

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Bernice Gainer,

Plaintiff,

v.

Civil No. 09-690 (JNE/JSM)
ORDER

Mylan Bertek Pharmaceuticals, Inc.,
and Mylan Pharmaceuticals, Inc.,

Defendants.

On March 25, 2009, Plaintiff Bernice Gainer brought this federal diversity action against Mylan Bertek Pharmaceuticals, Inc., and Mylan Pharmaceuticals, Inc. (collectively, Mylan), asserting products liability common law claims. The Court, applying Ohio law, dismissed the claims against Mylan without prejudice on January 11, 2010. Plaintiff filed an Amended Complaint on February 9, 2010, asserting the following counts: (1) strict liability—failure to warn; (2) strict liability—defective design or manufacture; (3) fraud; (4) breach of implied warranty; (5) breach of express warranty; (6) negligence; and (7) gross negligence. No count references the Ohio Products Liability Act (OPLA), Ohio Revised Code §§ 2307.71-80. On March 2, 2010, Mylan moved to dismiss counts three, four, five, and seven pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure. Plaintiff filed an untimely memorandum in opposition to Mylan's Partial Motion to Dismiss the Amended Complaint under the mistaken belief that the nondispositive motion briefing schedule applied. *See* D. Minn. LR 7.1. Rather than strike Plaintiff's memorandum, on April 16, 2010, the Court ordered Plaintiff's counsel to pay Mylan for the reasonable attorney's fees incurred by Mylan to address the tardiness of Plaintiff's memorandum. Mylan submitted an affidavit supporting its fees with its

reply memorandum. For the reasons discussed below, the Court denies Mylan's motion and orders Plaintiff's counsel to pay Mylan \$1,380 in attorney's fees.

I. BACKGROUND

Mylan manufactures, markets, and sells a generic equivalent of the prescription drug Dilantin, which contains the active ingredient Phenytoin.¹ Plaintiff was prescribed Phenytoin in 2002 to treat seizures. In late March 2003, Plaintiff was diagnosed with Stevens Johnson Syndrome (SJS), a severe skin condition that required hospitalization and lengthy treatments. Her doctor noted on March 25, 2003, that she was taking "Phenytoin, which is an offending agent in [SJS]." Plaintiff again took Phenytoin in June 2004 at which time she was diagnosed with SJS as well as Toxic Epidermal Necrolysis (TEN), another severe skin condition. These conditions required lengthy and painful treatments, including a skin graft, and resulted in permanent hair loss, dry skin, and scarring. As a result, Plaintiff has difficulty ambulating and performing many activities of daily living.

II. DISCUSSION

A. *Motion to dismiss*

When ruling on a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court must accept the facts alleged in the complaint as true and grant all reasonable inferences in favor of the plaintiff. *Crooks v. Lynch*, 557 F.3d 846, 848 (8th Cir. 2009). Although a complaint is not required to contain detailed factual allegations, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl.*

¹ The Amended Complaint variously refers to the relevant drug as "Dilantin/phenytoin," "Phenytoin/Phenytoin," and "Dilantin." The Court refers to Phenytoin to denote Dilantin and its generic equivalents.

Corp. v. Twombly, 550 U.S. 544, 555 (2007)). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Id.* (quoting *Twombly*, 550 U.S. at 570). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

Fraud

Mylan argues that Plaintiff has not alleged her fraud claim with sufficient particularity. Allegations of fraud are analyzed under Rule 9(b) of the Federal Rules of Civil Procedure, which requires particularity in pleading. To satisfy Rule 9(b), the pleading “must specifically allege the circumstances constituting fraud, including such matters as the time, place and contents of false representations, as well as the identity of the person making the misrepresentation and what was obtained or given up thereby.” *Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 920 (8th Cir. 2001) (quotation marks omitted). “Put another way, the complaint must identify the who, what, where, when, and how of the alleged fraud.” *United States ex rel. Joshi v. St. Luke’s Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). One of the primary purposes of Rule 9(b)’s particularity requirement is “to facilitate a defendant’s ability to respond and to prepare a defense to charges of fraud.” *Commercial Prop. Invs. v. Quality Inns Int’l, Inc.*, 61 F.3d 639, 644 (8th Cir. 1995). A court interprets Rule 9(b) “in harmony with the principles of notice pleading.” *Drobnak v. Andersen Corp.*, 561 F.3d 778, 783 (8th Cir. 2009) (quotation marks omitted).

The elements for fraud under Ohio law are:

(1) a representation (or concealment where there is a duty to disclose); (2) which is material to the transaction; (3) made falsely, with knowledge of or reckless disregard as to its falsity; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation or concealment; and (6) resulting injury proximately caused by the reliance.

Rose v. Zaring Homes, Inc., 702 N.E.2d 952, 955 (Ohio Ct. App. 1997). A duty to disclose exists if a “party fails to exercise reasonable care to disclose a material fact which may justifiably induce another party to act or refrain from acting, and the non-disclosing party knows that the failure to disclose such information to the other party will render a prior statement or representation untrue or misleading.” *Miles v. McSwegin*, 388 N.E.2d 1367, 1369 (Ohio 1979).

Here, Plaintiff alleges that Mylan knew or should have known of the connection between Phenytoin and SJS and TEN. To support this allegation, the Amended Complaint notes, among other things, that Phenytoin is the most dangerous “SJS/TEN offender”; nine out of ten of the other “SJS/TEN offenders” warn about SJS and TEN in their labels; cerebyx-fosphenytoin, a “far safer form of [Phenytoin],” warns of SJS and TEN; a 1995 epidemiological study of SJS and TEN determined that Phenytoin “had a relative risk of 53 of SJS and TEN associated with [Phenytoin] therapy”; and a 2002 case review from fifteen burn centers in the United States reported that more than twenty percent of patients diagnosed with TEN were caused by Phenytoin between 1995 and 2000. Plaintiff further maintains that despite such knowledge, Mylan represented that Phenytoin was safe and effective and failed to disclose the connection between Phenytoin and SJS and TEN. As a result of these misrepresentations and omissions, Plaintiff asserts that her “prescribing physician was deprived of the ability to fully assess the risks when making the decision to prescribe” Phenytoin, that she took Phenytoin in March 2003 and June 2004 without prior knowledge of its connection with SJS and TEN, and that she would not have taken Phenytoin if she had been warned that it might result in SJS or TEN. These allegations sufficiently identify the who, what, where, when, and how of the alleged fraud and permit a meaningful response by Mylan. Accordingly, the Court denies Mylan’s motion to dismiss Plaintiff’s fraud claims.

Breach of warranty

Mylan has identified no relevant Ohio law with respect to Plaintiff's breach of warranty claims. Rather, Mylan argues extensively that two non-Ohio lower court precedents preclude those claims. Specifically, relying on *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. 1987) and *Presto v. Sandoz Pharmaceuticals Corp.*, 487 S.E.2d 70 (Ga. Ct. App. 1997), Mylan argues that "claims for breach of warranty are inappropriate as brought against a prescription drug manufacturer." Even if the cases cited by Mylan stood for such a proposition, there is no indication that the Ohio Supreme Court would adopt such a rigid rule. *See Ashley County v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009) (noting that a federal court exercising diversity jurisdiction must predict how a state supreme court would decide an unsettled issue of state law). To the contrary, the Ohio Supreme Court has previously recognized breach of warranty claims against prescription drug manufacturers under Ohio law. *See, e.g., Wagner v. Roche Labs.*, 709 N.E.2d 162, 165 (Ohio 1999) (finding trial "record not totally devoid of evidence going to support a breach-of-express-warranty" claim against a pharmaceutical manufacturer). Therefore, the Court denies Mylan's motion to dismiss Plaintiff's breach of warranty claims.²

Gross negligence

Finally, Mylan repeats its arguments in favor of the dismissal of Plaintiff's fraud claim to support the dismissal of her gross negligence claim. *See Winkle v. Zettler Funeral Homes, Inc.*, 912 N.E.2d 151, 161 (Ohio Ct. App. 2009) ("Gross negligence is defined as the failure to

² The Court also notes that Mylan's motion to dismiss Plaintiff's breach of implied warranty claim but not her strict liability claims is seemingly inconsistent with Ohio law. *See Sapp v. Stoney Ridge Truck Tire*, 619 N.E.2d 1172, 1178 (Ohio Ct. App. 1993) ("[A]ny cause of action based upon implied warranty in tort is . . . considered a strict products liability action." (citing *Temple v. Wean United, Inc.*, 364 N.E.2d 267, 271 (Ohio 1977))).

exercise any or very slight care or a failure to exercise even that care which a careless person would use.” (quotation marks omitted)). Accordingly, for the reasons discussed above with respect to Mylan’s fraud claim, the Court denies Mylan’s motion to dismiss Plaintiff’s claim for gross negligence.³

B. Attorney’s fees

Local Rule 7.1(e) provides:

In the event a party fails to timely deliver and serve a memorandum of law, the Court may strike the hearing from its motion calendar, continue the hearing, refuse to permit oral argument by the party not filing the required statement, consider the matter submitted without oral argument, allow reasonable attorney’s fees, or proceed in such other manner as the Court deems appropriate.

See also D. Minn. LR 1.3 (“Failure to comply with a local rule may be sanctioned by any appropriate means needed to protect the parties and the interests of justice.”).

In compliance with the April 16, 2010, Order, requiring Plaintiff’s counsel to pay Mylan for the reasonable attorney’s fees incurred by Mylan in responding to Plaintiff’s late-filed opposition memorandum, Mylan submitted an affidavit with its reply memorandum requesting \$1,380. The affidavit asserts that Mylan’s counsel spent 4.6 hours at \$300 per hour “reviewing

³ Neither party addressed the effect of the OPLA on common law products liability claims in Ohio. The OPLA was enacted in 1988. *See White v. DePuy, Inc.*, 718 N.E.2d 450, 456 (Ohio Ct. App. 1998). The Ohio Supreme Court later determined that “all common-law products liability causes of action survive[d] the enactment of [the OPLA] unless specifically covered by the Act.” *Carrel v. Allied Prods. Corp.*, 677 N.E.2d 795, 800 (Ohio 1997) (quotation marks omitted). A subsequent amendment to the OPLA superseded *Carrel* by expressly abrogating “all common law product liability claims or causes of action” accruing after April 7, 2005. *See Doty v. Fellhauer Elec., Inc.*, 888 N.E.2d 1138, 1142 (Ohio Ct. App. 2008). Thus, from the time of the OPLA’s enactment until April 7, 2005, the OPLA precluded some common law products liability claims but left others intact. *See, e.g., White*, 718 N.E.2d at 459 (“The common law of breach of express warranty was codified at [Ohio Revised Code] 2307.77.”); *id.* at 456 (“[T]he common-law cause of action of implied warranty in tort continue[d] to exist even after the enactment of the [OPLA] in 1988.”); *Delahunt v. Cytodyne Techs.*, 241 F. Supp. 2d 827, 843-44 (S.D. Ohio 2003) (addressing the OPLA’s effect on negligence claims); *Hollar v. Philip Morris, Inc.*, 43 F. Supp. 2d 794, 808 (N.D. Ohio 1998) (addressing the OPLA’s effect on common law fraud claims).

the local rules related to timing, the proper mechanism to respond to the late filed brief, preparing a letter brief to the Court, reviewing plaintiff's response to Mylan's letter brief and preparing related attorney-client protected communications on the issue." The Court finds Mylan's request to be reasonable. Therefore, Plaintiff's counsel is ordered to pay Mylan \$1,380 in reasonable attorney's fees incurred by Mylan to address the tardiness of Plaintiff's memorandum.

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Mylan's Motion to Dismiss [Docket No. 25] is DENIED.
2. Plaintiff's counsel is ordered to pay Mylan \$1,380 in attorney's fees.

Dated: June 15, 2010

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge