

No. _____

In The
Supreme Court of the United States

JUDITH FREI, ET AL.,
Petitioners,

v.

TARO PHARMACEUTICALS (USA) INC.,
Respondent.

**On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Second Circuit**

PETITION FOR WRIT OF CERTIORARI

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Counsel for Petitioners

Dated: October 29, 2021

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QUESTION PRESENTED

Whether, consistent with Due Process and Federal Rule of Civil Procedure 15, a court has discretion to dismiss a plaintiff's complaint under Federal Rule of Civil Procedure 8(a) without leave to replead when a plaintiff has not had an opportunity to replead to address the court's concerns, absent a finding that there is "good reason" for not allowing the plaintiff to replead?

PARTIES TO THE PROCEEDING

Petitioners are plaintiffs in the district court and appellants in the Second Circuit:

Plaintiff/Appellant – Judith Frei
Plaintiff/Appellant – Sandra Rhodes
Plaintiff/Appellant – Charles Rhodes
Plaintiff/Appellant – Shirley Hart
Plaintiff/Appellant – Ray Hubler
Plaintiff/Appellant – Marie Hubler
Plaintiff/Appellant – William Murphy
Plaintiff/Appellant – Bonnie Murphy
Plaintiff/Appellant – James Walz
Plaintiff/Appellant – Mary Beth Walz
Plaintiff/Appellant – Trio Caldwell
Plaintiff/Appellant – Beverly Caldwell
Plaintiff/Appellant – Albert Delsantro
Plaintiff/Appellant – Charlotte Delsantro
Plaintiff/Appellant – Anna Thomas
Plaintiff/Appellant – Charles David Smedley
Plaintiff/Appellant – Edward Frisco
Plaintiff/Appellant – Rebecca Frisco
Plaintiff/Appellant – Larry E. Robinson
Plaintiff/Appellant – Cecil Barkley
Plaintiff/Appellant – Nancy Miller
Plaintiff/Appellant – Larry Junkin
Plaintiff/Appellant – Arthur L. Church
Plaintiff/Appellant – Mable Church
Plaintiff/Appellant – Jacqueline Boyd
Plaintiff/Appellant – Cortis Boyd
Plaintiff/Appellant – Brian Sukenik

Plaintiff/Appellant – Sandra White
Plaintiff/Appellant – Roger White
Plaintiff/Appellant – Mary Waters
Plaintiff/Appellant – Kevin Hilton
Plaintiff/Appellant – Clinton Humphrey
Plaintiff/Appellant – Tenna Humphrey
Plaintiff/Appellant – Bonnie Greene
Plaintiff/Appellant – Michael Hess
Plaintiff/Appellant – Sandra Bonekemper
Plaintiff/Appellant – Nancy Hagerman
Plaintiff/Appellant – Gary Melton
Plaintiff/Appellant – Dixie Melton
Plaintiff/Appellant – Christopher Freeman
Plaintiff/Appellant – Judith Freeman
Plaintiff/Appellant – Carolyn Sue Bean
Plaintiff/Appellant – Mark Thompson
Plaintiff/Appellant – Ada Duffy
Plaintiff/Appellant – Jefferie Harrison
Plaintiff/Appellant – Christen Harrison
Plaintiff/Appellant – Raniere Caserta
Plaintiff/Appellant – Couchita Caserta
Plaintiff/Appellant – Don Amburgey
Plaintiff/Appellant – Joyce Amburgey
Plaintiff/Appellant – Mona Simmons
Plaintiff/Appellant – Trina Owen
Plaintiff/Appellant – Rubie Hoda
Plaintiff/Appellant – Billy West
Plaintiff/Appellant – Mona Windham
Plaintiff/Appellant – Ronnie Windham
Plaintiff/Appellant – Jeanne Colborne
Plaintiff/Appellant – Tracie Shollenbarger

Plaintiff/Appellant – William Shelton
Plaintiff/Appellant – Janice Shelton
Plaintiff/Appellant – Pink Jones
Plaintiff/Appellant – Annie Jones
Plaintiff/Appellant – Cynthia Skiles
Plaintiff/Appellant – Raymond Skiles
Plaintiff/Appellant – Earl Hines
Plaintiff/Appellant – Debra Hines
Plaintiff/Appellant – James Skinner
Plaintiff/Appellant – David Whitlock
Plaintiff/Appellant – Jacqueline Whitlock
Plaintiff/Appellant – Connie Luye
Plaintiff/Appellant – Billy Karr
Plaintiff/Appellant – Robyn Garcia
Plaintiff/Appellant – Diane Mancinelli
Plaintiff/Appellant – Charles Hershiser
Plaintiff/Appellant – Mary Frances Hershiser
Plaintiff/Appellant – Shelby Campbell
Plaintiff/Appellant – Penny Watson
Plaintiff/Appellant – Antonio Burdier
Plaintiff/Appellant – Carmen Fernandez
Plaintiff/Appellant – Benjamin Lucas
Plaintiff/Appellant – Carla Ellis
Plaintiff/Appellant – Kelly Roberts
Plaintiff/Appellant – Rita Pennington
Plaintiff/Appellant – Jane Starnes
Plaintiff/Appellant – Linda Lanier
Plaintiff/Appellant – Harsharan Sandhu
Plaintiff/Appellant – James Thomas
Plaintiff/Appellant – Barbara Walker
Plaintiff/Appellant – David Sabo

Respondent Taro Pharmaceuticals (USA) Inc. was the defendant in the district court and the appellee in the Second Circuit.

STATEMENT OF RELATED CASES

Bennett, et al. v. Teva Pharmaceuticals, et al., No. 19-2126. U.S. District Court, District of Delaware. Dismissal entered March 2, 2021.

Bennett, et al. v. Teva Pharmaceuticals, et al., No. 21-1642. U.S. Court of Appeals for the Third Circuit.

Burns, et al. v. Mayne Pharma, et al., No. 20-248. U.S. District Court, District of Delaware. Dismissal entered March 18, 2021.

Collette v. Wyeth Pharmaceuticals, et al., No. 16-1034, U.S. District Court, Northern District of California. Judgment entered June 22, 2020.

Collette v. Wyeth Pharmaceuticals, et al., No. 20-16406, U.S. Court of Appeals for the Ninth Circuit. Mandate issued Aug. 16, 2021.

Cook v. Par Pharmaceutical, et al., No. 15-529, U.S. District Court, Northern District of Alabama. Dismissal Order entered April 24, 2020.

Cook v. Par Pharmaceutical, et al., No. 20-11926, U.S. Court of Appeals for the Eleventh Circuit. Mandate issued March 9, 2021.

Garcia v. Zydus Pharmaceuticals, et al., No. 17-412, U.S. District Court, Southern District of Texas. Judgment entered May 25, 2017.

In Re: Amiodarone Cases – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered Jan. 14, 2019.

In Re: Amiodarone Cases – No. A157035. California Court of Appeals, First Appellate District, Division Two. Remittitur issued Sept. 29, 2020.

In Re: Amiodarone Cases – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered June 11, 2019.

In Re: Amiodarone Cases – No. A158160. California Court of Appeals, First Appellate District, Division Two. Remittitur issued Sept. 29, 2020.

In Re: Amiodarone Cases – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered Dec. 2, 2019.

In Re: Amiodarone Cases – No. A159522. California Court of Appeals, First Appellate District, Division Two. Remittitur issued Sept. 29, 2020.

In Re: Amiodarone Cases – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered Sept. 8, 2020.

In Re: Amiodarone Cases – No. A161023. California Court of Appeals, First Appellate District, Division Two.

In Re: Amiodarone Cases – No. JCCP 04956. Superior Court of California, County of Alameda. Order entered May 22, 2020.

In Re: Amiodarone Cases – No. A161762. California Court of Appeals, First Appellate District, Division Two.

Jankowski, et al. v. Zydus Pharmaceuticals, et al., No. 20-2458. U.S. District Court, District of New Jersey.

Jordan, et al. v. Teva Pharmaceuticals, et al., No. 20-1209. U.S. District Court, District of Delaware. Dismissal entered June 30, 2021.

Jordan, et al. v. Teva Pharmaceuticals, et al., No. 21-2304. U.S. Court of Appeals for the Third Circuit.

McDaniel v. Upsher-Smith Pharmaceuticals, et al., No. 16-2604, U.S. District Court, District of Tennessee. Dismissal Order entered May 25, 2017.

McDaniel v. Upsher-Smith Pharmaceuticals, et al., No. 17-5741, U.S. Court of Appeals for the Sixth Circuit. Mandate issued Aug. 10, 2018.

McDaniel v. Upsher-Smith Pharmaceuticals, et al., No. 19-1246, Supreme Court of the United States. Petition for Writ of Certiorari denied Oct. 6, 2020.

Medford, et al. v. Eon Labs, et al., No. 20-412. U.S. District Court, District of New Jersey.

Polt v. Sandoz, et al., No. 16-2362, U.S. District Court, Eastern District of Pennsylvania. Judgment entered May 26, 2020.

Polt v. Sandoz, et al., No. 20-2125, U.S. Court of Appeals for the Third District. Dismissed March 10, 2021.

Roncal, et al. v. Aurobindo Pharma USA, et al., No. 20-2643. U.S. District Court, District of New Jersey.

Stelly v. Zydus Pharmaceuticals, et al., No. 20-570. U.S. District Court, Western District of Louisiana.

Villarreal v. Taro Pharmaceuticals, et al., No. 17-35.
U.S. District Court, Southern District of Texas.

Vining, et al. v. Zydus Pharmaceuticals, et al., No. 20-13439. U.S. District Court, District of New Jersey.

Walsh, et al. v. Upsher-Smith Laboratories, et al., No. 20-6531. District Court, State of Minnesota, County of Hennepin.

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PETITION FOR WRIT OF CERTIORARI

Petitioners respectfully petition this Court for writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit.

OPINIONS BELOW

The opinion of the court of appeals (Pet.App.1a) is reported at 844 Fed. Appx. 444. The opinion of the district court dismissing Plaintiffs' claims based on preemption (Pet.App.10a) is reported at 443 F. Supp. 3d 456.

JURISDICTION

The judgment of the court of appeals was entered on April 20, 2021. The court of appeals denied rehearing and rehearing *en banc* on June 21, 2021. (Pet.App.35a). This Court has jurisdiction under 28 U.S.C. § 1254(1).

RELEVANT CONSTITUTIONAL, REGULATORY, & STATUTORY PROVISIONS

This case involves the Due Process Clause of the Fifth Amendment of the United States Constitution and Federal Rule of Civil Procedure 15. (Pet.App.37a-40a)

INTRODUCTION

This Court should grant *certiorari* to address the important question of constitutional law presented here.

The Second Circuit dismissed Plaintiffs' claims as inadequately pleaded under Rule 8 of the Federal Rules of Civil Procedure on a basis Defendant had not

raised and the District Court had not addressed. The Second Circuit did not grant Plaintiffs an opportunity to replead, even though Plaintiffs were ready, willing, and able to do so to address any technical problems with their pleading. The Second Circuit also did not find that there was no “good reason” to allow repleading.

This Court has long recognized that a cause of action is a property right protected by constitutional Due Process. Refusing Plaintiffs an opportunity to replead without following Rule 15 of the Federal Rules of Civil Procedure violates Plaintiffs’ Due Process rights.

This Court should intervene to clarify that “[t]he provisions of [Rule 15] which are here involved must be read in light of the provisions of the Fifth Amendment that no person shall be deprived of property without due process of law.” *Societe Internationale Pour Participations v. Rogers*, 357 U.S. 197, 209 (1958).

STATEMENT OF THE CASE

A. Background facts

Plaintiffs’ doctors diagnosed them with non-life-threatening atrial fibrillation. (Pet.App.15a). Under Defendant’s influence, the doctors prescribed them amiodarone tablets to treat their atrial fibrillation. (*Id.*) They filled their prescriptions with Defendant’s amiodarone at various pharmacies. (*Id.*) Because they took amiodarone, they suffered severe and debilitating injuries. (*Id.*)

The FDA requires manufacturers to ensure consumers receive a warning called a “medication

guide.” But Plaintiffs did not receive medication guides when they filled their prescription, because Defendant did not provide sufficient medication guides (or the means of producing them) to the distributor or to the pharmacies where they filled their prescriptions. (Pet.App.22a-23a.) Had Plaintiffs received medication guides—which would have been adequate warnings under state law—they would not have taken amiodarone. (*Id.*) In failing to ensure Plaintiffs received medication guides, Defendant fell short of its duty to warn under state law. Although the learned intermediary doctrine can be a defense under some circumstances, several of Plaintiffs’ home states do not recognize the learned intermediary doctrine under these circumstances.

In their complaint, Petitioners alleged wrongful death based on Defendant’s failure to warn when it failed to ensure Plaintiffs received a medication guide and misled their doctors. (*Id.*)

B. The district court holds that Plaintiffs’ failure-to-warn-via-Medication-Guide claims is preempted and does not permit leave to replead, because repleading would be futile.

The district court had diversity jurisdiction under 28 U.S.C. § 1332. The district court held that Plaintiffs’ failure-to-warn claim—paralleling Defendant’s failure to provide a medication guide in accordance with FDA regulations—were preempted. It reasoned that the specific requirement to provide a medication guide is found in the FDCA. (Pet.App.23a). On the other hand, Plaintiffs had not cited a specific requirement to provide a medication guide under state law. (*Id.*) Instead, Plaintiffs relied on the state

tort principle of negligent failure to warn. “Although plaintiffs couch their failure to warn claims in traditional state tort law, it is clear the existence of the FDA’s medication guide regulation is the gravamen of these claims.” (*Id.*) The court based this conclusion on the fact that plaintiffs referenced medication guides 400 times in their complaint. (Pet.App.24a) The court did not perform a choice-of-law analysis even though several of Plaintiffs’ states do not recognize the learned intermediary doctrine that undergirded the district court’s holding. (Pet.App.10a-31a)

C. The Second Circuit affirms, holding that Plaintiffs’ failure-to-warn-via-Medication-Guide claim is preempted.

The Second Circuit affirmed on different ground. It held that Plaintiffs had not adequately pleaded their failure-to-warn claims under Rule 8 of the Federal Rules of Civil Procedure. Specifically, it held that Plaintiffs failed to plead an adequate factual basis for their failure-to-warn claims, because the complaint “lacks any allegation that Taro violated the minimal requirements of § 208.24” or that “Taro violated [a] hypothetical enhanced duty” in state law. (Pet.App.7a) In particular, Plaintiffs did not plead that Taro failed to provide the “means to produce” Medication Guides. The court did not grant Plaintiffs an opportunity to replead and did not discuss Rule 15(c) of the Federal Rules of Civil Procedure.

D. Proceedings after decision.

Plaintiffs timely moved for rehearing *en banc*, arguing that they should have received an opportunity to replead. On June 21, 2021, the

Second Circuit rejected their motion for rehearing. (Pet.App.35a) On October 29, 2021, Plaintiffs timely filed this petition for certiorari. *See* USCS SUPREME CT R 13(1), (3) (petition for certiorari must be filed within 90 days of the denial of a petition for rehearing); *Order List: 594 United States*, 2021 U.S. LEXIS 3591, at *1 (July 19, 2021) (extending time to file to 150 days for judgments or orders rendered before July 19, 2021).

REASONS FOR GRANTING THE WRIT

I. The Second Circuit’s Decision Implicates Important Constitutional Issues That Have Not Been Settled by this Court.

The Second Circuit’s summary order affirmed dismissal of Plaintiffs’ failure-to-warn claims under Rule 8, finding that Plaintiffs did not plausibly plead facts supporting their claims. It did not, however, find that repleading would be “futile” or find any “good reason” to deny repleading.

Thus, Plaintiffs request that this Court consider whether, consistent with Due Process and Federal Rule of Civil Procedure 15, a court can deny leave to replead when a plaintiff has not had an opportunity to replead to address the court’s concerns, absent a finding that there is “good reason” for not allowing the plaintiff to replead.

This Court has held that “a cause of action is a species of property protected by the Fourteenth Amendment’s” and the Fifth Amendment’s Due Process Clause. *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982). “[F]or example—where a plaintiff’s claim had been dismissed for failure to

comply with a trial court’s order—the Court read the ‘property’ component of the Fifth Amendment’s Due Process Clause to impose ‘constitutional limitations upon the power of courts, even in aid of their own valid processes, to dismiss an action without affording a party the opportunity for a hearing on the merits of his cause.’” *Id.* (quoting *Societe Internationale Pour Participations v. Rogers*, 357 U.S. 197, 209 (1958)).

Rule 15 of the Federal Rules of Civil Procedure provides that leave to amend a party’s pleading “shall be freely given when justice so requires.” FED. R. CIV. P. 15; *see also Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Day v. McDonough*, 547 U.S. 198, 209 (2006). “The Rule reflects … the most important principles behind the Federal Rules,” including “that ‘mere technicalities’ should not prevent cases from being decided on the merits.” *Monahan v. N.Y.C. Dep’t of Corr.*, 214 F.3d 275, 283 (2d Cir. 2000) (quoting *Foman*, 371 U.S. at 182).

Accordingly, a court has discretion to deny leave to re-plead only “for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party.” *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007); *Monahan*, 214 F.3d at 283.

Here, the district court dismissed Plaintiffs’ claims as preempted. It is, of course, futile to replead preempted claims. *See Spiegel v. Bekowies*, 669 F. App’x 38, 39 (2d Cir. 2016). At the district court, Plaintiffs fully addressed the only Rule 8 argument that Defendant made (which was different from the Second Circuit’s conclusion) and requested leave to re-plead in the event the district court dismissed under Rule 8. The Second Circuit, however, did not

address preemption or the learned intermediary doctrine in its summary order.

Instead, it held that Plaintiffs failed to plead an adequate factual basis for their failure-to-warn claims, because the complaint “lacks any allegation that Taro violated the minimal requirements of § 208.24” or that “Taro violated [a] hypothetical enhanced duty” in state law. (Pet.App. 7a).

The Second Circuit did not find that there was “evidence of undue delay, bad faith or dilatory motive on the part of the movant, undue prejudice to the opposing party, or futility” in the record. *Monahan*, 214 F.3d at 283.

In fact, Plaintiffs could easily remedy these defects in a new, good faith complaint. Therefore, repleading would not be futile. If they had been granted an opportunity to replead, Plaintiffs would have alleged that Defendant did not provide Medication Guides to pharmacies or distributors or the means to produce Medication Guides. Plaintiffs would also allege that Defendants’ distribution methods were inadequate under state law because they did not even attempt to distribute Medication Guides. As a district court recently held in an Amiodarone case applying Louisiana law, “The adequacy of [a generic drug manufacturer’s] distribution methods is a factual question which should be addressed after discovery.” *Stelly v. Zydus Pharm. United States*, No. 6:20-CV-00570, 2021 U.S. Dist. LEXIS 56380, at *21-22 (W.D. La. 2021). Repleading would also not prejudice Defendant or cause undue delay, because this case remains at the motion-to-dismiss stage.

Furthermore, as Plaintiffs explained in their motion for reconsideration, Defendants did not raise the arguments accepted by the Second Circuit and the district court did not address them.

In short, Plaintiffs could easily address the garden-variety pleading defects raised by the panel in an amended complaint. By refusing to allow Plaintiffs an opportunity to amend, the Second Circuit violated Rule 15 of the Federal Rules of Civil Procedure and Plaintiffs' Due Process rights.

II. The Question Presented Is Important and Recurring.

Until this Court clarifies the constitutional requirements of Due Process and Rule 15 of the Civil Rules of Procedure in dismissing a complaint for inadequate pleading, this problem is likely to reoccur continually.

To Plaintiffs' knowledge, this Court has never specifically addressed the constitutional limitations on dismissal under Rule 8 and the interplay between Due Process and Rule 15. In the Court's seminal decision on Rule 8, *Ashcroft v. Iqbal*, for instance, the Court remanded for the Court of Appeals to "decide in the first instance whether to remand to the District Court so that respondent can seek leave to amend his deficient complaint." 556 U.S. 662, 687 (2009).

Here, the Second Circuit dismissed Plaintiffs' claims for inadequate pleading without granting an opportunity to replead or even addressing Rule 15. It is not unusual for a first complaint to be deficient. If the Second Circuit's decision stands, it may create an

insurmountable procedural obstacle to Plaintiffs seeking to vindicate their rights in federal courts.

CONCLUSION

The petition for a writ of certiorari should be granted.

Dated: October 29, 2021

Respectfully submitted,

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