IN THE

Supreme Court of the United States

States

October Term, 2017

Alice IVERS,

Petitioner,

v.

WESTERLY PHARMACEUTICAL, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals For the Twelfth Circuit
QUESTIONS PRESENTED

I. Do the Supreme Court’s decisions in PLIVA v. Mensing and Mutual Pharmaceutical Co. v. Bartlett preempting state-tort claims against generic drug manufacturers for inadequate labels that conflict with federal ‘sameness’ duties under the federal Food, Drug, and Cosmetic Act (“FDCA”) also preempt state-tort claims against generic manufacturers that ultimately comply with the FDCA federal duties.

II. When petitioner files a duplicative action after a voluntary dismissal, is the petitioner required to pay the costs incurred by the respondent, including attorney’s fees, under Rule 41(d)?
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The opinion of the United States Court of Appeals for the Twelfth Circuit is unreported as Alice Ivers v. Westerly Pharmaceutical, No. 17-1620 (12th Cir. Feb. 2, 2017), and appears on pages 9-21 of the record. The opinion of the United States District Court for the District of Illinoza is unreported as Alice Ivers v. Westerly Pharmaceutical, Inc., No. 17-450-CV, (D. Ill. Dec. 20, 2015), and appears on pages 1-8 of the record.

STATEMENT OF JURISDICTION

The judgment of the United States Court of Appeals for the Twelfth Circuit was entered on February 2, 2017. R. at 9. The petition for writ of certiorari was granted on July 17, 2017. R. at 23. This Court has appellate jurisdiction pursuant to a grant of certiorari as required by 28 U.S.C. § 1254(1) (2012). This Court has subject matter jurisdiction under U.S. Const. art. III, § 2.

CONSTITUTIONAL AND STATUTORY PROVISIONS

This case involves Article VI, Clause 2 of the United States Constitution, which provides: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."
Federal Rule of Civil Procedure 41(d) states: "If a plaintiff who previously dismissed an action in any court files an action based on or including the same claim against the same defendant, the court: (1) may order the plaintiff to pay all or part of the costs of that previous action; and (2) may stay the proceedings until the plaintiff has complied."
STATEMENT OF THE CASE

I. STATEMENT OF FACTS

This case involves a generic drug manufacturer, Westerly Pharmaceutical, Inc. ("Westerly"), a Texas corporation headquartered in Florham Park, New Jersey, complying with the Drug Price Competition and Patent Term Restoration Act, colloquially known as the Hatch-Waxman Amendments. R. at 1.

Westerly manufacturers the generic form of ropidope hydrochloride ("ropidope"), a non-ergoline dopamine agonist, which inhibits the dopamine hormone reactions associated with the symptoms of Parkinson's disease. R. at 2. GlaxoCline, LLC., patented the brand name version of ropidope, Equip®, and it was approved for market by the Federal Food and Drug Administration (FDA) in 1997. R. at 2. Nine years later, the patent expired and, Westerly submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to market a generic version under 21 U.S.C. 355(j) (2012). R. at 4. The FDA requires generic manufacturers to certify that its version is equivalent in ingredients, dosage, strength, and labeling to the brand-name drug it copies. Id.; 21 C.F.R. § 320.1(c) (2015). Westerly's ropidope drug label mirrored Equip's label. R. at 2–3.

In January, 2011, GlaxoCline sought approval to update its Package Insert and associated labeling to reflect new information about possible side effects of using Equip. R. at 2. The Supplemental New Drug Application (sNDA) requested approval to add one 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. R at 2.

Six months after GlaxoCline submitted its request the FDA approved the change. GlaxoCline began implementing the label change in June, 2011. R. at 2. In January, 2012, Westerly notified the FDA that it would be updating its ropidope labels to comply with the sameness requirement as of February 1, 2012, which it did. R. at 3.

Alice Ivers ("Ivers") was diagnosed with Parkinson's Disease in February, 2011. R. at 1. She was prescribed ropidope and began taking the generic form starting in March, 2011. R. at 1. Ivers alleges that in July, 2011, one month after Equip updated its label, she began to develop compulsive behaviors. R. at 3. Over the course of several months, Ivers transferred a significant amount of her retirement savings into an online poker account, and won substantial sums of money. R. at 3. By the end of 2012, at least ten months after Westerly updated its warning label, she depleted her retirement savings on charities and antiques. R. at
3. Despite the updates to her medication warnings, Ivers nevertheless alleges that her actions were caused by the unwarned side-effects of ropidope. R. at 3.

II. NATURE OF PROCEEDINGS

The instant action was filed in the state court of Illinoza on September 15, 2015. Defendant timely removed the proceedings to the United States District Court for the District of Illinoza asserting diversity jurisdiction under 28 U.S.C. § 1332 and removal jurisdiction under 28 U.S.C. § 1441. The District Court granted Defendant's judgment on the pleadings, granted Defendant's award of costs—excluding attorney's fees—and dismissed the Complaint. Plaintiff-Appellant timely appealed. The United States Court of Appeals for the Twelfth Circuit granted review. On February 2, 2017, the Court of Appeals affirmed the district court's dismissal of the Complaint, affirmed the district court's Order awarding certain costs to Defendant but reversed and remanded the portion of the district court's Order denying attorney's fees. Plaintiff-Appellant petitioned for a writ of certiorari. This Court granted Petitioner's writ on July 17, 2017.
SUMMARY OF THE ARGUMENT

This case provides this Court with an opportunity to decide two important issues. First, 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 state-tort claims against generic drug manufacturers. Second, whether the Twelfth Circuit correctly found that attorney's fees are considered awardable "costs" under Federal Rule of Civil Procedure 41(d) when Ms. Ivers voluntarily dismissed her first Complaint against Westerly Pharmaceutical just days after that circuit issued an unfavorable opinion.

I.

This Court should AFFIRM the decision of the Twelfth Circuit below and find that state-tort claims predicated on the inadequacy of generic drug labels under state law duties conflict with the complex regulatory scheme established by Congress and the FDA and should be preempted under either the impossibility or obstacle preemption doctrines founded in Article VI, Clause 2 of the U.S. Constitution. First, the Hatch-Waxman Amendments provide the framework for the FDA to regulate generic drug manufacturers. This Court's decisions in Mensing and Bartlett preempted many state claims against generics because they directly conflicted with federal obligations. Ivers's is attempting to sidestep Buckman's prohibition on private enforcement of the FDCA and sneak past this Court's announced limitations on generic drug manufacturer liability. A number of state and federal district and appellate courts have found failure-to-update claims not
preempted, however, they are the minority and are distinguishable. Finally, the
difficulty generic manufacturers have complying with fifty separate state tort
regimes impedes their incentives to offer inexpensive generic drugs—frustrating
public policy and the FDA’s discretion.

II.

This Court should uphold the Twelfth Circuit below and find that Federal
Rule of Civil Procedure 41(d) authorizes an award of attorney’s fees. First, the
purpose of 41(d) is to prevent the type of strategic forum shopping that Ivers
engaged in and should thus be liable to defendant for covering the costs of litigation.
Second, the majority of Courts have found that the term "costs" under Rule 41(d)
includes both costs and attorney's fees. Third, although the general rule, known as
“the American Rule” states each party must bear the costs of his or her own
attorney’s fees, when the statute governing the litigation defines costs to include
attorney's fees, attorney's fees may be awarded by the district court. Finally, Rule
41(d) would become a "toothless" deterrent if it did not include attorney's fees in its
assessment.
STANDARD OF REVIEW

ARGUMENT

I. STATE-LAW CLAIMS AGAINST MANUFACTURERS OF GENERIC DRUGS ALLEGING DESIGN DEFECTS AND FAILURE-TO-WARN ARE IMPLIEDLY PREEMPTED BY THE FEDERAL DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT.

A. The 1984 Hatch-Waxman Amendments established the ANDA process for regulating generic drugs.


In 1992, the FDA published the final rules implementing many parts of the Hatch-Waxman provisions. 57 FR 17950-01. Notably, there were several comments to the proposed rules regarding labeling requirements. Id. at *17960-1. At the time, the FDA specifically noted that "[a]fter ANDA approval, FDA tracks the labeling status of the [brand] drug product and, if necessary, notifies ANDA holders when
and how they must revise their labeling. *Id.* While the FDA established a series of reporting requirements upon drug manufacturers, the FDA rejected the idea of providing ANDA manufacturers with a specific timeline for updating labels. *Id.*; 21 C.F.R. §§ 314.70, 314.81. Importantly, the FDA at all times retains the ability to withdraw an approval of an ANDA application and, specifically, if it finds that a generics label is inconsistent with the brand name drug. 21 C.F.R. § 314.150(b)(10). It is under this complex and comprehensive regulatory scheme that Westerly was granted approval to market its generic ropidope in 2009. R. at 2.

B. Ivers’s state-tort claims are an attempt to privately enforce FDA regulations which is prohibited under this Court’s decision in *Buckman Co. v. Plaintiff’s Legal Committee* and 21 U.S.C. § 337(a).

In 2001, this Court held in *Buckman* that state-law tort claims relying on violations of the federal Food, Drug, and Cosmetic Act (“FDCA”) were preempted. 531 U.S. 341, 348 (2001). As this Court noted, Congress explicitly prohibited private actions to enforce FDA regulations under chapter nine of the FDCA. *Id.* at n. 4; 21 U.S.C. § 337(a). Chapter nine includes the Hatch-Waxman (§ 355) provisions covering ANDAs. Despite the clear mandate from this Court, plaintiff’s have continued to look for novel theories of liability to escape *Buckman’s* gravitational pull. *Mensing*, 564 U.S. 604, 618 (2011) (preempting state failure-to-warn claims against generic manufacturers); *Bartlett*, 133 S.Ct. 2466 (2013) (preempting state design-defect claims against generic drug manufacturers). It is clear that Ivers’s is attempting to do just that in this case.

Ivers’s claims Westerly failed to immediately update its warning labels, which led to her injuries. The problem is that Ivers’ claims depend entirely upon the actions of a brand name manufacturer and, ultimately, alleged non-compliance with the FDCA requirement that generics maintain the same label. 21 U.S.C. § 355(j)(2)(A)(v). The dissent below argued that the “alleged duty of sameness is not . . . so essential to Ivers’s theory that it would convert it into a federal-law claim.” R. at 19. The opposite is unavoidable. Had GlaxoCline not updated its label to comply with its federal regulatory requirements, Ivers’s would have no viable claim. Westerly would have no federal duty and still no mechanism for independently changing its label to escape Illinoza product liability claims. Thus, Ivers is
attempting to privately enforce § 355(j)(2)(A)(v) which, this Court in Buckman and Congress through § 337(a), declared out of bounds for private litigants.

C. Ivers’s failure-to-update theory is a veiled failure-to-warn theory—preempted under a comprehensive reading of Mensing.

As noted above, Petitioner is attempting what may be commonly known as a “Jedi mind trick” on this Court by mischaracterizing a failure-to-update theory. As the late Justice Scalia once warned, “[b]e not deceived.” Navarette v. California, 134 S.Ct. 1683, 1692 (2014) (J. Scalia Dissenting). The majority below correctly noted, “[there is] no meaningful distinction between those preempted claims that generic labels are inadequate and Ivers’s claim that [this] generic label was inadequate.” R. at 13.

In 2011, this Court held in Mensing, that state-tort claims against generic drug manufacturers for inadequate labels are preempted by the FDCA. 564 U.S. at 618. Plaintiffs in Minnesota and Louisiana brought state claims against generic manufacturers for failing to strengthen warnings that long-term metoclopramide can cause tardive dyskinesia, a severe neurological disorder. Importantly, in Mensing, there was mounting evidence that patients taking metoclopramide for more than 12 weeks could be at risk for a serious disease, and yet, neither the FDA nor the brand-name manufacturer changed the warning labels until well after many patients were diagnosed with the disease. Id. at 610.

This Court relied on its decision in Wyeth v. Levine that the impossibility preemption doctrine should control. Id. (citing Wyeth, 555 U.S. 573). Ultimately, it
was impossible for generic manufacturers to do—unilaterally—what the state law required. *Id.* While Petitioner would have this Court read *Mensing* narrowly—to only preempt cases requiring unilateral action by generic manufacturers—a number of circuits have soundly rejected a narrow reading of *Mensing*—finding state-tort claims predicated on inadequate labels preempted. *See Morris v. PLIVA*, 713 F.3d 774 (5th Cir. 2013); *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378 (6th Cir. 2013); *Bell v. Pfizer, Inc.*, 715 F.3d 1087, 1095–96 (8th Cir. 2013) (rejecting ‘unduly’ narrow reading of *Mensing* under Arkansas failure-to-warn theory); *Guarino v. Wyeth*, LLC, 719 F.3d 1245, 1247–49 (11th Cir. 2013) (holding plaintiff’s state-law claims based on inadequate warnings of generics to medical providers were premised on adequacy of labels and, therefore, preempted by *Mensing*).

In this case, Ivers’s is attempting to capitalize on the alleged ambiguity as to the proper scope of *Mensing*. GlaxoCline found an increased likelihood that some patients taking ropidope may develop impulse control, which may be addressed through dosing changes by the patient’s physician. It took the FDA six months to approve of GlaxoCline’s label change. Moreover, despite the FDA being aware of the label change in the brand name drug and having the authority to withdraw approval for ANDAs, Westerly never received a warning that its approval may be withdrawn and, indeed, complied with its duties within months. 21 C.F.R. § 314.150(b)(10).

While it is true that *Mensing*’s rationale left those who had been given the generic drug no avenue to air their serious grievances, this Court recognized that
Congress created separate statutory schemes to achieve different objectives for brand name and generic drugs. 564 U.S. at 626 (2011) (“Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public.”). Moreover, it is not the Court’s role to second-guess an unusual statutory scheme. Id. at 625. Though this Court recognized in dicta that it may not always be easy to determine if a particular claim is preempted, it did not recognize any such exception in its holding. Id. at 623–24. Ivers’s attempts to read Mensing for the proposition that generic manufacturers better stay on guard. Plaintiffs need only to refresh their FDA message boards until the smallest inconsistency between the brand’s label and the generic’s label allows them to sneak through the gate. Mensing did not recognize such a restrained holding, and this Court should not entertain one now.

D. Bartlett expanded the reach of Mensing to preempt state design-defect claims requiring generic manufacturers to comply with conflicting state tort duties and federal ‘sameness’ obligations.

Two years after Mensing, this Court held in Bartlett that state design-defect claims against generic drug manufacturers were preempted. Plaintiff’s sued under New Hampshire’s product liability law alleging the generic manufacturer failed to strengthen warnings on inflammatory pain reliever’s label to advise about risks of toxic epidermal necrosis and Stevens-Johnson Syndrome. 133 S. Ct. 2466, 2466 (2013). The plaintiff’s suffered serious injuries and still this Court found the claims preempted. Id. This Court focused on New Hampshire’s risk-utility approach to liability. Id. at 2480. New Hampshire’s law required an affirmative duty to either
alter the design of the product, which 21 U.S.C. § 355(j)(2)(A)(iv) forbids (and was practically impossible as a one-ingredient drug), or alter the labeling—which § 355(j)(2)(A)(v) prohibits. Id. at 2477. This Court also rejected the argument that the manufacturers could comply with both state and federal law by removing the product from the market and avoid liability. Id. This narrow reading would leave impossibility preemption “all but meaningless.” Id.

Just like in Bartlett, Ivers’s is asking this Court to require generic manufacturers to comply with state duties that conflict with its federal duty of ‘sameness’ with brand-name drug labels. Illinoza has not enunciated a specific product liability rule in this case, but generally follows the Third Restatement of Torts: Products Liability. See Appendix B. The Restatement holds that a prescription drug is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings are not provided to the physician. Id. at § 6 (d)(1). First, the state-law duty of reasonableness required here does not comport with the federal duty of sameness. Westerly is obligated to follow the brand-name label—which it did. Under this rationale, Westerly could still be liable if a state jury were to decide that the brand-name’s label was not reasonable.\(^1\) Thus, Westerly would have to choose between violating a state duty—exposing it to possible monetary judgment OR violating the FDA’s regulations which could lead to

\(^1\) Moreover, under the § 6(d)(1) of the Restatement, warnings must be directed at providers. In this case, Ivers’s provider was a learned intermediary that should have been aware of the brand-name label change. Additionally, after the label was changed in February, Ivers’s physician still did not change her prescription, thus the label change had no affect on the provider’s behavior.
withdrawal of approval to market the drug. This Court recognized that absurdity in
Bartlett and promptly closed that avenue to private litigants. The FDA’s regulatory
scheme provides a complex and appropriate process for updating the labels and
ensuring the safety of drugs. Generic drug manufacturers should not be held
hostage to the whims of whatever novel state tort theory is popular that week.

E. The requirement of reasonableness distinguishes this case from Fulgenzi.

Ivers’s attempts to evade Buckman, Mensing, and Bartlett by citing to cases like the
Sixth Circuit’s decision in Fulgenzi v. PLIVA. 711 F.3d 578 (6th Cir. 2013) (holding
state duty to warn of risks of developing tardive dyskinesia not preempted); see also
In re Fosamax Products Liability Litigation, 965 F.Supp.2d 413 (S.D. N.Y. 2013)
(holding failure-to-update claims not preempted when manufacturers failed to
update for a year); Teva Pharmaceuticals USA, Inc. v. Superior Court, 217 Cal. App.
4th 96, 106, 158 Cal. Rptr. 3d 150, 156 (2013) (review denied) (holding that
manufacturers failed to make multiple changes over more than year timespan);
Huck v. Wyeth, 850 N.W.2d 353 (Iowa 2014) (holding failure-to-update not
preempted when generic never updated label and physician’s desk reference were
not updated either). However, Fulgenzi and its progeny are factually
distinguishable. In Fulgenzi, the brand-name manufacturers updated their labels to
warn about the dangers and the generic manufacturers never followed through to
update their labels for years. Here, Westerly did update its label within a few
months following the FDA process. Ivers’s suggests that it’s not different, but the
FDA is explicitly given power to withdraw approval for a drug if it is not meeting its
labeling obligations. 21 C.F.R. § 314.150(b)(10). The FDA did not warn Westerly to update its label or threaten to withdraw FDA approval. In fact, Westerly updated its label in the exact same amount of time it took the brand-name drug to recognize a potential issue, seek approval from the FDA, gain that approval, and work with distributors to update its label. Surely generic manufacturers, who must rely on actions of third parties before it can begin this process, should be allowed at least the same window of time to comply—the FDA’s certainly suggests this is ok.

Ivers’s faith in Fulgenzi and its family of cases are misplaced. The FDA has a process for approving drugs—which Westerly followed. There is no doubt that Congress and the FDA should clarify this process to aid manufacturers and patients. However, if this Court adopts Fulgenzi’s approach—that liability may attach faster than a game show buzzer—it will be the states—not the FDA—that are ultimately in control of generic drugs, contravening Congress’s objectives with FDCA and the Hatch-Waxman amendments.

F. State-tort claims predicated on the inadequacy of generic drug labels frustrate important public policy considerations and the FDA’s regulatory objectives and should be prohibited under the doctrine of obstacle preemption.

Just as Congress is struggling to deal with today’s skyrocketing cost of health care in this country, the 98th Congress attempted to come to the aid of Americans trying to afford the skyrocketing essential medications by passing the Drug Price Competition and Patent Term Restoration Act of 1984. Mensing (Brief of Petitioners at *8). Congress recognized that not just private citizens, but state and federal
programs were spending billions of dollars on brand-name prescription drugs. \textit{Id.}

The purpose of Hatch-Waxman was to “make available more low cost generic drugs . . . provide regulatory relief, increase competition, economy of government and, best of all, [allow the American people [to] save money. \textit{Id.} (quoting \textit{inter alia} Stmnt. On Signing S. 1538 Into Law, 20 Weekly Comp. Pres. Doc. 1359, 1360 (Sept. 24, 1984)).

More than thirty years after the passage of Hatch-Waxman, it is clear that the legislation had a dramatic impact on the rise of generic drugs in the U.S. Market. See Aaron S. Kesselheim and Jonathan J. Darrow, \textit{Hatch-Waxman Turns 30: Do We Need a Re-designed Approach For The Modern Era?}, 15 YALE J. HEALTH POL'Y, L., AND ETHICS Iss. 2, ART. 2, 295 (2015) (eighty-four percent of prescriptions dispensed today are generics). Yet there is no doubt that Hatch-Waxman was not perfect and has not addressed every issue of prescription drug prices or regulation in the country. \textit{Id.} at 296. As \textit{Mensing} and \textit{Bartlett} highlighted, the issue of product liability and the interaction between federal and state law has continued to vex the courts. Following these major decisions in 2011 and 2013 respectively, plaintiffs have attempted to evade their preemptive effect on state cases by positing novel theories that cloud the role of the FDA in regulating the safety of generic drugs.

State-tort claims against generic manufacturers pose as an obstacle to Congress’s objective to ensure that safe and affordable drugs are available on the U.S. market. Not only do state judgments risk passing massive awards along to consumers in the form of higher generic prices, they also discourage generic manufacturers to enter the market place in first place.
Many recent decisions involving generic drug labels have noted that the FDA is aware of the disparate treatment between brand-name and generic drug manufacturers. In 2013 the FDA announced its intent to reform the rules allowing generics to independently change its labels. Supplemental Applications Proposing Labeling Changes for Approved Drugs, 78 FR 67985-02, 2013 WL 5981469 at *67989 (proposed Nov. 13, 2013). The proposed rule would have allowed generics to engage in the same unilateral updates to drug labels that brand-name drugs are able to now. Id. Ultimately, the rule was harshly criticized for stepping outside the bounds of the FDA’s authority under Hatch-Waxman. Moreover, generic manufacturers were afraid that the additional cost of monitoring and reporting could increase costs, decrease incentives to offer generic drugs, and confuse providers and patients with inconsistent labels. James Matthews, et al., New FDA Rule on Drug Labeling May Mean Increased Exposure and Uncertain Path For Generic Pharmaceutical Manufacturers, 81 DEF COUNS. J. 306 (2014). After more than three years, the FDA recently announced it was not moving forward with the proposed rule. Zachary Brennan, FDA’s Punt on Finalizing Generic Drug Labeling Rule: Experts Debate, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (May 19, 2016).

Ultimately, the FDA’s decision reflects the understanding that Congress did not address every concern with Hatch-Waxman. At a time when access to prescription drugs, and health care in general, is under a microscope by Congress, this Court should affirm the lower courts decision and allow Congress to make the necessary changes to protect consumers, not fifty individual states.
II. THE TWELFTH CIRCUIT CORRECTLY FOUND THAT WHEN PETITIONER FILES A DUPLICATIVE ACTION AFTER A VOLUNTARY DISMISSAL, THE PETITIONER IS REQUIRED TO PAY THE COSTS WHICH INCLUDE ATTORNEY’S FEES UNDER RULE 41(d).

Federal Rule of Civil Procedure 41(a)(1)(A) permits a plaintiff to voluntarily and unilaterally dismiss an action without leave of court by filing a notice of dismissal at any time "before the opposing party serves [its] answer or a motion for summary judgment . . . ." Fed. R. Civ. P. 41(a)(1)(i). Although the first time the plaintiff files a voluntary dismissal notice it is without prejudice, "If a plaintiff who previously dismissed an action in any court files an action based on or including the same claim against the same defendant, the court: (1) may order the plaintiff to pay all or part of the costs of that previous action . . . ." Fed. R. Civ. P. 41(d).

The Rule is silent as to whether attorney's fees are included in the costs, however, "The costs available under Rule 41(d) have generally been held to include attorney's fees." 8-41 Moore's Federal Practice Civil § 41.70[6] (2008).

In this case, Ivers originally filed a Complaint against Westerly Pharmaceutical in the United States District Court for the Western District of East Texas, then filed a Notice of Voluntary Dismissal after an unfavorable decision in the same Circuit was issued. R. at 5. Ivers then deliberately searched for a court and jurisdiction that would most likely give her the result she wants. Id. Here, Ivers took advantage of Rule 41(a) to locate the best forum for her case and subsequently harassed Westerly with duplicative litigation. R. at 6. The result of Ivers’ unethical
and inefficient actions has cost Westerly $876.52 in court filing, copying, delivery, research, and telecommunications costs, as well as $3,442 in attorney and paraprofessional hourly fees in preparing the defense to Ivers’ East Texas Products Liability Law filing. R. at 7.

**A. The purpose of 41(d) is to prevent the type of strategic forum shopping that Ivers engaged in and should thus be liable to defendant for covering the costs of litigation.**

Rule 41(d) of the Federal Rules of Civil Procedure provides that when a plaintiff has dismissed an action but then recommenced it against the same defendant, the court may stay the second action and condition its re-litigation on the plaintiff's payment of costs of the first action." 8 Moore's Federal Practice § 41.70. "The purpose of Rule 41(d) is to prevent forum-shopping within the federal court system . . . [and] serves the broader purpose of penalizing a plaintiff for re-filing the very suit he has previously dismissed . . . ." Adams v. New York State Educ. Dep't, 630 F. Supp. 2d 333, 343 (S.D.N.Y. 2009).

Moreover, Rule 41(d) is an expression of power that is held by federal courts to dissuade unduly repetitive or vexatious litigation. R. at 17. Rule 41(d) includes the authority to require payment of costs and attorney's fees as a condition for commencing a subsequent lawsuit. Most recently, the Fourth Circuit ruled that Rule 41(d), which seeks to deter forum shopping and "vexatious" lawsuits, allows courts to award attorney's fees. The Fourth Circuit relied on the plain language meaning of vexatious as "without good or probable cause or excuse." Andrews v.
America's Living Centers, LLC., 827 F.3d 306 (4th Cir. 2016). However, common law presumes a second-filed lawsuit following a voluntary dismissal is vexatious:

Lake Agric. Co. v. Brown, 186 Ind. 30, 114 N.E. 755, 756 (1917) (‘a second action between the same parties for the same cause will be presumed to be vexatious’); Jones v. Barnard, 63 Mo. App. 501, 505 (1895) (‘the presumption is that the second action is vexatious’); Bridge v. Sumner, 18 Mass. 371, 371 (1823) (‘The second action in such case is deemed to be vexatious.’); Curler v. Vanderwerk, 1 Johns. Cas. 247, 247 (N.Y. Sup. Ct. 1800) (‘The plaintiffs having voluntarily suffered a nonsuit in the first suit, the second is to be deemed vexatious.’); Odegard v. North Wis. Lumber Co., 110 N.W. 809, 814 (Wis. 1907) (‘[W]here a plaintiff has been nonsuited and brings a second action for the same cause, a presumption arises either that the second action is vexatious or that the cause of action is without merit.’).


Here, Ivers filed a Complaint against Westerly in the state court of Illinoza on September 15, 2015. R. at 1. This Complaint alleged the same facts and legal theories, a state Products Liability Law, as the voluntarily dismissed January 15, 2013 filing in the Western District of East Texas. R. at 5. This matter is the second action between the same parties for the same cause, and per common law, is vexatious.

The purpose of Rule 41(d) to deter forum shopping and vexatious lawsuit filing is further supported by the Texas Supreme Court decision in Epps v. Fowler. The court held a defendant may recover its attorneys' fees as a "prevailing party" when a plaintiff voluntarily nonsuits its case if the defendant can show that
the nonsuit was taken "in order to avoid an unfavorable judgment." The court stated, "If the plaintiffs nonsuit is without prejudice, defendant is not deemed to be the prevailing party . . . [h]owever, if the court finds the plaintiff took the nonsuit to avoid an unfavorable ruling on the merits, and the nonsuit was filed without prejudice, defendant will be deemed to be the prevailing party and is entitled to attorney’s fees." *Epps v. Fowler* 351 SW3d 862 (Tex. 2011).

Here, it is clear that Ivers was forum shopping—the second action filed by Ivers involves the same claims against Westerly Pharmaceutical and seeks nearly identical relief. R at 5. By voluntarily dismissing the federal action in District Court for the Western District of East Texas and then re-filing to the State Court of Illinoza, Ivers attempted to find the most favorable court for her lawsuit. *Id.*

Ivers is a resident of Illinoza, however, she strategically chose to initially file in District Court for the Western District of East Texas. R. at 1. The strategy here is that East Texas is a system that has policies more favorable to plaintiffs and their speedy timetable for trials puts pressure on defendants to settle.² Although the Texas system was seen in her favor, the Fifth Circuit, where East Texas resides, issued an unfavorable opinion for Ivers in *Morris v. Pliva, Inc.*, holding that the FDCA preempted a similar failure-to-update claim regarding a

different FDA-approved drug. *Morris*, 713 F.3d at 778; R at 5. Because of this unfavorable decision, Ivers strategically filed in the State Court of Illinoza. R. at 5. Ivers' actions are clearly something that courts currently frown upon\(^3\)-- when a party takes advantage of the legal system by suing in a particular jurisdiction for the purpose of attaining the most favorable result.

**B. There is a current circuit split on the issue of whether attorney's fees should be included as part of an award of costs under Rule 41(d).** However, the majority of Courts have found that the term "costs" under Rule 41(d) includes both costs and attorney's fees

1. **The majority of courts have upheld an award of attorney fees under Rule 41(d)**

While a split of authority exists as to whether Rule 41(d) allows a defendant to recover attorney's fees as part of an award of "costs," the majority of courts have held that it is within a court's discretion to award attorney's fees as part of the costs available under Rule 41(d). *See Meredith v. Stovall*, 216 F.3d 1087 (10th Cir. 2000),

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\(^3\) This Court has issued three decisions this far discouraging forum shopping. *See Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, 137 S. Ct. 1773, 198 L. Ed. 2d 395 (2017) where the court held that a corporation that engages in a nationwide course of conduct cannot be sued in a state court by anyone not injured within that jurisdiction, unless the corporation has significant contacts there, such as conducting much of its business therein. Eight justices formed the majority, with only one, Sonya Sotomayor, dissenting; *TC Heartland v. Kraft Foods Group Brands*, 137 S. Ct. 1514, 197 L. Ed. 2d 816 (2017), a May 22 decision that limited patent infringement lawsuits primarily to the state of the defendant’s incorporation; and *BNSF Ry. Co. v. Tyrrell*, 137 S. Ct. 810, 196 L. Ed. 2d 596 (2017), that said the Fourteenth Amendment bars states from conducting trials when the corporation “is not ‘at home’ in the state and the episode-in-suit occurred elsewhere.
at 1 (Simeone v. First Bank Nat. Ass'n, 971 F.2d 103, 108 (8th Cir. 1992) (Affirming the award of fees under the district court's entire award of costs); Evans v. Safeway Stores Inc., 623 F.2d 121, 122 (8th Cir. 1980) (Eighth Circuit affirmed trial court's decision to award attorney's fees under Rule 41(a)(2) and (d)); Meredith v. Stovall, 216 F.3d 1087 (10th Cir. 2000) (unpublished) (Tenth Circuit affirmed trial court's decision to award attorney's fees under Rule 41(d)); Esposito v. Piatrowski, 223 F.3d 497, 502 (7th Cir. 2000) (holding a party may recover attorney fees as part of costs where underlying statute defines costs as such); Ross v. Infinity Ins. Co., No. 12-5050 (holding where a plaintiff obtained multiple and substantial tactical advantages when they voluntarily dismissed the federal action and then forum-shopped to file identical claims in state court, plaintiff will compensate attorney fee expenses of defendant); Esquivel v. Arau, 913 F. Supp. 1382, 1393 (C.D. Cal. 1996) (court for the Central District of California awarded attorney's fees under Rule 41(d)); Andrews v. America's Living Centers, LLC, 827 F.3d 306 (4th Cir. 2016) (District court may award attorneys' fees under 41(d) only if either the underlying statute provides for attorneys' fees or the court finds that the plaintiff acted in bad faith, vexatiously, wantonly, or for oppressive reasons).

Some courts have awarded attorney's fees under Rule 41(d) and have held that defendant cannot recover fees associated with work that can be used in the second action. Adams v. N.Y. State Educ. Dep't., 630 F. Supp. 2d 333 (S.D.N.Y. 2009). However, the attorney's fees requested here, by Westerly, cannot be used in the future actions because the fees incurred were a result of their need to produce
an answer to Ivers' East Texas Products Liability Law claims. R. at 5.

Further, per Esquivel v. Arau, 913 F. Supp. 1382, 1391 (C.D. Cal. 1996), "If Rule 41(d)'s purpose is to prevent undue prejudice to a defendant from unnecessary or vexatious litigation, there does not seem to be a clear reason why Rule 41(d) would provide only for an award of costs exclusive of attorney's fees, since the typical defendant cannot adequately defend a case without incurring such fees."

2. The Sixth Circuit, unaccompanied by other circuits, has ruled attorney fees can never be Rule 41(d) costs

The Sixth Circuit held, “Where Congress has intended to provide for an award of attorney fees, it has usually stated as much and not left the Courts guessing. Further, the law generally recognizes a difference between the term ‘costs’ and ‘attorney fees’ and we have no desire to conflate the two terms. Rather, we must assume that Congress was aware of the distinction and was careful with its words when it approved Rule 41(d). Rogers v. Wal-Mart Stores, Inc., 230 F.3d 868, 874 (6th Cir. 2000).

However, the Sixth Circuit does “realize that an award of attorney fees may be authorized, even if not expressly provided for, ‘if the statute otherwise evinces an intent to provide for such fees.’”

Overall, this split creates an inconsistent application of Rule 41(d) among these circuits, and a primary role of this Court is to ensure that laws are interpreted uniformly between intermediate courts of appeal. Therefore, to resolve this issue, this Court should uphold the view held by the majority of these circuits and authorize an award of attorney’s fees under Rule 41(d).
C. Although the general rule, known as “the American Rule” states each party must bear the costs of his or her own attorney’s fees, when the statute governing the litigation defines costs to include attorney's fees, attorney's fees may be awarded by the district court.

“The American Rule” is the general rule where each party of a suit must pay its own attorney’s fees. R. at 21 (citing Key Tronic Corp. v. United States, 511 U.S. 809, 815 (1994)). This Court, in Alyeska Pipeline, held “that only Congress, and not the courts, could authorize such an exception to the ‘American rule’ that attorney fees are not ordinarily recoverable by prevailing litigant in federal litigations in the absence of statutory authorization. Alyeska Pipeline Serv. Co. v. Wilderness Soc’y, 421 U.S. 240, 95 S. Ct. 1612, 44 L. Ed. 2d 141 (1975). This means, more specifically, that without an express statutory authorization, a court may not award attorney’s fees. Edward X. Clinton, Jr., Does Rule 41(d) Authorize an Award of Attorney's Fees?, 71 St. John’s L. Rev. 81, 83 (1997). Likewise, Andrews v. America's Living Centers, LLC held a district court may award attorneys' fees under 41(d) only if either the underlying statute provides for attorneys' fees or the court finds that the plaintiff acted vexatiously.

Motley, concurring only in the result of the district court’s decision to reverse the denial of attorney’s fees, mentions the applicability of East Texas Code Annotated § 12-12-12. R. at 22. Motley argues the state statute says nothing about awarding fees to the defendant part and asks the district court to resolve the issue on remand. Id. However, in addition to the East Texas Code Annotated, this suit involves a federal statute—21 USCA 9- the Federal Food, Drug, and Cosmetic Act. Here, although Ivers’ Complaint asserts a products liability claim against Westerly,
Ivers is attempting to enforce the FDA's "sameness" regulation through a state product liability action, which makes this an FDA suit in disguise.

This leaves 21 USC Chapter 9 as one of the underlying statutes in this case, and in addition to Ivers filing a vexatious lawsuit allowing for attorney's fees, the underlying federal statute provides for attorneys' fees under "costs." Per, 21 USC § 399d, "[A] sum equal to the aggregate amount of all costs and expenses (including attorneys' and expert witness fees) reasonably incurred . . ." And "The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys' and expert witness fees) to any party whenever the court determines such award is appropriate.

This Court similarly ruled in Marek v. Chesny, for purposes of Fed. R. Civ. Pro. 68(d), "where the underlying statute defines “costs” to include attorney's fees, such fees are to be included as costs." R. at 21 (citing Marek, 473 U.S. 1, 2, 105 S. Ct. 3012, 3013, 87 L. Ed. 2d 1 (1985)). Therefore, because this is an FDA suit in disguise, and because the FDA expressly includes attorney's fees as costs, this Court should conclude the term "costs" includes attorneys' fees.

**D. Rule 41(d) would become a "toothless" deterrent if it did not include attorney's fees in its assessment**

Frivolous lawsuits remain an exasperating feature of our legal system; however, procedural rules can play a significant role in deterring these types of lawsuits. Such as when a plaintiff employs voluntary dismissal to escalate a defendant's exposure to legal fees in defending against a frivolous lawsuit, courts must be able to levy a meaningful sanction. Brief Amicus Curiae of the Chamber of

*Behrle v. Olshansky* reasoned similarly--the Court held that Congress intended Rule 41(d) to have "teeth" and to include attorney's fees in "costs." The court further stated, "A cost award, comprised of only court costs is often insubstantial. Attorney's fees, however, comprise a majority of expenses in defending a lawsuit. If courts do not have the discretion to award attorney's fees as part of Rule 41(d)'s "costs," then the Rule "has no 'teeth' and is useless. If that is the law, the provision of Rule 41(d) will not serve its intended purpose of encouraging parties not to act as plaintiff has acted in this case, to the substantial detriment of the defendant." *Behrle*, 139 F.R.D. 370 at 373 (W.D. Ark. 1991).

It is important to recall what the civil procedure system is trying to accomplish: (1) that actions are decided on their merits; (2) that they are decided in an expeditious fashion; and (3) that they are decided in a cost-friendly manner. When plaintiffs forum shop, it is unlikely these goals are met. Therefore, Rule 41(d) must perform the same function it was designed to do as when it became law in 1938—to respond to liberal nonsuit provisions that permitted "the annoying of a defendant by being summoned into court in successive actions" and to curb abuses of these nonsuit rules.

In sum, whether Rule 41(d) includes attorneys' fees is a question upon which the lower courts do not agree. This circuit split leaves a non-uniform application of
this federal law which is troublesome. This Court has the authority to help
achieve uniformity of Rule 41(d) as well as the desire to discourage forum shopping.
Therefore, even if the Court were to conclude the term "costs" is ambiguous as used
in Rule 41(d)(1), the Court should conclude that the term includes attorneys' fees
and thus conclude that the court below properly interpreted the term to include
attorney's fees. Further, Rule 41(d) affords the Court, either way, discretion to
award attorney's fees as part of the "costs" of the action previously
dismissed. Respondent, therefore, asks the Court to affirm that attorney's fees are
included in "costs" under Rule 41(d), and AFFIRM the decision of the United States
Court of Appeals for the Twelfth Circuit.
CONCLUSION

Respondent, therefore, asks that this Court AFFIRM the decision of the United States Court of Appeals for the Twelfth Circuit finding state-tort claims against generic drug manufacturers for failure-to-warn preempted under this Court’s prior decisions in *Mensing* and *Bartlett*. This Court should also adopt the Twelfth Circuit’s interpretation of Federal Rule of Civil Procedure 41(d) that allows the award of attorney’s fees under the definition of costs. The Court should affirm the Twelfth Circuit’s ruling in favor of the Respondent.

Respectfully Submitted,

/s/ Counsel for Respondents

Counsel for Respondents
APPENDIX A

21 U.S.C. § 399d, in pertinent part:

(b) Process

(3) Final Order

(C) Penalty

If such an order is issued under this paragraph, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorneys’ and expert witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued . . . .

(7) Civil Action to Require Compliance

(A) In general

A person on whose behalf an order was issued under paragraph (3) may commence a civil action against the person to whom such order was issued to require compliance with such order. The appropriate United States district court shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

(B) Award
The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys’ and expert witness fees) to any party whenever the court determines such award is appropriate.
§ 6 Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices

(a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.

(b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:

(1) contains a manufacturing defect as defined in § 2(a); or

(2) is not reasonably safe due to defective design as defined in Subsection (c); or

(3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).

(c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.
(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

(e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:

(1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or

(2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.
CERTIFICATE OF SERVICE

We certify that a copy of Respondents’ brief was served upon Alice Ivers through counsel of record by certified U.S. mail return requested, on this, the 21st of September, 2017.

/s/ Counsel for
Respondents

Counsel for Respondents