IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

NORTHERN DIVISION

RONALD T. GRANGE, JR., et al., Plaintiffs, vs. MYLAN LABORATORIES, INC., et al., Defendants.	ORDER and MEMORANDUM DECISION Case No. 1:07-CV-107 TC

The underlying basis for this action is the death of Ronald Grange Sr., allegedly as a result of a defective drug patch. The suit was brought by Mr. Grange Sr.'s estate and two of Mr. Grange Sr.'s children, Ronald Grange Jr. and April Grange Holmes (collectively, the "Plaintiffs"). The drug patch was allegedly produced and marketed by Mylan Technologies, Inc. ("Mylan Tech"). Mylan Laboratories, Inc. ("Mylan Labs") is the corporate parent of Mylan Tech and other companies in the business of producing and selling drug products.

Now before the court is Mylan Lab's motion to dismiss based on lack of personal jurisdiction and Mylan Tech's motion to dismiss several of Plaintiffs' claims based on failure to state a claim. In response to Mylan Lab's motion, the Plaintiffs have moved for jurisdictional discovery or, in the alternative, for transfer to West Virginia. In opposing Mylan Tech's motion, the Plaintiffs assert that their claims (except the fraud claim) are all viable as pled.

Because there are controverted facts relevant to whether this court has jurisdiction over Mylan Labs, Plaintiffs' motion to allow discovery into the jurisdictional issue is GRANTED. Turning to Mylan Tech's motion to dismiss, it is GRANTED in part and DENIED in part for the

reasons discussed below.

BACKGROUND

All of the Plaintiffs are residents of Utah. Mylan Labs is incorporated and has its primary place of business in Pennsylvania. Mylan Tech is a West Virginia corporation with its principal place of business in Vermont. Mylan Labs asserts that it does not engage in any business involving drugs, but instead operates solely as a parent company to entities like Mylan Tech which do. Mylan Labs also denies any contacts with Utah.

For the purposes of this motion to dismiss, the court takes as true the Plaintiffs' allegations. According to Plaintiffs, Mylan Tech and Mylan Labs (together, the "Defendants") designed, manufactured, distributed, sold, and placed in the stream of commerce the Fentanyl Transdermal System (the "Fentanyl Patch"). Users of the Fentanyl Patch apply it directly to the skin to deliver fentanyl, a strong pain medicine. Doctors prescribe the Fentanyl Patch to relieve chronic moderate to severe pain. The patch should be worn for seventy-two hours and is supposed to deliver the medicine at a regulated rate. Due to a design and manufacturing defect, some Fentanyl Patches contain and deliver fentanyl in amounts far in excess of what is advertised. Defendants knew that the Fentanyl Patch was defective, but did not warn of the potential risk of overdose. Mr. Grange Sr. died on August 3, 2005, as a result of a fentanyl overdose caused by a defective Fentanyl Patch.

Plaintiffs filed this action on August 3, 2007. Plaintiffs allege eight causes of action against Defendants: (1) negligence; (2) strict product liability; (3) failure to warn; (4) breach of express warranty; (5) breach of implied warranty; (6) breach of implied warranty of merchantability; (7) negligent misrepresentation; (8) fraud and deceit. Plaintiffs allege that both Mylan Labs and Mylan Tech engaged in activities making them liable for damages caused by the

Fentanyl Patch and also seek punitive damages.

On January 18, 2008, the Defendants filed separate motions to dismiss. Mylan Tech also filed an answer at the same time. As mentioned, Mylan Labs asserts that this court lacks personal jurisdiction over it. For its part, Mylan Tech seeks dismissal of the strict liability claim, the claims for breach of express and implied warranties, the fraud claim, and the negligent misrepresentation claim. Mylan Tech also argues that Plaintiffs are barred from seeking punitive damages. For the reasons below, the court finds that more discovery is needed before the court can decide whether it has personal jurisdiction over Mylan Labs. Turning to Mylan Tech's arguments, the court finds that some have merit, while others do not. Accordingly, Mylan Tech's motion is granted in part and denied in part, as will be discussed below.

ANALYSIS

I. Motion to Dismiss Standards

A. Personal Jurisdiction

"To obtain personal jurisdiction over a nonresident defendant in a diversity action, a plaintiff must show that jurisdiction is legitimate under the laws of the forum state and that the exercise of jurisdiction does not offend the due process clause of the Fourteenth Amendment." Soma Medical Int'l v. Standard Chartered Bank, 196 F.3d 1292, 1295 (10th Cir. 1999) (quoting Far West Capital, Inc. v. Towne, 46 F.3d 1071, 1074 (10th Cir.1995)). The plaintiff "bears the burden of establishing personal jurisdiction over the defendant." OMI Holdings, Inc. v. Royal Ins. Co. of Canada, 149 F.3d 1086, 1091 (10th Cir.1998).

Here, Plaintiffs assert that this court has specific jurisdiction over Mylan Tech. To assess whether a court has such jurisdiction, the Tenth Circuit uses a three-part inquiry under Utah Code Ann. § 78B-3-205, the Utah long-arm statute: "(1) whether the defendant's acts or contacts are

described within the parameters of the Utah long-arm statute; (2) whether a 'nexus' exists between the plaintiff's claims and the defendant's acts or contacts; and (3) whether the attainment of personal jurisdiction over the defendant pursuant to the Utah long-arm statute satisfies the requirements of due process." Miner v. Rubin & Fiorella, LLC, 242 F. Supp. 2d 1043, 1045 (D. Utah 2003) (citation omitted). Activities giving rise to jurisdiction under Utah's long arm statute include transacting business in Utah, contracting to supply goods in Utah, and causing injury in Utah, whether by tort of breach of warranty. See Utah Code Ann. § 78B-3-205(1)-(3).

To determine whether personal jurisdiction over a party is appropriate, a court "may, in its discretion, proceed as to the issue of personal jurisdiction on affidavits alone, or it may permit discovery, or it may hold an evidentiary hearing." Nova Mud Corp. v. Fletcher, 648 F. Supp. 1123, 1124 (D. Utah 1986).

B. Failure to State a Claim

In considering a motion to dismiss under the Federal Rules of Civil Procedure 12(b)(6), the plaintiff's "well-pleaded factual allegations" are viewed "in the light most favorable to the plaintiff." Ridge at Red Hawk, LLC v. Schneider, 493 F.3d 1174, 1177 (10th Cir. 2007) (citing Beedle v. Wilson, 422 F.3d 1059, 1063 (10th Cir. 2005)). The question is "whether the complaint contains 'enough facts to state a claim to relief that is plausible on its face.'" Ridge at Red Hawk, 493 F.3d at 1177 (citing Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1969 (2007)).

II. Personal Jurisdiction Over Mylan Labs

Mylan Labs has denied any contacts with Utah that would subject it to personal jurisdiction here. Plaintiffs disagree, arguing that Mylan Labs' pleadings in six lawsuits in other jurisdictions suggest that Mylan Labs has direct involvement with drug products in general, and

the Fentanyl Patch in particular. Most significant are Mylan Labs' answer in an Oklahoma lawsuit where it asserted that it was involved with the fentanyl patch, and Mylan Labs' suit against the Federal Food and Drug Administration (the "FDA") involving approval of the fentanyl patch.

The court finds that Mylan Labs' court filings call into question Mylan Labs' contention that personal jurisdiction could not be found here. If Mylan Labs was sufficiently involved with the Fentanyl Patch that allegedly caused Mr. Grange Sr.'s death, a court in Utah would have personal jurisdiction over Mylan Labs. Accordingly, the Plaintiffs should be given an opportunity to engage in discovery as to whether Mylan Labs has a direct connection to the Fentanyl Patch at issue here. Mylan Lab's motion to dismiss for lack of personal jurisdiction is consequently DENIED without prejudice, and Plaintiffs' motion for jurisdictional discovery is GRANTED.[1]

III. Mylan Tech's Motion to Dismiss

A. Choice of Law

Mylan Tech's motion to dismiss is grounded on Utah law, which Mylan Tech asserts governs all of the claims at issue here. Plaintiffs dispute that Utah law governs all of their claims, arguing that the laws of Utah Vermont, and West Virginia all could be applied here. Due to the differences between these states's laws, resolving the choice of law issue at the outset will simplify matters here.

Utah uses the Restatement's "most significant relationship" approach to resolving the choice of law issue in tort cases. See Waddoups v. Amalgamated Sugar Co., 54 P.3d 1054, 1060

[1]At the hearing on this matter, Plaintiffs and Mylan Labs were instructed to conduct expedited discovery on the issue of whether Mylan Labs may have some responsibility for the Fentanyl Patch at issue here. The court assumes that the parties have followed this instruction.

(Utah 2002) (adopting Restatement (Second) of Conflict of Laws § 145). The factors considered in Utah's choice of law analysis are:

> (a) the place where the injury occurred,
>
> (b) the place where the conduct causing the injury occurred,
>
> (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and
>
> (d) the place where the relationship, if any, between the parties is centered.
>
> Further, "[t]hese contacts are to be evaluated according to their relative importance with respect to the particular issue."

Id. (citing Restatement (Second) Conflict of Laws § 145(2) (1971)).

In this case, the injury occurred in Utah. The conduct allegedly causing the injury, the creation of the Fentanyl Patch, allegedly took place in Vermont. The Plaintiffs are Utah residents, while the Defendants are incorporated and have their principal places of business in Pennsylvania, Vermont, and West Virginia. Mr. Grange Sr. apparently purchased the Fentanyl Patch in Utah, placing his relationship with the Defendants in Utah. The court finds that the quantity and quality of these factors support a finding that Utah bears the most significant relationship to the underlying torts.

While the court did not find any Utah state or federal authority directly on point, the federal district court for the Eastern District of Pennsylvania came to a similar conclusion in a slightly different context in Blain v. Smithkline Beecham Corp., 240 F.R.D. 179, 194 (E.D. Pa. 2007). In Blain, the court considered what state law or laws would apply in a potential nationwide class action based on state law claims relating to a tort suit based on harm done by the drug Paxil. See id. The court noted that Pennsylvania relied on the Restatement's "most significant relationship" test and continued as follows:

> [I]n light of [the Restatement] factors, I now evaluate the contacts and relationship to the issue of liability - the issue implicated by the plaintiffs' proposed common questions. Each putative class member suffered the injury in his or her home state. The tortious conduct took place not only in Pennsylvania but in every state, including each class member's home state, where Paxil was delivered, marketed and taken. Although [defendant] is a Pennsylvania corporation headquartered here, each plaintiff is presumably domiciled in his or her state. The parties' relationship is not centered in Pennsylvania. Most if not all contacts with the class members, such as marketing, prescribing and taking the drug, were in the home states. Thus, the state having the most significant contacts and relationship to the liability issue is each class member's home state.

Id. This reasoning is persuasive here.

Plaintiffs argue that comment (e) to Restatement (Second) Conflict of Laws § 146 ("comment (e)") tips the scales away from applying Utah law on issues where Vermont or West Virginia law allows claims that Utah does not. In particular, comment (e) states that if "the defendant would enjoy a special immunity for his conduct under the local law of the state of injury, it is not clear that the interests of this state would be furthered by application of its rule." Restatement (Second) Conflict of Laws § 146, comment (e).

The court is not persuaded by this argument. To properly analyze the effect of a state's granting immunity, a court must consider the "purpose sought to be achieved by the rule of the tort law involved." Id. Plaintiffs do not substantiate their view of why Utah adopted certain rules. Instead, they offer reasonable surmises. But Defendants offer equally probable reasons for Utah's rules. For example, Utah disallows strict liability for drug design defects. Plaintiffs contend that this rule is meant to encourage Utah companies to design new drugs. Since Defendants are not Utah companies, Plaintiffs conclude that Utah has no interest in enforcing that ban against these out-of-state Defendants. As Defendants point out, however, an equally plausible reason that Utah disallows design defect claims is to encourage drug companies located outside of Utah to make drugs available to patients in Utah. In that scenario, comment (e) does

not undercut applying Utah's immunity. Similar competing considerations apply to Utah's ban on punitive damages for harm caused by FDA-approved drugs. Because the parties offer no basis to determine the purpose of Utah's tort rules, Plaintiffs' comment (e) arguments are ineffective.

In the end, Utah has the most significant contacts to the torts alleged here. Accordingly, the court will apply Utah law to all of Plaintiffs' claims.

B. Strict Liability

Mylan Tech argues that Plaintiffs' strict liability claim is wholly barred under Utah law. Mylan Tech is not entirely correct. In Grundberg v. Upjohn Co., 813 P.2d 89, 99 (Utah 1991), the Utah Supreme Court interpreted comment (k) of the Restatement (Second) of Torts § 402A as eliminating a strict liability cause of action for FDA-approved drugs based on design defects. A strict liability cause of action based on manufacturing flaws and defective warnings, however, survive under Utah law. The Utah Supreme Court made this clear in Schaerrer v. Stewart's Plaza Pharmacy, Inc., 79 P.3d 922 (Utah 2003), when it stated:

> [C]omment k [of the Restatement (Second) of Torts § 402A] does not extinguish strict liability claims based on manufacturing flaws or inadequate warnings. Thus, this court protected manufacturers and sellers of prescription drugs from strict liability design defect claims while clearly assigning them the duty to warn of the risks associated with the use of their products.

Id. at 928 (citations omitted).[2]

Accordingly, to the extent that Plaintiffs base their strict liability claim on allegations of manufacturing flaws and defective warnings (see Compl. ¶ 45), their claim survives. Meanwhile, Plaintiffs' strict liability claim is dismissed to the extent that it is based on an alleged design

[2]The court notes a tension in Utah's allowing strict liability claims for manufacturing and labeling defects when there is no strict liability for design defects. But it is not the court's role to second-guess Utah precedent.

defect.

C. Punitive Damages

Mylan Tech next argues that Plaintiffs' request for punitive damages should be dismissed because a Utah statute, Utah Code Ann. § 78B-8-203, completely bars punitive damages for harm caused by FDA approved drugs. That statute has an exception for cases where a plaintiff can show that a defendant withheld information from the FDA, but Mylan Tech contends that this exception is preempted by federal law. Plaintiffs counter that federal law does not preempt the exception in Utah's statute. As explained below, although Mylan Tech is not entirely correct, Plaintiffs' claim for punitive damages is dismissed.

According to Utah Code Ann. § 78B-8-203(1):

> Punitive damages may not be awarded if a drug causing the claimant's harm:
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> (a) received premarket approval or licensure by the Federal Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301 et seq. or the Public Health Service Act, 42 U.S.C. Section 201 et seq;
>
> (b) is generally recognized as safe and effective under conditions established by the Federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

Utah Code Ann. § 78B-8-203(1). There is a an exception to this rule, however:

> This limitation on liability for punitive damages does not apply if it is shown by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented information required to be submitted to the Federal Food and Drug Administration under its regulations, which information was material and relevant to the claimant's harm.

Utah Code Ann. § 78B-8-203(2). Mylan Tech contends that § 78B-8-203(2)'s exception amounts to a *de facto* "fraud on the FDA" claim, which is preempted by federal law.

In support of its argument, Mylan Tech relies on Buckman Co. v. Plaintiff's Legal Comm'n., 531 U.S. 341, 348 (2000), which held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." The Buckman Court gave

two primary reasons for this holding. First, allowing state law claims of fraud on the FDA would interfere with the FDA's objectives and judgment. See id. at 350-51. Second, such claims could cause the FDA to face a deluge of unnecessary information in the approval process by drug companies attempting to avoid state law liability, jamming up the regulatory system. See id.

The decision in Buckman did not directly reach the issue presented here. In this case, unlike in Buckman, the state statite does not predicate liability on fraud on the FDA, but does allow damages based on such fraud. The Tenth Circuit has not addressed the question of whether this type of statute is preempted, and there is a split of authority between courts that have.

For example, in Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit extended Buckman's logic to a statute similar to Utah's. In Garcia, the court reviewed a Michigan statute that immunized drug companies from damages for harm caused by FDA-approved drugs unless the plaintiff proved that the defendant withheld or misrepresented information from or bribed the FDA during the drug approval process. See id. at 963-64. The Garcia court reasoned that Buckman compelled a ruling that the Michigan statute was impliedly preempted because Buckman's concerns were put squarely in play by the Michigan statute. See id. at 965-66. But the Garcia court did not rule that the exception was completely preempted. See id. at 966-67. Instead, it held that the statute's exception could be applied only in cases where a plaintiff relies on evidence from the FDA to prove fraud or bribery on the FDA. See id. The court explained that "it makes abundant sense to allow a State that chooses to incorporate a federal standard into its law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process." Id. at 966.

On the other hand, in Desiano v. Warner-Lambert & Co., 467 F.3d 85, 97 (2d Cir. 2006),

affirmed *sub nom* Warner-Lambert Co., LLC v. Kent, 128 S.Ct. 1168 (2008), the Second Circuit held that the same Michigan statute was not preempted by Buckman. The Desiano court, in sharp contrast to the Garcia court, found that the concerns cited by the Buckman Court were not directly implicated by the Michigan statute. See Desiano, 467 F.3d at 97. Rather, the Desiano court believed that the Michigan statute based liability directly on traditional state law principles and that Garcia's concerns about federalism and overburdening the FDA in that context were unfounded. See 467 F.3d at 96-98.[3]

The court is mindful of the presumption against finding that a state law is preempted. See e.g., Armijo v. Atchison, Topkea, and Santa Fe Ry. Co., 19 F.3d 547, 549-50 (10th Cir. 1994). That said, the Sixth Circuit's decision in Garcia is more persuasive here. The chief problems that Buckman sought to counteract are present whenever a plaintiff, as a prerequisite to collecting damages, is required to put on evidence that there was what amounts to fraud on the FDA. When such evidence is considered, state courts are essentially second-guessing the FDA and drug companies, nervous about state litigation, will have an incentive to flood the FDA with information. The court accordingly agrees with Garcia, and holds that Utah Code Ann. § 78B-8-203(2) is, in part, preempted.[4] Specifically, to the extent that Utah Code Ann. § 78B-8-203(2)

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[3] Because the Court affirmed Desiano on an equally divided vote, the court does not view the Court's affirmance of Desiano as giving Desiano precedential weight over Garcia. See Martin v. Franklin Capital Corp., 251 F.3d 1284, 1294 n.9 (10th Cir. 2001) ("An unexplained affirmance by an equally divided court is not entitled to any precedential weight.").

[4]Plaintiffs argue that Utah Code Ann. § 78B-8-203(2) is not the same as a "fraud on the FDA" claim of the type found preempted by Buckman and Garcia, because it would not require proof of fraud. But the plain import of § 78B-8-203(2) is that if a plaintiff can prove that a drug company committed fraud against the FDA, that is, show by clear and convincing evidence that the company knowingly withheld material information from the FDA, the plaintiff can collect punitive damages. Despite § 78B-8-203(2)'s limit on the evidence to information required by FDA regulations, the law is not saved the law from preemption. Even with this limitation, a state court will have to interpret what information is required under FDA regulations. Such a review will implicate both the Buckman concerns. That is, at the end of the FDA's approval process,

allows for an exception in cases where a plaintiff puts on his or her own independent evidence of information being withheld from the FDA, this statute is preempted. There is no preemption, however, in a situation where a plaintiff invokes Utah Code Ann. § 78B-8-203(2) to seek punitive damages in cases where the FDA itself has found that there was fraud in the application process.

Accordingly, the court dismisses Plaintiffs' punitive damages request. The face of the complaint makes clear that the Fentanyl Patch is an FDA-approved drug by alleging that it was prescribed by Mr. Grange Sr.'s doctor. (See Compl. ¶ 32.) As a result, Utah Code Ann. § 78B-8-203(1) bars Plaintiffs' request for punitive damages and Plaintiffs have not alleged that the FDA found fraud in the application process, making Utah Code Ann. § 78B-8-203(2) inapplicable.

D. Express and Implied Warranty

Mylan Tech argues that the learned intermediary rule bars Plaintiffs' warranty claims. Under the learned intermediary rule, "manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient." Schaerrer, 79 P.3d at 928. The logic behind this rule is that the doctor is "best situated to weigh the potential risks. . . against the possible benefits of the drug and the unique needs and susceptibilities of each patient" and is "the best conduit for any warnings that are deemed necessary." Id. at 928-929.

Mylan Tech argues that the learned intermediary rule acknowledges that drug companies do not make representations directly to patients, but rather to drug companies. Extending this logic, Mylan Tech maintains that drug companies cannot be held liable for any alleged

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state courts might disagree with the FDA about what was required by FDA regulations. This possibility could lead to a deluge of information to the FDA at the beginning of the process by companies trying to predict how state courts might view FDA regulations.

warranties made to patients. The Plaintiffs disagree. Neither party cited any Utah authority addressing this question, and authorities in other jurisdictions are split on the issue.

When faced with a question of state law that the state courts have not addressed, the court determines how it believes the Utah Supreme Court would resolve it. See Hartford Acc. & Indem. Co. v. U.S. Fidelity and Guar. Co., 962 F.2d 1484, 1487 (10th Cir. 1992). As the court reads Schaerrer, it appears that Utah views the learned intermediary rule as providing a defense to drug companies and pharmacists and not as a bar to warranty claims. See 79 P.3d at 928-29. Utah seems likely to follow the reasoning of the New York state court in Smith v. Johnson & Johnson Co., 800 N.Y.S.2d 357 (Table) (N.Y.Sup. Ct. Nov. 22, 2004), stating that:

> The defendants may not use the "learned intermediary" doctrine as a sword against plaintiff's breach of warranty claims in this action. The role of such doctrine is as a shield against product liability where a drug manufacturer has given an adequate warning of the potential danger of a prescribed drug to a patient's physician. The court has already held that such defense raises issues of fact that must be resolved at trial.

Id. at *6. Accordingly, the court will not dismiss Plaintiffs' breach of warranty claims.

D. Negligent Misrepresentation

Finally, Mylan Tech argues that the Plaintiffs did not plead their fraud and negligent misrepresentation claims with sufficient particularity. Plaintiffs concede that they did not sufficiently plead their claim of fraud and deceit, and agreed to the dismissal that cause of action. Plaintiffs' fraud claim is accordingly DISMISSED.

Plaintiffs dispute that their claim for negligent misrepresentation must be plead with the same level of detail as a fraud claim. Plaintiffs are correct. Rule 9(b) of the Federal Rules of Civil Procedure, requiring that fraud be pled with specificity, does not apply to negligent misrepresentation claims. See Tricontinental Indus. Ltd. v. PriceWaterhouseCoopers, LLP, 475 F.3d 824, 833 (7th Cir. 2007). Instead, such claims are governed by Rule 8(a) of the Federal

Rules of Civil Procedure. A review of the complaint leads to the conclusion that Plaintiffs have put Defendants on notice of their negligent misrepresentation claim.[5]

ORDER

For the reasons stated above, the court ORDERS as follows:

Mylan Labs' Motion to Dismiss (Dkt. No. 5) is DENIED without prejudice;

Mylan Tech's Motion to Dismiss (Dkt. No. 6) is DENIED in part and GRANTED in part, as specified above and

Plaintiffs' Motion for Discovery or to Change Venue (Dkt. No. 29) is GRANTED in part and DENIED in part, as specified above.

SO ORDERED this 30th day of October, 2008.

BY THE COURT

Tena Campbell

TENA CAMPBELL
Chief District Judge

[5]Mylan Tech's argument that the learned intermediary rule bars a negligent misrepresentation claim, raised for the first time in reply, is likewise without merit.