IN THE
Supreme Court of the United States

October Term, 2017

Alice IVERS,

v.

WESTERLY PHARMACEUTICAL, INC.,

Petitioner,

v.

Respondent.

On Writ of Certiorari to the
Twelfth Circuit Federal Court of Appeals

BRIEF FOR RESPONDENT

Attorneys for Respondent
Team 2607
QUESTIONS PRESENTED

I. Under the binding precedent set by PLIVA v. Mensing and Mutual Pharmaceutical v. Bartlett, federal law preempts a state-law failure-to-warn and design defect claims against a generic drug manufacturer. Petitioner filed both a failure-to-warn and design defect claim in Illinoza state court against Respondent, a generic drug manufacturer. Did the appellate court correctly find that federal law preempts the state-law claim against Respondent?

II. This Court has not yet addressed whether attorney’s fees are available under Federal Rules of Civil Procedure 41(d), which permits district courts to order a plaintiff to pay attorney’s costs if the plaintiff files an action based on the same claim and against the same defendant, after previously dismissing the action in any court. Petitioner actively engaged in forum shopping when she voluntarily dismissed her products liability claims against Respondent in the Western District of East Texas and subsequently filed the same claims against Respondent in the state court of Illinoza. Should this Court uphold the Twelfth Circuit’s finding that attorney’s costs include attorney’s fees under Federal Rules of Civil Procedure 41(d)?
TABLE OF CONTENTS

QUESTIONS PRESENTED .............................................................................................................................................. i

TABLE OF CONTENTS ...................................................................................................................................................... ii

TABLE OF AUTHORITIES ................................................................................................................................................... iv

OPINIONS BELOW .......................................................................................................................................................... 1

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED ........................................................... 1

STATEMENT OF THE CASE ........................................................................................................................................... 1

SUMMARY OF THE ARGUMENT .................................................................................................................................... 3

ARGUMENT ........................................................................................................................................................................... 6

I. STANDARD OF REVIEW ............................................................................................................................................. 6

II. THE TWELFTH CIRCUIT CORRECTLY REASONED THAT THE PRECEDENT
    THIS COURT ESTABLISHED IN MENSING AND BARTLETT EXTENDS TO
    SITUATIONAL STATE-LAW FAILURE-TO-UPDATE CLAIMS AND FOUND SUCH
    CLAIMS TO BE PREEMPTED UNDER FEDERAL LAW ..................................................................................... 6

A. This Court reached a logical and just outcome in its rulings in Mensing and Bartlett by
    reasoning that application of preemption of advances the purpose of Congress and the
    intentions of the FDA to the quick and safe delivery of generic drugs to the public. ............... 8

B. Law and public policy dictate that Petitioner’s artful failure-to-update claim be rendered
    without effect under obstacle preemption in order to bar the states from imposing situational
    standards of reasonableness and frustrating the federal regulatory process entrusted with
    achieving Congress’ purpose. ................................................................................................................................. 12

1. The Court should apply federal law because it appropriately accounts for practical
   delays in the federal regulatory process and bar state-law claims’ application of
   situational reasonableness .............................................................................................................................. 13

2. Public policy supports the application of federal law and obstacle preemption in
   order to reinforce the regulatory authority of the FDA and maximize generic drug
   manufacturers’ ability to provide vital medications to the public. ......................................................... 15

III. THIS COURT SHOULD UPDHOIL THE TWELFTH CIRCUIT’S RULING AND
    HOLD THAT ATTORNEY’S FEES SHOULD BE PERMISSIBLE AS ATTORNEY’S
    COSTS AWARDED UNDER FEDERAL RULE OF CIVIL PROCEDURE 41(d). ............... 18

A. This Court should allow the awarding of attorney’s fees to Respondent because the
    established specific intent of Rule 41(d) to deter forum shopping and vexatious litigation and
    the majority of the circuits hold Rule 41(d) permits attorney’s fees. .................................................... 19

1. The specific intent of Rule 41(d) is consistent with the Court permitting Respondent’s
   awarding of attorney’s fees because courts have acknowledged that the intent of Rule 41(d) is
   to deter forum shopping and vexatious litigation. ....................................................................................... 19

2. Under Rule 41(d), this Court should allow the awarding of attorney’s fees to Respondent
   because this holding is in line with the holdings of the majority of the federal circuits and will
   create uniformity and predictability among the circuits. .............................................................................. 21
B.  This Court should hold Rule 41(d) permits attorney’s fees because this interpretation is consistent with Rule 1, Rule 41(a)(2), and Rule 68 of the Federal Rules of Civil Procedure, which sets forth the Rules’ goal of justice................................................................. 23

1.  The common tools of statutory construction suggest this Court should permit attorney’s fees under Rule 41(d) because this is consistent with similar statutory provisions, Rule 41(a)(2) and Rule 68, that permit attorney’s fees................................. 23

2.  Comparing this Court’s interpretation of Rule 68 as constituting attorney’s costs implies Rule 41(d) should include attorney’s fees because Rule 41(d) has a stronger policy reason than Rule 68 and has a lower discretionary standard. ................................. 25

CONCLUSION.................................................................................................................. 27

APPENDIX A .................................................................................................................... A-1
APPENDIX B ................................................................................................................... B-1
APPENDIX C .................................................................................................................. C-1
# TABLE OF AUTHORITIES

## Cases

*Andrews v. America’s Living Centers, LLC.*, 827 F.3d 306 (4th Cir. 2016) .......................... 6, 19, 20, 21, 24

*Buckman Co. v. Plaintiffs’ Legal Committee*,

531 U.S. 341 (2001) ................................................................. 11, 14


*Celotex v. Catrett*,

477 U.S. 317 (1986) ................................................................. 6

*Duffy v. Ford Motor Co.*, 218 F.3d 623 (6th Cir. 2000) ................................................................. 21

*Esposito v. Piatrowski*,

223 F.3d 497 (7th Cir. 2000) ................................................................. 19, 21, 23


*Fulgenzi v. PLIVA Inc.*, 711 F.3d 578 (6th Cir. 2013) ................................................................. 12, 13


Hines v. Davidowitz,
312 U.S. 53 (1941) ............................................................... 13

Kent v. Bank of Am., N.A.,
518 F. App’x 514 (8th Cir. 2013) ..................................................... 21

Marek v. Chesny,
471 U.S. 1 (1985) ............................................................... 24, 25

Medtronic Inc. v. Lohr,
518 U.S. 470 (1996) ............................................................... 8

Meredith v. Stovall,
216 F.3d 1087 (10th Cir. 2000) ..................................................... 19, 21, 25

Morris v. PLIVA,
713 F.3d 774 (5th Cir. 2013) ..................................................... 12, 17, 18

Mutual Pharmaceutical Co., Inc. v. Bartlett,
133 S. Ct. 2466 (2013) ..................................................... 1, 3, 4, 7, 8, 9, 11, 12, 13, 17

Pardini v. Allegheny Intermediate Unit,
420 F.3d 181 (3d Cir. 2005) ............................................................... 23

PLIVA V. Mensing,
564 U.S. 604 (2011) ..................................................... 1, 3, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 17

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008) ............................................................... 15

Rogers v. Wal-Mart Stores, Inc.,
230 F.3d 868 (6th Cir. 2000) ..................................................... 19, 22

Salve Regina College v. Russell,
499 U.S. 225 (1991) .......................................................... 6

Sanderson v. Spectrum Labs, Inc.,
248 F.3d 1159 (7th Cir. 2000) .......................................................... 21

S.B. v. KinderCare Learning Ctrs., LLC,
815 F.3d 150 (3d Cir. 2016) .......................................................... 24

United States v. Miller,
833 F.3d 274 (3d Cir. 2016) .......................................................... 23

Wyeth v. Levine,
555 U.S. 555 .......................................................... 8, 11, 12

Constitution
United States Constitution, Article VI, Clause 2 .......................................................... 7

Statutes
Food, Drug & Cosmetics Act .......................................................... in passim
21 U.S. Code § 355(j) .......................................................... 9
21 U.S. Code § 393(b) .......................................................... 9

Rules
Fed. R. Civ. P.:
Rule 1 .......................................................... 23
Rule 41 .......................................................... 1, 3, 5, 6, 18, 19, 20, 21, 22, 23, 24, 25, 26
Rule 56 .......................................................... 6
Rule 68 .......................................................... 23, 24, 25,
Other Authorities

Food & Drug Administration Guidance

U.S. Food & Drugs Ass’n, Guidance for Industry: Changes to an Approved NDA or ANDA (2004)
OPINIONS BELOW

The unreported opinion of the United States Court of Appeals for the Twelfth Circuit appears on pages 9-22 of the record. The unreported opinion of the United States District Court of Illinoza appears on pages 1-8 of the record.

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The relevant statutory provisions analyzed, 21 U.S. Code § 355(j) and 21 U.S. Code § 393(b), are located in Appendix A. The constitutional provision at issue, the Supremacy Clause of Article VI, Clause 2, is located in Appendix B. The Federal Rule of Civil Procedure subsection at issue, Rule 41(d) – Costs of a Previously Dismissed Action, is located in Appendix C.

STATEMENT OF THE CASE

This case involves a dispute over this Court’s decisions in PLIVA v. Mensing, 564 U.S. 604 (2011) and Mutual Pharmaceutical v. Bartlett, 133 S. Ct. 2466 (2013) as preempting the Petitioner’s claims and the Federal Rule of Civil Procedure 41(d) consideration of awardable “costs” including attorney’s fees.

The FDA’s Approval of Respondent’s Generic Drug

Respondent manufactures a generic form of the drug ropidope Hcl (“ropidope”) used in the treatment of Parkinson’s disease. R. at 1. The Federal Food & Drug Administration (FDA) approved Respondent’s Abbreviated New Drug Application (ANDA) to market an equivalent generic version of the GlaxoCline’s (“Brand-Name”’s), ropidope. R. at 2. As a condition of FDA approval, Respondent complied with federal law and updated its label to have its label on its generic ropidope mirror the then-current label for the Brand-Name ropidope. Id.
Respondent Takes Action to Update its Label to Reflect Brand-Name’s Label Alteration

In response to the Brand-Name’s request to the FDA to approve and include an additional side-effect to the Brand-Name’s label, Respondent took action to satisfy its duty of sameness and comply with federal law. R. at 2-3. After Brand-Name’s FDA request to add “Impulse Control/Compulsive Behaviors” to the Brand-Name’s associated labeling, Respondent submitted an application to notify the FDA of Respondent’s desire to update its generic ropidope’s label to coincide with the Brand-Name’s new ropidope label. R. at 2-3.

Petitioner’s Previous Same Alleged Complaint Against Respondent

Petitioner began taking Respondent’s generic ropidope to treat her Parkinson’s disease and claims that she began to develop compulsive spending and gambling behaviors, resulting in the depletion of her retirement savings. R. at 1, 3. Petitioner alleges that generic ropidope is proximately responsible and alleged that the generic ropidope’s labels were defectively designed and contained inadequate warnings of her side effects, under Illinois Product Liability Act 1998-4(1). R. at 3. Notably, both Petitioner and Respondent agree that Respondent changed its label to match that of the brand-name drug, years before Petitioner filed her suit. R. at 1-3, 14. However, this is not the first time Petitioner has filed a claim against Respondent based on these facts. R. at 5. Petitioner had previously filed in the United States Western District Court of East Texas, located within the jurisdiction of the Fifth Circuit, state court alleging the same facts and legal theories under East Texas Products Liability Law and filed a Notice of Voluntary Dismissal eleven days after the Fifth Circuit held that the Food, Drug & Cosmetic Act (FDCA) preempted a similar failure-to-update claim regarding a different FDA-approved generic drug. R. at 5. As permitted by Federal Rules of Civil Procedure 41(d), Respondent filed a Motion for an Award of
Costs under Rule 41(d) in response to Petitioner’s filing of a complaint alleging the same facts and legal theories in another court against the same defendant. R. at 5-6.

**Procedural History**

Following the Petitioner’s filing of charges in the State Court of Illinoza, Respondent removed the case to the Illinoza District Court by correctly asserting diversity jurisdiction, under 28 U.S.C. § 1332, and removal jurisdiction, under 28 U.S.C. § 1441. R. at 3. The Illinoza District Court held that (1) Petitioner’s claim against Respondent was preempted and (2) Respondent’s awarded costs would not include attorney fees under Rule 41(d). R. at 4-8.

In a 2-1 concurrence-in-part and dissent-in-part, the Twelfth Circuit (1) affirmed Petitioner’s claim against Respondent as preempted and (2) affirmed in part the awarding of attorney’s costs yet reversed in par the district court’s ruling, thereby granting the order of attorney’s fees to Respondent. R. at 18.

This Court granted certiorari on July 17, 2017 and limited the review to two issues: (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; and (2) whether attorney’s fees are considered awardable “costs” under Federal Rule of Civil Procedure 41(d). R. at 23.

**SUMMARY OF THE ARGUMENT**

I. **In line with the precedent this Court laid out in Mensing and Bartlett and the joint purpose of Congress and the FDA, federal law rightfully preempts Petitioner’s state-law failure-to-update claim.**

Petitioner seeks to punish Respondent for fully complying with federal law and regulations. Petitioner’s failure-to-update claim is an attempt at artful pleading to circumvent preemption clearly required of failure-to-warn claims. The duties allegedly imposed by Illinoza state law conflict with federal requirements imposed by the Federal Food, Drug & Cosmetic Act
(FDCA), which in accordance with the precedent established by *Mensing* and *Bartlett*, renders Petitioner’s claim without effect. Petitioner’s claims mirror the failure-to-warn and design defect claims this Court clearly preempted in *Mensing* and *Bartlett* because allowing such claims to go forward would require manufacturers to take on the impossible task of simultaneously complying with both state and federal law. The Court should uphold these cases as they were decided in accordance with the Congress’ purpose to quickly deliver safe generic drugs to the public and the FDA’s own interpretation of its regulations. The precedent established by *Mensing* and *Bartlett* is a logical interpretation of Congress’ purpose and federal regulations that should be upheld by this Court.

Even if this Court chooses to recognize a distinction between such claims, it should hold that obstacle preemption renders the claim without effect in favor of reinforcing the FDA’s regulatory authority to achieve Congress’ purpose and supporting public policies that maximize the efficiency of the federal regulatory scheme. Obstacle preemption requires that federal law displace state law when it stands to exceedingly frustrate the execution of Congress’ purpose. Through the FDCA, Congress entrusted the FDA to regulate generic drug manufacturing in order to ensure the quick and safe delivery of generic drugs to the public. The FDA uses its discretion to account for the practical delay that generic drug manufacturers may encounter in the label updating process. Within that discretion, the FDA sees fit not to impose a deadline as to when generic drug manufacturers must update their label. Allowing states to impose situational standards for reasonableness as to how quickly the label should be updated will exceedingly frustrate Congress’ purpose as it will undermine the strength of the federal regulatory scheme. As plaintiffs turn to state courts, juries will undoubtedly produce widely divergent results given there is no uniform standard. Public policy calls this Court to preempt the claim, as such
inevitably differing verdicts not only contravenes Congress’ purpose, but also exposes generic drug manufacturers to forum shopping and vexatious litigation. Such exposure is not only unjust as Respondent complied fully with federal law, but will also implicate great financial burden on Respondent and other manufacturers that may affect the public’s access to drugs deemed safe by the FDA, contrary to the intent of Congress. Therefore, this Court should uphold the Twelfth Circuit’s decision and rule that obstacle preemption negates Petitioner’s failure-to-update claim in order to reinforce the primacy of the federal regulatory scheme in accordance with Congress’ purpose of quickly providing safe generic drugs to the public.

II. **Attorney’s fees should be permitted as attorney’s costs awarded under Federal Rule of Civil Procedure 41(d) because it promotes the intent of the rule, to serve justice.**

   This Court should affirm the Twelfth Circuit’s awarding of attorney’s fees to Respondent, under Rule 41(d). This holding is proper because it is consistent with the specific intent of Rule 41 to deter forum shopping and vexatious litigation, and is consistent with the majority of the federal circuit’s holdings to permit attorney’s fees under Rule 41(d). Petitioner engaged in forum shopping when she voluntarily dismissed the same claim against Respondent in Western District of East Texas and refilled in a different jurisdictional court, which had not yet set precedent against her improper claim. The majority of circuit courts have ruled attorney’s fees are allowable under Rule 41(d) and this Court should hold as such. Secondly, this Court should permit attorney’s fees under Rule 41(d) because it coincides with similar statutory provisions of the Federal Rules of Civil Procedure and furthers the overall goal of the Federal Rules of Civil Procedure to promote a just, speedy, and inexpensive trial.
ARGUMENT

I. STANDARD OF REVIEW

The first issue this Court will be reviewing is the Twelfth Circuit’s affirmation of the judgment on the pleadings, which dismissed the claim as preemption. The de novo standard of review applies to questions of law rather than questions of fact and allows independent appellate review that best serves the goals of doctrinal coherence and economy of judicial administration. See Salve Regina College v. Russell, 499 U.S. 225, 231-235 (1991). Respondent contends there is no issue of genuine fact and moves for summary judgment on the pleadings. The de novo standard of review doubly applies for an appeal for summary judgment. Celotex v. Catrett, 477 U.S. 317, 322 (1986). Where there is no genuine issue of material fact, this Court must grant summary judgment and award the movant a judgment as a matter of law. Fed. R. Civ. P. 56(c).

The second issue before the Court is also subject to review. This Court will address the proper interpretation of the scope of Federal Rule of Procedure 41(d) by determining whether Rule 41(d) permits attorney’s fees to be considered attorney’s costs, as a matter of law. Therefore, the de novo standard applies. Andrews v. Living Ctrs., LLC., 827 F.2d 306, 309 (4th Cir. 2016). As this Court is not evaluating whether the trial court should have awarded the costs, as Rule 41(d) grants a district court the discretion to order a plaintiff to pay costs, therefore, the abuse of discretion standard is not applied. Fed. R. Civ. P. 41(d).

II. THE TWELFTH CIRCUIT CORRECTLY REASONED THAT THE PRECEDENT THIS COURT ESTABLISHED IN MENSING AND BARTLETT EXTENDS TO SITUATIONAL STATE-LAW FAILURE-TO-UPDATE CLAIMS AND FOUND SUCH CLAIMS TO BE PREEMPTED UNDER FEDERAL LAW.

This case is about protecting generic drug manufacturers who have faithfully complied with federal law, in accordance with the precedent this Court established in Mensing and
Bartlett, from litigious petitioners seeking to enforce situational state products liability claims that frustrate the purpose of Congress to deliver quickly safe generic drugs to the public. Both the District Court of Illinois and the Twelfth Circuit Court of Appeals correctly held that federal law preempts Petitioner’s state-law failure-to-update claim. R. at 8, 18. The Supremacy Clause of the United States Constitution states that “the Laws of the United States … shall be the supreme Law of the Land … any Thing in the Constitution or Laws of any State to the Contrary notwithstanding”. U.S. Const., art. VI, cl. 2. This Court has interpreted this constitutional mandate to require state laws that conflict with federal law to give way, including those creating state-tort duties and claims. Bell v. Wyeth, Inc., 117 F. Supp. 3d 1355, 1362. (citing PLIVA v. Mensing, 564 U.S. 604 (2011)). In 2011, this Court held, after careful consideration of the FDA’s federal requirements imposed on brand-name and generic drug manufacturers, that federal law preempted state-law failure-to-warn claims. Mensing, 564 U.S. at 623-24. In 2013, this Court logically extended its holding in Mensing and ultimately found that federal law also preempts state-law defective design claims that require generic drug manufacturers to “render a drug safer by … altering its labeling ... in conflict with federal laws”. Bartlett, 133 S. Ct. at 2479. The precedent established by these two cases compels the Court to find that all forms of state-law design defect and failure-to-warn claims, should be preempted, including Petitioner’s failure-to-update claim. Such an application of precedent here would be especially just, as Respondent fully complied with federal laws and regulations. As the appellate court noted, Petitioner “does not contest that Westerly did change its label to match that of the [brand name drug],” as compelled by law, years before Petitioner filed her suit. R. at 1-3, 14. Nevertheless, the litigious Petitioner seeks to hold liable and punish Respondent for fully complying with federal law and agency regulations. Petitioner fails to distinguish her failure-to-update claim
from the failure-to-warn claims clearly preempted by federal law and articulately state her case as to why this Court should create an exception for such a claim. Rightfully, this Court should rule that the precedent established by Mensing and Bartlett extends to failure-to-update claims and find that such artful pleading will not allow Petitioner to circumvent preemption of such disfavored claims.

A. This Court reached a logical and just outcome in its rulings in Mensing and Bartlett by reasoning that application of preemption of advances the purpose of Congress and the intentions of the FDA to the quick and safe delivery of generic drugs to the public.

As the Petitioner contends that Respondent’s ropidope labels “were defectively designed and contained inadequate warnings of . . . side effects” she purports her claims to be traditional failure-to-warn and design defect claims, the same claims clearly preempted by Mensing and Bartlett. R. at 3. In each of these cases, this Court carefully considered all the factors weighed in preemption analysis and rightfully reasoned that state-law failure-to-warn and design defect claims, like Petitioner’s, should be preempted. First, this Court considered how, under the Supremacy Clause, state law that conflicts with its federal counterparts is “without effect”. Bartlett, 133 S. Ct. 2466, 2473. (quoting Maryland v. Louisiana, 451 U.S. 725, 747 (1981)). In determining whether federal law preempts a state-law claim, two “cornerstone” principles guide courts engaging in such analysis: (1) the presumption against preemption in fields traditionally occupied by the states, such as health and safety regulations and (2) the bedrock concept that “[t]he purpose of Congress is the ultimate touchstone”. Wyeth v. Levine, 555 U.S. 555, 565 (2009) (citing Medtronic Inc. v. Lohr, 518 U.S. 470, 485 (1996)). Bartlett slices through the presumption against preemption by analyzing Congress’ purpose and explains,

'The Court would welcome Congress’ “explicit” resolution of the difficult pre-emption questions that arise in the prescription drug context. . . . In the absence of that sort of “explicit” expression of congressional intent, we are left to divine Congress’ will from the
duties the statute imposes. That federal law forbids [generic drug manufacturers] to take actions required of it by state tort law evinces an intent to pre-empt.

_Bartlett_, 133 S. Ct. at 2480. This practical understanding of Congress’ intent to preempt is supplemented by Congress’ definition of the FDA’s mission proscribed in the FDCA—to ensure that any product regulated by the FDA is “safe” and “effective”. See 21 U.S.C. § 393(b). The fact that Congress provided the guidelines to accomplish this mission in the Hatch-Waxman Act, which enables the FDA to regulate the generic drug manufacturing and outlines the Abbreviated New Drug Application (ANDA) process and requires the generic manufacturer to use the same labeling as the brand-name manufacturer bolsters the strength of the reasoning this Court employed in _Bartlett_. See 21 U.S.C. § 355(j).

In concluding that state-law failure-to-warn claims should be preempted in _Mensing_, this Court honored and agreed with the FDA’s assertion that its imposition of the federal duty of sameness bars generic drug manufacturers from unilaterally acting to strengthen their labels through the “changes-being-effected” process. _Mensing_, 564 U.S. at 614-15. This Court reasoned, “We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.” _Id._ at 618. If Respondent had taken action to update its label as Petitioner requests, it would have been prevented from doing so given the structure of the federal regulatory process and would have still risked not satisfying the state’s reasonableness requirements. As such, it is as true in the instant case, as in _Mensing_, “It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers.” _Id._ at 626. Thus, this Court is correct in determining that the impossibility calls for preemption of state-law failure-to-warn claims.
Bartlett echoes and expounds upon the reasoning in Mensing and ultimately extends the holding of Mensing to include the rightful preemption of design defect claims pertaining to generic drug labels. In Bartlett, this Court considered how state tort law imposes a duty on generic drug manufacturers to redesign its drug label so that it not be “unreasonably dangerous” while the duty of sameness imposed by federal law prevents generic drug manufacturers from changing their labels. Bartlett, 133 S. Ct. 2476-77. Ultimately, this Court that concluded “it is impossible . . . [generic drug] manufacturers to comply with both state and federal law, [state-law] warning-based design-defect cause of action is preempted with respect to FDA-approved drugs”. Bartlett, 133 S. Ct. 2476-77. The same intractable dilemma exists here, and this Court should hold, once again, that federal law rightfully preempts state-law design defect claims.

In Mensing, this Court correctly reasoned that deference to the FDA’s interpretation of its own regulations and the policies that support them warrant preemption of state failure-to-warn claims, which was then extended to design defect claims in Bartlett. This reasoning is supported by this Court’s determination that, where preemption is implied, “[t]he agency’s own views should make a difference”. Geier v. American Honda Motor Co., 529 U.S. 861, 883 (2000). This reasoning in Mensing, Bartlett, and Geier is strengthened by this Court’s application of Chevron deference in Brown & Williamson Tobacco Corp. See generally Food and Drug Admin. v. 111 & Williamson Tobacco Corp., 529 U.S. 120 (2000). This Court held that deferring to an agency’s interpretation of Congress’ purpose is justified as, “[t]he responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones” and “the agency’s greater familiarity with the ever-changing facts and circumstances surrounds the subjects”. Brown & Williamson Tobacco Corp., 529 U.S. 120 at 132. (citing Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837

10
(1984) and Rust v. Sullivan, 500 U.S. 173, 187 (1991)). Here, just as this Court did in Mensing and Bartlett, this Court should consider the FDA’s view “‘controlling unless plainly erroneous or inconsistent with the regulation[s]’ for there is no other reason to doubt that they reflect the FDA’s fair and considered judgment”. Mensing, 564 U.S. at 607. (citing Auer v. Robbins, 519 U.S. 461, 462 (1997)). To date, the Court understands the FDA’s interpretations of its regulations to impose a duty of sameness on the generic drug manufacturer, which calls for state-law claims to be preempted. Mensing, 564 U.S. at 613. This Court, like the District Court and the Twelfth Circuit, should hold that there is no legal distinction between the claims made by the Petitioner and those made in Mensing and Bartlett and find the claims to be preempted in line with the careful reasoning enshrined in the precedent this Court laid out in those cases.

Stare decisis and separation of powers call for this Court to adhere this precedent. This case falls in the shadow of Mensing and Bartlett, cases decided upon legally and logically sound bases. Yet, the just effect of these cases may seem unjust to the aggrieved, like Petitioner. Those interested in justice, like Respondent and the members of this Court, should reflect on the words of Justice Alito, who said, “The dreadful injuries from which products liabilities cases arise often engender passionate responses. … But sympathy for [Petitioner] does not relieve us of the responsibility of following the law.” Bartlett, 133 S. Ct. at 2478. Under the precedent this Court established in Mensing and Bartlett, Petitioner’s state-law failure-to-update claim must be preempted by federal law. The FDA submitted to the Court in Levine that state tort suits will “disrupt the agency’s balancing health risks and benefits,” and the Court recognized that Congress’ clear purpose behind the FDCA “leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [Act]”.

Wyeth v. Levine, 555 U.S. 555, 625, Buckman Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341,
349 n.4 (2001). Should this Court hold that this case is not preempted, it will be legislating from the bench in blatant disregard of Congress’ purpose while simultaneously undermining the federal regulatory scheme. Congress and the FDA, the agency Congress chose to empower, are best equipped to resolve this issue as they possess the power to hold hearings and gather information relevant to appropriate reform whereas this Court does not. Should the Court choose today to overrule *Mensing* and *Bartlett*, it will be engaging in a form of ultimately unjust judicial activism by creating a means of legal recourse for Petitioner in order to punish Respondent for fully complying with the federal law that this Court swore to uphold. By following stare decisis, this Court can fully employ its own constitutional power to serve justice by ruling in favor of Respondent.

**B. Law and public policy dictate that Petitioner’s artful failure-to-update claim be rendered without effect under obstacle preemption in order to bar the states from imposing situational standards of reasonableness and frustrating the federal regulatory process entrusted with achieving Congress’ purpose.**

Petitioner artfully pleads failure-to-update as an alternative theory to the clearly preempted failure-to-warn claim in an attempt to carve out an exemption from preemption; however, as matter of law, even if this Court chooses to recognize a legal distinction between the claims, obstacle preemption renders Petitioner’s claim without effect. R. at 3, 15. Artful pleas similar to Petitioner’s, even in the wake of *Mensing* and *Bartlett*, provoked a jurisdictional split at the appellate level. Out of sympathy, it seems some circuits carved out exceptions for such pleas. The Fifth Circuit correctly held that, in similar circumstances, “[A] claim that [a generic manufacturer] breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted.” *Morris v. PLIVA*, 713 F.3d 774, 777 (5th Cir. 2013). Yet, the Sixth Circuit wrongfully disagreed and found obstacle preemption did not apply. *Fulgenzi v. PLIVA Inc.*, 711 F.3d 578, 585 (6th Cir. 2013). The *Fulgenzi* court erred in its reasoning that *Levine*
prevents obstacle preemption from being applied as Mensing and Bartlett make clear, state-law claims against generic drug manufacturers cannot be treated the same as those against brand-name drug manufacturers. Furthermore, the Fulgenzi court erroneously misinterprets Congress’ purpose and dismisses, in just few paragraphs, the vital policy arguments that support the preservation and execution of Congress’ purpose and seek to protect drug manufacturers and the public alike. As a practical matter, failure-to-update claims will exceedingly frustrate Congress’ purpose to entrust the FDA to ensure the efficient and safe regulation of the federal drug-safety regulatory scheme. The Twelfth Circuit recognized this to be true and comes out on the right side of the law and correctly applies obstacle preemption, as this Court should.

1. The Court should apply federal law because it appropriately accounts for practical delays in the federal regulatory process and bar state-law claims’ application of situational reasonableness.

Appropriate application of obstacle preemption demands that states’ situational understanding of reasonableness must give way to the FDA’s discretionary authority, which appropriately accounts for the practical delays generic drug manufacturers experience as they navigate the federally-mandated label updating process. Obstacle preemption displaces state law when it stands to exceedingly frustrate “the accomplishment and execution of the full purposes and objectives of Congress,” without creating a technically impossible conflict. Hines v. Davidowitz, 312 U.S. 52, 67 (1941). Imposing both state and federal standards on a case-by-case and state-by-state basis will frustrate the Congress’ objectives made clear in the FDCA.

Inevitably, there must be some practical delay before generic drug manufacturers can update their warning label to match its newly changed brand-name counterpart because the generic drug manufacturer is subject to a three-part process. First, the generic manufacturer must become aware that the FDA authorized the change to the brand-name drug’s label. Next, they must
prepare a revised label that accurately incorporates these changes and then supply multiple copies of the final printed label to the FDA for review. U.S. Food & Drugs Ass’n, Guidance for Industry: Changes to an Approved NDA or ANDA (2004) at 26. Once the FDA grants approval, the manufacturer must produce new labels and then distribute them throughout the market. Undeniably and critically, as the Twelfth Circuit recognized, “[F]ederal law does not prescribe a deadline for a generic manufacture to complete its label update.” Mensing, 564 U.S. at 626, R. at 15) (emphasis added). In Buckman, this Court recognized that, through the FDCA, the FDA wields regulatory authority that it utilizes to “achieve a somewhat delicate balance of statutory objectives.” Buckman, 531 U.S. at 341, 348. In the instant case, the FDA declined to penalize Respondent for these practical delays and did not issue any form of admonishment as Respondent fully complied with FDA regulations within six months of the brand-name drug’s label change. Allowing failure-to-update claims to go forward would demonstrate that this Court agrees with Petitioner that the FDA acted questionably, which would undoubtedly undermine the agency’s authority granted by Congress and frustrate its ability to actualize Congress’ purpose. Furthermore, this Court held in Buckman that “the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law”. Buckman, 531 U.S. at 347. Operating fully in accordance with the expectations established within an inherently federal relationship, Respondent acted so as to update its label and did so in line with the FDCA and other federal regulations promulgated by the FDA. Application of obstacle prevention is just because, under federal law, Respondent did not and need not have considered which of any of the fifty states would consider the mere six-month the duration of these practical delays to malign with that state’s conception of situational “reasonableness”. Under current law, the generic drug
manufacturer is in no way compelled to account for or comply with each of the states’ splintered understanding of reasonableness as it is not factored in to its inherently federal relationship with the FDA, and the claim should be preempted to prevent the Respondent from being punished for “failing” to do so. In this symbiotic, inherently federal relationship, between generic drug manufacturers, like Respondent, and the FDA, one that anticipates and accounts for practical delays in the federal regulatory process, application of obstacle preemption makes clear there is no place for the states.

2. **Public policy supports the application of federal law and obstacle preemption in order to reinforce the regulatory authority of the FDA and maximize generic drug manufacturers’ ability to provide vital medications to the public.**

Public policy dictates that this Court must apply obstacle preemption to Petitioner’s failure-to-update claim and bar states from imposing their situational understanding of reasonableness in a way that undermines the goals of the federal regulatory scheme. This Court previously reasoned that entrusting state law and juries with interpreting the legal concept of reasonableness would contravene the FDA’s authority as the administrator of federal drug-safety scheme. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). Maintaining such authority is key to accomplishing the FDA’s goal of regulating the production of generic drugs in a way that balances the need for speedily providing the public with access to these drugs and assurance of patient safety. This Court’s reasoning in *Riegel* is supported by public policy that derives in part from the fact that common-sense dictates that juries will come to differing conclusions when faced with sympathetic plaintiffs in cases like this. To a jury in Illinoza, six months of practical delay may be perfectly reasonable, whereas a jury in Florida may “reasonably” hold that a generic manufacturer must submit a new label to the FDA the day after the agency approves the brand-name manufacturer’s updated label. It is unreasonable to ask manufacturers to anticipate
and comply with individual states’ understanding of reasonableness because doing so produces inconsistent outcomes that Congress’ tasked the FDA to prevent. Asking manufacturers to contend with these situational standards may impose a huge economic burden on manufacturers. Such an economic burden may result from manufacturers attempting to comply with these widely varying standards and infliction of compensatory and punitive damages. Consequently, the manufacturer may be forced to raise prices and restrain production, thus, involuntarily restricting access to beneficial drugs considered safe by FDA standards to people who need them most, like the Petitioner herself. Furthermore, granting juries the power to critique not only the manufacturer’s actions but those of the FDA would cut against the presumption of non-reviewability by allowing them to question the FDA’s discretion not to enforce the regulations. See *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). This Court should hold that application of obstacle preemption is appropriate in accordance with public policy that favors a strong federal regulatory process, spearheaded by the FDA, that imposes uniform compliance standards on drug manufacturers to facilitate the quick and cost-effective delivery of safe drugs to the public.

Furthermore, public policy against forum shopping and vexatious litigation also supports the conclusion that this Court should apply obstacle preemption and render the failure-to-update claim without effect. Allowing claims based on situational reasonableness, despite the fact that FDA regulations that do not impose a deadline to update, invites litigation and forum shopping as soon as the FDA or a brand-name manufacturer announces an update. Petitioner’s own actions demonstrate why these concerns are legitimate. Petitioner initially filed this claim under Texas products liability law in January 2013, then after voluntarily dismissing the suit, later filed for suit in Illinoza in September 2015. R. at 1, 5. As the trial court observes, it is no coincidence that Petitioner came to disfavor Texas as a forum, a state smack in the middle of the Fifth Circuit,

Failing to preempt claims such as this will allow plaintiffs to target state jurisdictions that not only allow such claims to go forward but also those whose juries are known to be particularly sympathetic in order to strategically maximize the amount of damages they may receive. Such forum shopping to initiate vexatious litigation will assuredly implicate additional financial burdens on the manufacturer, given the likelihood of juries awarding high-figure damages to sympathetic plaintiffs and the inherent cost of litigation, that, yet again, may restrict the public’s access to drugs deemed safe by federal standards. These outcomes clearly contravene Congress’ purpose in establishing a singular federal regulatory scheme to ensure the quick and safe delivery of drugs to the public. To give effect to these public policies, this Court should apply obstacle prevention to shield the manufacturers and the public from the effects of such forum shopping and vexatious litigation that allowing failure-to-update claims will invite. Public policy against forum shopping and vexatious litigation in favor of a streamlined, cost-effective federal regulatory scheme supports the conclusion that this Court apply obstacle preemption and render Petitioner’s failure-to-update claim without effect.

In conclusion, this Court should rule that, given the precedent established by *Mensing* and *Bartlett*, federal law preempts the Petitioner’s state-law claim. Petitioner fails to create a legal distinction between her claim and the failure-to-warn and the design defect claims clearly preempted by *Mensing* and *Bartlett*. However, even if this Court choose to recognize such a distinction, Petitioner’s failure-to-update claim should be rendered without effect by obstacle preemption as allowing the states to advance situational standards of reasonableness would undermine the strength of the federal regulatory scheme, which would, in turn, produce
detrimental and inconsistent results. Preemption in this case is just as it prevents Petitioner from punishing Respondent for fully complying with federal law. This holding is proper because it aligns with stare decisis and public policy that favors advancing Congress’ purpose of ensuring quick delivery of safe generic drugs to the public through a uniform federal regulatory scheme, most effectively managed by the FDA.

III. THIS COURT SHOULD UPDHOULD THE TWELFTH CIRCUIT’S RULING AND HOLD THAT ATTORNEY’S FEES SHOULD BE PERMISSIBLE AS ATTORNEY’S COSTS AWARDED UNDER FEDERAL RULE OF CIVIL PROCEDURE 41(d).

The issue before the Court is one of first impression. Because this Court’s decision will resolve a circuit split, it is important that all implications of holding attorney’s fees as attorney’s costs under Federal Rule of Civil Procedure 41(d) (“Rule 41(d)”) are enlightened. Rule 41(d) states that the court may make an order for the payment of the costs of an action previously filed and dismissed by a plaintiff, if the plaintiff re-files an action based upon or including the same claim, against the same defendant, in any courtroom. Fed. R. Civ. P. 41(d). The Court possesses Petitioner’s Complaint before it, which proves to be a textbook example of why attorney’s fees should be awarded as costs. Petitioner thought she could utilize forum shopping to her unfair advantage when she pulled her Complaint from the Western District of East Texas, knowing that Morris v. PLIVA would demolish her claim. Petitioner acted exactly in a way that Rule 41(d) was and is intended to prevent, and the Court must remedy this. This Court should award Respondent’s attorney fees by holding Rule 41(d) permits the awarding of attorney’s fees because this holding is consistent with (1) the specific intent of Rule 41(d) to deter forum shopping and vexatious litigation, (2) the majority of the circuits that have held Rule 41(d) allows for attorney’s fees to be considered as attorney’s costs and awarded to defendant, when
appropriate, and (3) the broader intent of Rule 41(d) present in the Federal Rules of Civil Procedure’s ultimate goal of justice.

**A. This Court should allow the awarding of attorney’s fees to Respondent because**

the established specific intent of Rule 41(d) to deter forum shopping and vexatious litigation and the majority of the circuits hold Rule 41(d) permits attorney’s fees.

1. **The specific intent of Rule 41(d) is consistent with the Court permitting**

Respondent’s awarding of attorney’s fees because courts have acknowledged that the intent of Rule 41(d) is to deter forum shopping and vexatious litigation.


As numerous courts have recognized, if this Court construes “costs” under Rule 41(d) not to include attorney’s fees, this Court consequently nullifies Rule 41(d)’s purpose of deterring forum shopping and vexatious litigation on the part of the plaintiff. *See Andrews*, 827 F.3d at 311. Furthermore, Rule 41(d) would serve almost no deterrent function and would fail to compensate the defendant for the expense of defending both suits because “awarding such fees advances the purpose of Rule 41(d), which is to deter forum shopping and vexatious litigation”. *Esposito*, 223 F.3d at 501 (quoting *Simeone v. First Bank Nat’l Ass’n*, 971 F.2d 103, 108 (8th Cir. 1992)). Practically, attorney’s fees far exceed the attorney’s costs and amount to a greater
deterrence. Surely, the drafters of the rule intended Rule 41(d) “have some teeth”. *Andrews v. America’s Living Centers, LLC.*, 827 F.3d 306, 309 (quoting *Behrle v. Olshansky*, 139 F.R.D. 370, 374 (W.D. Ark. 1991)). Ruling against allowing attorney’s fees under Rule 41(d) effectively forces the defendant to bear the punishment for the plaintiff’s forum shopping and the resulting vexatious litigation costs because compensation for attorney’s costs is a meager offering compared to the substantial amount of the defendant’s attorney’s fees.

In the case at hand, Petitioner voluntarily dismissed her Complaint without prejudice and re-filed in a different jurisdictional state court. Petitioner’s actions completely disregarded the intended purpose of Rule 41(d) as a means of deterrence. Petitioner actively engaged in forum shopping when she voluntarily dismissed the suit from the Fifth Circuit and moved it to the Twelfth Circuit where the court had not yet definitively ruled on this issue. This Court cannot allow Petitioner to take advantage of the court system by finding and re-filing in the only remaining circuit forums that have left Rule 41(d) open to interpretation. This case exemplifies abusive forum shopping where Petitioner sought and successfully gained a tactical advantage. Petitioner additionally chose to initiate vexatious litigation for both the original court and the Respondent who expended substantial attorney’s fees on composing its answer to the Petitioner’s complaint pursuant to the precedent in the state of Texas, rather that the precedent set by the state of Illinoza. Petitioner’s tactical gaming of the district forums highlights the predominant reason why attorney’s fees should be recoverable under Rule 41(d) and therefore recoverable to Respondent.
2. Under Rule 41(d), this Court should allow the awarding of attorney’s fees to Respondent because this holding is in line with the holdings of the majority of the federal circuits and will create uniformity and predictability among the circuits.

This Court will be joining the Fourth, Seventh, Eighth, Tenth, and Twelfth Circuits when it concludes that a district court may award attorney’s fees under Rule 41(d)\(^1\). The Fourth Circuit held that under Rule 41(d), a district court may award attorney’s fees where the underlying statute provides for attorney’s fees or where bad faith or abuse forms a basis for doing so. *Andrews*, 827 F.3d 306, 309-12. The Seventh Circuit held that holding it is well settled that the district court may award attorney’s fees to a successful litigant when the opposing party has “acted in bad faith, vexatiously, wantonly, or for oppressive reasons”, *Sanderson v. Spectrum Labs, Inc.*, 248 F.3d 1159, 2000 WL 1909678, at *6 (7th Cir. 2000) (unpublished), and that under 41(d) a party may recover attorney’s fees when the recovery of the fees as costs is allowed by the substantive statute of the suit, *Esposito*, 223 F.3d at 501. The Eighth Circuit held attorney’s fees to be an appropriate remedy under Rule 41(d) when plaintiff’s conduct was “vexatious and targeted at forum shopping”. *Kent v. Bank of Am., N.A.*, 518 F. App'x 514, 517 (8th Cir. 2013) (unpublished). The Tenth Circuit held that the language of Rule 41(d) permits the district court’s imposition of attorney’s fees. *Meredith*, 2000 WL 807355, at *1. Finally, the Twelfth Circuit held “costs contemplated by Rule 41(d) include attorney’s fees”. *Ivers v. Westerly Pharmaceutical, Inc.*, No. AM-15-450-CV (12\(^{th}\) Cir. Feb. 2, 2017).

The majority of circuit courts have found that attorney’s fees are available under Rule 41(d). *Duffy v. Ford Motor Co.*, 218 F.3d 623, 632 (6th Cir. 2000). Out of all the circuits, only the Sixth Circuit held that district courts may not award attorney’s fees under Rule 41(d), but the

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\(^1\) The Third Circuit is currently considering the issue of attorney’s fees as attorney’s costs under Rule 41(4) as an issue of first impression in *Mario Lopez Garza v. Citigroup, Inc.*, No. 16-4332, 2017 WL 253362, at *1 (3rd Cir. June 7, 2017).
court did not reach this holding without significant hesitation. Rogers, 230 F.3d 868, 874. The Sixth Circuit in Rogers reasoned that despite the ambiguous structure of Rule 41(d), attorney’s fees are not available under Rule 41(d) in the absence of a specific reference to attorney’s fees. Id. at 875. However, the persuasiveness of the Rogers ruling is weakened when the Sixth Circuit highlights the uneasiness with which the court issued its ruling due to the ambiguity in the structure of Rule 41(d). It is understandable that the Sixth Circuit be hesitant to interpret Congress’ intent because it knows that its rulings are subject to this Court’s review and that this Court is best equipped to rule on Congress’ intent. Although the Rogers case does not consider attorney’s fees as costs under Rule 41(d), the court concedes that Rule 41(d) is, in fact, ambiguous. If Congress does not amend the Rule to include an express, unambiguous allowance or denial of attorney’s fees, it leaves the door wide open for this Court to exercise its supreme judgment and rule that Rule 41(d) does allow for the awarding of attorney’s fees.

As the circuits continue to align in agreement about Rule 41(d) permitting attorney’s fees, Petitioner is, rightfully, running out of available forums at which to shop around. By allowing attorney’s fees under Rule 41(d), the majority of the circuits have correctly allowed the district courts to theoretically and practically carry out the task of deterring forum shopping and avoiding vexatious litigation. This Court cannot allow Petitioner, or any other plaintiff, to unjustly take advantage of this loophole in Rule 41(d) any longer. The agreement of these circuits demonstrates that this Court’s allowance of Rule 41(d)’s awarding of attorney’s fees to Respondent is proper and benefits the judicial system by creating uniformity and predictability among the circuits.
B. This Court should hold Rule 41(d) permits attorney’s fees because this interpretation is consistent with Rule 1, Rule 41(a)(2), and Rule 68 of the Federal Rules of Civil Procedure, which sets forth the Rules’ goal of justice.

1. The common tools of statutory construction suggest this Court should permit attorney’s fees under Rule 41(d) because this is consistent with similar statutory provisions, Rule 41(a)(2) and Rule 68, that permit attorney’s fees.

Rule 41(d) is silent as to the scope of attorney’s costs. Fed. R. Civ. P. 41(d). Nowhere in the provision does the statute explicitly define “costs”, therefore, this Court is called upon to interpret Rule 41(d), keeping in mind its central goal of effectuating Congress' intent. Faced with such a lofty task of “trying to divine the intent of Congress”, the court should consider the larger structure of the statute in order to fully understand the entire scope of the relevant provision. United States v. Miller, 833 F.3d 274, 279 (3d Cir. 2016). In the case at hand, the context of Rule 41(d) is key because it will allow this Court to properly cure the ambiguity within the Rule.

Federal Rule of Civil Procedure 1 sets the stage for the context of Rule 41(d), which states the rules “should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding”. Fed. R. Civ. P. 1.

This Court should construe Rule 41(d) as including Petitioner’s payment of attorney’s fees to Respondent because it is consistent with the Federal Rules of Civil Procedure by allowing district courts to properly administer Rule 41(d) and employ truly just, speedy, and inexpensive litigation for both parties.

Exercising consistent reading among a statute’s provisions, a fundamental rule of statutory construction, compels the logical comparison of the other statutory provisions in Rule 41, with regard to Rule 41(d). Pardini v. Allegheny Intermediate Unit, 420 F.3d 181, 191 (3d Cir. 2005). Rules 41(a)(2) and Rule 41(d) should be interpreted in a consistent manner. Esposito, 223 F.3d at 501. Under Rule 41(a)(2), it is often customary practice for a plaintiff’s voluntarily dismissal and then refile to be conditioned by awarding defendant both attorney’s costs and
attorney’s fees. See *S.B. v. KinderCare Learning Ctrs., LLC*, 815 F.3d 150, 153 (3d Cir. 2016).

This is allowed by the court despite Rule 41(a)(2)’s failure to mention explicitly any award of attorney’s fees. Fed. R. Civ. P. 41(a)(2). By finding Rule 41(d) permits attorney’s fees, this “minimizes any inconsistency with Rule 41(a)(2)” thereby strengthening the force and effect of the provision. *Andrews*, 827 F.3d at 311. Without explicit language stating otherwise, it does not follow that a court has the discretion to award attorney’s fees under Rule 41(a)(2) and such a similar statutory provision as 41(d).

When it comes to this Court’s interpretation of Rule 68 as including attorney’s fees, a deeper analysis suggest that this Court should also interpret Rule 41(d) as including attorney’s fees. The Sixth Circuit mistakenly interpreted “costs” narrowly under Rule 41(d) to not incorporate attorney’s fees due to Congress’ lack of explicit language including “attorney’s fees”. See, e.g., *Rogers*, 230 F.3d at 875. But this Court should find this reasoning to be unpersuasive for two reasons. First, this outlier circuit was faced with an issue of first impression, which this Court had not yet spoken to. Consequently, the Sixth Circuit was hesitant to because it did not want to mistakenly expand Congress’ intent by an improper interpretation, which led it reach the wrong conclusion. This Court is charged with using its supreme judgment to correctly interpret Congress’ intent to allow attorney’s fees under Rule 41(d) and is not bound by the outlier circuit’s cautious interpretations. Secondly, the Sixth’s ruling is inconsistent with this Court’s reasoning in *Marek v. Chesny*, 471 U.S. 1, 8-9 (1985), where this Court considered whether “costs” under Rule 68 included attorney’s fees. In *Marek*, this Court held that, although Rule 68 refers only to “costs,” attorney’s fees are to be included as costs where the underlying statute defines “costs” to include attorney’s fees. *Id.* at 9. This Court further explained that the drafters of Rule 68 were fully aware of the exceptions to the American Rule
that allows federal statutes to direct courts to award attorney’s fees in particular cases. *Id.* at 8-9. This Court ruled that the drafters knew the importance of this distinction and that Congress would have explicitly disallowed attorney’s fees if it was clearly its intent. Under Rule 68, this Court permitted attorney’s fees and should use the same rationale for interpretation of this substantially similar provision, Rule 41(d), thereby and permit attorney’s fees as costs.

2. **Comparing this Court’s interpretation of Rule 68 as constituting attorney’s costs implies Rule 41(d) should include attorney’s fees because Rule 41(d) has a stronger policy reason than Rule 68 and has a lower discretionary standard.**

The two fundamental differences between Rule 68 and Rule 41(d) demonstrate that it would be a more obvious interpretation for Rule 41(d) to include attorney’s fees than the logical inference this Court correctly made in permitting Rule 68 to include attorney’s fees. First, the purpose of Rule 68 materially differs from the purpose of Rule 41(d). In *Marek*, this Court explained that the plain purpose of Rule 68 is neutral and is to encourage settlement and avoid litigation. *Marek*, 473 U.S. at 5. The underlying policy of Rule 68’s encouragement for the parties to settle does not favor plaintiff or defendant but rather it calls upon both parties equally to evaluate and balance the costs and risk of litigation with the likelihood of success at trial. *Id.* at 5, 10. Therefore, it is logical to connect attorney’s fees under Rule 68 to the statute that the right of action stems from, given that the intent of the statute itself was to encourage both parties to weigh all litigation costs. In stark contrast with the neutral settlement policy of Rule 68, Rule 41(d) is intended to serve strongly as a deterrent and to compensate parties for the costs of a vexatious litigation. See *Meredith*, 2000 WL 807355, at *1 (quoting *United Transp. Union*, 107 F.R.D. at 392. Rule 41(d)’s stronger policy is not neutral but rather seeks to punish the vexatious plaintiff by permitting reimbursement to the defendant for the plaintiff’s disfavored tactical forum shopping. Rule 41(d) does not merely seek to promote a neutral act; it strives to actively
disincentive a corrupt act of wasting the resources and time of both the court and the defendant. If Rule 68’s neutral settlement policy justifies the awarding of attorney’s fees, the ardent, deterrent policy of Rule 41(d)’s justification of awarding of attorney’s fees is an even stronger justification.

The second fundamental difference between Rule 68 and Rule 41(d) is the differing discretionary thresholds the courts are allowed under each Rule. Rule 68 states the offeree “must” pay the costs incurred while Rule 41(d) states the court “may” order the plaintiff to pay all or part of the costs. By choosing a discretionary standard for Rule 41(d), Congress intended a more flexible definition of “costs” such depending on the circumstances of the individual case. This Court used this interpretation of the discretionary standard when interpreting Rule 68’s use of the word “costs” to extend to attorney’s fees, at the district court’s discretion. As a practical matter, this discretionary standard also allows for the district courts to ensure that attorney’s fees are only being permitted under Rule 41(d) when applicable. Allowing attorney’s fees under Rule 41(d)’s deterrent effect will be undermined if its discretion to award attorney’s fees is not reinforced by this Court.

In conclusion, this Court should rule that Rule 41(d) permits attorney’s fees to be considered as attorney’s costs and uphold the Twelfth Circuit’s awarding of attorney fees to Respondent. This holding is proper because it is consistently applies Rule 41(d)’s specific intent to deter forum shopping and vexatious litigation, aligns with the majority of the Circuit Court’s holdings, and promotes the ultimate goal of the Federal Rules of Civil Procedure of just, speedy, and inexpensive determination of every trial and proceeding.
CONCLUSION

For the foregoing reasons, the Respondent, Westerly Pharmaceuticals, Inc., respectfully requests that this Court (1) affirm the district and appellate courts’ dismissal of the Complaint as preempted, thereby barring Petitioner from punishing Respondent for fully complying with federal law, and (2) affirm the Twelfth Circuit’s ruling, thereby allowing for awarding of attorney’s fees to Respondent under Federal Rules of Civil Procedure 41(d).

Respectfully Submitted,

Team 2607

Attorneys for Respondent
APPENDIX A

Food, Drug & Cosmetics Act - 21 U.S. Code § 355, 393


(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 subparagraph (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);
   (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)-
   (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) 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.


(b) **Mission:** The Administration shall—
(1) promote the public health by promptly and efficiently reviewing clinical research and
taking appropriate action on the marketing of regulated products in a timely manner;
(2) with respect to such products, protect the public health by ensuring that—
   (A) foods are safe, wholesome, sanitary, and properly labeled;
   (B) human and veterinary drugs are safe and effective;
   (C) there is reasonable assurance of the safety and effectiveness of devices intended for
      human use;
   (D) cosmetics are safe and properly labeled; and
   (E) public health and safety are protected from electronic product radiation
APPENDIX B

Supremacy Clause of Article VI, Clause 2
United States Constitution

U.S. Const. art. VI, cl. 2

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.
APPENDIX C

Rule 41 – Dismissal of Actions

Fed. R. Civ. P. 41

(a) Voluntary Dismissal.
   (1) By the Plaintiff.
      (A) Without a Court Order. Subject to Rules 23(e), 23.1(c), 23.2, and 66 and any
          applicable federal statute, the plaintiff may dismiss an action without a court order
          by filing:
              (i) a notice of dismissal before the opposing party serves either an answer
                  or a motion for summary judgment; or
              (ii) a stipulation of dismissal signed by all parties who have appeared.
      (B) Effect. Unless the notice or stipulation states otherwise, the dismissal is
          without prejudice. But if the plaintiff previously dismissed any federal- or state-
          court action based on or including the same claim, a notice of dismissal operates
          as an adjudication on the merits.
   (2) By Court Order; Effect. Except as provided in Rule 41(a)(1), an action may be
       dismissed at the plaintiff’s request only by court order, on terms that the court considers
       proper. If a defendant has pleaded a counterclaim before being served with the plaintiff’s
       motion to dismiss, the action may be dismissed over the defendant’s objection only if the
       counterclaim can remain pending for independent adjudication. Unless the order states
       otherwise, a dismissal under this paragraph (2) is without prejudice.

(b) Involuntary Dismissal; Effect. If the plaintiff fails to prosecute or to comply with these
    rules or a court order, a defendant may move to dismiss the action or any claim against it. Unless
    the dismissal order states otherwise, a dismissal under this subdivision (b) and any dismissal not
    under this rule—except one for lack of jurisdiction, improper venue, or failure to join a party
    under Rule 19—operates as an adjudication on the merits.

(c) Dismissing a Counterclaim, Crossclaim, or Third-Party Claim. This rule applies to a
    dismissal of any counterclaim, crossclaim, or third-party claim. A claimant’s voluntary dismissal
    under Rule 41(a)(1)(A)(i) must be made:
       (1) before a responsive pleading is served; or
       (2) if there is no responsive pleading, before evidence is introduced at a hearing or trial.

(d) Costs of a Previously DISmissed Action. 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.