UNITED STATES DISTRICT COURT
DISTRICT OF PUERTO RICO

HELEN RIVERA-ADAMS, et al.,

Plaintiffs,

v.

WYETH,

Defendant.

Civil No. 03-1713 (JAF)

OPINION AND ORDER

Plaintiffs, Helen Rivera-Adams ("Rivera"), Julio Santos-García, their conjugal partnership, and their children, Helen Marleen, Julio Antonio, Ellen Annette, and Ellen Marie, allege that treatment with Prempro, a drug prescribed for hormone replacement therapy ("HRT"),[1] caused Rivera to develop breast cancer. Plaintiffs allege (1) negligence in the design, testing, and manufacturing of Prempro; (2) strict liability for failure to warn of the risk of breast cancer and for defective product design; (3) unjust enrichment; (4) breach of express or implied warranty; and (5) liability of corporate alter egos. Plaintiffs also seek punitive damages for Defendant's alleged misconduct. (Docket No. 1 at 8–11.) Defendant moves for summary judgment. (Docket No. 49.) Plaintiff opposes (Docket No. 129), and Defendant responds (Docket No. 140).

[1] Prempro is a combination of the hormones estrogen and progestin used to treat symptoms of menopause and was approved by the FDA in 1994. (Docket No. 49-1 at 2–3.)

I.

Factual Synopsis

We derive the following facts from the parties' motions, statements of material facts, and exhibits. (Docket Nos. 49; 57; 129; 130; 140.) In June 2000, Plaintiff Rivera began taking Prempro, prescribed by her obstetrician/gynecologist Dr. Fernando Rampolla Briganti ("Dr. Rampolla") for menopausal symptoms. (Docket No. 49-1 at 1–2.) Both Rivera, a pharmacist, and her treating physician reviewed the warnings that accompanied Prempro in 2000, which stated at the time that the "effect of added progestins on the risk of breast cancer is unknown, although a moderately-increased risk in those taking combination estrogen/progestin therapy has been reported." (Docket No. 49-1 at 5.) Rivera allegedly continued to take Prempro until she was diagnosed with breast cancer on January 31, 2002. (Docket No. 129 at 1.)

II.

Summary Judgment Under Rule 56(c)

We grant a motion for summary judgment "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A factual dispute is "genuine" if it could be resolved in favor of either party and "material" if it potentially affects the outcome of the case. Calero-Cerezo v. U.S. Dep't of Justice, 355 F.3d 6, 19 (1st Cir. 2004). In evaluating a motion for summary judgment, we view the record in the light most favorable to the nonmovant. Adickes v. S.H. Kress & Co., 398 U.S. 144, 157 (1970).

The movant carries the burden of establishing that there is no genuine issue as to any material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). When the nonmoving party will bear the burden of persuasion at trial, the moving party may satisfy its burden of production at the summary judgment stage "in one of two ways. First, the moving party may submit affirmative evidence that negates an essential element of the nonmoving party's claim." Celotex, 477 U.S. at 331. Second, "the moving party may point to evidentiary materials already on file—such as answers to interrogatories, affidavits, or portions of depositions—that demonstrate that the non-moving party will be unable to carry its burden of persuasion at trial." Carmona v. Toledo, 215 F.3d 124, 132 (1st Cir. 2000) (citing Celotex, 477 U.S. at 325).

"Once the moving party has made a preliminary showing that no genuine issue of material fact exists, the nonmovant must 'produce specific facts, in suitable evidentiary form, to establish the presence of a trialworthy issue.'" Clifford v. Barnhart, 449 F.3d 276, 280 (1st Cir. 2006) (quoting Triangle Trading Co. v. Robroy Indus., Inc., 200 F.3d 1, 2 (1st Cir. 1999)). The nonmovant "may not rely merely on allegations or denials in its own pleading; rather, its response must . . . set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2).

III.

Analysis

Defendant offers four grounds in support of its motion for summary judgment. We discuss each below in turn.

A. Statute of Limitations

Plaintiff Rivera was diagnosed with breast cancer on January 31, 2002. (Docket No. 129 at 1.) This suit was filed on June 27, 2003. The parties do not dispute that Puerto Rico's one-year statute of limitations governs Plaintiffs' tort claims. (Id. at 4.)

The one-year statutory limitation period begins to run from "the time the aggrieved person has knowledge of the injury." 31 L.P.R.A. § 5298(2). A "plaintiff will be deemed to have 'knowledge' of the injury, for purposes of the statute of limitation, when she has 'notice of the injury, plus notice of the person who caused it.'" Rodriguez-Suris v. Montesinos, 123 F.3d 10, 15 (1st Cir. 1997) (citing Colon Prieto v. Geigel, 15 P.R. Offic. Trans. 313, 330 (1984)). Plaintiffs bear the burden of establishing when the damage became known to them. Id. at 13. Knowledge of the tortfeaser's identity can be "actual" or "deemed," Colon Prieto, 115 P.R. Offic. Trans. at 330, and actual knowledge is unnecessary if such knowledge could have been acquired by a plaintiff through due diligence. Villarini-Garcia v. Hosp. Del Maestro, Inc., 8 F.3d 81, 84 (1st Cir. 1993).

Plaintiffs claim that Rivera had no reason to know that she was injured by her treatment with Prempro, or to know the identity of the alleged tortfeasor until July 2002, upon publication of the Women's Health Initiative study ("WHI study") of the effects of HRT, which was highly publicized in the media and allegedly led Rivera to suspect Prempro as a cause of her breast cancer. (Docket No. 129 at 5–7.) Defendant argues that Rivera knew at the time of her diagnosis, and points to Rivera's deposition testimony, alleging that she "suspected" that Prempro caused her cancer. (Docket No. 49-3 at 11–12.) Specifically, Rivera replied in the affirmative when she was asked, "You suspected that your hormones might have something to

do with your breast cancer. Is that what you're trying to say?" (Id.) Unfortunately, the quoted text does not prove that Rivera suspected Prempro—or Prempro-derived hormones—as the cause of her breast cancer. Instead, Rivera simply acknowledged that she suspected her hormones played a role in her breast cancer.

Even if, as Defendant argues, Rivera could have discovered the identity of the alleged tortfeasor with due diligence thanks to her pharmaceutical training, the question of whether a plaintiff "exercised reasonable diligence is typically given to the jury, even where no raw facts are in dispute, because the issues of due diligence and adequate knowledge are still ones for the jury so long as the outcome is within the range where reasonable men and women can differ." Espada v. Lugo, 312 F.3d 1, 4 (1st Cir. 2002) (internal quotation marks and citations omitted). At this point in the proceedings, Rivera's response suffices to show a general issue of material fact exists as to whether she should have had knowledge of the tortfeasor's identity.

B. Failure to Warn

Plaintiffs claim that Defendant's failure to supply adequate warning of the increased risk of breast cancer renders Defendant strictly liable for her injury. (Docket No. 1 at 9.) To succeed on a failure-to-warn claim under Puerto Rico law, a plaintiff must show that "(1) the manufacturer knew, or should have known the risk inherent in the product; (2) there were no warnings or instructions, or those provided were inadequate; (3) the absence of warnings made the product inherently dangerous; and (4) the absence of adequate warnings or instructions was the proximate cause of plaintiff's injury." Cruz-Vargas v. R.J. Reynolds Tobacco, Co., 348 F.3d

271, 276 (1st Cir. 2001) (internal quotation marks omitted) (citing Aponte Rivera v. Sears Roebuck de P.R., Inc., 144 D.P.R. 830 (1998).[2]

Defendant argues that Plaintiffs' failure-to-warn claim should fail because (1) Rivera did not show that a failure to warn proximately caused her injuries, (2) a warning would have resulted in a different prescription from Dr. Rampolla, and (3) Rivera should have known of the risk of breast cancer, based on her pharmaceutical training.

When the product at issue is a prescription drug, the manufacturer's duty to warn does not run to the user of the drugs directly; instead, the manufacturer "has a duty to adequately warn prescribing physicians of the hazards posed by the use of its drugs."[3] Guevara v. Dorsey Labs., Div. of Sandoz, Inc., 845 F.2d 364, 366 (1st Cir. 1988) (citing Pierluisi v. E.R. Squibb & Sons, 440 F. Supp. 691 (D.P.R. 1977)). This "learned intermediary doctrine," however, can protect a manufacturer only "if the facts support the conclusion that a drug manufacturer adequately warns doctors of a drug's dangers; it does not shield drug manufacturers from liability if the warnings they provided to physicians would not permit the physicians to adequately advise their patients." De Oca v. Adventis Pharm., 579 F. Supp. 2d 222, 227–28 (D.P.R. 2008) (internal citations and quotation marks omitted).

At this stage in the proceedings, Defendant has failed to show there is no issue of material fact regarding the failure-to-warn claim. It is undisputed that the potential risk of breast cancer was identified as an important issue prior to FDA approval of Prempro in 1994.

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[2] "As to strict liability, Puerto Rico has . . . rejected the [inherently or] 'unreasonably dangerous' requirement of § 402A." Malave-Felix v. Volvo Car Corp., 946 F.2d 967, 971 (1st Cir. 1991) (citing Montero Saldana v. Am. Motors Corp., 107 P.R. Dec. 452 (1978)).

[3] As we find a genuine issue of material fact still exists, we do not reach Plaintiffs' novel legal argument – that Defendant's duty to warn ran to the patient under 21 C.F.R. s 310.515. (Docket No. 129-1 at 15.)

(Docket No. 49-1 at 3–4.) In 2000, Prempro's warning label noted that "the risk of breast cancer [was] unknown, although a moderately increased risk in those taking combination estrogen/progestin therapy [had] been reported. Other studies [had] not shown this relationship." (Id. at 5.) Dr. Rampolla testified that he prescribed Prempro less after learning the results of the WHI study. (Docket No. 129-1 at 142.) A jury might find that Prempro's label provided an insufficient warning given the concerns expressed during the FDA approval process, and that the lack of a sufficient warning prompted Dr. Rampolla to prescribe Prempro to his patients with less concern for the risk of breast cancer.[4]

Finally, Defendant argues that Rivera knew, based on her pharmaceutical training, of the risk of breast cancer related to HRT. Indeed, Defendant alleges that Plaintiff Rivera was "aware when she began taking Prempro that 'estrogens have several important uses but also some risks,'" asked her physician about such risks, and even attended seminars about Prempro. (Docket No. 49-3 at 18.) The fact that Rivera was a pharmacist who asked questions about the potential risk of breast cancer related to a combination estrogen-progestin drug such as Prempro neither demonstrates that Rivera was aware of the risks of breast cancer nor defeats Plaintiffs' failure-to-warn claim. As the First Circuit has noted, regarding a prescription drug manufacturer's duty to warn, it is not the knowledge "actually possessed by the plaintiff, individually [or, in this case, plaintiff's doctor], that determines whether the absence of warning renders a product unreasonably dangerous." Guevara, 845 F.2d at 367 (citing Jackson v. Coast

[4] We are unpersuaded by Defendant's brief argument built on Dr. Rampolla's statement that he continues to prescribe Prempro to other unnamed patients for unspecified amounts of time. Dr. Rampolla has also testified that he changed his prescribing pattern for Prempro, and prescribes it in a more limited fashion than he did in 2000. (Docket No. 129-1 at 59–60.)

Paint and Lacquer Company, 499 F.2d 809 (9th Cir. 1974)). In a failure-to-warn claim, the issue is "the adequacy of the warning, and that is measured against the general level of knowledge existent in the target community." Id.

C. Other Tort Claims

In addition to their failure-to-warn claim, Plaintiffs also bring claims under negligence and strict-liability theories for alleged design and manufacturing defects. Defendant also argues that Plaintiffs fail to show causation to support their product liability claims and that the Plaintiffs' experts offer inadmissible and unreliable testimony. We have already ruled upon Defendant's Daubert challenges, and Plaintiffs will offer expert testimony as to causation, which remains a very live and very disputed genuine issue of material fact.

Next, Defendant argues that Puerto Rico law does not recognize a claim for defective design with respect to prescription drugs. While Puerto Rico law does not offer guidance on point, the "Supreme Court of Puerto Rico has developed a strict liability standard for manufacturers of defective products." Guevara, 845 F.2d at 365. The Supreme Court of Puerto Rico has recognized "three types of defects which trigger application of strict liability principles. These are: manufacturing defects, design defects and defective warnings." De Oca, 579 F. Supp. 2d at 226 (citing Aponte-Rivera, 144 D.P.R. at 839–40). Additionally, as Defendant points out, the First Circuit has noted that the "Supreme Court of Puerto Rico has consistently relied upon California Supreme Court precedent when considering issues raised by the doctrine of strict product liability." Acosta-Mestre v. Hilton Int'l, 156 F.3d 49, 55 (1st Cir. 1998).

The California Supreme Court has held that a manufacturer of prescription drugs is not strictly liable or liable for breach of warranty for injuries caused by the drug, as long as "the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." Brown v. Superior Court, 751 P.2d 470, 483 (Cal. 1988). The California Supreme Court went on to note that its holding did not mean "that drug manufacturers are free of all liability for defective drugs. They are subject to liability for manufacturing defects, as well as under general principles of negligence, and for failure to warn of known or reasonably knowable side effects." Id. at n.12.

Later, in Carlin v. Superior Court, the California Supreme Court explained that a plaintiff may make claims in strict liability if the drug manufacturer failed to warn of "known or reasonably scientifically knowable risks" related to its product. 920 P.2d 1347, 1352 (Cal. 1996). Additionally, the court explained that Brown prohibited breach-of-warranty claims against prescription drug manufacturers based on unknown defects, not breach-of-warranty actions based on "known or reasonably scientifically knowable" defects. Id. at 1355. In the present case, however, Plaintiffs and their experts allege that Prempro suffered from a defective design and carried insufficient warning in 2000 of the risks of breast cancer known at the time.

Finally, Defendant argues that Plaintiffs' claims for unjust enrichment and alter ego should fail. But Defendant does not elaborate as to why these claims should fail, beyond stating that Plaintiffs have "adduced no evidence to support these claims." (Docket No. 49-3 at 21.) The movant seeking summary judgment "always 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, 477 U.S. at 323. However, it is "not enough to move for summary judgment without supporting the motion in any way or with a conclusory assertion that the plaintiff has no evidence to prove his case." Celotex, 477 U.S. at 328 (White, J., concurring); see also Russ v. International Paper Co., 943 F.2d 589, 591 (5th Cir. 1991) ("Simply filing a summary judgment motion does not immediately compel the party opposing the motion to come forward with evidence demonstrating material issues of fact as to every element of its case."). Here, Defendant did not even give a basic identification of the required legal standard for the claim or the elements of the claim that Plaintiff allegedly failed to prove. Defendant also failed to mention any specific issues where Plaintiffs lack supporting evidence. Merely listing the name of the claims at issue along with a conclusory statement that there is no evidence cannot satisfy the minimal burden of production at the summary judgment stage. See Russ, 943 F.2d at 594 ("The opposing party has no obligation to produce evidence concerning an argument that has not been raised.")

D. Punitive Damages

Defendant argues that Plaintiffs may not seek punitive damages under Puerto Rico law. (Docket No. 49-3 at 1.) Plaintiffs argue that Pennsylvania law, not Puerto Rico law, should govern on the matter of punitive damages. (Docket No. 129 at 21.) Puerto Rico law does not recognize punitive damages, Noble v. Corporacion Insular de Seguros, 738 F.2d 51, 54 (1st Cir. 1984), while Pennsylvania law does. Haugh v Allstate Ins. Co., 322 F.3d 227, 235 (3d Cir. 2003).

A federal court sitting in diversity applies the choice of law rules of the forum state. Day & Zimmerman, Inc. v. Challoner, 423 U.S. 3, 4 (1975). Under the "dominant or significant contacts" test established by the Supreme Court of Puerto Rico, we "apply the law of the jurisdiction with dominant contacts to the parties and the tort involved." Jimenez v. Am. Airlines, Inc., 579 F. Supp. 631, 632 (D.P.R. 1983) (citing Widow of Fornaris v. Am. Surety Co. of N.Y., 98 P.R.R. 28 (1966). We remain unpersuaded by Plaintiffs' argument that "there is no relationship between the parties as it relates to the punitive damages issue," and do not agree that, as Plaintiffs argue, Pennsylvania law should govern the damages issue simply because it is the state of Wyeth's domicile. (Docket No. 129 at 20–21.) Given that Plaintiffs are, and were, residents of Puerto Rico, the medication was prescribed in Puerto Rico, and the injury occurred in Puerto Rico,[5] "we find that Puerto Rico is the forum with the most significant interests in the controversy." Id.

Puerto Rico has the strongest interest in protecting its residents from tortious conduct such as that alleged in this case, and also has a strong interest in protecting the integrity of its civil law damages regime. See In re San Juan Dupont Plaza Hotel Fire Litig., 745 F. Supp. 79, 86 (D.P.R. 1990) (applying Puerto Rico law after finding Puerto Rico had strongest policy interest in preserving its civil law damages regime); see also McMillan v. Mass. Soc'y for the Prevention of Cruelty to Animals, 140 F.3d 288, 306 (1st Cir. 1998) ("[W]hen state law provides the basis of decision, the propriety of an award of punitive damages . . . [is a]

[5] The First Circuit has applied the older *lex loci delicti* test to tort claims under Puerto Rico law. Montalvo v. Gonzalez-Amparo, 587 F.3d 43, 46 (1st Cir. 2009) . But, even using this test, we would find that Puerto Rico law governed all claims, as the alleged injury—and the events leading up to it—occurred in Puerto Rico. See Marcano Diaz v. E. Airlines, Inc., 698 F. Supp. 18, 21 (D.P.R. 1988) (applying *lex loci delicti* test in the alternative to support choice of law determination).

question[] of state law."). Despite Plaintiffs' urging, we decline to selectively apply Pennsylvania law on the issue of punitive damages, and we grant Defendant's motion for summary judgment on this issue.

III.

Conclusion

For the foregoing reasons, we hereby **DENY IN PART** defendant's motion for summary judgment, (Docket No. 49). We **DISMISS** Plaintiffs' claim for punitive damages, which are not recognized under Puerto Rico law.

IT IS SO ORDERED.

San Juan, Puerto Rico, this 8h day of December, 2010.

s/José Antonio Fusté
JOSE ANTONIO FUSTE
Chief U.S. District Judge