76 F.Supp.3d 680
United States District Court,
N.D. Ohio,
Western Division.

Stephanie YATES, Plaintiff,
v.
ORTHO–McNEIL PHARMACEUTICAL, INC., et al., Defendant.

Case No. 3:09 oe 40023.
|
Signed Jan. 5, 2015.

Synopsis
Background: Consumer brought action against manufacturer of birth control patch in state court, alleging claims for strict liability in tort-failure to warn, strict liability in tort-manufacturing defect, negligence, breach of implied warranty, and breach of express warranty. Action was removed to federal court, and case was transferred by Judicial Panel on Multidistrict Litigation (MDL). Manufacturer moved for summary judgment, and former counsel for MDL plaintiffs moved to intervene and for leave to file an amici curiae brief.

Holdings: The District Court, Katz, J., held that:

[1] there was no evidence to support manufacturing defect claim against manufacturer;

[2] design defect claim under New York law was preempted by federal law;

[3] there was no evidence to support consumer's breach of express warranty claim against manufacturer under New York law; and

[4] motion to intervene was untimely.

Defendants' motion granted; Motion to intervene denied.

Attorneys and Law Firms

***681** Daniel G. Tronolone, Tronolone & Surgalla, Lawlor F. Quinlan, III, Terrence M. Connors, Connors & Vilardo, Buffalo, NY, Gerard A. Strauss, Hamburg, NY, Janet G. Abaray, Burg Simpson Eldredge ***682** Hersh Jardine, Cincinnati, OH, Michael S. Burg, Burg Simpson Eldredge Hersh Jardine, Englewood, CO, for Plaintiff.

John D. Winter, Patterson, Belknap, Webb & Tyler, New York, NY, Julie A. Callsen, Robert C. Tucker, Tucker Ellis, Cleveland, OH, Susan M. Sharko, Jennifer L. La Mont, Florham Park, NJ, for Defendant.

MEMORANDUM OPINION

KATZ, District Judge.

Stephanie Yates, who is a New York resident, sued Ortho–McNeil Pharmaceutical, Inc. (now know as Janssen Pharmaceuticals, Inc.), Alza Corporation, Johnson & Johnson Pharmaceutical Research and Development, LLC (now known as Janssen Research & Development, LLC), and Johnson & Johnson in the Erie County (New York) Supreme Court. Ms. Yates alleged that she had been prescribed the Ortho Evra® birth control patch which allegedly caused her to have a stroke. The Defendants moved for summary judgment. (Doc. No. 48). Ms. Yates filed a response (Doc. No. 57), and the Defendants filed a reply. (Doc. No. 65). Both parties also filed sur-replies. (Doc. Nos. 85, 86).

On April 7, 2014, 2014 WL 1369466, the Court granted Defendants' motion for summary judgment on Ms. Yates's failure to warn claim. Defendants' motion to dismiss Ms. Yates's manufacturing defect, negligence, breach of implied warranty, and breach of express warranty claims for failing to state a claim for relief was denied. The Court also denied Ms. Yates's motion to amend her complaint. (Doc. Nos. 88, 89).

Defendants have now moved for summary judgment on Ms. Yates's manufacturing defect, negligence, breach of implied warranty, and breach of express warranty claims. (Doc. No. 90). Ms. Yates has filed a response (Doc. No. 94), the Defendants have filed a reply (Doc. No. 95), and

Ms. Yates has filed a sur-reply. (Doc. No. 100).

On October 15, 2014, the Court heard oral argument on the pending motion for summary judgment. (Doc. No. 112). Thirty-nine minutes into the oral argument, former co-lead counsel Michael S. Burg and Janet G. Abaray for the Ortho Evra® Multidistrict Litigation (MDL) Plaintiffs, along with Michael A. London, former liaison counsel for the MDL Plaintiffs, moved to intervene pursuant to Federal Rule of Civil Procedure 24(b). (Doc. No. 105). The Defendants filed a response opposing the motion to intervene. (Doc. No. 106). The proposed intervenors have filed a reply. (Doc. No. 109). The proposed intervenors filed a motion for leave to file an amici curiae brief requesting the Court to deny the motion for summary judgment. (Doc. No. 113).

Following oral argument, the Court granted the parties leave to file supplemental briefing on the question of whether federal law preempts Ms. Yates's state law design defect claim. The Defendants filed their initial brief (Doc. No. 111), Ms. Yates filed a response (Doc. No. 114), and the Defendants filed a reply. (Doc. No. 116). The Defendants have also filed a brief opposing the request to file the amici curiae brief. (Doc. No. 115). The proposed intervenors have filed a reply in support of their motion to file an amici curiae brief. (Doc. No. 117).

I. Facts

On September 4, 2008, Ms. Yates sued the Defendants asserting that after she had been prescribed the Ortho Evra® birth control patch, she suffered a stroke on April 24, 2005. Ms. Yates alleged the following causes of action: 1) strict liability ***683** in tort-failure to warn; 2) strict liability in tort-manufacturing defect; 3) negligence; 4) breach of implied warranty; and 5) breach of express warranty.

The Defendants removed the case to the United States District Court for the Western District of New York. Following removal, the case was transferred to the undersigned as related to the Ortho Evra® litigation by the Judicial Panel on Multidistrict Litigation. *In re Ortho Evra Prods. Liab. Litig.,* 1:06 cv 40000 MDL 1742 (N.D.Ohio).

Ms. Yates first received counseling concerning different birth control options, including the Ortho Evra® patch, on November 3, 2004. Before then, Ms. Yates was unaware of the Ortho Evra® patch either from advertisements or from personal contacts. Ms. Yates admittedly had never heard of the Ortho Evra® patch until she met with OB/GYN Associates of Western New York in November 2004.

Jennifer Anne Smith is a licensed physician's assistant and, since 2001, specialized in obstetrics and gynecology at OB/GYN Associates. Her job included seeing, examining, diagnosing, and treating women for both routine gynecology examinations and gynecological problems. Ms. Smith also prescribes medicines, including hormonal contraceptives. Her knowledge and expertise concerning contraceptives comes from multiple sources, including her medical training, published literature in professional journals, professional conferences, continuing medical education classes, the *Physicians' Desk Reference,* office handouts, and product information provided by company sales representatives.

According to her deposition, Ms. Smith decides on what medications to prescribe based upon her clinical experience, knowledge of product, and patient assessment. With regards to birth control, Ms. Smith considers not only the medication, but also the circumstances of the particular patient, including the patient's health, physical condition, personal and family medical history, and potential contraindications. Ms. Smith weighs the risks and benefits of the medicine for the particular patient. Ms. Smith prescribes a birth control product based upon her independent medical judgment and her conclusion that the medicine will be safe and effective for the particular patient. Ms. Smith admittedly recognizes that all medicines have potential risks and only prescribes medications if she is satisfied that "the patient is more likely to be helped than hurt by the product."

Over the years, Ms. Smith has prescribed many different hormonal birth control products, which she concedes have risks, including an increased risk of blood clots, deep vein thrombosis, heart attack, and stroke. She also acknowledges that warnings about those risks have been included in the package inserts for healthcare professionals and patients for many years, long before she prescribed the Ortho Evra® patch to Ms. Yates in 2005. Ms. Smith stated she has counseled patients concerning these risks for many years.

Ms. Smith was and still is familiar with the risks and

benefits of the Ortho Evra® patch. This knowledge existed even before she prescribed the Ortho Evra® patch to Ms. Yates. Based upon her experience, Ms. Smith believes that the Ortho Evra® patch is easy to use and has a high compliance rate. Ms. Smith was familiar with the risks and contraindications set forth in the Ortho Evra® package insert, including the Detailed Patient Labeling, when she prescribed the Ortho Evra® patch to Ms. Yates. Based upon her clinical judgment, Ms. Smith feels that Ortho Evra® is a reasonable, safe, and effective birth control method for some patients, and continues to prescribe the product.

***684** On November 3, 2004, Ms. Yates was seventeen years old. She went to OB/GYN Associates in order to be placed on birth control because of "[s]evere menstrual cramps" and because she was sexually active. Ms. Yates's mother, Judy Yates, did not accompany her daughter to this meeting.

On that date, Ms. Smith counseled Ms. Yates concerning the options, risks, and benefits of the various birth control products on the market. Ms. Smith's office notes state she discussed the risks, benefits, and side effects of various contraceptive options. Ms. Smith's habit and custom was to discuss the risks involved, including headaches, nausea, breast tenderness, moodiness, blood clots, and stroke. She also discussed the benefits of preventing an unplanned pregnancy and the relief from menstrual cramping. Ms. Yates concedes she was counseled concerning the risk of a stroke and clotting associated with the Ortho Evra® patch.

Ms. Yates selected Depo–Provera because the injections were only required at three-month intervals. Ms. Yates received her first Depo–Provera injection on November 26, 2004. She never returned for the second shot, and on March 3, 2005, she told nurse Christine Palbo that she decided to discontinue Depo–Provera due to weight gain. Ms. Yates stated she wanted to try the Ortho Evra® patch. Ms. Yates complained of heavy or irregular bleeding, which was a recognized side effect of the Depo–Provera injection, and was a common complaint by Depo–Provera users. Nurse Palbo consulted Ms. Smith concerning Ms. Yates's request to change her birth control method. Ms. Smith approved the change to the Ortho Evra® patch, starting March 6, 2005. However, due to continuous bleeding and a possible pregnancy, Ms. Yates did not begin using the Ortho Evra® patch until April 17, 2005.

Ms. Smith stated in her deposition that when a patient decides to change her birth control method, it is her standard practice to re-counsel the patient concerning the risks of the product, including the risk of a stroke. On April 15, 2005, two days before Ms. Yates started using the patch, Ms. Smith advised Ms. Yates that the Ortho Evra® patch might be less effective due to her weight. Ms. Smith, per her routine, again reminded Ms. Yates concerning the potential risks and side effects associated with the use of the Ortho Evra® patch. Ms. Yates failed to perform any research regarding the Ortho Evra® patch because she trusted the medical advice she was given. Ms. Yates admitted in her deposition that she would still have used the Ortho Evra® patch if she read the warning in the Detailed Patient Labeling, including the warnings about the risk of stroke.

Judy Yates admitted knowing that her daughter was using the Ortho Evra® patch. In fact, Judy Yates accompanied her daughter to the facility and sat in the waiting room when the product was prescribed. She was also aware of the product samples provided to her daughter. Ms. Yates did not relate the counseling provided at OB/GYN Associates to her mother, nor did she relate the potential risks associated with the patch. Judy Yates, however, saw the package of samples, including an insert with instructions. Judy Yates never read, nor recalls reading, the instructions to the product, nor did she see her daughter read them. At her deposition, defense counsel read the warnings about the risk of stroke in Ortho Evra®'s Detailed Patient Labeling. Judy Yates testified that even if she had read the product warnings, she would have permitted ***685** her daughter to use the Ortho Evra® patch.

Thus, before Ms. Yates's stroke, Ms. Smith was aware that the Ortho Evra® patch could cause a stroke. Ms. Smith was familiar with the language of Ortho Evra®'s FDA approved package insert, including the Detailed Patient Labeling, which warned about the risk of stroke. Ms. Smith counseled Ms. Yates concerning the risks of the product, including the risk of a stroke, on multiple occasions. Ms. Smith concluded that the Ortho Evra® patch was a safe and effective product for Ms. Yates. Further, Ms. Smith continues to prescribe the Ortho Evra® patch to patients.

II. Summary Judgment

Summary judgment is proper where "there is no genuine dispute as to any material fact" and the moving party "is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). A party asserting a genuine issue of material fact must support the argument either by "citing to particular parts of materials in the record" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed.R.Civ.P. 56(c)(1). The Court views the facts in the record and reasonable inferences that can be drawn from those facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). The Court does not weigh the evidence or determines the truth of any matter in dispute. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

The party requesting summary judgment bears an initial burden of demonstrating that no genuine issue of material fact exists, which the party must discharge by producing evidence to demonstrate the absence of a genuine issue of material fact or "by showing ... that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett,* 477 U.S. 317, 323–25, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986) (internal quotation marks omitted). If the moving party satisfies this burden, the nonmoving party "may not rest upon its ... pleadings, but rather must set forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren,* 578 F.3d 351, 374 (6th Cir.2009) (citing Rule 56 and *Matsushita,* 475 U.S. at 586, 106 S.Ct. 1348). The party opposing the summary judgment motion must present sufficient probative evidence supporting its claim that disputes over material facts remain; evidence that is "merely colorable" or "not significantly probative" is insufficient. *Anderson,* 477 U.S. at 248–52, 106 S.Ct. 2505.

III. Manufacturing Defect

[1] In their respective briefs addressing the motion for summary judgment, the parties have blurred the lines regarding this claim. There appears to be confusion regarding Ms. Yates's second cause of action. Entitled "STRICT LIABILITY IN TORT–MANUFACTURING DEFECT," Ms. Yates alleges that the Ortho Evra® patch contained a defect in its manufacture and that the defect existed at the time the patch left the possession and control of the Defendants. (Doc. No. 1, p. 22, ¶ 25). However, in her brief opposing Defendants' motion for summary judgment, Ms. Yates argues that the patch was of a defective design. (Doc. No. 94–4, p. 18). A manufacturing defect is not the same as a design defect under New York law, they are two distinct and separate causes of action. *Reed v. Pfizer, Inc.,* 839 F.Supp.2d 571, 577 (E.D.N.Y.2012).

***686** [2] [3] Under New York law, a manufacturing defect claim is based on the relevant product being defective because it was not manufactured as design. *Id.* "A design defect claim, on the other hand, is premised on a manufacturer's failure to properly design a product, which is then placed on the market despite posing inappropriate risks." *Id.*

[4] To establish a manufacturing defect claim, Ms. Yates must show that the Ortho Evra® patch which she used had a defect as compared to other samples of the drug. *Id.* There is no evidence that the Ortho Evra® patches which Ms. Yates received differed from either the manufacturing specifications for that product or from other identical units. Therefore, the Defendants are entitled to summary judgment as a matter of law on this issue.

[5] [6] Regarding Ms. Yates's defective design argument presented in her response brief and during oral argument, the courts of New York have previously ruled the argument preempted by federal law. *Amos v. Biogen Idec Inc.,* 28 F.Supp.3d 164, 168–69 (W.D.N.Y.2014). Under New York law, an action based on an alleged defective design in strict liability or in negligence are "analyzed identically." *Id.* In *Mutual Pharm. Co. v. Bartlett,* —— U.S. ——, 133 S.Ct. 2466, 2477, 186 L.Ed.2d 607 (2013), the Supreme Court held that a state claim alleging a design defect is preempted with respect to FDA-approved drugs sold in interstate commerce. *See also Amos,* 28 F.Supp.3d at 168–69.

Although Ms. Yates' attorneys assert that the preemption is applicable to only generic drugs, the language in *Bartlett* and *Amos* is not so restrictive. The Supreme Court specifically stated that "[o]nce a drug—*whether generic or brand-name*—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.' 21 C.F.R. § 314.70(b)(2)(i)." *Bartlett,* 133 S.Ct. at 2471

(emphasis added). The Court held "that state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id.* at 2479. This language establishes that the Supreme Court did not limit its holding in *Bartlett* to generic drugs, although the drug in question was generic. *Id.* at 2471, 2480; *see also Amos,* 28 F.Supp.3d at 167 (drug in question was not generic).

Ms. Yates's lawyers urge the Court to adopt the decision of *Estate of Cassel v. ALZA Corp.,* No. 12–cv–771–wmc, 2014 WL 856023, 2014 U.S. Dist. LEXIS 27924 (W.D.Wis. Mar. 5, 2014). In *Cassel,* the district court narrowly read the language of *Bartlett,* restricting the Supreme Court's decision to generic drugs. *Cassel,* 2014 WL 856023, at *5, 2014 U.S. Dist. LEXIS 27924, at *13 ("Here, defendants are not subject to any such duty of sameness [which generic drugs must have], since their patches are brand-name, and their own proposed findings of fact demonstrate that fentanyl patches are amenable to various designs.").

Adopting the court's decision in *Cassel* creates two problems. First, it would require this Court to contradict the holding in *Amos,* creating a conflict in the jurisprudence of New York tort law. A federal court in New York has already addressed the issue and has found that New York design defect tort law regarding drugs is preempted by federal law. *Amos,* 28 F.Supp.3d at 168–69. Ms. Yates has failed to convince this Court why it should ignore ***687** *Amos* and create the unnecessary conflict in the law.

Second, *Cassel* ignores the plain and explicit language of *Bartlett.* As this Court has previously noted, *Bartlett* specifically recognized that "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes" without seeking approval from the FDA. *Bartlett,* 133 S.Ct. at 2471 (citing 21 C.F.R. § 314.70(b)(2)(i)). Further, the Court's holding in *Bartlett* is not limited to generic drugs. *Id.* at 2479. *Amos* is consistent with the Supreme Court's analysis in *Bartlett, Cassel* is not. Therefore, the Court declines to adopt the district court's analysis in *Cassel.*

Ms. Yates argues that *Wyeth v. Levine,* 555 U.S. 555, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009), undermines the Defendants' position. (Doc. No. 114, pp. 8–10). However, *Wyeth,* as Ms. Yates admits, addresses federal preemption concerning labeling responsibilities. *Wyeth,* 555 U.S. at 565–68, 129 S.Ct. 1187. The Court stated:

> Wyeth first argues that Levine's state-law claims are pre-empted because it is impossible for it to comply with both the state-law duties underlying those claims and its federal labeling duties. *See* [*Fidelity Fed. Sav. & Loan Assn. v.*] *de la Cuesta,* 458 U.S. [141], at 153, 102 S.Ct. 3014 [73 L.Ed.2d 664 (1982)]. The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label. *See* 21 U.S.C. § 355; 21 CFR § 314.105(b) (2008). Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. §§ 314.70(c)(6)(iii)(A), (C).

Id. at 568, 129 S.Ct. 1187.

The Court concluded:

> In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case.

Id. at 581, 129 S.Ct. 1187.

The issue in question does not concern the adequacy of Ortho Evra®'s labeling. This is a design defect issue. The

Court's discussion and holding in *Wyeth* concerning labeling simply does not apply to Ms. Yates's design defect claim.

Ms. Yates also cites the Supreme Court's decision in *PLIVA, Inc. v. Mensing,* —— U.S. ——, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011), to support her position. *PLIVA* addresses the preemption of state law claims regarding a drug manufacturer's alleged failure to provide adequate warning labels for a generic drug. *PLIVA,* 131 S.Ct. at 2572. *PLIVA,* like *Wyeth,* addresses the issue of labeling, not design defects.

***688** There is no dispute that the Ortho Evra® patch was approved by the FDA. Therefore, under *Bartlett* and *Amos,* the Defendants are entitled to summary judgment as a matter of law regarding any argument that the Ortho Evra® patch had a design defect. *Amos,* 28 F.Supp.3d at 168–69.

IV. Negligence

[7] Ms. Yates alleges that the Defendants "negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, researched, distributed, marketed, labeled, packaged, prepared for use and sold ORTHO EVRA® and failed to adequately test and warn of the risks and dangers of ORTHO EVRA®." The Defendants are also entitled to summary judgment as a matter of law regarding Ms. Yates's negligence claim. The courts of New York have held that state law claims of negligence, negligence per se, and breach of implied warranty are pre-empted when the article in question is regulated by federal law. *Mitaro v. Medtronic, Inc.,* 73 A.D.3d 1142, 900 N.Y.S.2d 899, 899 (2010). Therefore, the Defendants are entitled to summary judgment on this claim.

V. Breach of Implied Warranty

[8] Ms. Yates's breach of implied warranty claim, like her negligence claim, is deemed to be pre-empted by federal law. *Id.* Therefore, the Defendants are entitled to summary judgment on this claim.

VI. Breach of Express Warranty

[9] A prima facie claim for breach of express warranty requires the plaintiff to "show that there was an 'affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase' and that the warranty was relied upon to the plaintiff's detriment." *Tyler v. Kawaguchi, Inc.,* No. 00 Civ. 6366, 2006 WL 581184, at *5 (W.D.N.Y. Mar. 8, 2006) (quoting *Friedman v. Medtronic, Inc.,* 42 A.D.2d 185, 345 N.Y.S.2d 637, 643 (1973)).

[10] Ms. Yates first received counseling concerning different birth control options, including the Ortho Evra® patch, on November 3, 2004. Before then, Ms. Yates was unaware of the Ortho Evra® patch either from advertisements or from personal contacts. Ms. Yates admittedly had never heard of the Ortho Evra® patch until she met with OB/GYN Associates of Western New York in November 2004.

Ms. Yates was counseled at OB/GYN Associates concerning the options, risks, and benefits of the various birth control products on the market. Office notes establish that Ms. Yates was informed of the risks, benefits, and side effects of various contraceptive options. Ms. Yates concedes she was counseled concerning the risk of a stroke and clotting associated with the Ortho Evra® patch.

Ms. Yates failed to perform any research regarding the Ortho Evra® patch because she trusted the medical advice she was given. Ms. Yates admitted in her deposition that she would still have used the Ortho Evra® patch if she had read the warning in the Detailed Patient Labeling, including the warnings about the risk of stroke.

New York law specifically requires that to establish an express breach of warranty claim, Ms. Yates must "show that there was an affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase and that the warranty was relied upon to the plaintiff's detriment." *Tyler,* 2006 WL 581184, at *5 (internal quotation marks and citation omitted); *see also Nealy v. U.S. Surgical Corp.,* 587 F.Supp.2d 579, 584 (S.D.N.Y.2008). The record establishes ***689** that Ms. Yates never received an affirmation of fact or promise from the Defendants, nor did she ever receive an

expressed factual representation from the Defendants which induced her to use the Ortho Evra® patch. Therefore, the Defendants are entitled to summary judgment regarding Ms. Yates's breach of express warranty claim.

VII. Expert Witness

The parties have extensively discussed Dr. Suzanne Parisian, an expert witness for Ms. Yates, in their briefs and during oral argument. The parties dispute Dr. Parisian's qualifications as an expert, with Defendants citing numerous cases from around the country where she has been prevented from expressing her opinions. (Doc. No. 95, p. 5 n. 4). Ms. Yates noted during oral argument that the Defendants would be free during trial to question Dr. Parisian's positions regarding the safety of the Ortho Evra® patch, allowing the jury to make the decision regarding her credibility as a witness. The Court need not address the question of Dr. Parisian's expertise and the impact of her testimony on this case. The Court has previously found under *Bartlett* and *Amos* that the Defendants are entitled to summary judgment as a matter of law. Accordingly, Dr. Parisian's opinions regarding such things as the safety and formulation of the Ortho Evra® patch do not prevent the grant of summary judgment to the Defendants.

VIII. Motions to Intervene and to File an Amici Curiae Brief

[11] [12] A court ruling on a motion for permissive intervention under Rule 24(b) must consider two factors: (1) whether the proposed intervenor "has a claim or defense that shares with the main action a common question of law or fact"; and (2) "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed.R.Civ.P. 24(b)(1)(B); 24(b)(3); *Vassalle v. Midland Funding LLC,* 708 F.3d 747, 760 (6th Cir.2013). "To intervene permissively, a proposed intervenor must establish that the motion for intervention is timely and alleges at least one common question of law or fact." *United States v. Michigan,* 424 F.3d 438, 445 (6th Cir.2005). If these two requirements have been established, the district court must "balance undue delay and prejudice to the original parties, if any, and any other relevant factors to determine whether, in the court's discretion, intervention should be allowed." *Id.*

The Sixth Circuit has noted that Rule 24(b) provides no standard for timeliness. *FMC Corp. v. Keizer Equip. Co.,* 433 F.2d 654, 656 (6th Cir.1970). The court has explained "that: (1) [w]hether intervention be claimed of right or as permissive, it is at once apparent, from the initial words of both Rule 24(a) and Rule 24(b), that the application must be timely; and (2) we review the district court's conclusion about the timeliness element, under both types of intervention, for abuse of discretion." *Stupak–Thrall v. Glickman,* 226 F.3d 467, 472 (6th Cir.2000) (internal quotation marks and citations omitted). The Sixth Circuit has consistently looked to the circumstances of the case to determine timeliness. *Id.* at 475 ("[t]he absolute measure of time between the filing of the complaint and the motion to intervene is one of the least important circumstances," citing with approval *Sierra Club v. Espy,* 18 F.3d 1202, 1205 (5th Cir.1994) (when measuring timeliness of a motion to intervene, "absolute measures of timeliness should be ignored")). To determine timeliness, the Sixth Circuit reviews five factors:

> (1) the point to which the suit has progressed; (2) the purpose for which intervention is sought; (3) the length of time preceding the application during which the proposed intervenors knew or should ***690** have known of their interest in the case; (4) the prejudice to the original parties due to the proposed intervenors' failure to promptly intervene after they knew or reasonably should have known of their interest in the case; and (5) the existence of unusual circumstances militating against or in favor of intervention.

Jansen v. City of Cincinnati, 904 F.2d 336, 340 (6th Cir.1990) (discussing the factors of timeliness under Rule 24(a)); *see also Michigan Ass'n for Retarded Citizens v. Smith,* 657 F.2d 102, 105 (6th Cir.1981) (applying these timeliness factors to both Rules 24(a) and 24(b)).

This is the final case of the 1,518 cases which constituted this MDL. On April 11, 2014, Defendants moved for summary judge on the remainder of Ms. Yates's claims.

(Doc. No. 90). Ms. Yates did not file her response until July 16, 2014 (Doc. No. 94), and Defendants filed their reply on July 25, 2014. (Doc. No. 95).

On July 29, 2014, the Defendants moved for oral argument, which the Court granted on August 5, 2014. Oral argument was originally set for September 19, 2014, but was rescheduled for October 15, 2014. Ms. Yates was subsequently granted permission to file a sur-reply. (Doc. No. 100).

At 10:09 a.m., on October 15, thirty-nine minutes into the oral argument, the motion to intervene was filed. (Doc. No. 105). The proposed intervenors wished to file a brief opposing the Defendants' arguments concerning preemption and expert qualifications. (Doc. No. 105–1, p. 1). The Court finds that the motion to intervene is untimely.

[13] The intervenors had from July 25, 2014, when the Defendants filed their reply brief, to move to intervene. Rather, they chose to wait until the middle of oral argument on the motion for summary judgment to file their motion to intervene. A reason for the motion to intervene is clear in the proposed amicus brief—the intervenors disagree with the Court's decision in *Booker v. Johnson & Johnson,* 54 F.Supp.3d 868, No. 3:12–oe–40000, 2014 WL 5113305, 2014 U.S. Dist. LEXIS 145442 (N.D.Ohio Oct. 10, 2014), decided five days before oral argument. (Doc. No. 113–1, p. 13) (noting that this Court, among others, "failed to grapple with the actual text of *Bartlett* and *Mensing* ....").

In their proposed amicus brief, the intervenors are highly critical of the *Amos* decision. However, the *Amos* decision, which the Court relies on in this case as it is a New York court decision, was decided on June 25, 2014. *Amos,* 28 F.Supp.3d at 167. The Defendants notified the Court of the *Amos* decision a month later. Thus, the intervenors where on notice as of June 25, 2014, of the *Amos* decision, and should have known no later than July 25, 2014, when the Defendants filed their reply brief that the *Amos* decision existed.

The Court further finds that the parties would suffer prejudice should the intervenors be allowed in this case. The case is fully briefed and ready for final disposition. The parties would be forced to do additional briefing to either support or oppose the intervenor's amici curiae brief. The parties would thus incur additional expenses and the Court's final decision would be unnecessarily delayed.

The circumstances also mitigate against intervention. The proposed intervenors lack a substantial legal interest in the case. The intervenors have not been involved in the MDL for several years. They do not represent either of the parties in this remaining MDL case. They have made no attempt to intervene in any of the last few cases involving this MDL litigation. They admittedly seek to intervene because they wish to oppose the Defendants' position regarding the preemption and expert issues, ***691** but the Defendants' arguments pose no legal ramifications for the individual intervenors.

The parties are well represented by their respective counsel and the absence of the intervenors would not impair Ms. Yates's attorneys from protecting her interests, or those arguments asserted by the intervenors. Ms. Yates's attorneys did an excellent job during oral argument presenting her position to the Court, as did Defendants' counsel. The briefs of both parties are clear as to the issues involved. The representation of both parties by their respective attorneys is superior. The Court finds that the proposed intervenors have not established a claim or defense that shares a common question of law or fact with the main action. *Vassalle,* 708 F.3d at 760. The Court further finds that the intervention will unduly delay and prejudice the adjudication of this case to the detriment of the original parties. *Id.* Therefore, the motion to intervene is denied. Because the motion to intervene is denied, the motion to file the proffered amici curiae brief is also denied.

IX. Conclusion

Accordingly, the motion to intervene (Doc. No. 105) and the motion for leave to file an amici curiae brief (Doc. No. 113) are denied. Defendants' motion for summary judgment (Doc. No. 90) is granted.

IT IS SO ORDERED.

All Citations

76 F.Supp.3d 680, 90 Fed.R.Serv.3d 1319, Prod.Liab.Rep. (CCH) P 19,533

Yates v. Ortho-McNeil Pharmaceutical Inc., 76 F.Supp.3d 680 (2015)

90 Fed.R.Serv.3d 1319, Prod.Liab.Rep. (CCH) P 19,533

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