2013 WL 5939774
United States District Court,
N.D. Ohio,
Western Division.

Sarah E. MILLER, Plaintiff,
v.
ORTHO–McNEIL PHARMACEUTICAL, INC., et al., Defendant.

No. 3:11 oe 40008.
|
Nov. 5, 2013.

Attorneys and Law Firms

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MEMORANDUM OPINION

KATZ, District Judge.

***1** This matter is before the Court on Defendants' motions for summary judgement, judgment on the pleadings, and dismissal, Plaintiff's opposition, and Defendants' reply. This Court has jurisdiction pursuant to 28 U.S.C. § 1332. For the reasons that follow, Defendants' motion for summary judgment and dismissal is granted.

I. Background

This case is one of many to arise out of the litigation involving the Ortho Evra® birth control patch. In March 2006, the Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, centralized all civil litigation in the Northern District of Ohio, noting the following common allegations:

> i) the Ortho Evra contraceptive patch was defectively designed, and ii) plaintiffs received inadequate warnings regarding Ortho Evra's side effects and safety profile. All actions seek damages for personal injury and/or economic damages on behalf of users of Ortho Evra, asserting various state law claims, such as negligence, products liability, breach of warranties, and negligent and/or fraudulent misrepresentations regarding the risks of using Ortho Evra.

In re Ortho Evra Products Liability Litigation, 1:06–cv–40000, MDL 1742 (N.D.Ohio Mar. 9, 2006) (Doc. No. 1).

In the instant matter, two health care providers, Certified Nurse Practitioner Donna Cobb ("NP Cobb") and Certified Nurse Practitioner Traci Speights ("NP Speights") prescribed Ortho Evra® to Plaintiff. In October 2006, NP Cobb prescribed Ortho Evra® to Plaintiff. Her deposition testimony shows that NP Cobb had read and knew of the warnings associated with taking Ortho Evra® including the elevated risks of blood clots.[1] NP Cobb covered various complications with Plaintiff during her exam, "in particular ... blood clot[s]." (Cobb Dep., Doc. 28–5, Ex. D at 63:17.) Given all the information about Ortho Evra®, NP Cobb stated that she believed its benefits outweighed its risks when she prescribed Ortho Evra® to Plaintiff. (*Id.* at 68:19–69:5, 72:2–17.)

[1] In September 2006, Defendants added a warning to the label of Ortho Evra® about the potential increased risk of blood clots. For example, Defendants warned that "[i]ncreased estrogen exposure may increase the risk of adverse events, including venous thromboembolism." (Doc. 28, Ex. E at 12–13.) Similar warnings appear in the sections entitled: "Indications and Usage" (*Id.* at 8), "Thromboembolic Disorders and Other Vascular Problems" (*Id.* at 14), "Adverse Reactions" (*Id.* at 26), "Other Considerations Before Using Ortho Evra" (*Id.* at 45), and "Risks of Using Hormonal Contraceptives, Including Ortho Evra" (*Id.* at 47.).

In May 2007 and April 2008, Plaintiff received prescriptions for Ortho Evra® from NP Speights. At that time, NP Speights testified that she was aware that Ortho Evra® exposed patients to a higher concentration of hormones than typical birth control pills, increasing the risk for thrombotic disease and pulmonary embolism. (Speights Dep., Doc. 28–7, Ex. F at 30:16–31:20; *see also Id.* at 25:20–26:4, 30:8–13, 31:16–20, 35:14–36:16, 37:21–25.) She derived this knowledge from the FDA-approved package inserts, pharmaceutical representatives, and the Dear Healthcare Professional Letter ("DHCP"), which includes information regarding the risks of Orth Evra®. (*Id.* at 22:10–17.) Moreover, she reviewed the label warnings and discussed potential side effects with Plaintiff. (*Id.* at 47:1–8.) NP Speights also encouraged her patients to read the patient labeling and handouts included with the packet. (*Id.* at 26:17–27:11.) Given the totality of Plaintiff's health circumstances, NP Speights believed the benefits of Ortho Evra® outweighed the risks for Plaintiff. (*Id.* at 28:3–7, 47:19–48:1.)

***2** On April 5, 2008, Plaintiff Sarah Miller alleges she had a pulmonary embolism as a result of her use of Ortho Evra®. Plaintiff subsequently brought this action, and Defendants now move for summary judgment under the Learned Intermediary Doctrine as to Plaintiff's failure to warn claim. Defendants also move for judgment on the pleadings on the remainder of Plaintiff's claims. Alternatively, Defendants move to dismiss this action under the statute of limitations.

II. Legal Standards

A. Summary Judgment

Summary Judgment is appropriate where "the movant shows that there is no genuine disputes as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). 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 absences of a genuine issue of material fact." *Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986) quoting Fed.R.Civ.P. 56(c). 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 trail." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 250, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. *Id.* at 248. It is insufficient "simply [to] show that there is some metaphysical doubt as to the material facts." *Matsushita Electric Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). Rather, Rule 56(e) "requires the non-moving party to go beyond the pleadings" and present some type of evidentiary material in support of its position. *Celotex,* 477 U.S. at 324. A court must enter summary judgment "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 trail." *Id.* at 322.

"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 non-moving party." *60 Ivy St. Corp. v. Alexander,* 822 F.2d 1432, 1435 (6th Cir.1994). The court should not "weigh the evidence and determine the truth of the matter but ... determine whether there is a genuine issue for trial." *Anderson,* 477 U.S. at 249. Summary judgment, therefore, exists "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

***3** 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). Dismissal on a Rule 12(c) motion is appropriate "when the factual allegations contained in the complaint, accepted as true, do not show that the pleader

is entitled to relief under Federal Rule of Civil Procedure 8(a)(2).” *Hill v. Mr. Money Finance Co. & First Citizens Banc Corp.,* Nos. 07–3907, 07–3908, 309 Fed. Appx. 950, 955 (6th Cir.2009). A plaintiff must show that she is “entitled to relief” in the complaint. Fed.R.Civ.P. 8(a)(2).

A plaintiff must plead “more than labels and conclusions” masquerading as factual allegations. *Bell Atlantic Corp. v.Twombly,* 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). “[A] formulaic recitation of the elements of a cause of action” does not meet the pleading threshold. *Id.* Rather, a plaintiff must assert well-pleaded “factual allegations” that “raise a right to relief above the speculative level.” *Id.* at 554. In other words “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009).

III. Analysis

A. Defendant’s Summary Judgment Motion

Defendants have moved for summary judgment based on Mississippi’s Learned Intermediary Doctrine. The Learned Intermediary Doctrine provides a defense to drug manufactures in failure to warn claims. *Wyeth Lab., Inc. v. Fortenberry,* 530 So.2d 688, 691 (Miss.1988).[2] The Learned Intermediary Doctrine requires a manufacturer “to advise the prescribing physician of any potential dangers that may result from the drug’s use.” *Id.* (quoting *Reyes v. Wyeth Lab.,* 498 F.2d 1264, 1276 (5th Cir.1974)). Their duty to warn extends to physicians and not to laymen. *Id.* Consequently, the physician acts as a “learned intermediary” between the drug manufacturer and the patient because he “take[s] into account the propensities of the drug, as well as the susceptibilities of his patient.” *Id.* Each choice to use a certain drug becomes an informed one based on the “knowledge of both patient and palliative.” *Id.* (quoting *Reyes,* 498 F.2d at 1276). The Learned Intermediary Doctrine provides a defense to a defendant in his duty to warn a plaintiff where the defendant adequately warned the plaintiff’s prescribing professionals, and where a different warning to the prescribers would have changed the prescribing decision. *Fortenberry,* 530 So.2d at 691–92.

[2] The Mississippi legislature has codified that a product manufacturer is liable when the product “fail[s] to contain adequate warnings or instructions.” Miss.Code Ann. § 11–1–63(a) (i)(2).

Here, Defendants argue that the FDA-approved package inserts and DHCP letter sufficiently satisfy the Learned Intermediary Doctrine and therefore discharge Defendants’ duty to warn. Conversely, Plaintiff argues that Defendants did not provide adequate warnings with Ortho Evra® and that the prescribers were unaware of the risks in taking Ortho Evra®. Plaintiff also asserts that the warnings were inadequate as a matter of law.

1. Adequacy of the Warning

***4** The trier of fact typically decides the issue of a warning’s adequacy. *Fortenberry,* 530 So.2d at 692. A court, however, may find a warning adequate “where the adverse effect that was ultimately visited upon the patient was one that the manufacturer specifically warned against.” *Coleman v. Danek Medical Inc.,* 43 F.Supp.2d 637, 646 (S.D.Miss.1999) (quoting *Cather v. Cather Technology Corp.,* 753 F.Supp. 634, 640 (S.D.Miss.1991)); *see also Fortenberry,* 530 So.2d at 693 (finding a package insert warning adequate as a matter of law when the prescribing physician knew of the warning but did not warn the patient).

Here, Defendants specifically warned of the risk of blood clots. Plaintiff has not offered any evidence of a genuine issue of fact regarding the adequacy of the warning. *See Anderson,* 477 U.S. at 248 (holding that the non-movant “must set forth specific facts showing that there is a genuine issue for trial).

Plaintiff further asserts the treating health care providers were unaware of the level of estrogen exposure associated with Ortho Evra® prior to prescribing. The evidence does not demonstrate this issue. According to the depositions, NP Speights knew of the increased risks associated with Ortho Evra® when she prescribed it to Plaintiff:

> Q. Do you agree that there are a number of risks associated with using combination hormonal contraceptives?
>
> A. Yes.
>
> Q. And those risks include blood clots; is that correct?

A. Yes

Q. And specifically include pulmonary embolism and deep vein thrombosis; is that right?

A. Correct.

(Speights Dep. at 25:20–26:4. *See also Id.* at 30:8–13, 31:16–20, 35:14–36:16, 37:21–25.)

The same holds true for NP Cobb who originally prescribed Ortho Evra® to Plaintiff. In her deposition, she was asked:

Q: In prescribing the ORTHO EVRA patch on October 30th 2006 did you take into account the current risk profile for the ORTHO EVRA as published in the package insert for the ORTHO EVRA patch?

....

THE WITNESS: I did explain to her that the ORTHO EVRA patch does have a higher risk of blood clots than the pill.

(Cobb Dep. at 64:18–25.) NP Cobb also discussed with Plaintiff the very complications that she later suffered. (*Id.* at 64:12–17.) Thus, both prescribing professionals were aware of the warnings and even counseled Plaintiff about those warnings. This Court, therefore, finds no issue of fact regarding the adequacy of Ortho Evra®'s warnings.

2. Proximate Cause

Plaintiff also has failed to show an issue of fact regarding causation because she has not shown that a different warning would have changed the prescribing decision. In the case of prescription drugs, plaintiffs must show that a different warning would have prevented the treating physician from administering the drug. *Thomas v. Hoffman–LaRoche, Inc.,* 949 F.2d 806, 814 (5th Cir.1992). Here, Plaintiff offers no deposition testimony, affidavits, or other evidence that a different warning would have changed either NP Cobb's or NP Speights' decisions to prescribe Ortho Evra®. To the contrary, NP Cobb specifically acknowledged that she knew of the increased risks associated with Ortho Evra®, even counseling Plaintiff about those risks. (Cobb Dep. at 64:18–25.) NP Speights also recognized the risks associated with Ortho Evra®. (Speights Dep. at 25:20–26:4.) Plaintiff, therefore, has failed to produce a genuine issue of fact regarding causation of her injuries.

***5** In summary, this Court finds that Mississippi's Learned Intermediary Doctrine entitles Defendants to summary judgment on Plaintiff's failure to warn claim.

B. Judgment on the Pleadings

This Court next considers Defendants' motion for judgment on the pleadings under Fed.R.Civ.P. 12(c). Plaintiff has alleged other different causes of action—strict liability, negligence, breach of implied warranty, breach of express warranty, and negligent misrepresentation. Plaintiff's complaint does not offer any facts that support a plausible claim for relief. Rather, for each claim, Plaintiff has merely recited conclusory allegations devoid of any facts. (*see e.g.,* Doc. 29, Ex. D at ¶¶ 45–48.) More is needed than a formulaic recitation of the various elements to pass the pleading threshold. *Twombly,* 550 U.S. at 555. Accordingly, this Court grants Defendants' motion for judgment on the pleadings.

C. Statute of Limitations

In Mississippi, absent a specified period, "[a]ll actions ... shall be commenced within three (3) years ... after the cause of action accrued." Miss.Code Ann. § 15–1–49. In drug manufacturer product liability cases, Mississippi's Supreme Court has held that the "cause of action accrue[s] upon discovery of the injury, not discovery of the injury and its cause." *Angle v. Koopers, Inc.,* 42 So.3d 1, 5 (Miss.2010). In other words, the statute "begins to run from the time that injuries are sustained." *Ford Motor Co. v. Broadway,* 374 So.2d 207, 209 (Miss.1979). In this case, Plaintiff suffered and was aware of her injury in April 2008; she filed this suit in August 2011, more than three years after the date she sustained her injuries. Defendants affirmatively asserted the statute of limitations defense in their answer.

Plaintiff contends that the statute of limitations commences when a person knows or reasonably should know of her personal injury and also knows or reasonably should know that it was wrongfully caused. Plaintiff cites no case or statute to support her position. As described above, injury and knowledge of wrongful causation are not, as Plaintiff contends, necessary to trigger the statute of limitation's clock.[3] Thus, the application of the statute

of limitations bars this action commenced after the prescribed three years had already run.

[3] When the liable person "fraudulently conceal[s] the cause of action from the knowledge of the person entitled" to recovery, the statute of limitations does toll until the fraud is "known or discovered." Miss.Code Ann. § 15–1–67. Here, Plaintiff provides only conclusory allegations of fraud without any supporting facts.

IV. Conclusion

For the reasons stated herein, Defendants' combined motion for summary judgment, motion for judgment on the pleadings, and motion to dismiss is granted. (Doc. 28.)

IT IS SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2013 WL 5939774, Prod.Liab.Rep. (CCH) P 19,262

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