No. 17-230

IN THE SUPREME COURT OF THE UNITED STATES

ALICE IVERS,

Petitioner,

v.

WESTERLY PHARMACEUTICAL INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE TWELFTH CIRCUIT

Brief for Respondent

Team 2617
Attorneys for Respondent

Word Count: 8791

QUESTIONS PRESENTED

1. Whether Petitioner can circumvent the explicit holdings of *PLIVA* and *Mutual Pharmaceutical* which establish that all state law failure to warn claims brought against generic drug manufacturers are preempted by federal law.

2. Whether attorney's fees are considered awardable "costs" under Federal Rule of Civil Procedure 41(d) where the underlying purpose of the rule is to prevent vexatious litigation, and where Petitioner engaged in forum shopping to avoid undesirable law in a previously filed suit.

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The decision and Order of the United States District Court for the District of Illinoza is unreported and set out in the Record. (R. at 1-8.) The opinion of the United States Court of Appeals for the Twelfth Circuit is also unreported and provided in the Record. (R. at 9-22.)

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The constitutional provision involved is the Supremacy Clause. U.S. CONST., Art. VI, cl. 2. The text of this Article is reprinted in Appendix A. The statutory provisions involved are the Federal Food and Drug Cosmetic Act, 21 U.S.C. § 355(j)(2)(A), the Illinoza Products Liability Act 1998-4(1) and the East Texas Code Annotated. The text of these provisions is reprinted in Appendices B, C and D, respectively.

STATEMENT OF THE CASE

This case concerns allegations that Westerly Pharmaceutical Inc. ("Westerly"), a generic pharmaceutical manufacturer, failed to adequately warn Petitioner, Alice Ivers ("Petitioner"), of unwanted compulsive gambling side-effects.

A. Facts of the Case

In 1997, GlaxoCline, LLC ("GlaxoCline") began marketing Equip®, the brand name version of ropidope hydrochloride ("ropidope"), after receiving approval from the Federal Food & Drug Administration ("FDA"). (R. at 2.) Ropidope is a chemical compound that inhibits dopamine hormone reaction symptoms associated with Parkinson's disease. *Id.* In 2008, GlaxoCline's patent expired and Westerly, a generic manufacturer[1], submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to market an equivalent generic version of ropidope. *Id.* In 2009, Westerly received approval from the FDA and began selling its generic version of ropidope. As all generic manufacturers must do under the Hatch-Waxman Act, Westerly implemented labeling that mirrored the label Equip® utilized at the time. *Id.* In January 2011, GlaxoCline submitted a Supplemental New Drug Application ("sNDA") to the FDA requesting approval to change Equip®'s Package Insert and corresponding labels. *Id.* The sNDA contained a new paragraph added under the "Warnings and Precautions" section of the label. *Id.* The paragraph states:

[1] A generic manufacturer produces a drug with the same key active ingredient(s) as the brand-name drug, whose patent has expired. (R. at 10.)

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.

Id.

The Petitioner was diagnosed with Parkinson's disease in February 2011. *Id.* at 1. Petitioner began taking the generic version of ropidope manufactured by Westerly in March 2011 upon prescription by her doctor, even before the brand name warning had been implemented. *Id.* During the course of Petitioner's treatment, the FDA approved the brand-name's proposed label change for Equip® and implemented the new warning in June 2011. *Id.* at 2. In January 2012, only six months after GlaxoCline, Westerly submitted a Changes Being Effected ("CBE") notification to the FDA which stated that they would update their labels to match the FDA-approved Equip® labels effective February 1, 2012. *Id.* at 3.

Beginning in July 2011, Petitioner alleged that she began to develop compulsive spending and gambling behaviors. *Id.* Throughout 2011, Petitioner transferred the majority of her retirement savings into an online poker account and played poker constantly. *Id.* Petitioner won substantial amounts of money playing online poker, but stated that she felt compelled to spend all the earnings through various channels such as charity and auctions. *Id.* By the end of 2012, almost a full year after Westerly updated its label to correspond to Equip®'s labels, Petitioner's retirement savings were completely depleted. *Id.* Petitioner alleges that the absence of a side-effects warning proximately caused these gambling and spending behaviors which depleted her retirement finances and damaged her marriage. *Id.*

B. Procedural History

On January 15, 2013, Petitioner initially filed a Complaint against Westerly in the United States District Court for the Western District of East Texas alleging both defective design and inadequate instructions or warnings of Westerly's generic version of ropidope. *Id.* at 5. This claim was pled under the East Texas Products Liability Law. *Id.* at 5. Petitioner voluntarily dismissed the action before Westerly filed an answer, however, due to the Fifth Circuit's holding in *Morris v. PLIVA*, *Inc.,* 713 F.3d 774 (5th Cir. 2013) preempting a claim similar to Petitioner's. *Id.* Petitioner re-filed her Complaint, under the same legal theory, in the Illinoza state court on September 15, 2015. *Id.* at 1. Now, Petitioner now alleges that Westerly breached its duty owed to her pursuant to §1(b) and §1(c) of the Illinoza Products Liability Act, which provides relief "upon showing that a manufacturer's products

were unreasonably dangerous due to... (b) defective design, [or] (c) inadequate instructions or warnings...." *Id.* Petitioner seeks $500,000 in damages. *Id.* at 1.

Westerly removed the action from Illinoza state court to the District Court for the District Court of Illinoza on October 14, 2015 asserting diversity and removal jurisdiction. *Id.* at 3. Westerly filed its answer to the Complaint along with Motions for Judgment on the Pleadings and for an Award of Costs on November 2, 2015. *Id.* On December 20, 2015, the District Court for the District of Illinoza granted Westerly's Motion for Judgment on the Pleadings and granted in part and denied in part Westerly's Motion for an Award of Costs. *Id.* at 8.

Petitioner filed an appeal to the United States Court of Appeals for the Twelfth Circuit on January 14, 2016 contesting the opinion below. *Id.* at 11. Westerly filed a cross-appeal contesting the denial in part of awarding attorney's fees as costs by the lower court. *Id.* On February 2, 2017, the United States Court of Appeals for the Twelfth Circuit affirmed the District Court judgment granting the Motion for Judgment on the Pleadings and affirmed in part and reversed in part the District Court judgment on Westerly's Motion for an Award of Costs. *Id.* at 18.

Petitioner sought a writ of certiorari from the Supreme Court of the United States. The Supreme Court granted certiorari on 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).

(R. at 23.)

SUMMARY OF ARGUMENT

This Court should affirm the holding of the United States Court of Appeals for the Twelfth Circuit on both the preemption and attorney's fees issues.

I. Preemption

The Supremacy Clause, Article X of the United States Constitution, provides that federal law is the supreme law of the land and preemption exists to achieve that goal. The doctrines of both impossibility and obstacle preemption prohibit the Petitioner from advancing past a judgment on the pleadings because, under either, her claim is preempted. Impossibility preemption exists when it would be impossible for the manufacturer to comply with both state and federal law; obstacle preemption exists when state law poses an obstacle to the objectives of Congress. The FDA governs the arena of the adequacy of labels through statutes and regulations enacted by Congress. And as held by this Court and numerous lower courts, states have no business gap-filling with tort laws that conflict with federal law. Here, Illinoza's Products Liability Act does exactly that.

Petitioner rests her theory of liability on the premise that Westerly failed to update its label within a reasonable time. However, the state law "reasonableness" standard is unenforceable because it is incongruent with federal law. The FDA proscribes the regulations by which generic manufacturers update and change their

labels; so therefore, state law simply has no place. Westerly acted in conformance with these regulations, leaving Petitioner with no cause of action.

The Food, Drug, and Cosmetic Act sets the standard for warning label adequacy for both brand-name and generic pharmaceuticals. The Hatch-Waxman Act was enacted to promote a streamlined and more efficient way to place lower-costing, generic drugs on the market. While still a rigid and heavily-regulated process, the generic manufacturer's role is only to mimic the brand-name pharmaceutical. Accordingly, Westerly did not have a duty to act under any state law, especially one that posed an additional requirement that federal law does not. Federal law is silent about the six-month time span in between the brand-name's label update, and Westerly's update that followed, and states cannot create new liability when none exists under federal law.

II. Attorney's Fees

This Court should affirm the Twelfth Circuit's inclusion of attorney's fees as awardable "costs" under Federal Rule of Civil Procedure Rule 41(d). Rule 41(d) provides that a plaintiff who previously dismissed an action based on or including the same claim against the same defendant, may be ordered to pay all or part of the costs of the previous action. Rule 41(d), however, does not expressly define the term "costs." The Twelfth Circuit below correctly held that "costs," as contemplated by Rule 41(d), necessarily includes attorney's fees because of Congress' implied intent and the policy rationale behind Rule 41(d).

The inclusion of attorney's fees is supported by the plain language and structure of Rule 41. This Court, and the vast majority of circuits, have determined Congress' intent from parallel or comparable Federal Rules such as Rule 54 and Rule 68, and have articulated instances where attorney's fees may be awarded. Additionally, petitioner's refiling of her previously-dismissed suit constituted forum shopping, the exact type of vexatious litigation behavior Congress sought to curb when they enacted Rule 41(d). As a result, this Court should affirm the decision of the Twelfth Circuit below, so as to effectuate the core policy rationale and plain structure of Rule 41(d).

LEGAL ARGUMENT

I. THIS COURT SHOULD AFFIRM THE TWELFTH CIRCUIT'S HOLDING BECAUSE STATE LAW TORT CLAIMS ARE PREEMPTED BY FDA REGULATION UNDER BOTH THE DOCTRINES OF IMPOSSIBILITY AND OBSTACLE PREEMPTION.

Petitioner's claim under the Illinoza Products Liability Act is preempted by the Supremacy Clause of the United States Constitution. This Court's decisions in *PLIVA* and *Mutual Pharmaceutical*, which hold that when a federal law and state law conflict, federal law wins. The Supremacy Clause in the U.S. Constitution establishes that federal law "shall be the supreme Law of the Land…any Thing in the Constitution of Laws of any State to the Contrary notwithstanding." U.S. CONST., Art. VI, cl. 2. The doctrine of conflict preemption is grounded in the Supremacy Clause and "...consistent with that command, we have long recognized that state laws conflicting with federal law are 'without effect.'" *Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746

(1981)). "The purpose of Congress is the ultimate touchstone" in every preemption case. *Medtronic, Inc. v. Lohr,* 518 U.S. 479, 485 (1996). Moreover, "where state and federal law directly conflict, state law must give way." *Wyeth v. Levine,* 555 U.S. 555, 583 (2009).

This Court has found implied conflict preemption when it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 115 S.Ct. 1483, 1487 (1995) (quoting *English v. General Electric Co.,* 110 S.Ct. 2270, 2274 (1990)) (internal quotation marks omitted). State law actually conflicts with federal law if either (1) compliance with both is impossible, or (2) the state requirement is an obstacle to the full purposes and objectives of Congress. *See Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963), *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Notably, a presumption against preemption exists in various Supremacy Clause cases; however, this Court has never applied this presumption in areas such as drug labeling that have been "reserved for federal regulation." *Wyeth,* 555 U.S. at 624 (Alito, S., dissenting) (fn. 14). *See United States v. Locke*, 529 U.S. 89, 111 (2000), *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-348 (2001). Accordingly, this Court should affirm the Twelfth Circuit's holding that Petitioner's state law tort claim is preempted by federal law.

A. Under *PLIVA* and *Mutual Pharmaceutical*, Petitioner's claims are preempted because federal law governs the regulations surrounding warning labels.

The federal and state laws at issue deal with the responsibility bestowed on the manufacturers of generic prescription drugs to properly label and provide adequate warnings about their drugs. (R. at 12.) The Illinoza Products Liability Act ("IPLA") 1998-4(1) provides relief "upon showing that a manufacturer's products was unreasonably dangerous due to ...(b) defective design, [or] (c) inadequate instructions or warnings..." (R. at 3.) Petitioner claims under §1(b) and §1(c) of the IPLA that Westerly breached its duty because the ropidope labels were defectively designed and had inadequate warnings of her developed compulsion to gamble. *Id.*

The Food, Drug and Cosmetic Act ("FDCA"), as amended through the Hatch-Waxman Act, allows manufacturers of generic versions of reference-listed drugs ("RLD") to use an Abbreviated New Drug Application ("ANDA") to market the drugs after the RLD patent expires. (R. at 12.) The Hatch-Waxman Act allows generic drug manufacturers to "gain FDA approval simply by showing equivalence to a...drug that has already been approved by the FDA." *PLIVA v. Mensing*, 564 U.S. 604, 612 (2011) (citing 21 U.S.C. § 355(j)(2)(A)). The generic drug must be chemically equivalent to the RLD, containing the same active ingredient, route of administration, dosage form, strength and labeling. *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2471 (2013). The FDA can approve the ANDA as long as the drug is a "bioequivalent" to an RLD.[2] 21 U.S.C. § 355(j)(2)(A)(iv) (2012).

[2] The FDA definition of "bioequivalence" is "absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar circumstances in an appropriately designed study." 21 C.F.R. § 320.1(e). This is not an issue for the question on certiorari.

However, the generic manufacturer must use the exact same labeling as the RLD with FDA approval. *Id*. This is often referred to as "the duty of sameness". *Id.* 21 U.S.C. § 355(j)(2)(A)(v). The importance of the Hatch-Waxman Act and the prevalence of generic pharmaceuticals cannot be understated; from 1984 to 2009, the percentage of drugs sold in this country that were generic rose from 19% to 75%. *PLIVA,* 564 U.S. at 629 (Sotomayor, S., dissenting). The generic drug manufacturer market was a $66 billion dollar industry in 2009, and surely has only grown since then. *Id.* at 630. The FDA has exclusive governance of this arena. That should lead to the conclusion that federal law preempts Petitioner's state law tort claims.

In *PLIVA*, this Court, applying the impossibility doctrine, held that the state failure-to-warn claims were preempted because the generic manufacturer could not institute a label change without FDA prior approval. *PLIVA*, 564 U.S. at 624. The central question for the "impossibility doctrine" is "whether the private party could independently do under federal law what state law requires of it." *Wyeth v. Levine,* 555 U.S., 555, 573 (2000). Minnesota and Louisiana tort law required manufacturers that are or should have been aware of the product's dangers to label it using a method that renders it reasonably safe. *Id.* at 611. Both states agreed that the duty to warn falls specifically on the manufacturer. *Id*. The plaintiffs alleged that the manufacturers were liable under state tort law for the failure to provide adequate warning labels. *Id.* at 610. The plaintiffs claimed that despite evidence that the drug usage carried a far greater risk than the label indicated,

none of the manufacturers instituted a label change to adequately warn consumers of the drug. *Id.*

Federal law, under the FDCA and more specifically the Hatch-Waxman Amendments, allow "generic drug" manufacturers to gain FDA approval by showing bioequivalence to a RLD that has received previous approval by the FDA. *Id.* at 612, citing 21 U.S.C. § 355(j)(2)(A). The generic drug application must propose the same labeling that the FDA approved for the RLD. *Id.*, citing 21 U.S.C. § 355(j)(2)(A)(v). The FDA interprets the regulations imposed on the generic drug manufacturers as an "ongoing federal duty of 'sameness'." *Id.* at 613. FDA views and interpretations "are controlling unless plainly erroneous or inconsistent with the regulations." *Auer v. Robbins,* 519 U.S. 452, 461 (1997).

The plaintiffs, similar to Petitioner, insisted that the FDA's CBE process allows manufacturers to change labels when necessary. *PLIVA*, 564 U.S. at 614. Drug manufacturers, under the CBE process, are permitted "to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." *Id.* (citing 21 CFR § 314.70(c)(6)(iii)(A) (2006)). This Court agreed with the FDA, deferring to its judgment, that generic manufacturers cannot use the CBE process to unilaterally strengthen their warning label. *Id.* Generics are limited to changing the label only to match an updated RLD-label and any unilateral action would violate their duties under federal statutes and regulations. *Id.* This Court found impossibility preemption existed because if the manufacturers had independently changed their labels to satisfy their duties under state tort law,

they would have violated the federal law imposed on generic manufacturers by the FDA and Hatch-Waxman Act. *Id.* at 618.

To be clear, *Wyeth's* holding is not contrary to *PLIVA*, because it dealt with brand name manufacturers who under the FDA's CBE process have the unilateral authority to amend labels to add appropriate warnings, which is not available to generic drug manufacturers. Therefore, it is not impossible for brand name manufacturers to comply with the state tort law and federal law simultaneously, but it is impossible for generic drug manufacturers. This Court has acknowledged a seemingly apparent tension between brand name and generic manufacturers by stating that preemption in this case, but not in *Wyeth*, made little sense and seemed unfair. *Id.* at 625. However, this Court reaffirmed that this is the wrong arena to effectuate change by stating "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." *Id.* at 626, quoting *Cuomo v. Clearing House Assn., L.L.C.*, 557 U.S. 519 (2009).

In *Mutual Pharmaceutical*, this Court reversed the First Circuit and held that "state-law design-defect claims that turn on the adequacy of the drug's warnings are preempted by federal law under *PLIVA*." 133 S.Ct. at 2470. The respondent took the generic version of the NSAID (nonsteroidal anti-inflammatory drug) sulindac and developed toxic epidermal necrolysis. *Id.* at 2472. The drug label at the time respondent was prescribed, and when respondent developed the toxic epidermal necrolysis, did not specifically reference it. *Id.* However, shortly after respondent was suffering, the FDA recommended changes to the labeling of all

NSAIDs to explicitly warn against it. *Id.* New Hampshire law imposed on manufacturers the duty to ensure the drugs marketed are not unreasonably safe. *Id.* The unreasonably safe standard was analyzed by examining the chemical properties of the drug and the adequacy of the warnings. *Id.* at 2470. The First Circuit believed that Mutual Pharmaceutical could have stopped selling the drug to comply with federal and state law; however this Court found that rationale unpersuasive. *Id.* Moreover, the "stop-selling" method "would render impossibility preemption a dead letter and work a revolution in this Court's preemption case law." *Id.*

New Hampshire used a "risk-utility approach" in determining whether a product is unreasonably dangerous. *Id.* at 2474. That test states, "[A] product is defective as designed if the magnitude of the danger outweighs the utility of the product." *Id.* This approach required a "multifaceted balancing process involving evaluation of many conflicting factors." *Id.* This Court identified the three most important factors to the risk-utility analysis: (1) "the usefulness and desirability of the product to the public as a whole;" (2) "whether the risk of danger could have been reduced without significantly affecting the product's effectiveness or manufacturing cost;" and (3) "the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers of from foreseeable uses." *Id.* at 2475. This Court recognized that it was not possible for Mutual Pharmaceutical to increase the usefulness of the drug or reduce the risk of danger, the first two factors for the risk-utility analysis, without a complete redesign of the drug. *Id.* "Given the

impossibility of redesigning sulindac, the only way for Mutual to ameliorate the drug's 'risk-utility' profile…was to strengthen 'the presence and efficacy of warning'…" *Id.*

In applying the holdings from *PLIVA* and *Mutual Pharmaceutical* to our case-specific circumstances, it is undisputed that Westerly Pharmaceutical could not have possibly acted until June, 2011, when GlaxoCline implemented the changes on its Equip® label. *PLIVA* explicitly states that generic drug manufacturers cannot act unilaterally when the RLD has not updated or changed its label. Therefore, the crux of Petitioner's claim covers the period between June, 2011 and January, 2012; from when GlaxoCline updated its Equip® labels until Westerly submitted the CBE to the FDA informing them of their update to match the brand label. *Mutual Pharmaceutical* extends the holding from *PLIVA* to "design-defect claims." In our case, utilization of the New Hampshire "risk-utility approach" shows that Westerly could not have affected change as to the design of ropidope because it would not have complied with the FDA's requirement of equivalence. Also, ropidope itself is a chemical compound and therefore, if the compound were altered, it would have changed the entire drug. (R. at 2.) Similar to *Mutual Pharmaceutical*, the fact is that the design defect claim brought by the Petitioner is based on the adequacy of the warnings, therefore the only way for Westerly to comply was to strengthen its warnings.

This Court's decisions in *Wyeth, PLIVA,* and *Mutual Pharmaceutical* explicitly state that failure-to-warn claims against generic drug manufacturers are

preempted. Members of this Court in those decisions, majority and dissent included, tended to agree that it was odd that the issue of preemption and the ability to seek a remedy turned on whether the pharmacist prescribed the plaintiff the brand name or the generic drug. However, the current structure is strongly rooted in equitable principles because it holds the brand name manufacturers who possess a far superior amount of knowledge about the drug more responsible than the generic manufacturers. If there is the need for regulatory or Congressional action following the decisions of *PLIVA* and *Mutual Pharmaceutical* after *Wyeth* because of the drastic difference in liability between the brand name and the generic drug manufacturers Congress could act. It could overrule the holdings of *PLIVA* and *Mutual Pharmaceutical* by amending the FDCA with an express non-preemption clause that states state tort law failure-to-warn claims are allowed or could provide the generic drug manufacturers with the same unilateral amendment power under the CBE process as brand name manufacturers possess. If Congress wants to change the regulatory landscape of the generic drug manufacturers it has every right to, and this Court in *Mutual Pharmaceutical* has even suggested Congress do so. "Suffice to say, the Court would welcome Congress' 'explicit' resolution of the difficult preemption questions that arise...that issue has repeatedly vexed the Court...and produced widely divergent views." 133 S.Ct. at 2480. Until such time, however, this Court's jurisprudence dictates preemption.

Petitioner's claims cannot stand in the wake of federal law governing this area. Furthermore, there are public policy concerns about holding a generic

manufacturer liable under state law even though their actions are fully compliant with FDA regulation and statute. It would subject generic manufacturers to fact-sensitive inquiries about the reasonableness of their response to the brand name updates, and furthermore it would restrict the flow of generic drugs in certain states due to generic manufacturer concerns about potential state tort liability. The policy of federal law is to promote the presence and the availability of safe generic drugs; compliance under federal law accomplishes these objectives and the implementation of state law standards would do more harm than good in maintaining this federal objective.

B. Petitioner's attempt at reframing her allegations as something different than a label adequacy claim fails because lower courts have consistently applied preemption to all state tort law claims.

It is well established that state tort law failure to warn and inadequate labeling claims are preempted because the FDA mandates that generic manufacturers label their drugs identically to brand-name drugs. *See PLIVA*, 564 U.S. at 604, and *Mutual Pharmaceutical*, 133 S.Ct. at 2466. After this Court's decisions holding as such, plaintiffs began framing their allegations as "failure to *communicate*" negligence claims in order to avoid preemption. *See Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1248 (11th Cir. 2013), *Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013). A failure to communicate claim does not allege the warning labels themselves are inadequate, but rather that the manufacturer is "liable for failing to make medical providers aware of -- i.e, failing to communicate -- the

change in labeling." *Guarino*, 719 F.3d at 1248. Generic manufacturers operate under a "duty of sameness," which prohibits these manufacturers from acting unilaterally to change their label to something other than an identical brand-name label of the same drug. *Id*. at 1249. No matter what a plaintiff calls the claim, if the substance of the allegation involves a failure to warn for long-time use, the claim is federally preempted. *Id*.

Most recently, the Eleventh Circuit followed the lead of the Fifth Circuit in denying failure to communicate liability for generic manufacturers. *Guarino,* 719 F.3d at 1249. In May 2007, and up until August 2007, the plaintiff, Guarino, took metoclopramide, a generic version of the drug often sold under the brand name Reglan, which is used to treat symptomatic gastroesophageal reflux and recurrent diabetic gastric stasis. *Id*. at 1247. The plaintiff developed tardive dyskinesia, a severe neurological condition, after continuous use for twelve weeks. *Id.* Three years before the plaintiff's prescription, the FDA changed the label to explicitly warn against this prolonged use. *Id.* Two years after plaintiff's prescription, the FDA ordered its strongest warning. *Id.* Plaintiff thereafter sued the generic manufacturer under theories of negligence, strict liability, breach of warranty, misrepresentation and fraud, and negligence per se, but most specifically that the drug label did not adequately warn medical providers of the risks associated with long term use of the drug. *Id*. at 1247. After the decision in *PLIVA v. Mensing*, the district court dismissed the failure to warn claims because they were simply preempted. *Id.*

In *Morris v. PLIVA, Inc.*, the plaintiff suffered from the same unfortunate timeline and disorder as a result of the generic drug metoclopramide. *Morris,* 713 F.3d at 776. In accordance with *Mensing v. PLIVA*, the plaintiff's state law tort claim was dismissed because it was federally preempted by FDA regulations. *Id.* On appeal, plaintiff masked her allegations as a failure to communicate *approved* warnings. *Id.* at 777. Specifically, "they allege the generic defendants are liable for failing to convey FDA-approved information; information communicated by generic manufacturers that is consistent with the brand-name labeling does not violate the duty of sameness." *Id.* This conveyance of information would involve unilateral action by the generic manufacturer. *Id.* The duty of sameness prohibits these types of affirmative steps (such as alerting consumers, doctors or pharmacists of drug label changes), and such generics are dependent on brand-names taking the lead. *Id.* As such, *Mensing* again preempts this claim because it would be impossible for PLIVA to comply with the federal law duty of sameness and the state law duty to warn. *Id.*

The preemption analysis emanates throughout circuit and district court decisions. These courts have consistently held that state law claims, in any form, are preempted where the FDA governs. *See Gardley-Starks v. Pfizer, Inc.*, 917 F..Supp. 2d 597 (N.D. Miss. 2013) (holding that plaintiff's failure-to-withdraw, failure to communicate, failure to conduct post-marketing surveillance and reporting, failure to update label and defective design claims under Mississippi law were all preempted under *PLIVA* and *Mutual Pharmaceutical's* ambit.); *Wilson v.*

Amneal Pharms., L.L.C., 2013 U.S. Dist. LEXIS 181953, 2013 WL 6909930 (D. Idaho 2013) (holding that plaintiff's failure to warn, failure to update and design defect claims are preempted because of impossibility preemption). For example, in *Bell v. Wyeth, Inc.*, the plaintiff framed her claim by stating that because the generic manufacturer chose not to comply with federal law when it failed to update its labels, it could have complied with the state's tort laws. 117 F. Supp. 3d 1355, 1360 (M.D. Alabama 2015). Specifically, the generic manufacturers did not update the package insets to match those accompanied by the brand-name drug.

Currently, the Sixth Circuit is alone in holding that a plaintiff's state law tort claims about the adequacy of labels could proceed. Petitioner's reliance on *Fulgenzi* is misplaced, and the case provides no support for her claim here. The plaintiff in *Bell* found merit in her claim based on the limited holding from *Fulgenzi v. PLIVA, Inc.* 711 F.3d 578 (6th Cir. 2013). In *Fulgenzi*, the Sixth Circuit held that the plaintiff's claims could go forward to the extent that they failed to comply with the brand-name's durational warning on the labeling. *Id.* at 584. The generic manufacturer *never* updated the warning label to match the brand name. *Id.* This holding was founded upon the generic's failure to comply with federal regulations, i.e., the brand-name had different language, and the generic did not hold "sameness." *Id.* When a plaintiff's allegations so much as suggest unilateral action on the part of the generic manufacturer, this Court has made it abundantly clear: "generic manufacturers cannot be held liable for violating state-tort laws in failing to take unilateral actions that would be prohibited by federal law. *Bell*, 117 F. Supp.

3d at 1364 (citing *Mensing*, 131 S. Ct. at 2577-78, *PLIVA*, 564 U.S. at 624). Accordingly, since the plaintiff in *Bell* continually asserted that the federally compliant labeling did not satisfy state law, the claims were preempted and subsequently dismissed. *Id*. at 1365.

Here, Petitioner relies on sections (1)(b) and (c) of the IPLA to allege that unwarned side effects of ropidope proximately caused compulsive gambling behaviors. (R. at 3.) Specifically, these sections address defective design and inadequate warnings of the potential side effects. *Id*. It is undisputed that Westerly's label matches the RLD's, therefore Petitioner must cloak her complaint in order to try and avoid preemption. *Id.* at 10. Unlike the facts in *Fulgenzi*, Westerly submitted a CBE in January 2012, and the warning label change came into effect one month later. (R. at 2.) Equip® changed its label in June of 2011. *Id.* At all times Westerly complied with federal law since there is no time frame as to when the label update must take effect. The Sixth Circuit holding is an outlier because the generic manufacturer never took any steps to comply with FDA regulations; therefore it was not impossible to comply with state law since the generic wasn't complying with federal law either.

Petitioner premises Westerly's supposed liability on Illinoza's "reasonableness" standard. *Id.* at 10-11. This claim is indistinguishable from the long line of cases that follow the very explicit rule that state law tort claims for "failure to update" theories and the like are preempted by federal law. *Id.* at 13. Westerly complied with federal law in updating its label. *Id.* To impose additional

state-by-state standards would make generic manufacturing unduly burdensome and would contravene the purpose of the Hatch-Waxman Act. *Id.* Most importantly, state law conceptions of reasonableness have no place in the already heavily regulated federal process. (R. at 15.) Just as recent plaintiffs have failed in bringing "failure to communicate" lawsuits against generic manufacturers, so too must the Petitioner for this alleged failure to warn "reasonably". Besides the most basic tenant that these claims are preempted, these claims, if successful, would require additional unilateral action by generics that they are not at liberty to take. For example, Westerly's "duty" to comply with Illinoza state law would require the company to understand what is reasonable in Illinoza, while still completely complying with federal law. The FDA is tasked with pharmaceutical safety – this is their arena, and states imposing additional standards does not accomplish any goal that federal regulations are not already set out to cover.

C. Reasonableness standards under state law would frustrate, and subsequently pose an obstacle, to the FDA's regulation of generic manufacturers.

In addition to impossibility preemption, Petitioner's claims are still preempted under the doctrine of obstacle preemption. Obstacle preemption exists when state law "stands as an obstacle to the accomplishment and the execution of the full purposes and objectives of Congress." *See Crosby v. Nat'l Foreign Trade Council,* 530 U.S. 363, 372-373 (2000); *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941). This Court has discussed preempting state law that "under the circumstances of the particular case...stands as an obstacle to the accomplishment and execution of the

full purposes and objective of Congress...whether that 'obstacle' goes by the name of 'conflicting; contrary to; ...inconsistency; violation; curtailment…'" *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000) (quoting *Hines,* at 67). Furthermore, sometimes preemption reflects a desire to subject the industry to a single, uniform federal safety standard. *Id.* at 871 (stating "...the preemption of all state standards, even those that might stand in harmony with federal law, suggests an intent to avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create."). "The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." *Id.* at 883, citing *Medtronic*, 518 U.S. at 496.

The reasonableness standard stemming from the IPLA stands as an obstacle to the federally mandated process that is implemented by the FDA because it would create compliance uncertainty for generic drug manufacturers. It is undisputed that Westerly did change the label to match that of the RLD within six months of the RLD label change. (R. at 14.) Westerly complied with the FDA regulations discussed under 21 U.S.C. § 355(j) and the Code of Federal Regulations. It is not difficult to foresee issues if this Court were to allow state tort law similar to the reasonableness standard to be implemented in every state. It would subject generic drug manufacturers to fifty different reasonableness standards that could be individually tailored by the specific state. A situation where the generic drug manufacturer complies with the FDA, but not with a state law, is difficult enough to

remedy, however a situation where the generic drug manufacturer complies with federal law, some state law, but yet not other state law, could have even more serious consequences downstream. Generic drug manufacturers would fear the widespread liability, therefore they would tailor their distribution into states that they felt they could comply with.

The implementation of state law standards more stringent than federal law would be antithetical to the goals of the Hatch-Waxman Act because it would discourage the widespread usage of generic drugs due to the near impossibility of compliance. Hatch-Waxman streamlined the process for generic drugs. It allows generic drug manufacturers to use the RLD research and information to get the generic drug on the market as fast as it possibly can, as long as it complied with what the FDA had already approved for the RLD. Furthermore, it would be counterproductive to impose so many levels of regulation on the generic drug manufacturers when there is state law, for example like in *PLIVA*, that wants and sometimes requires pharmacists to prescribe the generic version of a drug when possible. *PLIVA*, 564 U.S. at 625. Currently, all fifty states have a form of a generic substitution law, either requiring pharmacists to substitute the generic drug for the brand name when possible, or highly encouraging that it be done. Christensen, Kirking, Ascione, Welage, & Gaither, Drug Product Selection: Legal Issues, 41 J. Am. Pharmaceutical Assn. 868, 869 (2001).

The FDA should be accorded deference when interpreting its regulations and methods of accomplishing its objectives. The FDA heavily regulates the complicated

field of RLD and generic drug manufacturers with extensive regulations and statutes governing the processes of bringing new drugs to market. The extensive regulation implemented by the FDA is evident in the regulations and statutes governing new drug applications (NDAs) and ANDAs under Hatch-Waxman for generic drug manufacturers. The processes are onerous, supported by the statistics that a NDA could take up to 2 years for the FDA to approve. FDA Review: Independent Institute, *The Drug Development and Approval Process* (2016), http://www.fdareview.org/ 03_drug_development.php. It is noteworthy that the FDA when mandating the processes stemming from the ANDA (such as: bioequivalence, dosage and administration, label mirroring, etc.,), that the FDA did not find it necessary to include a time period by which the generic must effectuate the CBE process to mirror the RLD label. FDA deference and intent, similar to *Geier*, seems to point towards a single, federal standard so that all generic drug manufacturers are aware of their obligations and requirements. Furthermore, it allows the FDA, not state law and juries, to police and further their objective purpose. Forcing Westerly and other generic drug manufacturers to comply with state-specific tort law standards of reasonableness would present a clear obstacle to the federal objective promulgated by the FDA and would lead to uncertainty, conflict, cost, and risk, as highlighted in *Geier*. Therefore, even if Westerly could have complied with both the state and federal law, Petitioner's state law claim should still be preempted under obstacle preemption.

The Supremacy Clause language provides the foundation for the doctrine of federal preemption, which demands state law cede to federal law when they are in conflict. Under implied conflict preemption, either impossibility or obstacle, Petitioner's claim is preempted because the state law reasonableness standard renders it impossible for Westerly to comply with state and federal law simultaneously. It also presents an obstacle to the federal objectives for generic drug regulation. Therefore, this Court should affirm the holding of the United States Court of Appeals for the Twelfth Circuit that Petitioner's claims under the IPLA are preempted.

II. THE TWELFTH CIRCUIT CORRECTLY HELD THAT "COSTS," AS CONTEMPLATED BY RULE 41(d), NECESSARILY INCLUDES ATTORNEY'S FEES BECAUSE OF CONGRESS' IMPLIED INTENT AND THE POLICY RATIONALE BEHIND RULE 41(d).

This Court should affirm the holding of the Twelfth Circuit because Congress intended costs to be included under attorney's fees. At issue is whether attorney's fees are considered awardable "costs" under Federal Rule of Civil Procedure 41(d) where the underlying purpose of the rule is to prevent vexatious litigation, and where Petitioner engaged in forum shopping to avoid undesirable law in a previously filed suit.

Rule 41(d) provides:

> 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.

Fed. R. Civ. P. 41(d) (emphasis added). The purpose of the rule is "to prevent the maintenance of vexatious law suits and to secure, where such suits are shown to have been brought repetitively, payment of costs for prior instances of such vexatious conduct. *Meredith v. Stovall*, No. 99-3350, 2000 U.S. App. LEXIS 14553, at *4 (10th Cir. June 23, 2000) (citing *United Transp. Union v. Maine Central R.R.*, 107 F.R.D. 391, 392 (D. Me. 1985). Although "costs" are central to the Rule, the Rule does not expressly define the term. The majority of Circuits ruling on the issue of whether attorney's fees are subsumed under the definition of "costs" in Federal Rule of Civil Procedure Rule 41(d) have found that such fees are rightly considered "costs." *See Robinson v. Bank of Am., Nat'l Ass'n*, 553 F. App'x 648, 652 (8th Cir. 2014) (holding attorney's fees are included in the definition of "costs" and that the court below did not abuse its discretion in electing to reward them); *Stovall*, 2000 U.S. App. LEXIS 14553, *4 (holding the award of attorney's fees as "costs" is within the discretion of the trial court, as supported by the rule's purpose to "prevent the maintenance of vexatious law suits").

Almost every other circuit which has held attorney's fees are not categorically included in the definition of "costs" has, at the very least, articulated exceptions and conditions under which attorney's fees may be awarded to a defendant. *See Esposito v. Piatrowski*, 223 F.3d 497, 500 (7th Cir. 2000) (holding reasonable attorney's fees may be considered "costs" "only where the underlying statute defines costs to include attorney's fees"); *see also Andrews v. America's Living Ctrs., LLC*, 827 F.3d

306, 309 (4th Cir. 2016) (adopting the *Esposito* rationale, but also allowing courts to reward attorney's fees "where it makes a specific finding that the plaintiff acted 'in bad faith, vexatiously, wantonly, or for oppressive reasons.'"). Only the Sixth Circuit and the United States District Court for the District of Illinoza below have elected to exclude attorney's fees entirely. *See Rogers v. Wal-Mart Stores, Inc.,* 230 F.3d 868, 875 (6th Cir. 2000); (R. at 7.)

Like the majority of circuit courts ruling on the issue, this Court should find that Congress intended for attorney's fees to be included in the definition of "costs" because: (1) the plain language of 41(d), as well as that of comparable Federal Rules, suggests Congress intended to include attorney's fees; and (2) effectuation of Congress' policy objectives in drafting Rule 41(d) requires reading attorney's fees into the definition of "costs."

A. The plain language of Rule 41(d), as well as comparable Federal Rules, suggest that Congress intended to include attorney's fees as "costs."

The plain language of Rule 41(d), as well as comparable Federal Rules, suggest that Congress intended to include attorney's fees as "costs." When statutory interpretation is at issue, we begin with the statutory language. *Williams v. Taylor*, 529 U.S. 420, 431 (2000). The statute's plain meaning is derived from its text and its **structure**. *Alexander v. Sandoval*, 532 U.S. 275, 288 (2004) (emphasis added).

Rule 41(d) does not define "costs," but elements of Rule 41's structure indicate that Congress intended for it to include attorney's fees. For example, there is necessary parallelism between Rule 41(a)(2) and 41(d). Rule 41(a)(2) provides that "an action may be dismissed at the plaintiff's request only by court order," and

"unless the order states otherwise, a dismissal under this paragraph (2) is without prejudice. Fed. R. Civ. P. 41(a)(2). The Sixth Circuit in *Rogers* points out that there exists a certain important parallelism between Rule 41(a)(2), and 41(d). *See Rogers*, 230 F.3d at 875 (("because both rules are intended to prevent vexatious litigation and forum shopping, 'it would be inconsistent to conclude that a court has discretion to condition Rule 41(a)(2) voluntary dismissal without prejudice on payment of attorney fees, but that a court does not have discretion to exact the same payment from a plaintiff who has noticed a Rule 41(a)(1) dismissal in a previous case'") (citing *Esquival v. Arau*, 913 F. Supp.1382, 1391 (C.D. Cal. 1996))). The Sixth Circuit in *Rogers* likewise acknowledges the argument that both provisions, read in this manner, would appear to mutually reinforce the underlying policy rationale to "prevent vexatious litigation and forum shopping." *Id.*

Many other courts making interpretations of congressional intent regarding Rule 41(d) have also done so through reference to similar provisions in the Federal Rules of Civil Procedure. One significant example of this intent is the construction of Rule 54(d). Rule 54 generally addresses judgments and costs. Fed. R. Civ. P. 54. While subsection (d) of this Rule addresses attorney's fees separately from other types of fees, the explicit mention of attorney's fees at all, as a category under the rule governing judgments and costs, would seem to indicate that Congress considered such fees to be "costs" under the Federal Rules.

Petitioner advances the Sixth Circuit and District Court's view that attorney's fees are categorically excluded from the definition of "costs." This view is

neither supported by the plain structure of the Rule, nor by the vast majority of circuit courts. Interestingly, the Sixth Circuit rejects the trend in decisions, tacitly following a law review article's hypothesis that the two rules are perhaps intended to "operate differently." *Id.* (citing Edward X. Clinton, Jr., Does Rule 41(d) Authorize an Award of Attorney's Fees, 71 St. John's L. Rev. 81, 86 (1997)). The Sixth Circuit offers no other rationale for the categorical exclusion of attorney's fees apart from the apparent and undisputed fact that Congress did not explicitly provide for attorney's fees in Rule 41(d). *Id.* Indeed, Congress did not explicitly provide for attorney's fees in Rule 41(d), but according to basic principles of statutory interpretation, this does not mean that attorney's fees are categorically excluded. There is simply no reason to rule against this trend where there exists tangible and convincing evidence that Congress intended for Rule 41(d) to include attorney's fees under "costs."

Further, even if Congress did not intend for Rule 41(d) "costs" to always include attorney's fees, the Court in *Marek v. Chesny*, found that under Rule 68, a similar Rule which likewise does not explicitly define the term "costs," the omission of "attorney's fees" was very unlikely to be an oversight, and that there were indeed instances whereby attorney's fees could be awarded. *Marek v. Chesny*, 473 U.S. 1, 9 (1985). The Court concluded that the "most reasonable inference is that the term "costs" in Rule 68 was intended to refer to all costs properly awardable under the relevant substantive statute or other authority. *Id.* In other words, whatever costs are allowable under the substantive authority are allowable under Rule 68,

regardless of whether or not Congress explicitly included such a cost within the Rule. Following *Marek*, those Circuit Courts not subscribing to a categorical inclusion have likewise adopted an identical rationale for Rule 41(d). The Seventh Circuit in *Esposito v. Piatrowski* applied *Marek* directly to Rule 41(d), holding that "a party may recover reasonable attorney's fees as part of its "costs" under Rule 41(d) only where the underlying statute defines costs to include attorney's fees." *Esposito v. Piatrowski*, 223 F.3d 497, 500 (7th Cir. 2000) (citing *Marek*, 473 U.S. at 9).

The governing statute here, the East Texas Products Liability Law ("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.**

East Texas Code Annotated § 12-12-12 (emphasis added). The ETPLL plainly contemplates the award of attorney's fees as a recoverable cost. Indeed, § 12-12-12 makes no express mention of a defendant's entitlement to fees, but rather only a plaintiff's. This was noted in the concurring opinion of Justice Motley below, who would ask the District Court to resolve the question of whether this statute applies to Respondent on remand.

Justice Motley's concerns are not warranted here because, following the Court's reasoning in *Marek*, we need only ascertain whether the underlying statute defines "costs" to include attorney's fees. *Marek*, 473 U.S. at 9. Here, the ETPLL

does just that. We are not, as Justice Motley suggests, supplementing a standard, but rather a definition. The inquiry is limited merely to whether or not the underlying statute included attorney's fees in the definition of "costs," not whether the standard for awarding "costs," pursuant to the substantive statute, is satisfied in the instant case. The parties do not dispute that Respondent is already entitled to "costs" under Rule 41(d). We therefore do not need, nor are we required, to ask whether a defendant is entitled to the relief listed in § 12-12-12.

B. Effectuation of the policy rationale behind Rule 41(d) requires reading attorney's fees into the definition of "costs" because Petitioner's refiling of her previously dismissed suit constituted an egregious example of forum shopping.

This Court should award attorney's fees in the present matter because Petitioner's voluntary dismissal of her initial suit amounts to nothing more than forum shopping and therefore offends the core policy rationale behind Rule 41(d). Rule 41(d) is "intended to serve as a deterrent to forum shopping and vexatious litigation." *Robinson v. Bank of Am., Nat'l Ass'n*, 553 F. App'x 648, 652 (8th Cir. 2014) (quoting *Simeone v. First Nat'l Ass'n*, 971 F.2d 103, 108 (8th Cir. 1992). This includes attempts to "gain any tactical advantage by dismissing and refiling the suit." *Andrews v. America's Living Ctrs., LLC*, 827 F.3d, 306, 309 (4th Cir. 2016).

Petitioner's competing policy approach embraces the so-called "American Rule." The American Rule represents an older policy whereby, in American jurisdictions, "costs" generally do not include attorney's fees. *Marek v. Chesny*, 473 U.S. 1, 8 (1985). The Court in *Marek* acknowledges, however, that the rule has been subject to many exceptions over the years as a result of the "inherent power in the

courts to allow attorney's fees in a particular situation." *Id.* The Court in *Marek* carved out such an exception to Rule 68, reasoning that the rule drafters were aware of the American Rule's exceptions, and could provide for the award of attorney's fees if they so choose. *Id.*

Further, each circuit addressing this issue has alluded to the importance of the policy rationale behind Rule 41(d), but none have formally integrated it into a workable rule save for The Fourth Circuit in *Andrews v. America's Living Ctrs., LLC. See Andrews*, 827 F.3d 306, 311 (4th Cir. 2016).The *Andrews* court articulated a two-pronged approach whereby a district court may award attorney's fees where either: (1) the underlying statute provides for attorney's fees; or (2) a court, within its discretion, makes a specific finding that the plaintiff has acted "in bad faith, vexatiously, wantonly, or for oppressive reasons." *Id.* In effect, the Fourth Circuit hybridized the *Marek* rationale with a policy prong aimed to preserve Rule 41(d)'s intent. Under this framework, the Court does not need to categorially include or exclude attorney's fees in all instances. Instead, federal courts will have the discretion to make determinations on a case by case basis, taking into account the language of the substantive authority, and the plaintiff's conduct in dismissing prior suits.

Unlike the *Andrews* approach, the American Rule simply does not harmonize with the intent of Rule 41(d). Accordingly, this Court should not afford it any deference in this matter. All courts agree on rule 41(d)s purpose, and this Court has acknowledged, as well as created, exceptions to the American Rule where a given

policy goal would be hindered by strict adherence. *Id.* The present matter is no different. This court should effectuate Congress' vision for Rule 41(d) by categorically including attorney's fees within the definition of "costs."

Without the inclusion of attorney's fees under the definition of costs, Rule 41(d) does not have the teeth necessary to deter forum shopping and other types of gaming conduct that Congress intended to curb with its creation of. Without the fear of being on the hook for attorney's fees accumulated during a previous and frivolous lawsuit, a party has no reason to exercise restraint in repetitively refiling a matter in a more appealing forum.

Here, the parties do not dispute that Petitioner's voluntary dismissal of her initial suit was a direct response to The Fifth Circuit's issuance of its *PLIVA* opinion. (R. at 5.) Petitioner plainly dismissed her suit in an attempt to avoid unfavorable law and then proceeded to refile what amounts to the same claim in a forum where she believes she will be more likely to succeed. *Id.* This type of activity is precisely what the drafters of Rule 41(d) were seeking to curb by imposing costs on the vexatious party. Therefore, even if the Court is disinclined to impose a bright line rule regarding the inclusion of attorney's fees within "costs," the Court should apply the *Andrews* test and take into account Petitioner's problematic behavior during her initial suit. Doing so reaches the core of the issue and preserves Congress' intent in drafting Rule 41(d).

In summation, this Court should affirm the Twelfth Circuit's determination that Congress intended for attorney's fees to be awarded alongside other "costs"

pursuant to Rule 41(d). The plain language and structure of Rule 41(d), as well as the language and structure of comparable Federal Rules suggests a strong intent to incorporate attorney's fees into the definition of "costs." Additionally, the underlying policy rationale for Rule 41(d) as a deterrent for vexatious litigation requires awarding attorney's fees in the instant case because Petitioner engaged in forum shopping when dismissing her previous suit, only to refile the same suit later in a more advantageous forum.

CONCLUSION

For the foregoing reasons, this Court should affirm the Twelfth's Circuit decision.

APPENDIX A

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. U.S. CONST., Art. VI, cl. 2.

APPENDIX B

(j) Abbreviated new drug applications

(2)(A) An abbreviated application for a new drug shall contain--

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active
ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of
the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under
subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug

referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under sub paragraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is
seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section--

(I) that such patent information has not been filed,
(II) that such patent has expired,
(III) of the date on which such patent will expire, or
(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

21 U.S.C. § 355(j)(2)(A)(i)-(viii).

APPENDIX C

The Illinoza Products Liability Act ("IPLA") 1998-4(1) provides relief "upon showing that a manufacturer's products 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."

APPENDIX D

(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.

East Texas Code Annotated § 12-12-12