2017-2018

SOUTHERN ILLINOIS UNIVERSITY

NATIONAL HEALTH LAW MOOT COURT COMPETITION

Transcript of Record
Docket No. 17-230

Alice IVERS,
Petitioner,

v.

WESTERLY PHARMACEUTICAL. INC.,
Respondent.

COMPETITION PROBLEM

SPONSORED BY:

Southern Illinois University School of Law

Department of Medical Humanities
Southern Illinois University School of Medicine

The American College of Legal Medicine

The American College of Legal Medicine Foundation

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ILLINOZA

No. 17-450-CV

Alice IVERS, Plaintiff	)	
	)	No. AM-15-450-CV
v.	)	
WESTERLY PHARMACEUTICAL, INC., Defendant.	)	

MEMORANDUM OPINION

ALAN MCBEAL, District Judge

This matter comes before the Court on Defendant's Motion for Judgment on the Pleadings and Motion for an Award of Costs. Plaintiff Alice Ivers is a resident of Cardozo, Illinoza. Defendant Westerly Pharmaceutical, Inc., is a Texas corporation, headquartered in Florham Park, New Jersey. Plaintiff initially filed the instant Complaint against Westerly in the state court of Illinoza on September 15, 2015. Defendant removed the proceeding to this Court on October 14, 2015. The Complaint asserts a products liability claim against Westerly under the Illinoza Products Liability Act and seeks $500,000 in damages.

I. FACTUAL AND PROCEDURAL HISTORY

The following facts, as well-pleaded in the Complaint, are treated as undisputed for purposes of the instant motion.

In February, 2011, Plaintiff was diagnosed with Parkinson's disease. As a course of treatment, Plaintiff's doctor prescribed *ropidope hydrochloride*, a prescription drug, among other interventions. Plaintiff began taking a generic form of ropidope Hcl ("ropidope"), manufactured by Westerly Pharmaceuticals, Inc., daily starting in March, 2011.

Ropidope is a chemical compound that acts as a non-ergoline dopamine agonist and, therefore, inhibits the dopamine hormone reactions associated with the symptoms of Parkinson's. GlaxoCline, LLC initially patented ropidope and received approval from the Federal Food & Drug Administration (FDA) to market it as a new drug in 1997. GlaxoCline sells ropidope under the brand name Equip®. In 2008, GlaxoCline's patent for ropidope expired and Westerly submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to market an equivalent generic version of the drug. The FDA approved Westerly's ANDA, and Westerly began selling its generic version in 2009. As a condition of the FDA's approval, Westerly submitted labeling that mirrored the then-current label for Equip.

In January, 2011, GlaxoCline submitted to the FDA a Supplemental New Drug Application (sNDA) requesting prior approval of proposed changes to its Package Insert and associated labeling. The sNDA requested approval to add a new paragraph under the "Warnings and Precautions" section stating:

> **5.6 Impulse Control/Compulsive Behaviors**
> Reports suggest that patients can experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge or compulsive eating, and/or other intense urges, and the inability to control these urges while taking one or more of the medications, including EQUIP, that increase central dopaminergic tone and that are generally used for the treatment of Parkinson's disease …. In some cases, although not all, these urges were reported to have stopped when the dose was reduced or the medication was discontinued. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while being treated with EQUIP. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking EQUIP.

The FDA approved this change and GlaxoCline implemented it on its Equip labels beginning in June, 2011. In January, 2012, Westerly submitted a Changes Being Effected (CBE)

notification to the FDA notifying the agency that it would be updating its ropidope labels to match the newly-approved label for Equip effective as of February 1, 2012, which it did.

The Complaint alleges that, beginning in July 2011, Plaintiff began to develop compulsive spending and gambling behaviors. Over the course of several months in 2011, Ivers transferred the majority of her retirement savings into an online poker service account. She played online poker almost continuously in her waking hours. From 2011 to 2012, Ivers won substantial sums of money through her online poker habit, but felt compelled to spend it all on charitable gifts and antique auctions. By the end of 2012, she had entirely depleted her retirement savings. The complaint alleges that unwarned side-effects of ropidope proximately caused these behaviors and their attendant damage to her finances and relationships.[1]

Ivers contends that Westerly breached the duty owed to her under Illinoza products liability law, which provides relief "upon showing that a manufacturer's product was unreasonably dangerous due to (a) manufacturing defect, (b) defective design, (c) inadequate instructions or warnings, or (d) failure to conform to an express warranty." Illz. Prod. Liability Act. 1998-4(1). In her Complaint, Plaintiff relies on sections (1)(b) and (c), alleging that ropidope's labels were defectively designed and contained inadequate warnings of these side effects.

Defendant timely removed the action from the state court of Illinoza to this Court, correctly asserting diversity jurisdiction under 28 U.S.C. § 1332 and removal jurisdiction under 28 U.S.C. § 1441. Defendant filed its answer to the complaint and this Motion for Judgment on the Pleadings and a Motion for an Award of Costs on November 2, 2015.

[1] The Complaint alleges, *inter alia*, that after her husband of 35 years discovered that Ivers had depleted their retirement fund in November 2012, he filed for divorce.

II. DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS

Motions for judgment on the pleadings under Rule 12(c) are held to the same standards as motions to dismiss for failure to state a claim under Rule 12(b). *Cleveland v. Caplaw Enters.*, 448 F.3d 518, 521 (2d Cir. 2006). The pleadings must state a claim that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

In addition to the denials of factual matters in its Answer, Defendant raises in its Rule 12(c) motion a legal objection to Plaintiff's claims, namely that federal law preempts Plaintiff's recovery even if all of her facts may be proven. The Supremacy Clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby." U.S. Const. art. VI, cl. 2. Defendant contends that because the duties allegedly imposed by Illinoza state law conflict with federal requirements imposed by the Federal Food, Drug & Cosmetic Act (FDCA), the FDCA renders the Illinoza products liability law without effect and entitles Defendant to a judgment on the pleadings. In support of its preemption argument, Defendant relies on the Supreme Court's recent opinions in *PLIVA v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical v. Bartlett*, 133 S.Ct. 2466 (2013).

Mensing and *Bartlett* illustrate the workings of conflict preemption for generic prescription drugs like the one at issue in this case. For new drugs, the FDCA imposes strict federal requirements for approval as a prerequisite to selling these products to consumers. *See generally* 21 U.S.C. §§ 355-355(g) (2012). After the patent expires on an approved new drug, manufacturers may sell generic versions of it after receiving an "abbreviated" review by the FDA. *Id.* § 355(j). For abbreviated approval, a generic manufacturer must receive FDA certification that its version is equivalent in ingredients, dosage, strength, and labeling to the brand-name drug it copies. *Id.* § 355(j) (2012); 21 C.F.R. § 320.1(c) (2015). A generic drug

manufacturer has no discretion in the contents of its label; it must mirror the brand-name label and it may not make changes unless the brand-name drug does. *PLIVA*, 564 U.S. at 2577.

Because "federal law prevents generic drug manufacturers from changing their labels" independently, the Supreme Court has held that state tort claims premised on failure-to-warn or on design defects in the warning labels are preempted. *See Bartlett*, 133 S.Ct. at 2476. Likewise, the claim in this case, at its core, alleges that the manufacturer of an FDA-approved generic drug negligently failed to warn of side-effects she suffered and that this failure proximately caused her injury. This Court does not see any legal distinction between the claims made by the Plaintiff and those made in *PLIVA* and *Bartlett*. Because Plaintiff alleges that a generic drug manufacturer breached its state-law duty by failing to alter its FDA-mandated warning label, her claim is preempted. *See Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (finding *Mensing* controlling).

III. DEFENDANT'S MOTION FOR AN AWARD OF COSTS

This is not the first time this Plaintiff has filed a Complaint against this Defendant based on these facts. On January 15, 2013, Plaintiff filed a Complaint against Westerly in United States District Court for the Western District of East Texas[2] state court alleging the same facts and legal theories under the East Texas Products Liability Law. On February 14, 2013, the Fifth Circuit issued its opinion in *Morris v. PLIVA, Inc.*, holding that the FDCA preempted a similar failure-to-update claim regarding a different FDA-approved generic drug. *Morris*, 713 F.3d at 778. On February 25, 2013, before Defendant had filed an answer, Plaintiff filed her Notice of Voluntary Dismissal, as provided for in Federal Rule of Civil Procedure 41(a).

Federal Rule of Civil Procedure 41(a)(1)(A) permits a plaintiff voluntarily and unilaterally to dismiss an action without leave of court by filing a notice of dismissal at any time

[2] Eds. note: East Texas is within the Fifth Circuit.

"before the opposing party serves [its] answer or a motion for summary judgment . . . ." Fed. R. Civ. P. 41(a)(1)(i). The first time the plaintiff files a voluntary dismissal notice under this rule, the dismissal is without prejudice. Fed. R. Civ. P. 41(a)(1)(B). If the plaintiff later files "an action based on or including the same claim against the same defendant" in any court, the second court may "order the plaintiff to pay all or part of the costs of that previous action . . . ." Fed. R. Civ. P. 41(d). The plaintiff's second litigation may proceed, but plaintiff must comply with any order to pay costs incurred as a result of the previous litigation and the second court may stay proceedings to ensure compliance.[3] Accordingly, Westerly has filed a Motion for an Award of Costs under Rule 41(d), seeking a total of $4,318.52 it expended in defending the Western District of East Texas action.

Federal Rule of Civil Procedure 41(d) grants broad discretion to district courts in determining whether to award costs incurred by a defendant in response to a duplicative action after a voluntary dismissal. *See, e.g., Simeone v. First Bank Nat'l Ass'n*, 971 F.2d 103, 108 (8th Cir. 1992) (upholding district court's entire award of costs). Rule 41(d) is but one tool in district courts' arsenal of inherent powers to protect defendants from harassing and duplicative litigation.

By its terms, Rule 41(d) does not condition an award of costs on a finding of bad faith or improper motive in plaintiff's dismissal or subsequent refiling, and so plaintiff's good faith or innocent intent in refiling does not bear on the decision whether to award costs. *See Rogers v. Wal-Mart Stores, Inc.*, 230 F.3d 868, 874 (6th Cir. 2000). Nor is a district court required to award costs; the decision is committed soundly to the district court's discretion. *See id.*

Factors which district courts may consider in the exercise of their broad discretion to impose costs include the plaintiff's financial ability to pay the costs and the plaintiff's likelihood

[3] A second 41(a)(1) dismissal of the same claims, however, would be prejudicial. Fed. R. Civ. P. 41(a)(1)(B). Were plaintiff to file a third time, after two 41(a)(1) dismissals, defendant could resist the litigation by asserting claim preclusion.

of success in the second suit, *e.g.*, *Starr v. Hill*, No. 10-2070-STA, 2010 WL 2521378, at *12 (W.D. Tenn. June 16, 2010), as well as whether defendant's work may be useful in the second suit, *see Belkow v. Celotex Corp.*, 722 F. Supp. 1547, 1553 (N.D. Ill. 1989), and any responsibility defendant might bear for the multiplicity of actions, *e.g.*, *Lozano v. Am. Express Travel Related Servs., Inc.*, No. CV 02-0039-HA, 2002 WL 31968994, at *2 (D. Or. Dec. 6, 2002). Those factors weigh in favor of awarding costs in this case, and this Court therefore finds it appropriate to award Defendant's requested costs in defending the original action. Defendant has claimed $876.52 in court filing, copying, delivery, research, and telecommunications costs, itemized in Appendix A to its motion.

Defendant also claims, as itemized in Appendix A to its motion, $3,442 in attorney and paraprofessional hourly fees incurred in preparing the defense to the original filing. Plaintiff further objects to paying Defendant's requested fees on the ground that Rule 41(d) provides only for "costs," which Plaintiff argues naturally excludes attorney's "fees."[4] The Court agrees. The plain language of Rule 41(d) authorizes an award of "costs" and does not expressly include attorney's fees. Thus, Rule 41(d) does not authorize the award of fees Defendant seeks. *Accord Caldwell v. Wells Fargo Bank*, N.A., 2014 WL 789083, at *7 (N.D. Cal. 2014). The Twelfth Circuit has not held otherwise. This Court holds, therefore, that Defendant is not entitled to an award of attorney's fees under this Rule. An appropriate Order follows.

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[4] Plaintiff also alleges the amount sought was not reasonable or necessary, but because the Court finds as a matter of law costs do not include attorney's fees, the Court does not address her specific claims in that regard.

ORDER

For the foregoing reasons, Defendant's Motion for Judgment on the Pleadings is GRANTED; Defendant's Motion for an Award of Costs is GRANTED in part and DENIED in part. The Complaint is DISMISSED and Plaintiff is ORDERED to pay Defendant the sum of $876.52 within 60 days of this Order.

IT IS SO ORDERED.

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Alan McBeal, District Judge
December 20, 2015

IN THE UNITED STATES COURT OF APPEALS
FOR THE TWELFTH CIRCUIT

No. 17-1620

ALICE IVERS, *Appellant/Cross-Appellee,*

v.

WESTERLY PHARMACEUTIAL, INC., *Appellee/Cross-Appellant.*

Appeal from the United States District Court for the District of Illinoza
No. AM-15-450-CV – Alan McBeal, Judge

Argued November 15, 2016 – Decided February 2, 2017

Before: Judy, Barry, Motley, Circuit Judges

BARRY, Circuit Judge:

Appellant/Cross-Appellee Alice Ivers filed this suit against Appellee/Cross-Appellant Westerly Pharmaceutical, Inc. under the products liability law of the state of Illinoza.[5] Her complaint alleged that Westerly breached its duty to her under Illinoza law by marketing a generic pharmaceutical with insufficient warnings, which proximately caused her to suffer injurious side effects not mentioned on the drug's label. The United States District Court for the District of Illinoza granted judgment on the pleadings in favor of Westerly and dismissed the Complaint. Further, the District Court ordered Ivers to pay certain costs incurred by Westerly in defending a prior suit filed in, and dismissed from, the district court in the Western District of East Texas. This appeal followed.

[5] Westerly removed the suit from Illinoza state court to the United States District Court for the District of Illinoza on October 15, 2015. No issues are raised on appeal about the propriety of that removal and we see no jurisdictional defects.

We agree with the district court's judgment on the pleadings, although we believe the preemption analysis is not quite as straight-forward as the lower court presented it. We therefore affirm the district court's dismissal of the Complaint. We further agree with the district court's decision to award costs to Westerly under Federal Rule of Civil Procedure 41(d) and affirm this portion of its order. But we disagree with that court's decision to exclude attorney's fees from its award. Because we hold that Rule 41(d)'s provision for "costs" necessarily includes attorney's fees, we reverse the portion of the district court's order denying these fees.

FACTS

The parties dispute few of the relevant facts in the record, but disagree on the proper interpretation and application of the legal standards in this case. The district court ably and thoroughly recounted the relevant facts in its memorandum opinion, and we now incorporate its articulation of those facts for purposes of this opinion. Suffice to say, Ivers alleges she suffered side effects relating to impulsive behavior from a generic drug called "ropidope," manufactured by Westerly, which were not sufficiently warned about on the label. The labeling on Westerly's generic ropidope had been identical to the approved brand-name or "reference-listed drug" (RLD) Equip® in all relevant respects, prior to Equip requesting and receiving the federal Food & Drug Administration's (FDA) approval to change its label to add a warning about the risk of "impulsive behavior" as a side-effect. Six months after the RLD's label changed, Westerly notified the FDA it would be updating its label, and the new label took effect February 1, 2012.

Ivers alleges she developed a compulsive gambling habit while on ropidope, after the RLD's label change but before Westerly's label change, and that this side-effect continued after Westerly's change. She does not allege that Westerly's label does not match the RLD, as both parties agree Westerly updated its label to match Equip's. Instead, Ivers's theory of liability

under state law is premised on the allegation that Westerly unreasonably failed to update its label to include warnings of the side-effect she suffered.

The district court granted Westerly's Rule 12(c) motion, holding that the federal Food, Drug, & Cosmetic Act (FDCA), and the FDA's implementing regulations, preempted Ivers's theory of liability. The district court therefore dismissed the Complaint in its entirety in its Memorandum Opinion and Order issued December 20, 2015. The December 20 order further granted Westerly's motion for an award of costs, in part. The district court ordered Ivers to pay $876.52 in costs to Westerly, but denied Ivers's request for $3,442 in attorney's fees.

Ivers filed a timely notice of appeal in this Court on January 14, 2016, contesting the decisions to dismiss and to award any costs. Westerly filed a timely cross-appeal on January 15, 2016, contesting the decision denying it attorney's fees as costs. The parties submitted briefing and presented oral argument. We now turn to the resolution of this appeal.

DISCUSSION

IV. JUDGMENT ON THE PLEADINGS

We review a district court's judgment on the pleadings *de novo*. *St. Jude Med. S.C., Inc. v. Cormier,* 745 F.3d 325, 327 (8th Cir. 2014). The District Court properly stated the standards guiding its decision as equivalent to those applied to Rule 12(b)(6) motions to dismiss. In the instant case, Westerly contends that, even if all of the Complaint's allegations are taken as true, federal law preempts Ivers's recovery. The District Court agreed, and so do we.

A. Preemption Doctrine

Preemption analysis begins with the Constitution's Supremacy Clause, which gives duly enacted federal law the supreme—or preemptive—position with respect to conflicting state laws. U.S. Const. art. VI, cl. 2. Congress's intent to preempt state laws is the ultimate touchstone for preemption analysis. *E.g. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Congress may explicitly state its intent to preempt, but in the absence of an explicit statement from Congress, federal preempts state law if Congress's intent to do so may fairly be implied. *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883–86 (2000).

While the Supreme Court has developed a complex taxonomy of preemptions – both express and implied – the form at issue in this case is conflict preemption. The first form of conflict preemption is known as "impossibility" preemption, *see Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995), and the second as "obstacle" preemption, *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). We find Ivers's claims in this case preempted under either form.

The federal and state laws at issue here concern the labeling and warning duties for manufacturers of generic prescription drugs.[6] The FDCA, as amended by the Hatch-Waxman Act, allows manufacturers of generic versions of RLD drugs to undergo an "Abbreviated New Drug Application," or "ANDA," process to market the generic drug after the RLD patent expires. The FDA may approve an ANDA as long as the generic manufacturer proves it is "bioequivalent" to an approved, reference-listed drug. 21 U.S.C. § 355(j)(2)(A)(iv) (2012). The generic manufacturer must use the same labeling as the FDA has approved for the RLD. *Id.* § 355(j)(2)(A)(v).

[6] Generic drugs are those that are not under patent protection.

Interpreting these federal requirements in the context of state-law tort suits, the Supreme Court held that claims alleging a drug's label fails to adequately warn of risks may proceed against the RLD manufacturer because it is technically possible for the RLD manufacturer to take unilateral action to strengthen its warnings without violating the FDCA. *Wyeth v. Levine*, 555 U.S. 555 (2009). As applied to *generic* drug manufacturers, by contrast, the Supreme Court held that such failure-to-warn claims were in fact preempted by the FDCA and FDA regulations because the generic manufacturer may not change its label without the FDA's prior approval. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011); *citing Wyeth*, 555 U.S. at 573. It would thus be impossible for a generic manufacturer to comply with an imposed state-law tort duty to strengthen its warning label and the federal requirement that it may not do so unless the RLD drug does so or it is explicitly authorized by the FDA. *PLIVA, Inc.*, 564 U.S. at 624. This same intractable dilemma, the Supreme Court recently held, preempts state-law claims alleging design defects in a generic drug's labeling. *Mutual Pharmaceutical Co. v. Bartlett*, 133 S.Ct. 2466, 2473 (2013) ("[I]t was impossible" to comply "with both its state-law duty to strengthen the warnings . . . and its federal-law duty not to alter [its] label.").

B. "Failure to Update" Theories of Recovery

Despite the Supreme Court's reiteration that federal law preempts state-law claims alleging fault in a generic drug's warnings, Ivers contends that her particular claim challenging the adequacy of warnings on a generic drug's label should survive. She argues that her claim can be distinguished from the claims preempted in the Supreme Court cases. We cannot agree.

First, we see no meaningful distinction between those preempted claims that generic labels are inadequate and Ivers's claim that a generic label was inadequate. As the Fifth Circuit has reasoned, "any state law duty requiring generic manufacturers to act unilaterally" to change

their labeling "is preempted by federal law." *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (citing *Mensing*, 131 S.Ct. at 2580-81). The federal law for generic labeling makes any change pursuant to a state law duty impossible, unless the state duty is identical in all respects to the federal law's requirements. Because the Illinoza Products Liability Act § 1998-4(1) imposes liability for "unreasonable" dangers including "inadequate" warnings, without regard to the federal requirements of sameness, its collision with federal law seems unavoidable. *See Bartlett*, 133 S.Ct. at 2476-77; *see also Smith v. Wyeth*, 657 F.3d 420 (6th Cir. 2011) (rejecting argument that state law could require earlier disclosure by generic manufacturers of changes to their FDA-approved warnings).

Preempting these impossible conflicts with state law is uniquely important to the federal laws encouraging the swift and efficient development of generic drugs and therefore bears on our conclusion. The Drug Price Competition and Patent Term Restoration Act, referred to colloquially as the Hatch-Waxman Act, streamlined the FDCA's stringent requirements to encourage developing lower-price generic versions of drugs. 21 U.S.C. § 355(j)(2)(A) (2012). After the expiration of the RLD's patent protection, Hatch-Waxman encourages price competition by promoting the entry of generics into the market. To that end, brand manufacturers are "responsible for the accuracy and adequacy" of the warnings in their labels. *PLIVA*, 564 U.S. at 613(citing 21 U.S.C. §§ 355(b)(1), (d)). A generic manufacturer, by contrast, is only "responsible for ensuring that its warning label is the same as the brand name's." *Id.* (citing 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G) and 21 C.F.R. §§ 314.94(a)(8), 127(a)(7)).

Second, Ivers does not contest that Westerly *did* change its label to match that of the RLD Equip. Westerly submitted a Changes Being Effected ("CBE") notification to the FDA within six months of the RLD label change. The CBE notice mechanism allows manufacturers to "add

or strengthen a . . . warning, [or] precaution," 21 CFR § 314.70(c)(6)(iii)(A) (2016). But the FDA at all times relevant to this action interpreted the CBE regulation to allow generic manufactures to initiate CBE only after the RLD effectuates a change and only to the extent that the generic CBE will match the updated brand-name label. *See Mensing*, 131 S.Ct. at 2575 (explaining FDA's interpretation of 21 CFR § 314.94(a)(8)(iv)). Westerly complied with these federal laws and thus maintained its approval to sell ropidope with its given labels.

Ivers's theory of liability therefore must rest on the theory that Westerly failed to updated its labeling *within a reasonable time* after Equip's label change. The reasonableness of an action is the hallmark of many state tort claims – including the Illinoza statute employed here.[7] *Accord Bell v. Wyeth*, 117 F.Supp.3d 1355, 1365 (5th Cir. 2015). But the state-law "reasonableness" standard is not congruent with the federal law on label changes, and therefore cannot be enforced. Although the federal law does not prescribe a deadline for a generic manufacturer to complete its label update, it does prescribe the process that must be followed before the generic manufacturer may do so. *See Mensing*, 131 S.Ct. at 2575. State tort law conceptions of situational "reasonableness" do not account for this federally-mandated process.[8]

Finally, even if Westerly technically could comply with the state tort law's reasonableness deadline and the federally required procedures, imposing both standards on manufacturers on a fact-specific and state-by-state basis would frustrate the objectives of the Hatch-Waxman Act and therefore run afoul of obstacle preemption. Obstacle preemption displaces state law even where state law merely stands as an "obstacle" to "the accomplishment

[7] Illinoza has not addressed the specific parameters of unreasonable warnings regarding prescription drugs, but it generally follows the Restatement of the Law, Third, Torts: Products Liability.

[8] Ivers would fare no better if her claim alleged that Westerly breached its duty to update under federal law. We view such a claim as preempted under *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 349 (2001); *see also* 21 U.S.C. § 337(a) (2012) (authorizing federal government to institute proceedings to enforce the FDCA). The FDCA does not have its own private right of action, so there is no federal claim available under the statute and allegations that misrepresentations to the FDA caused tort injuries are preempted. *See* 21 U.S.C. § 337(a) (2012). It does not appear, however, that Ivers has directly made such an allegation here.

and execution of the full purposes and objectives of Congress" without creating an impossible conflict. *See Hines*, 312 U.S. 52 at 67. Imposing additional duties of "reasonableness" for the process of updating would create additional compliance burdens on generic manufacturers that contravene the intent of the streamlined ANDA process in Hatch-Waxman. Moreover, leaving reasonableness up to state law and juries would contravene the FDA's role as administrator of national drug-safety policy. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008).

Ivers points to decisions from other circuits and district courts that hold the failure-to-update theory survives preemption. *E.g.*, *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). We are not persuaded. These cases do not squarely address the state-law "reasonableness" inquiry at the heart of this Court's preemption analysis. Rather, they deal with claims that defendants plainly failed to update their warnings, violating the duty of sameness imposed by federal law. This makes them distinguishable.

Accordingly, we find that federal law preempts Ivers's state-law claims for failure-to-update, as pled, and AFFIRM the district court's judgment on the pleadings to this effect.

V. RULE 41(d) AWARD OF COSTS

Rule 41(d) invests the district court with the discretion to grant or deny costs to a defending party. *See* Fed. R. Civ. P. 41(d). To the extent, however, that the district court's order also concerns interpretation of the proper scope of a Federal Rule of Civil Procedure, that question of law is reviewed de novo. *Andrews v. America's Living Ctrs, LLC*, 827 F.3d 306, 309 (4th Cir. 2016).

In the case before us, the district court granted Westerly's motion in part and awarded $876.52 in costs, but denied the motion in part and refused to order payment of $3,442 in claimed attorney's fees based on its holding that Rule 41(d) does not permit an award of

attorney's fees. Accordingly, we find no abuse of discretion in the district court's decision to grant the motion for an award of costs, but we take de novo review of the holding on the scope of permissible "costs" under Rule 41(d).

This question presents an issue of first impression for this Court, though many of our sister circuits have already considered the issue. The Sixth Circuit, like the district court below, holds that the plain language of Rule 41(d) does not permit recovery of attorney fees. *Rogers*, 230 F.3d at 874; *Duffy v. Duffy*, 218 F.3d 623, 632-33 (6th Cir. 2000). The Sixth Circuit went further, acknowledging that the structure of the Rules *might* manifest an intent to include attorney's fees, but reasoning that other Rules' and procedural statutes' explicit provision for such fees evinced an intention to exclude them from Rule 41. *See Rogers*, 230 F.3d at 874-75.

The Rules themselves, however, do not define "costs" one way or the other. Faced with this unavoidable ambiguity, a majority of other circuits to have addressed the issue have held that attorney's fees are properly included in Rule 41(d) costs. *See Andrews*, 827 F.3d at 309 (surveying circuits and joining with those finding attorney's fees may be awarded as costs). The circuits that include fees do so based on the Rule's underlying purpose: to deter forum shopping and vexatious litigation. *E.g.*, *Esposito v. Piatrowski*, 223 F.3d 497, 501 (7th Cir. 2000). Increasing the deterrent force of Rule 41(d) by including attorney's fees in the potential costs of voluntary dismissal and refiling directly serves both of these purposes and would best effectuate the Rule's intent.

The Rule's role as an antidote to forum-shopping is illustrated by the case before us. Although Rule 41 does not require a statement of purpose to accompany a notice of dismissal, Ivers's Rule 41(a) dismissal from the Western District of East Texas plainly seeks to trade

disadvantageous law in one forum for advantageous law in another. This is the very definition of forum shopping.

Moreover, there is considerable agreement among the circuits that Rule 41(a)(2) allows attorney's fees, even though that provision makes no explicit reference to fees. *See, e.g., Davis v. USX Corp*., 819 F.2d 1270, 1276 (4th Cir. 1987) (finding no prejudicial error in district court's order that plaintiff pay costs including attorney's fees under 41(a)(2)). To avoid inconsistent interpretations within the same Rule, the same definition of costs should apply to 41(d). For these reasons, we hold that the costs contemplated by Rule 41(d) include attorney's fees.

The order of the district court awarding Westerly $876.52 in costs is therefore AFFIRMED, and the portion of the order denying $3,442 in attorney's fees is REVERSED and remanded for proceedings consistent with this opinion.

CONCLUSION

We AFFIRM the district court's dismissal of the Complaint as preempted. We further AFFIRM the district court's Order awarding $876.52 in costs to Westerly, but we REVERSE and remand the portion of that Order denying $3,442 in attorney's fees.

MOTLEY, concurring in part and dissenting in part.

I write separately to contest the reasoning underlying this Court's opinion. My quarrels with the Court's reasoning leave me to dissent from its decision to affirm the dismissal of the Complaint, and to concur only in the result of its decision to reverse the denial of attorney's fees as Rule 41(d) costs.

I. PREEMPTION

The majority holds that federal law preempts Ivers's claims as pled. I disagree with this result and its underlying rationale. The majority's opinion goes astray from its inception by

ignoring the presumption against preemption for health care regulation that has been part of the Supreme Court's interpretive canon for decades. The FDCA does not contain any explicit statement of preemptive intent; to the extent that such intent exists, it must be implied. The statute's context and structure, as a whole, as well as the relevant traditions against which it legislated are relevant to resolving this ambiguity. *See Medtronic v. Lohr*, 518 U.S. 470, 485-86 (1996). Chief among these contextual tools is the longstanding presumption against preemption, applied with particular force to those fields – like health and safety regulation – that states law has traditionally occupied. *Id*. at 485. This presumption renders it less likely that Congress would have – without saying – intended to wipe out state remedies that bolster federal requirements.

I disagree with the majority's conclusion on impossibility as well as its reliance on obstacle preemption. Here, the complaint alleges that Westerly violated its federal duty of sameness by employing an outdated label different from the RLD for a period of more than six months. In this procedural posture, we must accept these facts as true. It is not impossible for Westerly to comply with its federal duties to update its label *and* a state duty to do so reasonably. Simultaneous compliance under these circumstances would be *required*, rather than preempted. *Accord Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). The alleged duty of sameness is not, however, so essential to Ivers's theory that it would convert it into a federal-law claim preempted by *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001). Ivers does not allege strict liability or negligence *per se* premised on violation of the federal law. Instead, the complaint relies on a theory that the delay in fulfilling the duty of sameness was also "unreasonable" under state tort law and proximately caused her injuries. This theory is not preempted. *See Fulgenzi*, 711 F.3d at 588.

The majority further ignores the dual "purposes and objectives" of the Hatch-Waxman Act in its analysis, and relies on an increasingly disfavored "obstacle preemption" doctrine. *See Wyeth*, 555 U.S. at 604 (Thomas., J., concurring in judgment but expressing doubts about the constitutionality of obstacle preemption doctrine). Encouragement of generic drug manufacturers is not Hatch-Waxman's sole purpose. The statute balances the need for speed and cost-effectiveness in approving generic drugs with the paramount concern for patient safety that underlies the entirety of the FDCA. It is thus a mistake to hold that allowing state tort law to bolster the duty of sameness in warnings conveyed to patients and their doctors would "frustrate" the purposes and objectives of the generic drug regulations.

I would join the majority of our sister circuits who have held that these types of claims are not preempted by the federal labeling laws.

II. RULE 41(d)

On the Rule 41(d) issue, I concur with the panel's judgment only. Ultimately, I believe the Rule's context and underlying rationale support including attorney's fees in the 41(d) costs in this case. But I believe this is the correct result because the Rule, the state statute creating the claim, and the plaintiff's litigation conduct permit the imposition of attorney's fees. The majority, I believe, errs in relying solely on its interpretation of Rule 41(d). Because Rule 41(d) is silent on the scope of its definition of "costs," it does not support the majority's interpretation that "costs" categorically includes attorney's fees.

Rule 41(d)'s plain language fails to adequately support the district court and Sixth Circuit's categorical *exclusion* of attorney's fees in "costs." The Rule admits of far more ambiguity and is not so neatly answered by the existing contextual clues. The Advisory Committee Notes to Rule 41 do not deal with subsection (d). The broader Rules of Civil

Procedure nowhere define "costs," but offer contextual information about the intended scope of that term. Rule 54(d) provides that "costs—other than attorney's fees—should be allowed to the prevailing party." Fed. R. Civ. P. 54(d)(1). This construction implies that costs *include* attorney's fees as a subset. Yet it does not directly state the majority's definition, and it further deals with costs available to a "prevailing party," which is a more substantive outcome than the dismissal without prejudice contemplated in Rule 41.

In light of this significant textual ambiguity, I believe Rule 41's purposes and objectives should inform its interpretation. An award of attorney's fees is not to be lightly imposed. It contravenes the default "American Rule" that each side generally pays its own way and that attorney's fees usually are not available. *See Key Tronic Corp. v. United States,* 511 U.S. 809, 815 (1994). Congress and the Supreme Court may alter this default rule, but we must endeavor to find stronger evidence that they have intended to do so. Such evidence exists, but it also warrants qualifying this exception to the default rules. *See Esposito v. Piatrowski,* 223 F.3d 497, 501 (7th Cir. 2000).

Rule 68 offers a clue. Rule 68(d) permits an award of "costs" after an unaccepted offer of judgment without defining the term. Fed. R. Civ. P. 68(d). The Supreme Court has interpreted this provision to include attorney's fees "where the underlying statute defines 'costs' to include attorney's fees." *Marek v. Chesny*, 473 U.S. 1, 9 (1985). Because Rule 41(d) does not automatically award costs as of right, it seems logical that an award of costs should reflect only those costs to which the defending party would have a right under the law of the claim. *See Andrews v. America's Living Ctrs, LLC*, 827 F.3d 306, 311 (4th Cir. 2016). This important qualification balances the competing considerations in Rule 41: that plaintiffs have an efficient

mechanism to dismiss a complaint at an early time before defendants have expended much effort, but that this mechanism not be used as a tool for harassment or abuse. *See id*.

The district court failed to consider whether the state law governing Ivers's original claim permits recovery of attorney's fees. On appeal, Westerly argues that it does. Westerly points to the Record containing the initial Complaint filed in the United States District Court for the Western District of East Texas, asserting a claim under the East Texas Products Liability Law (ETPLL). The ETPLL is subject to East Texas Code Annotated § 12-12-12, which states:

> (a) In actions for personal injury, where plaintiff's claim for damages exceeds twenty-five thousand dollars ($25,000) and includes a written demand for fees, there shall be taxed and allowed to the plaintiff, as part of the costs of the action, a reasonable amount to be fixed by the court as attorney's fees.

The statute says nothing about awarding fees to the defending party. *See id*. I would ask the district court to resolve this issue on remand.

To account for Rule 41(d)'s structure and purpose, I would affirm the award of costs and direct on remand that the district court additionally determine whether the additional qualifications for an award of attorney's fees have been satisfied.

Supreme Court of the United States

Alice IVERS, Petitioner,

v.

WESTERLY PHARMACEUTICAL, INC., Respondent.

No. 17-230
July 17, 2017

Petition for writ of certiorari to the Twelfth Circuit Court of Appeals is GRANTED limited to the following questions:

1. Whether this Court's decisions in *PLIVA v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical v. Bartlett*, 133 S. Ct. 2466 (2013), preempt the Petitioner's claims in this case.

2. Whether attorney's fees are considered awardable "costs" under Federal Rule of Civil Procedure 41(d).

IT IS SO ORDERED.