Bayer for negligence, design defect, failure to warn, strict liability, breach of implied and express warranties, negligent and fraudulent misrepresentation, and fraud by suppression and concealment. She contends that levonorgestrel “causes or contributes to the development of PTC/IIH, increases the risk of developing PTC/IIH, and/or worsens or exacerbates PTC/IIH” and that Bayer concealed its knowledge of these defects. (Docket No. 40 at ¶ 64.) According to Babich-Zacharias, Mirena’s label and patient information booklet fail to warn users of this “known link” between the device and these conditions. (Docket No. 40 at ¶¶ 39-41.) She further argues that despite medical literature reflecting a need for additional research, Bayer failed to conduct clinical tests investigating this purported connection. (Docket No. 40 at ¶ 42.) Finally, she points to Bayer’s “Mirena Simple Style Statements Program,” consumer-directed live presentations directed toward “busy moms.” According to Babich-Zacharias, the Simple Style script omitted information regarding serious risks associated with using Mirena. (Docket No. 1 at ¶ 164-167.)

## Legal Standard

The Federal Rules of Civil Procedure require that pleadings, including complaints, contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). A complaint may be attacked for failure “to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, a court will presume that all the factual allegations in the complaint are true and will draw all reasonable inferences in favor of the nonmoving party. *Total Benefits Planning Agency v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 434 (6th Cir. 2008) (citing *Great Lakes Steel v. Degendorf*, 716 F.2d 1101, 1105 (6th Cir. 1983)). “The court need not, however, accept unwarranted factual inferences.” *Id.* (citing *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 12 (6th Cir. 1987)).

Even though a “complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, 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.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (citations omitted). Instead, the plaintiff’s “[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Id.* (citations omitted). That is, a complaint must contain enough facts “to state a claim to relief that is plausible on its face.” *Id.* at 570. A claim becomes plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 556). If, from the well-pleaded facts, the court cannot “infer more than the mere possibility of misconduct, the complaint has alleged—but has not ‘show[n]’—‘that the pleader is entitled to relief.’” *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)). “[O]nly a complaint that states a plausible claim for relief survives a motion to dismiss.” *Id.*

Moreover, a plaintiff alleging negligent misrepresentation under Kentucky law must adhere to the heightened pleading standard articulated by Federal Rule of Civil Procedure 9(b), which is “designed to

prevent ‘fishing expeditions,’ to protect defendants’ reputations from allegations of fraud, and to narrow potentially wide-ranging discovery to relevant matters.’” *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 4677 (6th Cir. 2011) (citing *United States ex rel. SNAPP, Inc. v. Ford Motor Company*, 532 F.3d 496, 504 (6th Cir. 2008)). The Sixth Circuit has acknowledged a lack of clarity regarding the pleading standard that applies to negligent misrepresentation claims, point to a circuit split among federal courts of appeals as to this issue. *See Republic Bank & Trust Co. v. Bear Stearns & Co., Inc.*, 683 F.3d 239, 247 (6th Cir. 2012). Looking to Sixth Circuit precedent, though, *Republic Bank* advised that “[w]hether a state-law claim sounds in fraud, and so triggers Rule 9(b)’s heightened standard, is a matter of substantive state law, on which we must defer to the state courts.” *Id.* Because Kentucky law “holds parties pleading negligent misrepresentation to Kentucky’s version of Rule 9(b),” a plaintiff’s negligent misrepresentation claim must satisfy this higher standard to survive dismissal. *Id.* at 248. *See also Morris Aviation, LLC v. Diamond Aircraft Indus., Inc.*, 536 Fed. App’x 558, 562 (6th Cir. 2013) (also applying the Rule 9(b) standard to negligent misrepresentation claims).

### **Analysis**

Bayer now moves to dismiss Babich-Zacharias’s claims for strict liability, breach of implied warranty, and negligent misrepresentation. The Court will address each in turn.

#### **I. The Court will deny Bayer’s motion to dismiss the strict liability claim.**

Count IV of Babich-Zacharias’s Amended Complaint asserts a claim for strict liability, alleging that when her Mirena device “left the hands of the manufacturer and/or supplier, it was unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other contraceptives.” (Docket No. 40 at ¶ 276.) She asserts that Bayer is “strictly liable for placing an unreasonably dangerous product on the market that [was] not safe for its intended use[.]” (Docket No. 40 at ¶ 298.)

Bayer moves the Court to dismiss this claim, noting first that Babich-Zacharias has raised separate claims for design defect and theory to warn. Bayer argues that to the extent that the strict liability claim is also grounded upon these theories, it must be dismissed as duplicative. The Court, however, disagrees. Kentucky law permits a plaintiff to advance claims for both strict liability and negligence against a manufacturer whose product caused her injury. *Waltenburg v. St. Judge Medical, Inc.*, 33 F. Supp. 3d 818, 836 (W.D. Ky. 2014) (citing *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 535 (Ky. 2003)). Although “[t]he foundation of both theories is that the product is ‘unreasonably dangerous,’” *Ostendorf*, 122 S.W.3d at 535, the claims are distinct. “Whereas negligence examines the conduct of the manufacturer—could the manufacturer foresee the harm to the plaintiff and did the manufacturer act reasonably to prevent that harm—strict liability typically evaluates the condition of the product.” *Id.* Because Babich-Zacharias’s claims are not duplicative, the Court need not dismiss them at this stage.

Bayer further moves to dismiss any portion of the claim asserting a manufacturing defect. The Company argues that Babich-Zacharias failed to specify any manufacturing defect that deviated from Bayer’s specifications. In response, Babich-Zacharias clarifies that she has not levied a manufacturing defect claim. (*See* Docket No. 44 at 3.) Accordingly, the Court will deny as moot Bayer’s motion to dismiss the perceived manufacturing defect claim.

## **II. The Court will grant Bayer’s motion to dismiss the claim for breach of implied warranty.**

Bayer next argues that Babich-Zacharias’s claim for breach of implied warranty fails as a matter of law, as no privity of contract existed between the parties. The Court agrees. “Under Kentucky law, privity of contract is an essential element for breach of warranty.” *Allen v. Abbott Labs.*, No. 11-146-DLB, 2012 WL 10508 (E.D. Ky. Jan. 3, 2012). Babich-Zacharias does not contest this principle, nor does she allege that she purchased Mirena directly from Bayer. Therefore, the Court will grant Bayer’s motion to dismiss this claim.

**III. The Court will permit Babich-Zacharias's negligent misrepresentation claim to proceed.**

Finally, the Court turns to Babich-Zacharias's negligent misrepresentation claim. According to Bayer, the scope of this tort does not encompass circumstances involving advertising and packaging associated with a defective product. Bayer's argument is not without basis. *Bland v. Abbott Labs., Inc.*, addressed a negligent misrepresentation claim based on marketing and packaging materials associated with the defendant's product. No. 3:11-CV-430-H, 2012 WL 524473, at \*1 (W.D. Ky. Feb. 16, 2012). The Court observed that the Kentucky Supreme Court had adopted Section 552 of the Restatement (Second) of Torts. *Id.* (citing *Presnell Construction Managers, Inc. v. EH Construction, LLC*, 134 S.W.3d 575 (Ky. 2004)). This Section provides, in pertinent part:

One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communication the information.

*Giddings*, 348 S.W.3d at 744-45 (quoting Restatement (Second) of Torts § 552 (1977).) Looking to Section 252, Judge Heyburn dismissed the plaintiffs' claim. *See Bland*, 2012 WL 524473, at \*2 (“[T]he true injury in [products liability cases] is ‘the failure of the product to function properly,’ not reliance on false information.”) (quoting *Giddings*, 348 S.W.3d at 745)).

Despite Bayer's reliance upon *Bland* and similar cases, more recent precedent reflects that a different section of the Restatement now governs. In *Morris Aviation, LLC v. Diamond Aircraft Indus., Inc.*, the Sixth Circuit pointed to *Giddings*' acknowledgement of Section 9 of the Restatement (Third) of Torts: Products Liability, which provides:

One engaged in the business of selling or otherwise distributing products who, in connection with the sale of a product, makes a fraudulent, negligent, or innocent misrepresentation of material fact concerning the product is subject to liability for harm to person or property caused by the misrepresentation.

536 Fed. App'x 558, 567-68 (6th Cir. 2013) (quoting *Giddings*, 348 S.W.3d at 736 n. 11). Accordingly, Kentucky law now provides for negligent misrepresentation claims associated with the sale of a product. Because Section 9 applies to Babich-Zacharias's claim, the *Bland* reasoning does not compel its dismissal.

The Sixth Circuit also noted that "the negligent- and fraudulent-misrepresentation torts are parallel, and both must relate to misrepresentations of 'material fact.'" *Id.* at 568. Babich-Zacharias has adequately alleged that Bayer made affirmative false statements with regard to Mirena. Therefore, her claim survives Bayer's motion. *Accord Stanley v. Bayer Healthcare Pharmaceuticals, Inc., et al.*, No. 3:15-cv-00230-JHM, 2015 WL 4511973 at \*2-3 (allowing another Mirena plaintiff's claim to proceed for these reasons). *But see Baird v. Bayer Healthcare Pharmaceuticals, Inc.*, No. 6:13-077-DCR, 2013 WL 5890253 at \*3-4 (E.D. Ky. Oct. 31, 2013) (relying upon *Bland* to dismiss a Mirena plaintiff's negligent misrepresentation claim).

#### **Conclusion and Order**

For the reasons set forth above, IT IS HEREBY ORDERED that the motion filed by Defendant Bayer Healthcare Pharmaceuticals, Inc., is GRANTED IN PART and DENIED IN PART. Babich-Zacharias's breach of implied warranty claim is hereby DISMISSED. Her claims for strict liability and negligent misrepresentation may proceed.