UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

BRITTANY S. SMITH PLAINTIFF

vs CIVIL ACTION NO. 3:14CV-00006-CRS

BAYER HEALTHCARE PHARMACEUTICALS INC.,
BAYER PHARMA AG, AND BAYER OY DEFENDANTS

MEMORANDUM OPINION

This matter is before the Court on motion of Defendant Bayer Healthcare Pharmaceuticals Inc. to dismiss certain counts of Plaintiff Brittany S. Smith's Second Amended Complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6) [DN 67]. This motion mirrors other such motions filed in a number of cases which have now been transferred to this court for further proceedings. These actions are related inasmuch as they seek to redress alleged personal injuries purportedly suffered from the plaintiffs' use of the Mirena® interuterine system ("IUS") [1] prescribed and placed by their healthcare providers. These motions to dismiss have generated decisions which employ a similar analysis of claims, with the exception of the challenge to the claims for negligent misrepresentation associated with the sale of the product. This court will now issue its own opinion, with the benefit of learned views on both sides of the issue.

[1] Also referred to from time to time as an "interuterine device" or "IUD."

I. BACKGROUND

Plaintiff, Brittany S. Smith ("Smith"), filed this action against Defendants, Bayer Healthcare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy,[2] for personal injuries she alleges she suffered after she had the Mirena® IUS placed by Dr. Eugene C. Dorf for purposes of contraception and to address perimenopausal dysfunctional uterine bleeding. (2d Am. Compl., ¶¶ 169-170). The Mirena® IUS, manufactured by Bayer and approved by the Federal Food and Drug Administration in December of 2000, is a prescription intrauterine system that must be inserted by a healthcare practitioner during an office visit. The Mirena® is described as a levonorgestrel-releasing implant, consisting of a t-shaped polyethylene frame with a steroid reservoir that releases levonorgestrel ("LNG"), a synthetic progestogen, into the uterus for birth control.

Smith alleges that Dr. Dorf placed the device on October 19, 2012, and one month later she began experiencing severe migraine-like headaches, tinnitus, and vision problems, including blurred vision and blind spots. She claims that on November 26, 2012, she was diagnosed with bilateral papilledema. Smith had a lumbar puncture performed on December 2, 2012, and two days later was purportedly diagnosed with idiopathic intracranial hypertension, also known as pseudotumor cerebri"IIH/PTC." PTC is a potentially permanent brain condition that arises when too much cerebrospinal fluid in the brain causes increased intracranial pressure and increased pressure on the optic nerve leading to vision problems, and in some cases, blindness. Smith alleges that the use of the Mirena® caused, contributed to, and/or triggered her development of IIH/PTC. She had the IUS removed.

On December 13, 2013, Smith filed suit in the Jefferson County, Kentucky, Circuit Court

[2] Bayer Pharma AG was served October 16, 2015 through the Hague Convention. Bayer OY has not been served. By agreement with the plaintiff, Bayer Pharma AG is not required to answer the complaint until Bayer OY is also served through the Hague Convention, at which time these two defendants will file one answer. (DN 78).

asserting claims of negligent design, failure to warn, strict liability, breach of express and implied warranties, negligent and fraudulent misrepresentation, and fraud by concealment. The complaint has been amended twice. Bayer has moved for dismissal of the strict liability claim (Count III), breach of implied warranty claim (Count IV), and the negligent misrepresentation claim (Count VI).

II. STANDARD OF REVIEW

In considering a motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), a court "must construe the complaint in the light most favorable to plaintiff[]," League of United Latin Am. Citizens v. Bredesen, 500 F.3d 523, 527 (6th Cir. 2007) (citation omitted), "accept all well-pled factual allegations as true[,]" id., and determine whether the complaint "states a plausible claim for relief[,]" Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). Under this standard, the plaintiff must establish his or her entitlement to relief which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). A plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. A complaint fails to meet this standard if it pleads facts "merely consistent with a defendant's liability" or if the alleged facts do not "permit the court to infer more than the mere possibility of misconduct." Id. at 678, 679. Instead, the allegations must "show[ ] that the pleader is entitled to relief." Id. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

III. DISCUSSION

Bayer has moved to dismiss the strict liability claim (Count III), breach of implied warranty claim (Count IV), and the negligent misrepresentation claim (Count VI). We will

address the grounds asserted for dismissal seriatim.

A. Strict Liability

In moving to dismiss Smith's strict liability claim, Bayer argues, in footnote (DN 67-1, p. 4, n. 1) that, to the extent this claim is based upon her assertion of a negligent design or a failure to warn, strict liability is duplicative of other counts and should be dismissed. However, "[u]nder Kentucky law, a plaintiff can advance both a strict liability claim and a negligence claim against the manufacturer of a product for injury suffered by that product." Waltenburg v. St. Jude Medical, Inc., 33 F. Supp. 3d 818, 836 (W.D. Ky. 2014). "Strict liability typically focuses on the condition of the product while a negligence inquiry examines whether the manufacturer exercised the proper degree of care to protect against foreseeable dangers when manufacturing the product for the consumer." Prather v. Abbott Laboratories, 960 F.Supp.2d 700, 712 (W.D. Ky. 2013)(citing Ostendorf v. Clark Equip. Co., 122 S.W.3d 530, 535 (Ky. 2003)). Therefore, Bayer's motion to dismiss the strict liability claim as duplicative will be denied.

Bayer further argues that, to the extent the strict liability claim is based on a manufacturing defect, Smith has failed to allege any specific manufacturing defect in the product. See Bosch v. Bayer Healthcare Pharms. Inc., 13 F. Supp. 3d 730, 744 (W.D. Ky. 2014). Smith has responded that she is not alleging strict liability for a manufacturing defect in the product. Therefore, Bayer's motion to dismiss the strict liability claim on this second ground will also be denied.

B. Implied Warranty Claim

Bayer argues that privity of contract is an essential element in a breach of warranty claim (citing Pruitt v. Genie Indus., Inc., 2013 WL 139701, *3 (E.D. Ky. Jan. 10, 2013)). Bayer notes

that Smith has not alleged that she purchased the Mirena® directly from Bayer. Rather, Smith alleged in her complaint that she "had the Mirena® IUS inserted into her body without complication according to the manufacturer's instructions on October 19, 2012, by Dr. Eugene C. Dorf…" DN 65, p. 27. Smith has failed to respond to this argument addressing the implied warranty claim. We find, therefore, that she has waived opposition to this ground for dismissal, and we find that Bayer's motion is meritorious. Scott v. State of Tennessee, 878 F.2d 382, *2 (Table), 1989 WL 72470 (6th Cir. 1989). Bayer's motion to dismiss the implied warranty claim will be granted.

C. Negligent Misrepresentation Claim

Bayer seeks dismissal of Smith's negligent misrepresentation claim on the ground that such a claim is not viable in product liability cases in Kentucky. Bayer urges that "Kentucky law limits negligent misrepresentation claims to instances where a party supplies 'false information for the guidance of others in their business transactions.'" (quoting Our Lady of Bellefonte Hosp., Inc. v. Tri–State Physicians Network, Inc., 2007 WL 2903231, *7 (E.D. Ky. Sept. 27, 2007)). Accordingly, Bayer asserts that the scope of this tort, historically grounded in the Restatement (Second) of Torts § 552, does not encompass claims based upon a defective product or statements in its advertising or packaging. Courts that have reached this conclusion have quoted Giddings & Lewis v. Industrial Risk Insurers, 348 S.W.3d 729, 746 (Ky. 2011) in which the court noted that "…the language of Section 552 is poorly suited to a product sale…" See Bland v. Abbott Laboratories, Inc., Civil Action No. 3:11-CV-430-H, 2012 WL 524473 (W.D.Ky. Feb. 16, 2012; Baird v. Bayer Healthcare Pharmaceuticals, Inc., Civil Action No. 6:13-077-DCR, 2013 WL 5890253 (E.D.Ky. Oct. 31, 2013).

We find the better reasoned result in other opinions rendered in this district, however. In

the cases of Stanley v. Bayer Healthcare Pharmaceuticals, Inc., Civil Action No. 3:15CV-230-JHM, 2015 WL 4511973 (W.D.Ky. July 24, 2015); Babich-Zacharias v. Bayer Healthcare Pharmaceuticals, Inc., Civil Action No. 5:14CV-101-TBR, 2015 WL 711057 (W.D.Ky. Feb. 18, 2015); and Martin v. Bayer Healthcare Pharmaceuticals, Inc., Civil Action No. 3:14CV-398-TBR (Aug. 25, 2015) the courts cited to Morris Aviation, LLC v. Diamond Aircraft Indus., Inc., 536 Fed.Appx. 558 (6th Cir. 2013). The Sixth Circuit in Morris recognized that the Restatement (Third) of Torts §9 now applies to negligent misrepresentation claims associated with the sale of a product:

> The awkward fit of certain cases with the language of § 552 is a possibility that the Kentucky Supreme Court has recognized after Presnell: "Section 552 is poorly suited to a product sale." Giddings, 348 S.W.3d at 746. Instead, in product-sale cases, the court has called for application of a different section of the Restatement, which provides that: "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 persons or property caused by the misrepresentation."

Morris, 536 Fed. Appx. at 567-568 (quoting Giddings, 348 S.W.3d at 746 n. 11 (quoting Restatement (Third) of Torts: Products Liability § 9 "Liability of Commercial Product Seller or Distributor for Harm Caused by Misrepresentation")).

Accordingly, as negligent misrepresentation claims associated with the sale of a product are now governed by the Restatement (Third) of Torts § 9 in Kentucky, Smith's claim will be permitted to proceed. Bayer's motion to dismiss Count VI will be denied.

IV. CONCLUSION

For the reasons stated herein, Bayer's motion to dismiss will be granted in part and denied

in part. A separate order will be entered herein this date in accordance with this opinion.

IT IS SO ORDERED.

November 20, 2015

Charles R. Simpson III, Senior Judge
United States District Court