2013 WL 5939720
United States District Court,
N.D. Ohio,
Western Division.

Gena HANHAN, Plaintiff,
v.
JOHNSON & JOHNSON, et al., Defendant.

No. 1:11 oe 40007.
|
Nov. 5, 2013.

Attorneys and Law Firms

Amanda H. Kent, James G. O'Callahan, Thomas V. Girardi, Girardi & Keese, Los Angeles, CA, for Plaintiff.

Julie A. Callsen, Tucker Ellis, Cleveland, OH, Michael C. Zellers, Tucker Ellis, Mollie F. Benedict, Sarah Cat Tien Trankiem, Su–Lyn Combs, Tucker Ellis & West, Los Angeles, CA, Susan M. Sharko, Drinker Biddle & Reath, Florham Park, NJ, for Defendants.

MEMORANDUM OPINION

KATZ, District Judge.

***1** Plaintiff Gena Hanhan sued Defendants when she experienced a pevlic blood clot and deep vein thrombosis after using Defendants' Ortho Evra® brith control patch. Currently pending is Defendants' combined motion for summary judgment and motion to dismiss as to all of Plaintiff's claims. For the reasons that follow, Defendants' motion is granted.

I. Background

On March 31, 2009, Plaintiff presented at the Teen Clinic of the Kaiser Permanente Medical Group in Dale City, California ("Teen Clinic"), for screening and birth control counseling. At the time, the clinic was run by Dr. Adekemi Oguntala, M.D. Dr. Oguntala supervised a health educator at the clinic, Jennifer Field Chancy.

During her visit to the Teen Clinic, Plaintiff's vital signs were taken and Ms. Chancy counseled Plaintiff on various birth control methods. Plaintiff selected the Ortho Evra® patch and Ms. Chancy presented this selection to Dr. Oguntala. Dr. Oguntala then prescribed the Ortho Evra® patch for Plaintiff, and Ms. Chancy provided Plaintiff with a six month supply of Ortho Evra®.

Defendants claim that Plaintiff was provided with the Teen Clinic's Ortho Evra® handout, as well as the Ortho Evra® detailed patient labeling, which included information on the risks associated with Ortho Evra®. Conversely, Plaintiff claims she never received any such warnings. In any event, the record reflects that at the time of Plaintiff's visit to the Teen Clinic, Dr. Oguntala and Ms. Chancy were both fully informed of Ortho Evra®'s risks and were familiar with Ortho Evra®'s package insert, including the detailed patient labeling. Dr. Oguntala is was familiar with the Dear Healthcare Professional Letter ("DHCP") from Ortho's Women's Health and Urology, which includes information regarding the risks of Ortho Evra®. Further, Dr. Oguntala testified that she prescribed Ortho Evra® for Plaintiff because she believed Ortho Evra®'s benefits outweighed its risks, and further testified that she still believes she made the right prescription decision.

In May 2009, Plaintiff experienced sharp pain in her abdomen and was subsequently diagnosed at a Kaiser Permanente Clinic in San Francisco with a pelvic vein blood clot. Plaintiff contends the clot was caused by the Ortho Evra® patch and therefore sued Defendants in California state court for failure to warn, manufacturing defect, negligence, breach of warranty and negligent misrepresentation. The action was subsequently removed to the U.S. District Court for the Central District of California and then transferred to this Court's Ortho Evra® multidistrict litigation docket. Defendants now move for summary judgment under the learned intermediary doctrine as to Plaintiff's failure to warn claim. Defendants also move to dismiss the remainder of Plaintiff's claims.

II. Legal Standards

A. Summary Judgment

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)).

***2** 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. Judgment on the Pleadings

The Court construes Plaintiff's motion to dismiss as a Fed.R.Civ.P. 12(c) motion for judgment on the pleadings.

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).

In deciding the motion, 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").

III. Discussion

A. Summary Judgment

***3** Defendants move for summary judgment on Plaintiff's failure to warn claim, arguing that the claim is barred by California's learned intermediary rule. The learned

intermediary rule provides that a pharmaceutical manufacturer discharges its duty to warn of drug-related risks if the manufacturer adequately warns the patient's prescribing physician. *Brown v. Superior Court,* 44 Cal.3d 1049, 245 Cal.Rptr. 412, 751 P.2d 470, 477 n. 9 (Cal.Super.Ct.1988) (citing *Magee v. Wyeth Labs. ., Inc.,* 214 Cal.App.2d 340, 345, 29 Cal.Rptr. 322 (Cal.App.1963)). This is so because a prescription decision "is essentially a medical one involving an assessment of medical risks in light of the physician's knowledge of his patient's needs and susceptibilities." *Davis v. Wyeth Labs., Inc.,* 399 F.2d 121, 130 (9th Cir.1968). Here, Defendants argue that the FDA-approved package inserts and DHCP letter, which specifically warned Dr. Oguntala of increased blood clot risks, were sufficient to satisfy the learned intermediary rule and thus discharge Defendants' duty to warn.

Conversely, Plaintiff contends that the learned intermediary rule is not applicable to contraception, arguing that physicians passively allow patients to make most birth control decisions such that the physician's medical judgment, which undergirds the learned intermediary rule, is not operable in contraception matters. Yet, Plaintiff has not offered any cases showing that California has abrogated the learned intermediary rule for contraception, nor has she otherwise persuaded this Court that California would do so. This Court therefore rejects Plaintiff's argument that California's learned intermediary rule is inapplicable to contraception for want of physician participation in contraception decisions.

Plaintiff also contends the learned intermediary rule is not applicable to contraception because federal regulations impose upon manufacturers an affirmative duty to directly warn patients about the risks of drugs that contain estrogen, such as Ortho Evra®. *See* 21 C.F.R. § 310.515 (requiring patient package inserts for estrogen-containing drugs). Plaintiff relies on *Hill v. Searle Labs.,* 884 F.2d 1064 (8th Cir.1989), which held that Arkansas' learned intermediary rule was not applicable to intrauterine contraceptive devices, in part because of the above-noted FDA regulations. *Id.* at 1070 n. 1, 1071. Nevertheless, this Court is not persuaded that the FDA's regulations exclude operation of a state's learned intermediary rule. Rather, the Court agrees with those courts holding that the FDA regulations requiring direct patient warnings are an addition to-not a replacement of-states' learned intermediary rules. *See, e.g., Spychala v. G.D. Searle & Co.,* 705 F.Supp. 1024, 1031–33 (D.N.J.1988) (applying New Jersey's learned intermediary rule notwithstanding FDA regulations). This is especially true given that "the FDA has explicitly stated that its regulation[s] should not affect civil tort liability for drug manufacturers and dispensers." *In re Norplant Prods. Liab. Litig.,* 165 F.3d 374, 379 (5th Cir.1999). Thus, the Court finds that California's learned intermediary rule is applicable to contraception.

***4** Plaintiff argues that even if the learned intermediary rule is applicable, Defendants have not satisfied it in this case. Even though California's learned intermediary rule requires warning to the prescribing physician, Plaintiff argues that the knowledge of Ms. Chancy, the medical assistant, is most relevant here because Plaintiff only interacted with Ms. Chancy. In this vein, Plaintiff contends that the learned intermediary rule is not satisfied because Ms. Chancy had no knowledge that Ortho Evra® can double the risk of blood clots. Plaintiff's argument is not well-taken. A full reading of Ms. Chancy's deposition demonstrates that although she did not recall whether the Ortho Evra® package insert warned of a doubling of the risk, she nevertheless was fully aware of the risk at the time she counseled Plaintiff.

Plaintiff also contends, albeit without any argument whatsoever, that Defendants' warnings are inadequate as a matter of law. *See Brown,* 245 Cal.Rptr. 412, 751 P.2d at 477 n. 9 (learned intermediary defense requires adequate warning). Plaintiff's naked assertion is insufficient to create a factual dispute on the adequacy of Defendants' warnings. *See* Fed.R.Civ.P. 56(c)(1). This is especially true where, as here, Defendants' warnings were approved by the FDA and specifically warned of the increased risk of blood clots.

In summary, the Court finds that California's learned intermediary rule entitles Defendants to summary judgment on Plaintiff's failure to warn claim.

B. Judgment on the Pleadings

Defendants move for judgment on the pleadings as to the remainder of Plaintiff's claims, which include manufacturing defect, negligence, breach of warranty and negligent misrepresentation. Defendants' motion will be granted. Neither Plaintiff's complaint, nor her response brief, offer any facts or argument that support a plausible claim for relief. Rather, Plaintiff's filings offer a "formulaic recitation" of the elements of each claim. Such

pleadings are insufficient under Fed.R.Civ.P. 8(a), and Defendants' motion for judgment on the pleadings is therefore granted. *See Iqbal,* 556 U.S. at 678 (citing *Twombly,* 550 U.S. at 555) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

IV. Conclusion

For the reasons stated herein, Defendants' motion for summary judgment and for judgment on the pleadings is granted. (Doc. 50). Case closed.

IT IS SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2013 WL 5939720, Prod.Liab.Rep. (CCH) P 19,261

End of Document