UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION

PATRICIA WASHINGTON, ON BEHALF OF AND AS MOTHER AND NEXT FRIEND OF OLIVIA WASHINGTON, A MINOR — PLAINTIFF

VS. — CIVIL ACTION NO. 3:12cv126-DPJ-FKB

MEDICIS PHARMACEUTICALS CORP., et al. — DEFENDANTS

ORDER

This pharmaceutical-injury case is before the Court on Defendant Medicis Pharmaceuticals Corp.'s Motion to Dismiss [24]. In general terms, Plaintiff asserts a products-liability claim against Medicis, the manufacturer of a brand-name pharmaceutical, although Plaintiff ingested the generic equivalent of Medicis's product. Having fully considered the parties' submissions and the relevant authorities, the Court finds that Mississippi law would not recognize the causes of action alleged against the brand-name manufacturer. Medicis's motion is therefore granted, but Plaintiff is nonetheless afforded one additional opportunity to seek leave to amend.

I. Facts and Procedural History

In summer 2010, Olivia Washington, a minor, was prescribed a generic minocycline-hydrochloride-based drug, manufactured by Teva Pharmaceuticals USA, Inc., to treat her acne. After she began using this generic minocycline, Washington experienced numerous adverse side effects and was hospitalized as a result. Following a lengthy stint of observations, tests, and preliminary diagnoses, Washington's doctors diagnosed her with "Drug Hypersensitivity Syndrome, or alternately Drug Reaction (or Rash) with Eosinophilia and Systemic Symptoms

(DRESS syndrome)." Pl.'s Am. Compl. [11] ¶ 8. Thereafter, the FDA updated the labeling requirements for brand-name minocycline-based drugs, Minocin and Solodyn, to warn of the heightened risk of DRESS syndrome in pediatric patients using minocycline.

On January 20, 2012, Washington, acting through her mother, filed suit against Teva in the Circuit Court of Hinds County, Mississippi, for Teva's alleged failure to warn against the risk of DRESS syndrome from taking its generic minocycline. Teva removed the case to this Court on the basis of diversity jurisdiction and moved to dismiss citing *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), which held that federal law preempts failure-to-warn claims against generic drug manufacturers. Washington opted to voluntarily dismiss Teva but moved to amend her complaint to add new defendants.

Leave was granted, and on June 1, 2012, Washington amended her Complaint adding Medicis (which manufactures Medicis) and Pfizer, Inc., (which manufacturers Minocin).[1] Although Washington ingested the generic equivalent of Solodyn, the amended pleading alleges that Medicis is nonetheless liable for both failure to warn and defective design. Medicis moved to dismiss Washington's claims against it on August 27, 2012, asserting that it cannot be held liable for Washington's injuries because it did not manufacture the drug she ingested. The parties have fully briefed the motion and the Court is prepared to rule.

II. Standard

In considering a motion under Rule 12(b)(6), the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" *Martin K. Eby Constr. Co. v.*

[1]Washington has since voluntarily dismissed her claims against Pfizer. Order [41] Feb. 6, 2013.

Dallas Area Rapid Transit, 369 F.3d 464, 467 (5th Cir. 2004) (quoting *Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir.1999)). To overcome a Rule 12(b)(6) motion, Plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations and footnote omitted). "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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). It follows that "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)). "This standard 'simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *In re S. Scrap Material Co.*, 541 F.3d 584, 587 (5th Cir. 2008) (citing *Twombly*, 550 U.S. at 556).

III. Analysis

In her Amended Complaint, Washington alleges that Medicis is liable because its brand-name minocycline product, Solodyn, was defectively designed or included an insufficient warning. Because jurisdiction is based on diversity of citizenship, the Court applies the substantive law of the State of Mississippi. *Scott v. Dorel Juvenile Grp., Inc.*, 456 F. App'x 450, 452 (5th Cir. 2012). And in Mississippi, the Mississippi Products Liability Act (MPLA) normally provides the starting point for products-liability claims.

Washington brings no such claim, but an understanding of the MPLA is necessary to evaluate the theories she does advance. Under the MPLA, "in any action for damages caused by a product . . . [t]he manufacturer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer or seller" the product was defective in one of four specified ways, including failure to warn and defective design. Miss. Code Ann. § 11-1-63(a). The wrinkle in this case is that Medicis neither manufactured nor sold the generic minocycline-hydrochloride-based drug Washington ingested. As such, it faces no liability under the MPLA. *Lawson v. Honeywell Int'l, Inc*., 75 So. 3d 1024, 1029 (Miss. 2011) (affirming dismissal of MPLA claim because the act does not cover mere designers of a product).

Washington apparently recognizes this obstacle and notes that this is not "a traditional products liability case." Pl.'s Resp. [28] at 1. She claims instead that Medicis "as innovator" of Solodyn—a brand-name minocycline-based medication—breached its duties to customers who later purchased generic forms of Solodyn from other manufacturers or sellers. Pl.'s Am. Compl. [11] at 7. The so-called innovator theory of liability took root in *Conte v. Wyeth, Inc.*, a case decided by one of California's many district courts of appeals. 85 Cal. Rptr. 3d 299, 313, 317–18 (Cal. Ct. App. 2008). In that case, the court held, "[W]e have no difficulty concluding that [the brand-name drug maker] should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic [versions of the drug]." *Id.* at 313.

But as Washington correctly notes, the Mississippi Supreme Court has neither ruled on the innovator theory of liability nor adopted the *Conte* decision. Thus, the Court "must make an '*Erie*-guess', predicting how that court would rule." *Hodges v. Mack Trucks Inc.*, 474 F.3d 188,

199 (5th Cir. 2006) (citing *Centennial Ins. Co. v. Ryder Truck Rental, Inc.*, 149 F.3d 378, 382 (5th Cir. 1998)). Courts consider several factors in making this prediction:

> (1) decisions of the [Mississippi] Supreme Court in analogous cases, (2) the rationales and analyses underlying [Mississippi] Supreme Court decisions on related issues, (3) dicta by the [Mississippi] Supreme Court, (4) lower state court decisions, (5) the general rule on the question, (6) the rulings of courts of other states to which [Mississippi] courts look when formulating substantive law and (7) other available sources, such as treatises and legal commentaries.

Id. (quoting *Centennial Ins. Co.*, 149 F.3d at 382).

Starting with clues from within Mississippi, Washington believes the innovator theory is at least consistent with the Mississippi Supreme Court's decision in *Lawson v. Honeywell International, Inc*. 75 So. 3d 1024. There, the plaintiff was involved in a single-car accident and claimed that her seatbelt failed. *Id.* at 1026. In addition to suing the vehicle's manufacturer, the plaintiff sued Honeywell, claiming that it designed a defective seatbelt and sold the design to the manufacturer. *Id.* After the trial court dismissed the case as preempted by the MPLA, the Mississippi Supreme Court was asked to consider whether the MPLA precluded a common-law negligence claim against Honeywell as the designer of the seatbelt. *Id.* The court concluded that "[b]ecause the statute applies only to manufacturers and sellers, a person or entity other than the manufacturer or seller—who negligently designs a product—may be held liable for common-law negligence or under any other available theory of liability." *Id.* at 1029–30.

Though *Lawson* reversed dismissal of a negligence claim against a product designer, it stopped well short of endorsing innovator liability as adopted in *Conte*. Unlike innovator liability, the designer in *Lawson* allegedly designed a defective part and sold it directly to the manufacturer of the vehicle plaintiff was driving when the accident occurred. Thus, there existed

a direct foreseeable link between the design and the subject product. *Cf. Craig v. Pfizer, Inc.*, No. 3:10-00227, 2010 WL 2649545, at *4 n.3 (W.D. La. May 26, 2010) (noting similar *designer liability* under Texas law does "not extend liability to designers or manufacturers that did not design, manufacture, or sell the specific product that caused the plaintiff's injuries." (citing *Firestone Steel Prods. Co. v. Barajas*, 927 S.W.2d 608, 615–16 (Tex. 1996))). *Conte*, on the other hand, goes much further concluding that the "duty of care in disseminating product information" extends to patients injured by generic drugs manufactured by companies with no connection to the alleged innovator. 85 Cal. Rptr. 3d at 315. *Lawson* appears to be distinguishable.

At least one other federal court has distinguished *Lawson* in this exact context. In *Gardley–Starks v. Pfizer, Inc*., the court rejected products-liability claims against a brand-name pharmaceutical manufacturer when the plaintiff took the generic equivalent. — F. Supp. 2d —, No. 4:10-CV-099-SA-JMV, 2013 WL 139900, at *5 (N.D. Miss. Jan. 10, 2013). There, Judge Sharion Aycock first noted that the "court in *Lawson* was careful to limit its holding to non-manufacturing, non-selling designers of a product" whereas the brand-name defendants both manufactured and sold their products. *Id.* at *4. The court then held that "Mississippi law, consistent with the vast majority of courts to consider this issue, would not recognize a cause of action—however styled—against a brand manufacturer for injuries caused by use of its competitors' generic product." *Id.* at *5. This Court agrees that *Lawson* is distinguishable and that Mississippi has yet to recognize innovator liability.

Because Mississippi has not spoken on this issue, the Court looks to the general rule on the question. *Hodges*, 474 F.3d at 199. And "'[a]bsent evidence to the contrary we presume that

the Mississippi courts would adopt the prevailing rule if called upon to do so.'" *Centennial Ins. Co.*, 149 F.3d at 382 (quoting *Jackson v. Johns-Manville Sales Corp.*, 781 F.2d 394, 398 (5th Cir. 1986) (en banc)). This rule is consistent with the Fifth Circuit's "long[-]followed . . . principle that we will not create 'innovative theories of recovery or defense' under local law, but will rather merely apply it 'as it currently exists.'" *Barfield v. Madison Cnty.*, 212 F.3d 269, 272 (5th Cir. 2000) (quoting *Johnson v. Sawyer*, 47 F.3d 716, 729 (5th Cir. 1995) (en banc)).

Conte's innovator theory is certainly "innovative." The majority rule on this point comes from *Foster v. American Home Products Corp.*, where the Fourth Circuit held under Maryland law that a brand-name drug maker may not be liable on the basis of negligent misrepresentation for injuries caused by a generic drug. 29 F.3d 165, 168 (4th Cir. 1994). *Conte* broke from this rule, and in doing so recognized "that in declining to follow *Foster* we depart from the majority of courts to have wrestled with this particular issue." 85 Cal. Rptr. 3d at 317 (citations omitted). And since that departure, *Conte* has gained little traction. As one court recently noted while rejecting the *Conte* position: "Fifty-five decisions from twenty-two states have rejected arguments similar to those put forward by the plaintiffs. . . . These courts have all concluded that a brand name defendant owes no duty of care to consumers of the generic bioequivalents of its product." *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 856 F. Supp. 2d 904, 912 (E.D. Ky. 2012) (citations omitted) (collecting cases); *see also Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 184 (5th Cir. 2012) ("We do not view *Mensing* as overruling *Foster* . . . ."); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011) ("As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company."). *But see*

Wyeth, Inc. v. Weeks, 2013 WL 135753, at *19 (Ala. Jan. 11, 2013) ("Under Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation . . . , based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company."). Indeed, Medicis cites numerous cases that have either followed the reasoning in *Foster* or rejected the rationale in *Conte*, or both. *See* Def.'s Mem. [25] App. A & B.

The last relevant *Erie* consideration is the decisions of other courts to which Mississippi looks when formulating substantive law. *Hodges*, 474 F.3d at 199. In that regard, Mississippi often looks to federal courts that have interpreted Mississippi law, and as stated, *Gardley–Starks* rejected a nearly identical claim. — F. Supp. 2d —, 2013 WL 139900, at *5. *Gardley–Starks* relies in part on two post-*Lawson* opinions that likewise rejected innovator-liability claims against brand-name manufacturers under Mississippi law. *Id.* at *4–5 (citing *In re Darvocet*, 856 F. Supp. 2d at 906–09; *Lashley v. Pfizer, Inc.*, 877 F. Supp. 2d 466 (S.D. Miss. 2012)). Given these rulings under Mississippi law, the prevailing rule nationally, and the absence of countervailing Mississippi authority, the Court finds that the Mississippi Supreme Court would reject the holding in *Conte*.

Having found that Washington's current claims should be dismissed, the Court must consider the request for leave to amend "to bring the common-law negligence claim based upon defective design as articulated in *Lawson*." Pl.'s Resp. [28] at 8. Although Washington's ability to amend and pursue a claim against Medicis under *Lawson* is not yet apparent, courts should not dismiss cases "without granting leave to amend, unless the defect is simply incurable or the plaintiff has failed to plead with particularity after being afforded repeated opportunities to do

so." *Hart v. Bayer Corp*., 199 F.3d 239, 248 n.6 (5th Cir. 2000) (citation omitted). And although this would be a second amended complaint, it would be the first amendment as to any averments regarding Medicis. Leave will therefore be granted, but Washington is cautioned that the amended complaint may not rely on the innovator theory of liability and must instead aver a theory that *Lawson* would recognize.

IV. Conclusion

With the United States Supreme Court's *Mensing* decision, plaintiffs injured by generic medications are precluded from pursuing failure-to-warn claims against generic manufacturers, yet most states have not adopted innovator liability against brand-name manufacturers. While this may present a potential "catch 22," the Court can see valid policy arguments on both sides of the issue. Regardless, it is not an issue this Court can remedy because it lacks authority to certify the question and is charged with applying the law "as it currently exists." *Barfield*, 212 F.3d at 272 (citation and quotations omitted). Based on that law, the Court follows the other federal district courts that have rejected similar claims and grants Medicis's Motion to Dismiss [24]. Washington is hereby granted leave to file a motion to amend that attaches the proposed amended complaint within 14 days, otherwise the Court will fully dismiss the case at that time. The Court has considered all of the parties' arguments. Those not addressed would not change the result.

SO ORDERED AND ADJUDGED this the 7th day of February, 2013.

s/ *Daniel P. Jordan III*
UNITED STATES DISTRICT JUDGE