2014 WL 1224581
United States District Court,
N.D. Ohio,
Western Division.

Tash CASSO, etc., Plaintiff,
v.
ORTHO–MCNEIL PHARMACEUTICAL, INC., et al., Defendants.

No. 1:11 oe 40006.
|
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Attorneys and Law Firms

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MEMORANDUM OPINION

KATZ, District Judge.

***1** Plaintiff Tash Casso brought this action against defendants Ortho–McNeil Pharmaceutical Inc., Johnson and Johnson, Johnson and Johnson Research and Development LLC, Alza Corporation and ten John Does. Her complaint alleges she took Defendants' transdermal birth control product Ortho Evra® and it caused a pulmonary embolism and blood clots. Originally filed in the Los Angeles County (California) Superior Court, Defendants removed the case to the Central District of California. Subsequently, the Judicial Panel on Multidistrict Litigation transferred the case to this Court. Before the Court now is Defendants' summary judgment motion and motion for judgment on the pleadings.

I. Background

Ortho Evra® is a hormone-based birth control medication delivered transdermally by a patch. (Dear Healthcare Professional letter, Doc. 55–6.) A user wears one patch per week on her skin for three weeks, wears no patch for the fourth week, then begins the cycle again. (*Id.*) To work transdermally, Ortho Evra® delivers a higher dosage-approximately 60% higher-of estrogen than oral contraceptives. (*Id.*)

> The risk of venous thromboembolic events (blood clots in the legs and/or the lungs) may be increased with ORTHO EVRA® use compared with use of birth control pills. Studies examined the risk of these serious blood clots in women who used either ORTHO EVRA® or birth control pills containing one of two progestins (levonorgestrel or norgestimate) and 30–35 micrograms of estrogen. Results of these studies ranged from an approximate doubling of risk of serious blood clots to no increase in risk in women using ORTHO EVRA® compared to women using birth control pills.

(*Id.*)

In April 2009, Ms. Casso suffered blood clots that led to a pulmonary embolism in her right lung and caused her to be hospitalized for several days. Ms. Casso claims the blood clots and pulmonary embolism were caused by her use of Ortho Evra®.

II. Jurisdiction and Choice of Law

Ms. Casso originally filed this action in the Superior Court of the State of California, Los Angeles County and the defendants removed the matter to the District Court for the Central District of California. (Notice of Removal, Doc. 1.) Ms. Casso is a citizen of Minnesota (Shortform Compl, Doc. 55–3 at ¶ 2); Ortho–McNeil Pharmaceutical Inc. is a citizen of Pennsylvania and New Jersey (Notice of Removal, Doc. 1 at ¶ 19); Johnson and Johnson is a citizen of New Jersey (*Id.* at ¶ 18); Johnson and Johnson Research and Development LLC is a citizen of Delaware and New Jersey (*Id.* at ¶ 20); and Alza Corporation is a citizen of Delaware and California (Longform Compl.,

Doc. 55–5 at ¶ 12).[1] Therefore, complete diversity exists. The amount in controversy exceeds $75,000, so the removed-to court had subject matter jurisdiction. 28 U.S.C. § 1332. The Judicial Panel on Multidistrict Litigation consolidated this case with numerous others under MDL Number 1742 and assigned them to this Court pursuant to 28 U.S.C. § 1407. (*See* Conditional Transfer Order 80, Doc. 13.)

[1] At the time of removal, the defendants claimed Alza was improperly joined to defeat diversity jurisdiction under the "forum defendant rule." However, that rule is procedural only, *Lively v. Wild Oats Markets, Inc.,* 456 F.3d 933, 942 (9th Cir.2006), and Ms. Casso did not move for remand, so no jurisdictional defect remains.

***2** The parties agree Minnesota law applies, and the Court will accordingly apply Minnesota law to Ms. Casso's common law claims. Three other claims arise under California statutes, and, while the parties do not separately address choice of law on that, the Court must apply the California statute where specified.

III. Summary Judgment Motion

A. Standard

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). The moving party bears the initial responsibility of "informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 2553, 91 L.Ed.2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant's claim. *Id.* at 323–25. Once the movant meets this burden, the opposing party "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 250, 106 S.Ct. 2505, 2541, 91 L.Ed.2d 202 (1986) (*quoting* Fed.R.Civ.P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient "simply [to] show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586, 106 S.Ct. 1348, 1356, 89 L.Ed.2d 538 (1986). Rather, Rule 56(e) "requires the nonmoving party to go beyond the pleadings" and present some type of evidentiary material in support of its position. *Celotex,* 477 U.S. at 324, 106 S.Ct. at 2553; *see also Harris v. General Motors Corp.,* 201 F.3d 800, 802 (6th Cir.2000). Summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex,* 477 U.S. at 322, 106 S.Ct. at 2552.

"In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party." *Williams v. Belknap,* 154 F.Supp.2d 1069, 1071 (E.D.Mich.2001) (citing *60 Ivy Street Corp. v. Alexander,* 822 F.2d 1432, 1435 (6th Cir.1987)). However, " 'at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter,' " *Wiley v. U.S.,* 20 F.3d 222, 227 (6th Cir.1994) (quoting *Anderson,* 477 U.S. at 249); therefore, "[t]he Court is not required or permitted ... to judge the evidence or make findings of fact." *Williams,* 154 F.Supp.2d at 1071. The purpose of summary judgment "is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried." *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.,* 130 F.Supp.2d 928, 930 (S.D.Ohio 1999). Ultimately, this Court must determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson,* 477 U.S. at 251–52; *see also Atchley v. RK Co.,* 224 F.3d 537, 539 (6th Cir.2000).

B. Minnesota's Learned Intermediary Doctrine

***3** The premise of Ms. Casso' strict product liability claim is that Defendants failed to warn her of the dangerous side effects of Ortho Evra®. In moving for summary judgment, Defendants invoke the learned intermediary doctrine and claim they fulfilled their duty by warning the prescribing physician.

Minnesota follows the "learned intermediary doctrine." *Mulder v. Parke Davis & Co.,* 288 Minn. 332, 181 N.W.2d 882, 885 (Minn.1970) ("We agree that where the only issue is failure to communicate a warning, the manufacturer is not liable if the doctor was fully aware of the facts which were the subject of the warning."). "Under the learned intermediary doctrine, as adopted in Minnesota, prescription drug manufacturers can satisfy their duty to warn by warning prescribing physicians of the risks associated with a drug, rather than warning patients directly." *In re Levaquin Products Liab. Litig.,* 700 F.3d 1161, 1166 (8th Cir.2012) (footnote omitted). A proper warning of a drug's danger to the prescribing doctor obviates the duty to disclose the danger directly to the consumer. Furthermore, even if the manufacturer did not transmit the warning to the doctor, but the doctor knew of the dangers, the chain of causation is broken and the manufacturer is not liable. *Mulder,* 181 N.W.2d at 885.

Defendants assert Ms. Casso's doctor, Eric W. Trygstad, M.D., received Defendants' updated 2008 labeling information and a "Dear Healthcare Professional" letter ("DHCP letter") that warned prescribing physicians of certain concerns with Ortho Evra®, including the one that affected Ms. Casso. Defendants say Dr. Trystad took the warnings in the letter and label information into account when he prescribed Ortho Evra® to Ms. Casso. (Trygstad Dep ., Doc. 53–7 at 72–73 ("And in making your prescribing decision to prescribe the Ortho Evra patch for Ms. Casso, you were familiar with and took into consideration all of the information that's contained in [the February 2008 DHCP letter and the January 2008 revised labeling]? A: Yes.").)

Ms. Casso, however, points out that Dr. Trygstad also said that he does not precisely remember receiving Defendants' DHCP letter. (*Id.* at 77–78, 181 N.W.2d 882 ("Do you have an independent recollection of receiving the Dear Doctor letter that was marked as, I believe Exhibit 5? Yes? A: I don't have a specific recollection, but it is my practice to read all of the letters from manufacturers that I'm prescribing.").) He then acknowledged that, although he recalls reading the DHCP letter, it was "possible, but unlikely" that he read it "after [he] had already prescribed the Ortho Evra patch to Ms. Casso." (*Id.* at 78, 181 N.W.2d 882.)

Ultimately, Ms. Casso has pointed to no evidence that Defendants did not warn Dr. Trystad. Moreover, "where the only issue is failure to communicate a warning, the manufacturer is not liable if the doctor was fully aware of the facts which were the subject of the warning. *Mulder,* 181 N.W.2d at 885; *see also Cornfeldt v. Tongen,* 262 N.W.2d 684, 698 (Minn.1977) (excluding an expert who would testify about a warning's adequacy was proper where the defendant doctor was aware of allegations of a drug's danger "but discounted them from his own knowledge and experience."). During Dr. Trystad's deposition, Defendants went through each of the pertinent dangers of Ortho Evra® and Dr. Trystad acknowledged he understood each of them at the time he prescribed the drug to Ms. Casso. (Doc. 53–7 at 50–65.) Defendants say Ms. Casso cannot point to any evidence he did not understand the risks.

***4** In answer to this, Ms. Casso stretches the meaning of Dr. Trystad's deposition testimony:

> Q Was this the first time that you had discussed the Ortho Evra patch with Ms. Casso in reference to the April 8, 2008, phone call?
>
> A I don't believe so. I saw Ms. Casso for an IUD insertion back in 2007, and it's very likely that I would have stated to her that the IUD was a safer option for her than combination hormonal contraception—you know, endorse her decision to go to the IUD.
>
> Q Okay. So at the same time would you have discussed with her the—do you have an independent recollection of discussing with her the Ortho Evra patch?
>
> A I don't have an independent recollection of it, but commonly it is my practice to discuss relative safety of contraceptive options.

(Doc. 53–7 at 80–81.) From this, Ms. Casso claims Dr. Trystad now understands IUDs to be safer than Ortho Evra®, but, since he prescribed Ortho Evra® in 2009, he must not have understood the danger at that time. However, the testimony does not support this conclusion; Dr. Trystad testified he understood IUDs to be safer than Ortho Evra® in 2007, which indicates he understood the risk was heightened at that time. Nothing in his testimony supports Ms. Casso's theory that Dr. Trystad learned of the dangers only recently. Therefore, Ms. Casso has not pointed to any evidence that Defendants did not warn Dr. Trystad.

C. Sufficiency of the Warning to the Learned Intermediary

Even though the adequacy of a warning is usually a question of fact left for the jury, because the plaintiff bears the burden of establishing, at trial, that the warning was inadequate, *Balder v. Haley,* 399 N.W.2d 77, 81 (Minn.1987), a defendant may be entitled to summary judgment if the plaintiff can point to no evidence the warning was inadequate. Ms. Casso points to Dr. Trystad's comment that he would have affirmed her 2007 choice of an IUD over Ortho Evra® as proof that the warning was inadequate. Once again, this stretches the meaning of the doctor's statement to nearly its opposite. If Dr. Trystad knew in 2007–more than a year before he prescribed Ortho Evra® to Ms. Casso-that Ortho Evra® was less safe than the IUD, then this tends to show that Defendants' warning was at least partially effective in conveying that very message.

Ms. Casso points to no other evidence tending to show Defendants' warning was inadequate. While the Court cannot pass on the adequacy of the warning, it can grant summary judgment where the plaintiff has no evidence of something she must prove. Such is the case here; Ms. Casso can point to no evidence Defendants' warning was inadequate. Defendants are entitled to summary judgment on Ms. Casso's claim it is strictly liable for a dangerous product for failure to warn of those dangers.

IV. Motion for Judgment on the Pleadings

In addition to moving for summary judgment as to the failure-to-warn claim, Defendants also move for judgment on the pleadings as to Ms. Casso's other claims, which are: strict liability in tort due to a manufacturing defect, negligence, breach of implied warranty, breach of express warranty, California statutory deceit by concealment, negligent misrepresentation, and violations of California Business and Professions Code Sections 17200 and 17500.

***5** A Fed.R.Civ.P. 12(c) motion for judgment on the pleadings is analyzed under the same standard as a Fed.R.Civ.P. 12(b)(6) motion to dismiss. *Sensations, Inc. v. City of Grand Rapids,* 526 F.3d 291, 295 (6th Cir.2008). To defeat such a motion, the complaint must state sufficient facts, accepted as true, to state a claim "that is plausible on its face." *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). The Court must accept as true all of the non-movant's factual allegations. *Erickson v. Pardus,* 551 U.S. 89, 94, 127 S.Ct. 2197, 167 L.Ed.2d 1081 (2007); *Thurman v. Pfizer, Inc.,* 484 F.3d 855, 859 (6th Cir.2013). The complaint "need not contain 'detailed' factual allegations, [but] its 'factual allegations must be enough to raise a right to relief above the speculative level....' " *Ass'n of Cleveland Fire Fighters v. City of Cleveland, Ohio,* 502 F.3d 545, 548 (6th Cir.2007) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). Conclusory allegations and legal conclusions masquerading as factual allegations will not suffice. Twombly, 550 U.S. at 555 (holding that a complaint must contain more than "a formulaic recitation of the elements of the cause of action").

In their motion, Defendants claim "plaintiff's alternative theories of recovery—beyond failure to warn—are couched in terms of conclusory allegations and [are] all based on defendants' alleged failure to warn." (Memo., Doc. 54 at 22.) It also, in a footnote, asserts the claim for strict product liability (i.e., the failure to warn claim) subsumes the claims for negligence and breach of implied warranty under Minnesota law. (*Id.* at 22 n. 50.)

In response, Ms. Casso points to both her short-form and long-form complaint, attempting to demonstrate that each contained allegations tying Defendants' conduct to each element of each claim. She does not, however, address Defendants' claim that her negligence and breach of implied warranty claims must be dismissed because they are subsumed by the strict liability claim.

Defendants use their Reply to raise several additional colorable issues. For instance, Defendants say the complaint does not identify a manufacturing defect sufficient to maintain a strict liability claim; it adds negligent misrepresentation to the list of claims subsumed by a strict product liability claim; and it asserts Ms. Casso has no evidence of an express warranty or her reliance on it. (Doc. 56 at 11–12.) The Reply does not address Ms. Casso' three California statutory claims.

Defendants cannot raise an issue for the first time in their reply. *Scottsdale Ins. Co. v. Flowers,* 513 F.3d 546, 553 (6th Cir.2008) ("Raising the issue for the first time in a reply brief does not suffice; reply briefs *reply* to arguments made in the response brief-they do not provide the moving party with a new opportunity to present yet

another issue for the court's consideration." (quoting *Novosteel SA v. U.S., Bethlehem Steel Corp.,* 284 F.3d 1261, 1274 (Fed.Cir.2002))). Therefore, Defendants' motion for judgment on the pleadings is bounded by the issues it raised in its motion: whether the complaint states a claim as opposed to just making conclusory allegations and whether the negligence and breach of implied warranty claims are merged into the strict liability (failure to warn) claim. To the extent the Reply expounds on these by replying to arguments made in Ms. Casso's response, *Scottsdale,* 513 F.3d at 553, the Court may consider it and to the extent the Reply raises a novel argument, the Court must ignore it.

A. Strict Liability in Tort Due to a Manufacturing Defect

***6** Defendants claim Ms. Casso's complaint lacks an allegation of a "deviation from a flawless product" and that is a necessary element to maintain a manufacturing defect claim under Minnesota law. *See Kapps v. Biosense Webster, Inc.,* 813 F.Supp.2d 1128, 1147 (D.Minn.2011) (citing *Bilotta v. Kelley Co., Inc.,* 346 N.W.2d 616, 622 (Minn.1984)). Defendants are correct; for her second claim to be distinct from her strict liability for failure to warn, she must allege the product deviates from its design or other flawless products because of a manufacturing defect. *Bilotta,* 346 N.W.2d at 621–22 (distinguishing design defects from manufacturing defects). Yet, Ms. Casso does say: "The defects resulted in a product that was not in conformity with the manufacturers' intended result and manufacturing specifications for ORTHO EVRA®." (Doc. 55–5 at ¶ 46.) Of course, Defendants have not asked for summary judgment on this point and, in considering a motion for judgment on the pleadings, the Court cannot assess whether Ms. Casso can point to any evidence of such a defect; it can only examine the complaint to see if it lacks the necessary allegations to state a claim. The complaint's allegation that the product Ms. Casso consumed was different from Defendants' design for it is a sufficient allegation to maintain the manufacturing defect claim.

B. Negligence, Breach of Implied Warranty, and Negligent Misrepresentation

In their Reply, Defendants assert Minnesota law merges claims for negligence, breach of implied warranty, and negligent misrepresentation into the strict product liability claim. Defendants raised the contention about the merger of negligence and implied warranty in its motion and this is supported by case law. *See Westbrock v. Marshalltown Mfg. Co.,* 473 N.W.2d 352, 356 (Minn.Ct.App.1991) ("*Bilotta* merged strict liability, negligence, and implied warranty remedies into a single products liability theory."). Even though the Eighth Circuit called part of that conclusion into question, Ms. Casso did not make any contrary argument. *See Piotrowski v. Southworth Products Corp.,* 15 F.3d 748, 751 (8th Cir.1994) ("The *Bilotta* court did not address the theory of implied warranty, however, and thus *Westbrock* and *Gross* do not appear to be proper readings of *Bilotta,* at least insofar as the implied warranty of fitness theory is concerned ."). The Court need not further disseminate Defendants' supported and unopposed proposition that negligence and breach of implied warranty are subsumed by strict product liability claims; it has shown it is entitled to dismissal of those two claims.

In contrast to merger of negligence and implied warranty, Defendants first raised their claim of merger of negligent misrepresentation in their Reply, so Ms. Casso has not had an opportunity to address it. Unlike Defendants' claim that Ms. Casso's complaint lacked an element of a manufacturing defect claim, this merger contention is not an offshoot of Defendants' statement in its motion that Ms. Casso's complaint contains conclusory allegations that are based on failure to warn. The Court need not now decide whether Minnesota law would extend the merger concept to this tort; Defendants are not entitled to dismissal of the negligent misrepresentation claim.

C. Breach of Express Warranty

***7** Defendants claim Ms. Casso has no evidence of an express warranty or her reliance on it. This, however, is a claim for summary judgment, not an attack on the sufficiency of the pleadings.

Other than their Reply-based claim that Ms. Casso lacks supporting evidence, the Court can find no deficiency in Plaintiff's complaint. Under her breach of express warranty claim, Ms. Casso lays out each element of the claim and says the defendants are liable: the defendants made an express warranty and Ms. Casso relied on it by taking the drug, (Doc. 55–5 at ¶ 61); Ms. Casso relied on the expertise of the defendants, accepted the statements as warranties, and those statements were false (*id.* at ¶ 62); and Ms. Casso sustained injuries (*id.* at ¶ 63).

Furthermore, while she does not point the Court to it explicitly, Ms. Casso's complaint also contains more detailed facts: defendants knew or should have known of the higher risk of adverse effects and their dangers to consumers (*id.* at ¶ 21); defendants issued press releases and statements reassuring the public that Ortho Evra® was safe (*id.* at ¶ 36); Ms. Casso used Ortho Evra® (Doc. 55–3 at ¶¶ 1, 2); and Ms. Casso suffered a pulmonary embolism and blood clots as a result (*id.* at ¶ 3). In sum, Plaintiff's complaint satisfies the applicable pleading standard.

D. California Statutory Claims

Neither Defendants' motion nor their Reply mentions Ms. Casso's three theories of liability based on California statutes. Regardless, Ms. Casso's complaint makes sufficient allegations regarding each claim. (Doc. 55–5 at ¶¶ 64–69 (Deceit by Concealment—California Civil Code §§ 1709, 1710); *id.* at 77–85 (Violation of Business & Professions Code § 17200); *id.* at 86–94 (Violation of Business & Professions Code § 17500).) The pleading in each of these is specific. For instance, Ms. Casso alleges Defendants had specific information about the dangers of the drug but nonetheless engaged in a sales and marketing campaign intending to conceal the negative information and continue to market the product. (*Id.* at ¶¶ 67–68.) She also alleges four ways in which Defendants promulgated untrue and misleading advertising and created unfair competition. (*Id.* at ¶ 80(a)-(d).) Further, she alleges these same four acts were untrue or misleading statements intended to induce consumers to purchase Ortho Evra®. (*Id.* at ¶ 89(a)-(d).)

In short, Ms. Casso's complaint contains sufficient factual matter to put the defendant on notice of her California statutory claims.

E. Summary

Defendants are entitled to judgment in their favor on Ms. Casso's negligence and breach of implied warranty claims. Defendants are not entitled to judgment on her claims for strict liability in tort due to a manufacturing defect, breach of express warranty, negligent misrepresentation, California statutory deceit by concealment, and violations of California Business and Professions Code Sections 17200 and 17500.

V. Conclusion

***8** The Court grants Defendants' summary judgment motion as to Ms. Casso's strict product liability claim (failure to warn). The Court grants Defendants' motion for judgment on the pleadings as to Ms. Casso's negligence claim and breach of implied warranty claim and denies the motion as to her strict liability in tort due to a manufacturing defect, breach of express warranty, negligent misrepresentation, California statutory deceit by concealment, violation of California Business and Professions Code Section 17200, and violation of California Business and Professions Code Section 17500 claims. (Doc. 54.)

IT IS SO ORDERED.

All Citations

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