In the Missouri Court of Appeals
Eastern District

DIVISION III

HELEN FRANZMAN,	)	No. ED100312
	)	
Appellant,	)	Appeal from the Circuit Court of St. Louis County
	)	
vs.	)	
	)	Honorable Richard C. Bresnahan
WYETH, INC., et al.	)	
	)	
Respondents.	)	FILED: August 26, 2014

Introduction

This appeal presents a poignant scenario raised in numerous lawsuits throughout the country against manufacturers of the prescription drug metoclopramide. Metoclopramide, also sold under the brand name Reglan, is used to treat digestive problems including diabetic gastroparesis and gastroesophageal reflex disorder. Users of metoclopramide have alleged that manufacturers of the drug failed to adequately warn physicians, pharmacists, and consumers of the risks of developing tardive dyskinesia from prolonged use of the drug. Tardive dyskinesia is a movement disorder characterized by involuntary and repetitive movements of the extremities, lip smacking, grimacing, tongue protrusion, rapid eye movements, puckering and pursing of the lips, and impaired movement of the fingers. Persons who ingest metoclopramide for extended

periods of time have an exceptionally elevated risk of developing tardive dyskinesia, which is often irreversible and permanent.

In the matter before us, Appellant Helen Franzman ("Franzman"), a Kentucky resident, pursued a pharmaceutical tort action under Kentucky law in Missouri state court. Franzman was diagnosed with tardive dyskinesia following her prolonged use of metoclopramide. Although Franzman ingested only the generic form of the drug, she seeks damages from all parties responsible for disseminating information about the risks associated with long-term use of brand-name Reglan and generic metoclopramide. Franzman generally alleges that the manufacturers and sellers of the generic metoclopramide she ingested (collectively "Generic Defendants")[1] failed to reasonably and adequately warn of the risks and dangers associated with its long-term use. Franzman similarly seeks to hold the manufacturers and sellers of brand-name Reglan (collectively "Brand Defendants")[2] liable for her injuries as a result of their failure to reasonably and adequately warn of the risks and dangers associated with long-term use of metoclopramide. Lastly, Franzman seeks damages for her injuries from First Databank, Inc. ("First Databank"), a company that provided prescription drug information services to pharmacists and physicians and that disseminated information about metoclopramide.[3]

The Generic Defendants filed a motion to dismiss arguing that all of Franzman's claims against them are preempted by the Federal Food, Drug, and Cosmetic Act pursuant to the Supreme Court's decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011). First Databank also moved to dismiss Franzman's claims, arguing that her claims against them were barred by the Kentucky statute of limitations. Finally, the Brand Defendants filed a motion for summary

[1] Watson Laboratories, Inc. and Watson Pharma, Inc. are the manufacturers of generic metoclopramide sued by Franzman in this action.
[2] Wyeth LLC, Wyeth Pharmaceuticals Inc., and Schwarz Pharma Inc. n/k/a UCB Inc. are the manufacturers of brand-name Reglan sued by Franzman in this action.
[3] All defendants will be referred to collectively as "Defendants."

judgment on the ground that Franzman's claims against them lacked the required legal causation because Franzman never ingested brand-name Reglan manufactured by them. The trial court granted all three motions and entered final judgment in the Defendants' favor and against Franzman on all of her claims.

We reverse the trial court's judgment in favor of the Generic Defendants on that portion of Franzman's failure-to-warn claim relating to the Generic Defendants' failure to update their warning labels to reflect the 2004 brand-name label revision, as that claim is not pre-empted under Mensing. We affirm the trial court's judgment in favor of the Generic Defendants in all other respects. We affirm the trial court's grant of summary judgment in favor of the Brand Defendants because under Kentucky product liability law, the Brand Defendants' product was not the legal cause of Franzman's injuries. We reverse the trial court's judgment in favor of First Databank because when Franzman discovered or should have reasonably discovered her injury, so as to trigger the Kentucky statute of limitations, is a question of fact not appropriate for resolution on a motion to dismiss. We remand Franzman's claims against the Generic Defendants and First Databank for further proceedings consistent with this opinion.

Background

I. Statutory and Regulatory Background

Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, prescription drug manufacturers must gain approval from the United States Food and Drug Administration ("FDA") before marketing any drug in interstate commerce. 21 U.S.C. § 355(a). Manufacturers seeking approval to market a new drug must submit a New Drug Application ("NDA"), which must include "full reports of [all clinical] investigations," § 355(b)(1)(A), relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any

source." 21 C.F.R. §§ 314.50(d)(2), 314.50(d)(5)(iv). Importantly, an NDA must include "the labeling proposed to be used for such drug," 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling." 21 C.F.R. § 314.50(d)(5)(viii). The FDA may approve an NDA only if it determines that the drug is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). By approving a drug as safe, the FDA makes a judgment that the drug's "expected therapeutic gain justifies the risk entailed by its use." United States v. Rutherford, 442 U.S. 544, 555 (1979). The NDA process is both lengthy and expensive.

Originally, the same rules and requirements for the approval, marketing and labeling of prescription drugs applied to new, brand-name drugs (referred to as the reference listed drug or "RLD") as well as their generic counterparts. Mensing, 131 S. Ct. at 2574. Because the process of submitting an NDA is onerous, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch–Waxman Act," to "make available more low cost generic drugs by establishing a generic drug approval procedure." Id. at 2583 (citing H.R.Rep. No. 98–857, pt. 1, p. 14 (1984)). The Act provides for an expedited, less costly approval process for generic versions of drugs whose name-brand predecessors have already obtained FDA approval. Once the brand-name manufacturer's patent expires, generic manufacturers are able to enter the market with the benefit of a far more streamlined approval process. "This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." Id. at 2574.

"Under the Hatch–Waxman Act, a generic drug may be approved by an abbreviated new drug application ("ANDA") showing that the drug is equivalent to its RLD and that 'the [safety

and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug.' 21 U.S.C. § 355(j)(2)(A)(v)." In re: Darvocet, Darvon and Propoxyphene Products Liab. Litig., No. 12–5368, 2014 WL 2959271, at *1 (6th Cir. June 27, 2014). Under this approach, the generic drug's design and warning label must identically match that of the brand-name version of the drug in all material respects. As the Supreme Court recently summarized:

> First, the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same "active ingredient" or "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart. 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii). Second, a proposed generic must be "bioequivalent" to an approved brand-name drug. § 355(j)(2)(A)(iv). That is, it must have the same "rate and extent of absorption" as the brand-name drug. § 355(j)(8)(B). Third, the generic drug manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug." § 355(j)(2)(A)(v).

Mut. Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466, 2471 (2013).

Once an NDA or ANDA has been approved, the manufacturer is prohibited from making any material changes to the drug's design. 21 C.F.R. § 314.70(b). Further, a generic drug manufacturer is also prohibited from making unilateral changes to the drug's warning label. See § 314.150(b)(10).

Over time and with continued use, new information regarding the risks and benefits of a drug may become available. Both brand-name and generic drug manufacturers are required to monitor and review post-marketing adverse drug experience information from all sources, and comply with FDA post-marketing report requirements. See 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7). If significant new adverse information comes to light, the FDA may withdraw approval of the drug, 21 U.S.C. § 355(e), or advise the manufacturer to remove the product from the market. Bartlett, 133 S. Ct. at 2492. In other situations, new information changing the risk/benefit profile of the drug may be addressed through labeling changes. Id.

The FDA has implemented procedures allowing manufacturers to make changes to a drug's approved labeling or other changes to an approved application. Drug manufacturers may submit either "Prior Approval Supplements," which require FDA approval before the proposed change may be implemented, or "Changes Being Effected" ("CBE") Supplements, under which the proposed labeling change may be implemented before the FDA has acted on the supplemental application. 21 C.F.R. §§ 314.70(b), 314.70(c). While most changes to a drug's approved labeling must be requested through a Prior Approval Supplement, manufacturers may "add or strengthen a contraindication, warning, precaution, or adverse reaction" through a CBE supplement. § 314.70(c)(6)(iii)(A). Notably, these procedures for implementing labeling changes are available only to manufacturers of brand-name drugs.

Although manufacturers of both brand-name and generic drugs are authorized to use the same procedures to supplement their product labels, generic manufacturers are subject to the requirement that their labeling always match that of the RLD. Mensing, 131 S. Ct. at 2575. Generic manufacturers may invoke the CBE process only "to match an updated brand-name label or to follow the FDA's instructions." Id. "As a result, while a brand-name manufacturer is responsible for the accuracy and adequacy of its label, see, e.g., 21 U.S.C. §§ 355(b)(1), (d), a generic manufacturer is responsible for ensuring that its warning label is the same as the brand-name's." In re: Darvocet, 2014 WL 2959271, at *2. These federal regulations "require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'" Mensing, 131 S. Ct. at 2574-75.

II. Regulatory History of Metoclopramide

Metoclopramide was first approved by the FDA in 1980 under the brand name Reglan.[4] Over time, evidence accumulated that long-term use of metoclopramide poses a substantial risk of causing tardive dyskinesia. As a result of this evidence, the warning labels for metoclopramide have been strengthened several times. In 1985, the label was modified to warn that "tardive dyskinesia . . . may develop in patients treated with metoclopramide," and the package insert included with the drug stated that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." Mensing, 131 S. Ct. at 2572 (citing Physician's Desk Reference 1635-36 (41st ed., 1987)). In 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a labeling change to add a bold-face warning that: "**Therapy should not exceed 12 weeks in duration.**" After this change was made to the brand-name label, various generic manufacturers of metoclopramide (including, Franzman alleges, the Generic Defendants) failed to update the warning label on their products to match the new FDA approved warning. The generic manufacturers also failed to communicate any change in the brand-name warning label to any physicians.

In February 2009, the FDA ordered a further revision to the warning label for metoclopramide. This revised warning included a "black-box warning" which is the strongest form of warning the FDA requires. Mensing, 131 S. Ct. at 2573. The black-box warning advised of the serious risk of developing tardive dyskinesia from taking metoclopramide. The black-box warning reads:

[4] Reglan was initially manufactured and sold by the holder of the NDA for metoclopramide. Five years later, when patent exclusivity for metoclopramide expired, other manufacturers began to produce and sell metoclopramide in generic form.

WARNING TARDIVE DYSKINESIA

Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose.

Metoclopramide therapy should be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.

Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare causes where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.

III. Procedural History

In March 2002, Franzman was prescribed a regimen of Reglan/metoclopramide to treat gastroparesis, an intestinal disorder. Pursuant to Kentucky's generic-substitution law, Franzman's pharmacy filled the prescription with generic metoclopramide manufactured by the Generic Defendants.[5] Franzman continued to use metoclopramide until October 2005, when she sought treatment for involuntary movements of her jaw, mouth, and tongue. At that time, Franzman discontinued her use of metoclopramide. In March 2006, Franzman was diagnosed with tardive dyskinesia secondary to Reglan/metoclopramide.

On June 28, 2012, Franzman filed a 12-count amended petition against the Defendants.[6] The counts alleged were as follows:

> Count I: negligence, negligent misrepresentation, and negligent supply of information for the guidance of others against the Brand Defendants;

[5] Kentucky has a generic-substitution law requiring pharmacies to fill prescriptions with a lower-priced, therapeutically equivalent generic drug unless the doctor or purchaser explicitly instructs otherwise. Smith v. Wyeth, 657 F.3d 420,422 (6th Cir. 2011) (citing KRS § 217-822(1) (2010)).

[6] Franzman initially filed this action jointly with several other plaintiffs in the Circuit Court of the City of St. Louis. The court severed the claims, and Franzman's case was eventually transferred to the Circuit Court of St. Louis County. There, pursuant to local practice, the court consolidated Franzman's case with other Reglan/metoclopramide cases for pre-trial matters before the Honorable Richard C. Bresnahan. Due to this consolidation, some of the filings in this case were made on behalf of multiple defendants not individually sued by Franzman. We will only address claims relevant to the six defendants named in Franzman's Second Amended Petition.

Count II: negligence, negligent misrepresentation, and negligent supply of information for the guidance of others against the Generic Defendants;

Count III: breach of warranty against the Generic Defendants;

Count IV: misrepresentation and fraud against the Generic Defendants;

Count V: misrepresentation and fraud against the Brand Defendants;

Count VI: negligence against First Databank;

Count VII: strict product liability against the Generic and Brand Defendants;

Count VIII: violation of the Missouri Merchandising Practices Act and/or Kentucky Consumer Protection Act against all Defendants;

Count IX: joint and several liability against all Defendants;

Count X: breach of warranty against First Databank;

Count XI: punitive damages against all Defendants; and

Count XII: damages against all Defendants.

On July 11, 2012, the Generic Defendants moved to dismiss Franzman's claims against them for lack of jurisdiction or, in the alternative, for failure to state a claim.[7] The Generic Defendants argued that under Mensing, Franzman was precluded from pursuing her claims against them because federal law preempts all state law failure-to-warn claims against generic pharmaceutical manufacturers. The Generic Defendants reasoned that no matter how Franzman characterized her various causes of action, each was substantively based upon the Generic Defendants' failure to warn of the risks associated with long-term use of metoclopramide. Because the Supreme Court declared in Mensing that the FDCA preempts such claims against generic manufacturers of prescription drugs, the Generic Defendants argued Franzman's claims

[7] Whether the trial court had personal jurisdiction over the Generic Defendants is not at issue in this appeal, and thus will not be discussed.

must be dismissed with prejudice. The trial court agreed and dismissed each of Franzman's claims against the Generic Defendants.

On July 24, 2012, First Databank also moved to dismiss Franzman's claims against it alleging, *inter alia*, that Franzman's claims were barred by the Kentucky statute of limitations. The trial court found that under Kentucky law, a one-year and two-year statute of limitations applied to Franzman's separate claims against First Databank. The trial court further found that under Kentucky's discovery rule, the statute of limitations began to run in March 2006, when Franzman was diagnosed with tardive dyskinesia secondary to Reglan/metoclopramide. Because Franzman did not file her initial cause of action against First Databank until February 25, 2010, the trial court concluded that all of Franzman's claims against First Databank were barred by the statute of limitations and granted First Databank's motion to dismiss.

When discovery revealed that Franzman ingested only generic metoclopramide and not brand-name Reglan, the Brand Defendants moved for summary judgment on all of Franzman's claims against them. In their motion filed July 31, 2012, the Brand Defendants maintained that all of Franzman's claims were product liability claims governed by the Kentucky Products Liability Act ("KPLA"),[8] and that under the KPLA, a manufacturer cannot be held liable for harm caused by a product it did not manufacture or sell. Because Franzman conceded she did not ingest any product manufactured or sold by the Brand Defendants, the Brand Defendants asserted they owed Franzman no duty and thus were entitled to judgment as a matter of law. The trial court agreed and granted the Brand Defendants' motion for summary judgment.

Franzman now appeals the judgments of the trial court dismissing her claims against the Generic Defendants and First Databank and entering summary judgment in favor of the Brand Defendants.

[8] It is not disputed that under Missouri's choice of law principles, Kentucky law applies to Franzman's claims.

Points on Appeal

Franzman presents three points on appeal. First, Franzman asserts that the trial court erred in finding that federal law preempts all of her claims against the Generic Defendants and therefore granting the Generic Defendants' motion to dismiss. Franzman posits that preemption does not apply to the numerous claims she has asserted against the Generic Defendants that involve state law duties that do not conflict with federal law, and therefore the trial court erred when it dismissed her case against the Generic Defendants in its entirety. Franzman next challenges the trial court's entry of summary judgment in favor of the Brand Defendants. In this point on appeal, Franzman contends that the trial court erred by characterizing her claims against the Brand Defendants as product liability claims, and consequently finding that her claims fail as a matter of law for lack of legal causation. Franzman insists that Kentucky law allows her to pursue non-product liability theories of negligence and fraud against Brand Defendants and that she is not limited to bringing her claims against the Brand Defendants under the KPLA. In her third point on appeal, Franzman argues the trial court erred in finding that her claim was barred by the statute of limitations and therefore granting First Databank's motion to dismiss. Franzman argues that under Kentucky's discovery rule, her cause of action did not accrue until February 26, 2009, when the FDA issued its black box warning advising of the increased risk of developing tardive dyskinesia with long-term use of metoclopramide. Because she filed her petition within one year of the issuance of the black box warning, Franzman contends her claims were timely filed.

Standards of Review

Our review of a trial court's judgment granting a motion to dismiss is *de novo*. Stein v. Novus Equities Co., 284 S.W.3d 597, 601 (Mo. App. E.D. 2009). A motion to dismiss for failure to state a claim upon which relief can be granted is solely a test of the adequacy of the

plaintiff's petition. Id. "In reviewing the dismissal of a petition for failure to state a claim, including a dismissal due to the bar of a statute of limitations, we assume as true every fact pleaded and construe the allegations favorably to the petitioner." Hamdan v. Bd. of Police Comm'rs for City of St. Louis, 37 S.W.3d 397, 399 (Mo. App. E.D. 2001). We do not attempt to weigh whether the factual allegations are credible or persuasive. Stein, 284 S.W.3d at 601. Instead, the petition is reviewed to determine if the facts alleged meet the elements of a recognized cause of action or one that might be adopted in the case. Id. If the plaintiff's petition sets forth any set of facts which, if proven, would entitle him to relief, then the petition states a claim. Id.

Our review of a grant of summary judgment is essentially *de novo*. ITT Commercial Fin. Corp. v. Mid–America Marine Supply Corp., 854 S.W.2d 371, 376 (Mo. banc 1993). The propriety of summary judgment is purely an issue of law, and the criteria for testing it on appeal are no different from those employed by the trial court in its initial determination to grant summary judgment. Id. We will affirm a grant of summary judgment if there are no genuine disputes of material fact and the movant is entitled to judgment as a matter of law. Id. at 378. We review the record in the light most favorable to the party against whom judgment was entered. Id. at 376.

Discussion

I. The Generic Defendants' Motion to Dismiss

Franzman's first point on appeal highlights certain challenges presented by the current federal regulation of prescription drugs. Under the existing regulatory scheme, consumers who seek redress for injuries caused by inadequate warnings on generic prescription drugs face an almost insurmountable barrier to relief. To fully understand the challenges of failure-to-warn claims brought by consumers of generic prescription drugs, we deem it beneficial to briefly

review the framework of federal preemption as impacted by recent United States Supreme Court cases.

A. Wyeth v. Levine and PLIVA v. Mensing

In two recent decisions, the United States Supreme Court has cut clear but differing paths to the preemption of state law failure-to-warn claims by federal prescription drug labeling regulations. In Wyeth v. Levine, 555 U.S. 555 (2008), the Supreme Court held that failure-to-warn claims against manufacturers of brand-name prescription drugs premised upon state law are not preempted by federal law. There, the Court found that brand-name manufacturers of prescription drugs could comply consistently with both their state law and federal law duties to strengthen warnings when they learned of new risks associated with their products. Specifically, the Court found that the FDCA and its accompanying regulations permitted a brand-name drug manufacturer like Wyeth "to unilaterally strengthen its warning" without prior FDA approval. Id. at 573. Accordingly, the federal regulations applicable to Wyeth allowed the company to independently strengthen its label, thereby allowing it to comply with its state tort duty without violating federal law. Id. Because it was "not impossible for Wyeth to comply with its state and federal law obligations" the Court concluded that the plaintiff's state law claims were not preempted by federal law. Id. at 581.

In contrast to its decision in Wyeth, the Supreme Court in PLIVA v. Mensing, 131 S. Ct. 2567 (2011), held that state law failure-to-warn claims against manufacturers of generic prescription drugs are preempted by federal drug regulations. Like Franzman, the plaintiffs in Mensing sought to hold generic manufacturers of metoclopramide liable under state tort law for failing to provide adequate warning labels advising of the risk of developing tardive dyskinesia following long-term use of metoclopramide. The generic manufacturers reasoned that the FDCA and its accompanying regulations preempted any state tort claims based upon a manufacturer's

failure-to-warn because federal law required the same safety and efficacy labeling for generic metoclopramide that was used at the time for brand-name Reglan.

The Supreme Court began its discussion by observing that a preemption analysis requires a comparison of federal and state law. Accordingly, the Court identified the state tort duties allegedly breached by the generic manufacturers and the federal labeling requirements applicable to the generic manufacturers. The Court noted that the Louisiana and Minnesota tort laws at issue "require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe." Mensing, 131 S. Ct. at 2573. Importantly, the parties agreed that satisfying these state law duties would require the generic manufacturers to use a different, safer label than the label they had actually used. Id. at 2574.

The Court then turned to the labeling requirements imposed upon the generic manufacturers by federal law. As explained above, the FDA imposes different drug-labeling duties upon generic drug manufacturers and brand-name manufacturers. While "[a] brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label . . . [a] manufacturer seeking generic drug approval . . . is responsible for ensuring that its warning label is the same as the brand name's." Id. at 2574. The Court summarized the generic drug manufacturers' duty as "an ongoing federal duty of 'sameness.'" Id. at 2575.

Having identified and compared the relevant state and federal law duties, the Court then addressed the question of preemption. The Supremacy Clause of the United States Constitution establishes that federal law "shall be the supreme Law of the Land. . . . . anything in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl.2. Thus, "[w]here state and federal law directly conflict, state law must give way." Mensing, 131 S.Ct. at 2577. The Supreme Court explained that for the purposes of preemption, state and

federal law conflict where it is "impossible for a private party to comply with both state and federal requirements." Id. Applying this test, the Court found the plaintiffs' claims preempted:

> We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. . . . If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking Mensing and Demahy's allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. See, e.g., 21 CFR § 314.150(b)(10). Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

Id. at 2577-78.

In so holding, the Court made clear that the generic drug manufacturers' ongoing federal duty of "sameness" severely limits the remedies available to persons injured by the prolonged use of generic metoclopramide. The ruling has led to "the unfortunate hand that federal drug regulation has dealt" to consumers whose pharmacies filled their prescriptions with generic metoclopramide instead of Reglan. Mensing, 131 S. Ct. at 2581.

B. Mensing does not provide blanket immunity to the Generic Defendants

Franzman asserts various individual claims against the Generic Defendants alleging different theories of recovery, including negligence, negligent misrepresentation, negligent supply of information for the guidance of others, misrepresentation, fraud, strict product liability, and breach of warranty. In their motion to dismiss, the Generic Defendants argued that each of Franzman's claims, no matter how titled or characterized, are claims based upon a failure to provide adequate warnings. The Generic Defendants further argued that Mensing left no avenue of relief for plaintiffs seeking damages for failure-to-warn against manufacturers of generic drugs, and, therefore, Franzman's claims cannot survive. Agreeing with the Generic Defendants

that Franzman's claims all "sound in the same failure to warn claims preempted in Mensing," the trial court dismissed Franzman's suit against the Generic Defendants in its entirety.

Franzman rejects the argument that Mensing provides blanket immunity to manufacturers of generic drugs and insists the trial court erred when it failed to perform the impossibility preemption analysis set forth in Mensing to determine whether federal law preempted her individual state law claims. Franzman posits that she pleaded several duties based upon Kentucky state law that the Generic Defendants could have performed without violating federal law. Because at least some of her state law claims are not preempted by federal law, Franzman alleges the trial court erred in dismissing her suit against the Generic Defendants in its entirety.

We agree with the Generic Defendants that, however titled, the core allegation of each claim brought by Franzman against the Generic Defendants is that they failed to adequately warn of the risks associated with long-term use of metoclopramide. Under Kentucky law, all of Franzman's claims are subsumed by the KPLA, which defines a product liability action as "any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, advertising, packaging or labeling of any product." KRS § 411.300. The Kentucky Supreme Court has clearly held that "The [KPLA] applies to all damage claims arising from the use of products, regardless of the legal theory advanced." Monsanto Co. v. Reed, 950 S.W.2d 811, 814 (Ky. 1997). Thus, we treat all of Franzman's claims as product liability claims based upon a theory of failure to adequately warn. However, we reject the Generic Defendants' contention that *all* state law failure-to-warn suits brought against manufacturers of generic drugs may be summarily dismissed without analysis after Mensing. Following the dictates of Mensing, we

consider whether a conflict exists between the relevant state law and federal law requirements to determine if simultaneous compliance by the Generic Defendants is possible or impossible.

Under Kentucky product liability law, drug manufacturers have a duty to adequately warn of the foreseeable risks associated with use of their product. Larkin v. Pfizer, Inc., 153 S.W.3d 758, 764 (Ky. 2004). Kentucky courts have defined an adequate warning as one "sufficient to apprise the general practitioner as well as the 'unusually sophisticated medical man' of the dangerous propensities of the drug."[9] Id. Franzman has alleged, *inter alia*, that the Generic Defendants failed to adequately warn of the dangers of long-term use of metoclopramide by failing to update their label to conform to the Reglan label revision approved by the FDA in 2004. Thus, the warning label on the generic metoclopramide ingested by Franzman did not include the same bold-face language that was featured on the brand-name Reglan label: **"Therapy should not exceed 12 weeks in duration."** While the Generic Defendants were limited with respect to the warnings they could provide by their "federal duty of sameness," Mensing, 131 S. Ct. at 2575, federal law did not prohibit the Generic Defendants from updating their label to conform to the 2004 Reglan label revision. Simply stated, it was not impossible for the Generic Defendants to comply with their duties under Kentucky state law and fulfill their duty under the FDCA and its accompanying regulations by updating their label to conform to the Reglan legal revision of 2004. We therefore conclude that Franzman's state law failure-to-warn claim is not preempted by federal law to the extent her claim is limited to the Generic Defendants' failure to adopt the additional warning language approved in 2004. See Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 584 (6th Cir. 2013) (impossibility preemption inappropriate to preempt state law claim where generic manufacturer could have independently updated its

[9] Pursuant to Kentucky's learned intermediary doctrine, a prescription drug manufacturer's duty is to warn the doctor, rather than the ultimate consumer. However, the manufacturer is directly liable to the patient for a breach of such duty. Id.

labeling to match that of the brand-name manufacturer); see also Huck v. Wyeth, No. 12–0596, 2014 WL 3377071, at *8 (Iowa July 11, 2014) (listing judicial opinions holding that failure-to-warn claims based on failure to update to 2004 Reglan revision are not preempted).

C. Franzman's cause of action is not premised on federal law, but on an independent state duty.

The Generic Defendants further argue that Franzman's suit should be dismissed because there is no state law duty for generic drug manufacturers to conform their labeling to that of the brand-name manufacturer. The Generic Defendants contend that the duty Franzman alleges they breached arises solely under the FDCA, and the FDCA explicitly prohibits private causes of action to enforce its provisions. Citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001), the Generic Defendants maintain that because Franzman's suit is premised on violations of federal law, it is impliedly preempted.

The Sixth Circuit confronted this same issue in Fulgenzi, a Relgan/metoclopramide case addressing facts and arguments nearly identical to those in this case. In Fulgenzi, the court explained that where "the [federal] statute specifically excludes a private cause of action, 21 U.S.C. § 337(a), state tort suits premised on violations of federal law may be impliedly preempted, since they deprive the agency of the ability to use its enforcement authority to achieve a delicate balance of statutory objectives." Fulgenzi, 711 F.3d at 586 (citing Buckman, 531 U.S. at 348). In contrast however, "[w]here the claim is based on traditional state-tort-law principles, the lack of a private cause of action within a federal regulatory scheme will not preempt the claim for damages. . . . But if the claims 'exist solely by virtue of' the regulatory scheme, they are preempted." Id. (citing Buckman, 531 U.S. at 353). The court then concluded that the plaintiff's claims were not impliedly preempted as they were not premised on federal law, but rather on an independent state duty: "The alleged breach arises from the same act, but

the legal basis is different. . . . Failure to update from one adequate warning to another would violate the FDCA, but not Ohio law. Her suit instead relies upon the adequacy of the warnings and the causation of her injuries." Id. at 586-87.

As in Fulgenzi, here, Franzman's claims are not premised on federal law. Franzman's claims do not exist solely by virtue of the federal regulatory scheme, but stem from an independent state law duty. Kentucky law requires manufacturers to adequately warn of the foreseeable risks associated with their product. Larkin, 153 S.W.3d at 764. This duty exists independent and separate of any duty imposed on the Generic Defendants by the FDCA. Franzman alleges that the Generic Defendants breached their state law duty by failing to update their warning labels to match the 2004 brand-name Reglan revision. While the Generic Defendants' failure to update their labels may also constitute a violation of federal law, the legal basis for Franzman's claim is Kentucky product liability law, not federal law. Accordingly, we hold that Franzman's claim is not impliedly preempted under Buckman. See Fulgenzi, 711 F.3d at 587; Neeley v. Wolters Kluwer Health, Inc., No. 4:11-CV-325 JAR, 2013 WL 3929059, at *9 (E.D. Mo. July 29, 2013); Huck v. Wyeth, Inc., No. 12-0596, 2014 WL 337707, at *11-12 (Iowa July 11, 2014).

While we recognize that the Supreme Court's holding in Mensing will necessarily preclude many state law failure-to-warn claims against manufacturers of generic drugs, Mensing does not offer blanket immunity to the generic drug market. For this reason, it is incumbent upon courts to perform a thorough preemption analysis when generic drug manufacturers raise preemption as an affirmative defense. We are careful to caution that any claims by Franzman that the Generic Defendants should have included stronger warning labels other than those approved for use on brand-name Reglan are clearly preempted by federal law. Mensing, 131 S. Ct. at 2577-78. Therefore, Franzman is limited to arguing that the Generic Defendants' label

was inadequate to the extent that it did not include the language contained in the updated 2004 brand-name Reglan label.[10] See Fulgenzi, 711 F.3d at 584.

We reverse the trial court's judgment dismissing Franzman's failure-to-warn claim only to the extent that such claim is based on the Generic Defendants' failure to include the additional warning language approved in 2004 Reglan label revision. We affirm the trial court's judgment relating to the Generic Defendants in other respects, and remand for further proceedings consistent with this opinion. Point One is granted.

II. The Brand Defendants' Motion for Summary Judgment

Franzman next challenges the trial court's entry of summary judgment in favor of the Brand Defendants. The trial court found that Franzman's claims against the Brand Defendants, though premised upon negligence, negligent misrepresentation, and negligent supply of information, were subsumed within the KPLA, KRS §§ 411.300-411.350. Relying on the Sixth Circuit's reasoning in Smith v. Wyeth, 657 F.3d 420 (6th Cir. 2011), the trial court "regrettably" concluded that Franzman's product liability claims must fail because Franzman ingested only generic metoclopramide, and Kentucky product liability law requires that Franzman prove the Brand Defendants' product was the legal cause of her injury. We also conclude that because Franzman's claims against the Brand Defendants fall within the broad scope of the KPLA, her claims fail as a matter of law. Accordingly, we affirm the entry of summary judgment.

The definition of a product liability action is found in Section 411.300(1) of the KPLA, which states: "a 'product liability action' shall include ***any action*** brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly,

[10] On appeal, Franzman also alleges that the Generic Defendants violated Kentucky's misbranding statute. We do not find this claim in her Second Amended Petition and therefore do not consider it now.

testing, listing, certifying, ***warning, instructing, marketing, advertising,*** packaging or labeling of any product." KRS § 411.300 (emphasis added). The Kentucky Supreme Court has clearly held that "The [KPLA] applies to all damage claims arising from the use of products, regardless of the legal theory advanced." Monsanto Co., 950 S.W.2d at 814 (Ky. 1997).

To succeed on a product liability claim under Kentucky law, a plaintiff must show that the defendant's product is the legal cause of her injuries. Holbrook v. Rose, 458 S.W.2d 155, 157 (Ky. 1970) ("Proof of legal causation is required in cases involving liability for products including drugs . . . legal causation may be established by a quantum of circumstantial evidence from which a jury may reasonably infer that the product was a legal cause of the harm."). Whether the product liability claim is brought on a theory of negligence or strict liability, the plaintiff must establish that the product was the factual and legal cause of the harm. C & S Fuel, Inc. v. Clark Equip. Co., 524 F. Supp. 949, 954 (E.D. Ky. 1981).

Despite the broad statutory definition of "a product liability action," Franzman argues that her negligence, misrepresentation, and fraud claims against the Brand Defendants need not be characterized as product liability claims. Citing Monsanto, Franzman asserts that the KPLA merely codified common law principles and was not intended to supplant or otherwise eliminate the remedies available to her at common law. Franzman argues that the KPLA addresses only the liability of manufacturers and sellers, and she does not seek to hold the Brand Defendants responsible as manufacturers or sellers of a product. Rather, Franzman premises her claims of negligence on the Brand Defendants' duty to warn Franzman about the dangers of generic metoclopramide, irrespective of any duties owed by the actual manufacturers and sellers of the product ingested by her. Franzman posits that because her causes of action fall outside the scope of the KPLA, the fact that she ingested only generic metoclopramide is not fatal to her claims.

In Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011), the Sixth Circuit addressed a nearly identical action brought by three individuals who, like Franzman, developed tardive dyskinesia as a result of their use of generic metoclopramide. Like Franzman, the plaintiffs in Smith argued that their claims against manufacturers of brand-name Reglan need not be characterized as product liability claims and instead may be pursued as they were pleaded – as common law negligence, misrepresentation, and fraud claims. Applying Kentucky law, the Sixth Circuit held that the KPLA applied to all of the plaintiffs' claims, regardless of how they were pleaded. Id. at 423 (quoting Monsanto, 950 S.W.2d at 814) ("'[t]he [KPLA] applies to all damage claims arising from the use of products, regardless of the legal theory advanced."). The Sixth Circuit then concluded that the plaintiffs' claims did not "satisfy the threshold requirement of a products-liability action—that the defendant's product ha[s] injured the plaintiff." Id. (citing Holbrook, 458 S.W.2d at 157). Accordingly, the plaintiffs' claims were dismissed.

While the Smith decision does not bind this Court, we have found no cases to suggest the Sixth Circuit misapplied Kentucky law or that the Kentucky Supreme Court would reach a contrary result. Like the plaintiffs in Smith, Franzman seeks to recover damages for injuries suffered as a result of the Brand Defendants' warning, marketing, and labeling of the product Reglan. The definition of a product liability action under the KPLA specifically includes actions brought on account of personal injury resulting from the "warning, instructing, marketing, advertising**,** packaging or labeling of any product." KRS § 411.300. Thus, Franzman's claims fall squarely within the definition of a product liability action.[11] Further, as noted by the Sixth

[11] Were the language of the KPLA not so broad, Franzman's argument may fare better. See Dolin v. SmithKline Beecham Corp., No. 12 C 6403, 2014 WL 804458, at *4 (N.D. Ill. Feb. 28, 2014) (noting that while some states statutorily define what constitutes a product liability claim, Illinois has not, and nothing in Illinois common law compelled the court to construe the plaintiff's common law negligence claims as product liability claims). However, the KPLA broadly defines a product liability action as any action brought on account of injury caused by a product, including the warning and marketing of a product, and, therefore, clearly encompasses Franzman's claims. See also

Circuit, the KPLA applies to all damage claims arising from the use of products, regardless of the legal theory advanced. Monsanto, 950 S.W.2d at 814. Given this admonition by the Kentucky Supreme Court, we are not persuaded that a Kentucky court would find these claims to fall outside of the KLPA. Thus, regardless of whether Franzman's claims were pleaded as negligence, misrepresentation, or fraud, the KPLA applies.

In every product liability case, Kentucky law requires a plaintiff to show that the defendant's product is the legal cause of the injury. Holbrook, 458 S.W.2d at 157. Because Franzman admits that she ingested only generic metoclopramide, she cannot prove the Brand Defendants' product is the legal cause of her injury. Accordingly, Franzman's claims fail as a matter of Kentucky law.

We acknowledge those few judicial opinions holding that a consumer of a generic drug may seek damages from the manufacturer of the corresponding brand–name drug under a simple common law theory of negligence. [12] However, Kentucky law dictates a different result. We have examined thoroughly the arguments both for and against what has become characterized an "innovator liability." Deciding the issue of innovator liability is important given the potentially ruinous consequences for consumers of generic prescription drugs who find themselves already cut adrift in a sea of hopelessness by our constitutional mandate to preempt their state tort claims against the generic manufacturers due to the current federal regulation of prescription drugs. We acknowledge the inherent unfairness of our tandem rulings first substantially preempting a consumer's tort claims against the generic manufacturer, and next concluding that the same

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Bell v. Pfizer, Inc., 716 F3d 1087, 1092-1093 (8th Cir. 2013) similarly applying the Arkansas Products Liability Act.

[12] See Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010); Dolin, 2014 WL 804458.; Wyeth, Inc. v. Weeks, No. 1101397, 2013 WL 135753 (Ala. Jan. 11, 2013), *reh'g granted*, (June 13, 2013); Conte v. Wyeth, Inc., 168 Cal. App. 4th 89 (2008); See also Victor A. Schwartz, et al., Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects, 81 Fordham L. Rev. 1835 (2013); Martin A. Ramey, Conte v. Wyeth: Caveat Innovator and the Case for Perpetual Liability in Drug Labeling, 4 Pitt. J. Envtl Pub. Health L. 73 (2010)

consumer's tort claims are also barred against the brand-name manufacturer responsible for the product design, formula, dosage, labeling and warning that are at the core of the consumer's claims. We are not alone in recognizing how these companion rulings adversely impact consumers of generic prescription drugs. See, e.g., Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378, 407 (6th Cir. 2013) (noting the inherent unfairness in this "Catch 22" situation when applying the Tennessee Products Liability Act). However, we regrettably find ourselves perpetuating this unjust result due to the breadth of the KPLA we are bound to uphold.

The trial court properly entered summary judgment in favor of the Brand Defendants. Point Two is denied.

III. First Databank's Motion to Dismiss

Franzman's third point on appeal addresses the trial court's application of the statute of limitations. Missouri considers statute of limitations issues procedural, and therefore governed by Missouri law. Wright v. Campbell, 277 S.W.3d 771, 773 (Mo. App. W.D. 2009). However, when a cause of action originates in another state, the foreign state's statute of limitations applies through Missouri's borrowing statute, Section 516.190. Alvarado v. H & R Block, Inc., 24 S.W.3d 236, 241-42 (Mo. App. W.D. 2000). Section 516.190 provides that "[w]henever a cause of action has been fully barred by the laws of the state . . . in which it originated, said bar shall be a complete defense to any action thereon, brought in any of the courts of this state." Thus, if the statute of limitations of the foreign state bars the action, then Missouri's borrowing statute also bars the action.

Because Franzman's claim originated in Kentucky, we apply Kentucky's statute of limitations. In her petition, Franzman asserts separate claims of common law negligence and violations of the Kentucky Consumer Protection Act ("KCPA") against First Databank. Negligence actions in Kentucky are governed by KRS 413.140(1(a)), which provides for a one-

year statute of limitations. The KCPA has a two-year statute of limitations pursuant to KRS 367.220(5).

Kentucky courts hold that an action may not accrue until a plaintiff has knowledge of sufficient facts to state a cause of action. Hazel v. Gen. Motors Corp., 863 F. Supp. 435, 438 (W.D. Ky. 1994). When the injury to a party is not readily ascertainable or discoverable, the discovery rule provides a method of identifying when the statute begins to run. Under this rule, "a cause of action will not accrue until the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, not only that [she] has been injured but also that [her] injury may have been caused by the defendant's conduct." Id. Thus, to trigger the statute of limitations, the plaintiff must have knowledge: (1) that she has been wronged, and (2) by whom the wrong has been committed. Wiseman v. Alliant Hosps., Inc., 37 S.W.3d 709, 712 (Ky. 2000).

When applying the discovery rule, Kentucky courts draw a distinction between the discovery of harm and the discovery of injury. In Wiseman, the Kentucky Supreme Court explained that harm is "the existence of loss or detriment in fact of any kind to a person resulting from any cause," whereas injury is "the invasion of any legally protected interest of another." Id. (quoting the Restatement (Second) of Torts § 7, comment (1965)). Under the discovery rule, the date of actual or constructive knowledge of the injury triggers the running of the statute of limitations. Id. Thus, "the statute of limitations does not begin to run even though a harmful condition is known to a plaintiff so long as its negligent cause and its deleterious effect are not discovered." Id.

Here, Franzman alleged that she was diagnosed with tardive dyskinesia secondary to Reglan/metoclopramide in March 2006. Based upon this allegation, the trial court concluded that her cause of action accrued in March 2006 because at that time she "knew she had been

injured, and by whom it may have been caused." Franzman argues that the date of her tardive dyskinesia diagnosis is not determinative of when her injury accrued because that date represents only when Franzman discovered the harm – tardive dyskinesia. Franzman posits that she did not discover her injury until she learned that her tardive dyskinesia was caused by long-term use of metoclopramide. Only then could she have known that she was wronged by First Databank's failure to adequately warn of the risks of long-term use of metoclopramide. Franzman avers that she had no knowledge her tardive dyskinesia resulted from long-term use of metoclopramide until February 2009, when the FDA issued its black box warning. Because she filed her petition on February 25, 2010, within one year of the black box warning, Franzman insists her claim was timely filed.

First Databank contends that Franzman's claim accrued the moment she knew (1) that she was injured by metoclopramide, and (2) that the information she received from her pharmacy about metoclopramide was published by First Databank. Because Franzman either knew or should have known these facts by March 2006 when she was diagnosed with tardive dyskinesia secondary to Reglan/metoclopramide, First Databank argues that the trial court properly found her cause of action accrued in March 2006. Alternatively, First Databank claims that even if it were necessary for Franzman to know that *long-term use* of metoclopramide caused her injury, Franzman could have discovered the link between tardive dyskinesia and long-term use of metoclopramide long before the black box warning. In support of its argument, First Databank points to allegations in Franzman's petition that decades of studies dating back to at least 1993 showed that long-term use of Reglan/metoclopramide can cause tardive dyskinesia. First Databank further asserts that numerous cases relying on the same allegations made by Franzman have been on file since at least 2002.

We agree with Franzman that the date of her tardive dyskinesia diagnosis is not determinative of when her cause of action accrued. Under Wiseman, a cause of action accrues when the plaintiff discovers her legal injury - the invasion of a legally protected interest. Id. at 713. Here, the legally protected interest Franzman asserts is her right to have been properly informed of the risks associated with long-term use of metoclopramide. Franzman avers that First Databank failed to adequately warn of the risk of developing tardive dyskinesia from using metoclopramide for longer than 12 weeks. As a result, Franzman took the drug for more than 12 weeks and thereafter developed the disorder. While it is clear from the allegations in Franzman's petition that she discovered the harm – tardive dyskinesia – by March 2006, Franzman alleges she did not discover First Databank's wrongful conduct – their failure to adequately warn – until the FDA issued its black box warning on February 26, 2009. Although First Databank urges this Court to find that Franzman should have discovered the allegedly wrongful conduct long before the black box warning, we do not decide when Franzman acquired knowledge of her legal injury as that is a question of fact to be decided by the jury. 3M Co. v. Engle, 328 S.W.3d 184, 189 (Ky. 2010) (citing Lipsteuer v. CSX Transp., Inc., 37 S.W.3d 732, 737 (Ky. 2000)) ("when a plaintiff is put on notice of his injury is a question of fact for the jury."). For now it is sufficient to hold that the trial court erred in finding Franzman's claim barred by the statute of limitations and therefore granting First Databank's motion to dismiss. Franzman is entitled to present evidence to support her claim as to when she acquired the requisite notice of her legal injury. Point Three is granted.

Conclusion

We reverse the trial court's judgment as to Franzman's failure-to-warn claim against the Generic Defendants to the extent the claim is based upon the Generic Defendants' failure to update their warning labels to match the 2004 Reglan label revision. We affirm the trial court's

judgment dismissing Franzman's claims against the Generic Defendants in all other respects. Because Franzman's claims against the Brand Defendants must be brought as product liability actions under the KPLA, we affirm the trial court's dismissal of Franzman's claims against them. Lastly, we reverse the trial court's dismissal of Franzman's claims against First Databank. We remand Franzman's failure-to-warn claim against the Generic Defendants and her claim against First Databank for proceedings consistent with this opinion.

Kurt S. Odenwald, Judge

Mary K. Hoff, P.J., Concurs
Angela T. Quigless J., Concurs