54 F.Supp.3d 868
United States District Court,
N.D. Ohio,
Western Division.

Donna BOOKER, etc., Plaintiff,
v.
JOHNSON & JOHNSON, et al., Defendant.

Case No. 3:12 oe 40000.
|
Filed Oct. 10, 2014.

Synopsis

Background: Consumer's mother brought action against manufacturer of birth control patch, alleging that consumer experienced a pulmonary embolism and died as a result of her use of patch. Manufacturer moved for summary judgment as to mother's claims for design and manufacturing defects and intentional infliction of emotional distress, and derivative claims of loss of consortium, per quod, and wrongful death.

Holdings: The District Court, Katz, J., held that:

[1] mother presented jury issue for design defect claim under Georgia law; but

[2] as a matter of first impression, design defect cause of action under Georgia law was preempted by federal law;

[3] allegation that defects in patch resulted in a product that was not in conformity with manufacturer's intended result and caused it to fail was properly construed as a design defect claim, not a manufacturing defect claim; and

[4] manufacturer's conduct was not extreme and outrageous, as would support intentional infliction of emotional distress claim.

Motion granted.

Attorneys and Law Firms

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Julie A. Callsen, Tucker Ellis, Cleveland, OH, Susan M. Sharko, Florham Park, NJ, for Defendant.

MEMORANDUM OPINION

KATZ, District Judge.

I. Introduction

Plaintiff Donna Booker, a Georgia resident, brought this action on behalf of her daughter, Raissa Booker, against Defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, LLC, and Ortho–McNeil Pharmaceutical, Inc. (collectively "Defendants"). Donna Booker ("Plaintiff") alleges her daughter, Raissa Booker ("Ms. Booker"), experienced a pulmonary emboli and passed away as a result of her use of the Ortho Evra® birth control patch. (Doc. No. 1).

Prior to this action, the Court granted Defendants' motion for summary judgment on Plaintiff's failure to warn, negligence, breach of warranty, and fraud based claims, but denied Defendants' motion for judgment on the pleadings for design and manufacturing defects, intentional infliction of emotional distress, and the derivative claims of loss of consortium, per quod, and wrongful death. *Booker v. Johnson & Johnson,* No. 3:12–oe–40000, 2014 WL 2834975, 2014 U.S. Dist. LEXIS 85055 (N.D.Ohio June 23, 2014).

Defendants now move for summary judgment on Plaintiff's remaining claims of design and manufacturing defects, intentional infliction of emotional distress, and the derivative claims of loss of consortium, per quod, and wrongful death. (Doc. No. 11). Plaintiff filed a response (Doc. No. 13) and Defendants replied (Doc. No. 14). On September 23, 2014, the Court heard oral argument on the pending motion for summary judgment in this case and several other cases concerning the Ortho Evra® birth

control patch. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

II. Facts

Ms. Booker was prescribed the Ortho Evra® birth control patch in October 2009 by Dr. Elizabeth W. Killebrew, M.D., a Georgia Board-certified OB/GYN. Before then, neither Ms. Booker nor Plaintiff had ever seen any advertisements, read anything, or performed any internet research about Ortho Evra®. Plaintiff admits she and Ms. Booker had not communicated with Defendants or their representatives before, during, or after Ms. Booker was prescribed and used Ortho Evra®.

The record reflects that at the time Dr. Killebrew prescribed the patch to Ms. Booker, she was informed of Ortho Evra®'s risks and was familiar with Ortho Evra®'s September 2009 package insert, which specifically warned of increased risk of blood clots and pulmonary embolism. Further, Dr. Killebrew testified that she prescribed Ortho Evra® for Ms. Booker because she believed its benefits outweighed its risks.

III. Summary Judgment

Summary judgment is proper where "there is no genuine dispute as to any ***872** material fact" and the moving party "is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). A party asserting a genuine issue of material fact must support the argument either by "citing to particular parts of materials in the record" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed.R.Civ.P. 56(c)(1). The Court views the facts in the record and reasonable inferences that can be drawn from those facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). The Court does not weigh the evidence or determines the truth of any matter in dispute. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

The party requesting summary judgment bears an initial burden of demonstrating that no genuine issue of material fact exists, which the party must discharge by producing evidence to demonstrate the absence of a genuine issue of material fact or "by showing ... that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett,* 477 U.S. 317, 323–25, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986) (internal quotation marks omitted). If the moving party satisfies this burden, the nonmoving party "may not rest upon its ... pleadings, but rather must set forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren,* 578 F.3d 351, 374 (6th Cir.2009) (citing Rule 56 and *Matsushita,* 475 U.S. at 586, 106 S.Ct. 1348). The party opposing the summary judgment motion must present sufficient probative evidence supporting its claim that disputes over material facts remain; evidence that is "merely colorable" or "not significantly probative" is insufficient. *Anderson,* 477 U.S. at 248–52, 106 S.Ct. 2505.

IV. Discussion

[1] At the outset, Plaintiff argues the Court already decided Defendants were not entitled to summary judgment on Plaintiff's product liability claims of design defect and manufacturing defect, and intentional infliction of emotional distress. However, Defendants' previous motion on these counts, which was the subject of the Court's prior memorandum opinion, was for judgment on the pleadings, not for summary judgment. *Booker,* 2014 WL 2834975, 2014 U.S. Dist. LEXIS 85055. A ruling on a motion brought pursuant to Federal Rule of Civil Procedure 12(c) does not preclude a later summary judgment motion brought pursuant to Rule 56(a). *Averhart v. Ortho–McNeil Pharm., Inc.,* No. 3:09–oe–40028, at *4, 2014 WL 3866026 (N.D.Ohio August 6, 2014). Therefore, the Court may consider summary judgment for Plaintiff's claims of design defect and manufacturing defect, intentional infliction of emotional distress and Plaintiff's derivative claims of loss of consortium, per quod, and wrongful death.

A. Design Defect

[2] The Supremacy Clause provides that the laws and treaties of the United States "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any

State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. It has been long settled that state laws that conflict with federal law are "without effect." *Maryland v. Louisiana,* 451 U.S. 725, 746, 101 S.Ct. 2114, 68 L.Ed.2d 576 (1981). Even without the express preemption provision, the United States Supreme Court has found state law to be impliedly preempted where it is "impossible for a private party to comply with both federal ***873** and state requirements." *English v. General Elec. Co.,* 496 U.S. 72, 79, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990).

In the instant case, the Court must consider whether Georgia's design defect claim is preempted by the United States Supreme Court's ruling in *Mutual Pharmaceutical Co. v. Bartlett,* —— U.S. ——, 133 S.Ct. 2466, 2477, 186 L.Ed.2d 607 (2013). The Court, having carefully read *Mutual Pharmaceutical Co.,* concludes that it was impossible for Defendants to comply with both its state-law obligation to alter the drug's composition, and its federal-law duty not to do so.

[3] [4] Georgia courts employ a risk-utility analysis for defective design claims. *Banks v. ICI Ams.,* 264 Ga. 732, 450 S.E.2d 671, 673–75 (1994). This test requires any court applying Georgia law to balance the risks inherent in a product design against the utility of the product so designed. *Id.* Georgia courts have emphasized that the "heart" of a design defect case is whether "an alternative design would have made the product safer than the original design and was a marketable reality and technologically feasible." *Id.* at 674. In determining whether an alternative safer design existed, a court may consider the feasibility of an alternative design as well as "the availability of an effective substitute for the product which meets the same need but is safer." *Id.* at 675 n. 6. As part of the risk utility analysis, the Georgia Supreme Court set forth the following non-exhaustive general factors to be considered:

> the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger, i.e., the user's knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger; the user's ability to avoid danger; the state of the art at the time the product is manufactured; the ability to eliminate danger without impairing the usefulness of the product or making it too expensive; and the feasibility of spreading the loss in the setting of the product's price or by purchasing insurance.

Id.

[5] Georgia courts have recognized that some products, like pharmaceutical drugs, are incapable of being made safe. *Frazier v. Mylan, Inc.,* 911 F.Supp.2d 1285, 1296 (N.D.Ga.2012) (citing cases within). In doing so, Georgia adopted Restatement (Second) of Torts § 402A cmt. k, which provides that "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." *Bryant v. Hoffmann–La Roche, Inc.,* 262 Ga.App. 401, 585 S.E.2d 723, 728 (2003). It is only after a plaintiff establishes a prima facie case that "a pharmaceutical manufacturer will be relieved from strict liability [ ] when it demonstrates it has met the requirements of Comment k." *Frazier,* 911 F.Supp.2d at 1296 (citing *Bryant,* 585 S.E.2d at 728). To establish the affirmative defense, a manufacturer must demonstrate that "(1) the product is properly manufactured and contains adequate warnings; (2) its benefits justify its risks; and (3) the product was at the time of the manufacture and distribution incapable of being made more safe." *Bryant,* 585 S.E.2d at 728.

[6] [7] "Because courts are not in a position to weigh the various *Banks* factors against one another, judgment as a matter of law will rarely be granted in design defect cases when any of these elements [are] disputed." ***874** *Weaver v. PACCAR, Inc.,* 52 F.Supp.3d 1342, 1350, 2014 WL 4926208, at *7, 2014 U.S. Dist. LEXIS 139204, at *19 (S.D.Ga. Sept. 30, 2014) (citing *Ogletree v. Navistar Intern. Transp. Corp.,* 271 Ga. 644, 522 S.E.2d 467, 470 (1999)) (internal quotations omitted). "Indeed, the adoption of the risk-utility analysis in [Georgia] has actually increased the burden of a defendant, in seeking judgment as a matter of law, to show plainly and indisputably an absence of any evidence that a product design is defective." *Ogletree,* 522 S.E.2d at 470.

[8] Defendants argue Plaintiff has failed to show evidence of a reasonable alternative design which would have reduced the foreseeable risks of the alleged harm. Plaintiff counters she has met the prima facie burden for design

defect under Georgia law because oral birth control pills, which existed on the market when the Ortho Evra® birth control patch was manufactured, evidence a feasible alternative design. Plaintiff further argues Defendants have failed to meet their burden with respect to Comment k's affirmative defense.

[9] Under Georgia law, Plaintiff has established a prima facie case sufficient to present a jury issue for a design defect claim. The prima facie case for design defect in Georgia is not onerous. *Weaver,* 52 F.Supp.3d at 1350, 2014 WL 4926208, at *7, 2014 U.S. Dist. LEXIS 139204, at *19; *Ogletree,* 522 S.E.2d at 470. While Defendants did provide adequate warnings with respect to increased risks associated with the use of the Ortho Evra® birth control patch, Georgia courts explicitly emphasize the importance of the alternative safer design factor, which includes the "availability of an effective substitute for the product which meets the same need but is safer." *Banks,* 450 S.E.2d at 674–675 n. 6.

Plaintiff alleges at least two effective substitutes existed at the time the Ortho Evra® birth control patch was manufactured—the oral birth control pill and intrauterine device. Plaintiff points out that Defendants knew of these safer alternatives because the Ortho Evra® warning label explicitly acknowledged that "users of the birth control patch were at a higher risk of developing serious blood clots, also known as venous thromboembolism (VTE), than women using birth control pills." (Doc. 13–5, Ex. E).

[10] Defendants respond that birth control pills were not an effective substitute for Ms. Booker because she did not like taking pills and would likely forget to take the pills on a daily basis. While convenience is one factor to be considered, it does not trump Georgia's stated emphasis on an alternative safer design. The Court further finds Defendants have failed to meet their burden under Comment k, as they have not argued or demonstrated the required elements to sustain the affirmative defense. Plaintiff has presented a sufficient jury question under Georgia's risk utility analysis. Therefore, according to Georgia law, Defendants' motion for summary judgment would be denied with respect to the design defect claim.

However, in 2013, the United States Supreme Court, considering a design defect claim governed by New Hampshire law, held that "warning-based design-defect cause[s] of action [are] preempted with respect to FDA-approved drugs sold in interstate commerce." *Mut. Pharm. Co.,* 133 S.Ct. at 2477. The Supreme Court explained that "state-law design defect claims ... that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id.* at 2479.

***875** [11] The essential inquiry of design defect preemption centers on whether the elements of the state law require remedial action. As the Supreme Court explained, when a state imposes a "duty to ensure that one's products are not unreasonably dangerous," it also involves a duty to make one or several changes to the composition of the drug, which conflicts with federal law prohibiting alteration of an FDA-approved design. *Id.* at 2480 (internal quotations omitted).

[12] [13] Like the pre-empted New Hampshire law, Georgia employs a risk-utility approach under which a product is defective as designed if the magnitude of the danger outweighs the utility of the product.[1] *Id.* at 2474; *Banks,* 450 S.E.2d at 673–75. Georgia courts have emphasized that the key factor to the risk-utility inquiry is whether "an alternative design would have made the product safer than the original design and was a marketable reality and technologically feasible." *Banks,* 450 S.E.2d at 674–75. Creating an alternative design would, by its very essence, require changing the composition of the drug, which is prohibited by federal law. *See Mut. Pharm.,* 133 S.Ct. at 2479. Moreover, this remedial "alternative design" requirement was precisely the type contemplated by the United States Supreme Court when it preempted New Hampshire's design defect law. *Banks,* 450 S.E.2d at 674. Accordingly, the Court finds Georgia's design defect cause of action preempted by federal law with respect to FDA-approved drugs sold in interstate commerce.

1 Both New Hampshire and Georgia adopted the doctrine of strict liability in tort as set forth in Section 402A of the Restatement (Second) of Torts.

[14] The Court recognizes this is a case of first impression under Georgia law, and in any district court applying Georgia law. The Court is also cognizant that Plaintiff would have otherwise stated a valid design defect cause of action under Georgia law. However, "[w]hen federal law forbids an action that state law requires, the state law is 'without effect.' " *Mut. Pharm.,* 133 S.Ct. at 2473 (citing *Maryland v. Louisiana,* 451 U.S. 725, 746, 101

S.Ct. 2114, 68 L.Ed.2d 576 (1981)). There is no dispute the Ortho Evra® patch was approved by the FDA. *Yates v. Ortho–McNeil Pharm., Inc.,* No. 1:09–oe–40023, 2014 WL 1369466, at *3, 2014 U.S Dist. LEXIS 47722, at *7 (N.D.Ohio Apr. 7, 2014). Therefore, it was impossible for the Defendants to comply with both its state-law duty to alter the composition of the drug, and its federal-law duty not to alter an FDA-approved design. Accordingly, Plaintiff's design defect claim fails as a matter of law.

B. Manufacturing Defect

[15] [16] [17] Under Georgia law, if a product is "properly prepared, manufactured, packaged, and accompanied with adequate warnings and instructions ... [it] can not be said to be defective." *Ctr. Chem. Co. v. Parzini,* 234 Ga. 868, 218 S.E.2d 580, 582 (1975). In manufacturing defect cases, "it is assumed that the design of the product is safe and had the product been manufactured in accordance with the design it would have been safe for consumer use." *Frazier,* 911 F.Supp.2d at 1298 (citing *Banks,* 450 S.E.2d at 673). A manufacturing defect can be ascertained by "comparing it to a properly manufactured item from the same product line." *Banks,* 450 S.E.2d at 673.

[18] In the case at bar, Plaintiff merely restates her allegation in the form of a legal conclusion—that defects in the Ortho Evra® birth control patch resulted "in a product that was not in conformity with ***876** manufacturer's intended result and caused the device to fail during the time that [Ms. Booker] used it." (Doc. 13 at 6). Plaintiff briefly argues she has established a manufacturing defect because the same product (Orth Evra® birth control patch) caused the same side-effects (pulmonary embolisms). However, when a plaintiff calls into question the entire product line, it is properly construed as a design defect claim, not a manufacturing defect claim. *See Banks,* 450 S.E.2d at 673. Here, Plaintiff has failed to show Defendants deviated from manufacturing specifications. As such, Plaintiff's claim fails as a matter of law.

C. Intentional Infliction of Emotional Distress

[19] [20] To state a claim for intentional infliction of emotional distress under Georgia law, a plaintiff must show: "(1) the defendant's conduct was extreme and outrageous; (2) the defendant acted intentionally or recklessly; (3) the defendant's conduct caused emotional distress; and (4) the resulting emotional distress was severe." *Lightning v. Roadway Express,* 60 F.3d 1551, 1557 (11th Cir.1995). To succeed on such a claim, "[t]he defendant's conduct must be so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community." *Blue View Corp. v. Bell,* 298 Ga.App. 277, 679 S.E.2d 739, 741 (2009).

[21] Plaintiff argues Defendants conduct was extreme and outrageous when it placed goods into the stream of commerce knowing it contained a high level of estrogen that increased the risk of blood clots. As Defendants note, the Court has already found the warnings provided by Defendants with respect to increased risk of blood clots and pulmonary embolism were adequate as a matter of law. In addition, there is no dispute that the Ortho Evra® patch was approved by the FDA. *Yates,* 2014 WL 1369466 at *3, 2014 U.S Dist. LEXIS 47722 at *7. Because Plaintiff has failed to establish Defendants' conduct was extreme and outrageous, Defendants are entitled to summary judgment.

D. Derivative Claims

In Georgia, "[w]here the injured person and the spouse combine their separate claims into one suit, ... it has been held that the loss of consortium claim is a derivative' claim[.]" *White v. Hubbard,* 203 Ga.App. 255, 416 S.E.2d 568, 569 (1992). Thus, Plaintiff's derivative actions stem from the right of the injured party, and if Defendants are not liable for injuries to Ms. Booker, then Plaintiff has no claim for loss of consortium, per quod, or wrongful death. *Id.* at 570. Because the Court has found Defendants are not liable for Ms. Booker's injuries, Plaintiff's derivative claims must also be dismissed.

V. Conclusion

Accordingly, the Defendants' motion for summary judgment (Doc. 25) is granted.

IT IS SO ORDERED.

All Citations

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