No. 13-1236

In The Supreme Court of the United States

UNITED STATES EX REL. HELEN GE, M.D.,

Petitioner,

vs.

TAKEDA PHARMACEUTICAL COMPANY LIMITED; TAKEDA PHARMACEUTICAL NORTH AMERICA, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

REPLY BRIEF FOR PETITIONER

MICHAEL L. BAUM
Counsel of Record
R. BRENT WISNER
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, California 90025
Telephone: (310) 207-3233
Facsimile: (310) 207-4204
MBaum@baumhedlundlaw.com

MICHAEL SULLIVAN
THE ASHCROFT GROUP
1 Post Office Square, Suite 3750
Boston, Massachusetts 02109
Telephone: (617) 573-9400
Facsimile: (617) 933-7607
MSullivan@ashcroftlawfirm.com

Counsel for Petitioner

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

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REPLY BRIEF FOR PETITIONER

Certiorari should be granted because, absent some direction from this Court, the ability of litigants to amend pleadings and have the merits of their claims addressed, one way or the other, will frequently depend on the happenstance of geography, not the uniform application of law. Dr. Helen Ge filed her case in the First Circuit where the pleading standards for a False Claims Act were in flux. She nonetheless believed her allegations were sufficient to state a claim under existing law, but in an abundance of caution, requested leave to amend should the district court disagree. Ultimately, the district court rejected the sufficiency of Dr. Ge's allegations, but completely ignored her pre-judgment request to amend and entered a final judgment against Dr. Ge. Unsure why the district court was silent about her pre-judgment request to amend, Dr. Ge filed a post-judgment motion to amend, replete with proposed amended complaints, expert testimony, and eight witness declarations. Her motion was again denied without explanation. On appeal, Dr. Ge was told her pre-judgment efforts to amend were insufficient and her post-judgment efforts were "too little, too late." Thus, in effect, Dr. Ge was given *one* shot to state a perfect claim to the district court.

This is just wrong. The court of appeals' ruling conflicts with this Court's holding in *Foman v. Davis*, 371 U.S. 178, 180-82 (1962) and the law in the Second, Third, Fourth, Fifth, Sixth, and Eighth Circuits (and likely the Ninth as well). A litigant should be

allowed to proceed with a case unless amendment is futile, prejudicial, or in bad faith. *Certiorari* should be granted to resolve this divided issue.

I. BY MISSTATING THE ISSUE PRESENTED IN THIS PETITION, TAKEDA GLOSSES OVER THE CIRCUIT SPLIT REGARDING WHAT STANDARD OF REVIEW IS APPLIED TO POST-JUDGMENT MOTIONS TO AMEND

Takeda tries to reframe the issue by asking the wrong question: "[s]hould all courts continue to exercise discretion in analyzing motions to amend filed after the entry of judgment by balancing the interest of finality against a liberal amendment policy[?]" That is not what is at stake. Dr. Ge never argued that courts should *stop* exercising discretion in considering post-judgment requests to amend. Dr. Ge believes that the *standard* applied in exercising discretion should be consistent in each circuit. And, as Dr. Ge explained in her opening brief, they are not. (Pet. 24-29.)

Before the court of appeals, Dr. Ge argued that her post-judgment request to amend should have been allowed or, at a minimum, denied with explanation. Dr. Ge was entitled to at least one opportunity to correct the deficiencies identified by the district court since there was no indication that allowing amendment would be futile, prejudicial, or in bad faith. The court of appeals rejected this argument, holding "[t]here was also no abuse in denying Dr. Ge's second

request. It came after judgment, when the liberal leave to amend language of Rule 15([a]) *does not apply*." (App. 27 (emphasis added).) According to the court of appeals, even if amendment could cure the deficiencies in a complaint, it does not matter. A request to amend after judgment does not implicate Rule 15.

The First Circuit's ruling is in *direct conflict* with the Third, Fourth, Fifth, and Sixth Circuits, but comports with similar holdings in the Seventh, Tenth,[1] and Eleventh Circuits (and, in a technical sense, the Ninth Circuit[2]). *Compare United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1361 n.22 (11th Cir. 2006) ("Fed. R. Civ. P. 15(a) ***has no application*** once the district court has dismissed the complaint and entered final judgment for the defendant"

[1] In her opening brief, Dr. Ge stated that the Tenth Circuit was also in conflict with the court of appeals, relying on language in *Glenn v. First Nat. Bank in Grand Junction*, 868 F.2d 368, 371 (10th Cir. 1989). However, upon further research, it is clear the Tenth Circuit joined the First, Seventh, and Eleventh Circuits in holding that Rule 15's liberal pleading considerations do not apply to post-judgment requests to amend. *The Tool Box, Inc. v. Ogden City Corp.*, 419 F.3d 1084, 1087 (10th Cir. 2005).

[2] The Ninth Circuit, while refusing to apply Rule 15 considerations to post-judgment motions, *see Lindauer v. Rogers*, 91 F.3d 1355, 1357 (9th Cir. 1996), front-loads Rule 15's considerations by requiring any dismissal with prejudice be accompanied by a specific finding of futility, prejudice, or bad faith in the first instance, *see Bowles v. Reade*, 198 F.3d 752, 758 (9th Cir. 1999).

(emphasis added))[3] *with Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 193 (4th Cir. 2009) ("We made clear in *Laber*[4] that 'a post-judgment motion to amend is evaluated under ***the same legal standard***' – grounded on Rule 15(a) – 'as a similar motion filed before judgment was entered'" (emphasis added)).[5] The First, Seventh, Tenth, and Eleventh Circuits refuse to apply Rule 15 to post-judgment requests to amend, whereas the Third, Fourth, Fifth, and Sixth Circuits *exclusively* apply Rule 15 considerations. If these conflicting standards were not enough to create confusion, the Second and Eighth Circuits take a *third* approach, balancing the interests of finality against Rule 15's liberal pleading considerations. *See* Pet. 25-29 (examining and quoting Second and Eighth Circuit case law).

Takeda attempts to gloss over this split of authority by focusing on the fact that a post-judgment request to amend is discretionary – a fact applicable in all circuits. Takeda argues that, "because any given set of facts may support several outcomes, all evincing the sound exercise of discretion, while the circuits

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[3] *Accord Tool Box*, 419 F.3d at 1087; *First Nat. Bank of Louisville v. Cont'l Illinois Nat. Bank & Trust Co. of Chicago*, 933 F.2d 466, 468 (7th Cir. 1991).

[4] *Laber v. Harvey,* 438 F.3d 404 (4th Cir. 2006).

[5] *Accord Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 864 (5th Cir. 2003); *Morse v. McWhorter*, 290 F.3d 795, 799 (6th Cir. 2002); *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 272 (3d Cir. 2001).

may use slightly different words in describing how the district courts should exercise that discretion, all formulations are nonetheless compatible and can produce the same *discretionary* results, no matter the circuit." (Opp. 17.) This argument misses the point. To be sure, one would hope every district court exercises some discretion in resolving a post-judgment request to amend. And, as such, different courts can come to the same or different results while considering those motions. But, the mere exercise of discretion is not what is at stake here. This appeal focuses on the *standard applied in exercising that discretion*, and whether the district court and court of appeals were correct in completely disregarding Rule 15 for a post-judgment motion to amend – even when a pre-judgment request to amend was ignored.

There is a split of authority on what standard applies. A district court in the First Circuit will not consider whether the plaintiff could remedy the deficiencies that caused the case to be dismissed because Rule 15 "***does not apply***." However, a district court in the Fourth Circuit, for example, exclusively considers Rule 15 and must permit post-judgment amendment unless it finds that such amendment is futile, prejudicial, or in bad faith. Both courts may ultimately deny the request – they may exercise discretion – however, the standard applied, and the access to recourse ultimately available to litigants differs widely.

II. THE CLAIM THAT DR. GE "SQUANDERED" HER CHANCE TO AMEND THE COMPLAINTS OR IS ATTEMPTING TO GAME THE SYSTEM ARE COMPLETELY UNFOUNDED

Takeda states, and the court of appeals noted, that Dr. Ge amended her complaints twice before the district court entered its order, suggesting Dr. Ge squandered her chance to correct the complaints before the district court entered judgment. This is incorrect.

First, Dr. Ge's two amendments were made as a matter of course, not in response to a motion to dismiss. Dr. Ge amended the complaints because, during the Department of Justice's twenty-month investigation, new information became available. When Takeda moved to dismiss the complaints, it was the first time anyone challenged the pleadings. And, when the district court dismissed both 110-page complaints in eight paragraphs of analysis, it was the first (and only) substantive ruling by the district court. Indeed, since the district court did not entertain oral argument or conduct a status conference, Dr. Ge's counsel never even appeared before the court before the case was terminated. Thus, the only opportunity Dr. Ge had to invoke Rule 15's liberal pleading standard was while Takeda's motion to dismiss was pending. This means Dr. Ge had three options: (1) concede to the motion to dismiss and immediately

seek leave to amend, (2) file a motion to amend concurrently with an opposition to the motion,[6] or (3) waive her ability to invoke Rule 15 and oppose the motion to dismiss. Dr. Ge did not have any meaningful opportunity to address or correct any deficiencies in the complaints under Rule 15, absent wholesale concession to Takeda in an area of law that was unsettled. (*See* Pet. 10 n.8.)

Second, Dr. Ge did not know that her pre-judgment request to amend would be ignored. Dr. Ge believed, relying on and citing to *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 723 (1st Cir. 2007), that making a request to amend as part of a separate section in her opposition was sufficient. In *Rost*, the First Circuit held that a relator's one-sentence request to amend in footnote 135 of its opposition was "sufficient to invo[ke] for leave to amend under Rule 15(a)." *Id.* Dr. Ge did not know the district court would ignore her request altogether, or that the court of appeals would find her request insufficient to invoke Rule 15, in contravention of its holding in *Rost*.

[6] This option is untenable. Dr. Ge would be required to argue, on one hand, that her pleadings were sufficient, i.e., oppose the motion to dismiss, while on the other hand, argue that additional facts are needed to state a claim, i.e., move to amend the complaint. Forcing a litigant to take awkward and/or contradictory legal positions does not serve the interests of justice.

Third, Takeda's accusation that Dr. Ge deliberately waited until the last minute to seek amendment, "holding potential grounds for an amendment in her pocket [to] see how a motion to dismiss is resolved, and then spring a new amendment request on the court and other litigants" is nonsense. (Opp. 2.) When Dr. Ge filed her complaints, she did not know she would be required to solicit independent third-party testimony about specific examples of fraudulent claims, or that she would need to retain expert testimony from a pharmaceutical economist. The case was at the pleading stage and the law governing the pleading requirements for a false claims act claim was (and continues to be) unresolved. (*See* Pet. 10 n.8 (describing the unsettled nature of False Claims Act pleading requirements among the circuits and within the First Circuit).) It was not until the district court explained that Dr. Ge needed specific examples of false claims and/or expert testimony – prior to any discovery – that she then went out and solicited that information (information she *did not have* when she filed her complaint, nor reasonably believed she *needed to have* to file a complaint). And, remarkably, Dr. Ge was able to obtain the declarations of eight consumers who submitted false claims to the government because of Takeda's fraud as well as the expert testimony of a pharmaceutical economist. According to the court of appeals (and possibly the district court, although it did not provide any explanation in its ruling), this new information did not matter even if the new information cured the deficiencies identified by the district court. Dr. Ge got *one*

chance to predict how the district court would interpret unsettled law and if she got it wrong, the case was over.

III. TAKEDA'S ARGUMENT THAT ANY AMENDMENT WOULD BE FUTILE IGNORES THE PURPOSE OF THIS APPEAL AND SPEAKS TO THE INJUSTICE DR. GE HAS ENDURED

In a tacit admission that there is a split of authority among the circuits, Takeda argues that "[t]his case is a poor vehicle for review because regardless which rule carries the day, the result will not necessarily change." (Opp. 29 (conceding there are, in fact, different rules).) Takeda argues that, regardless of which rule the district court applied, Dr. Ge's "proposed amendment alone would have been futile" and, thus, she would not have been entitled to file an amended complaint under either standard. This argument, however, is out of sequence. Whether Dr. Ge's claims have any merit is the precise question Dr. Ge would like to take to the district court and resolve. However, *before* Dr. Ge is allowed to get to the merits, she should have been allowed to express those claims in an amended complaint. She needed access. But the district court and the court of appeals shut the door to any amendment – the district court through silence, and the court of appeals through refusing to apply Rule 15. This appeal is about opening that door so the very issue raised by Takeda, i.e., whether her claims have merit, can be addressed.

Dr. Ge alleges that Takeda's fraudulent conduct caused millions of false claims to be submitted to government reimbursement programs to pay for various prescription drugs manufactured by Takeda in violation of the False Claims Act. These allegations are espoused in three theories of liability:

- Takeda's fraudulent conduct prompted prescribers and patients to submit claims to government reimbursement programs that would otherwise never have been submitted, based on a fraudulently induced belief that the drugs were safer than they actually were.[7]
- Takeda's conduct prompted the submission of claims for the subject drugs that were not "reasonable and necessary" for medical treatment, in violation of a material precondition for federal reimbursement pursuant to 42 U.S.C. § 1395y(a)(1)(A).
- Takeda's conduct prompted the submission of claims for drugs that were, pursuant to 21 U.S.C. § 355(a), misbranded drugs because their labels contained

[7] The fact that sales of Actos plummeted over 60% immediately after the 2011 bladder cancer warning (even though Takeda knew about the risk in 2005, or as recent evidence suggests, in 2002), illustrates that most purchases for Actos were based on a false belief that Actos was not associated with bladder cancer.

> false and misleading information and warnings.

As it stands, the viability of these theories of False Claims Act liability, i.e., whether they are futile, has not been addressed by *any* court.[8] The district court ignored these theories by focusing its four-paragraph Fed. R. Civ. P. 12 analysis on whether duping the FDA regarding adverse event reporting could render claims for drugs false. (App. 41-43.) The court of appeals noted these theories and then held they were not sufficiently raised in Dr. Ge's opposition to Takeda's motion to dismiss and, thus, were waived. (App. 18, 19-23.) Although the court of appeals conceded that Dr. Ge raised these theories in her post-judgment motions, at that point, "it was too little, too late." (App. 20, 22.)[9] Thus, neither the

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[8] The court of appeals' analysis of these theories was limited to whether it met Fed. R. Civ. P. 9's specificity requirements, not whether the theories, themselves, are viable causes of action. (App. 18-23.)

[9] Since this case has been on appeal, substantial evidence has come to light vindicating Dr. Ge's allegations. For example, a federal jury recently returned a $6 billion punitive damages verdict against Takeda for its conduct in concealing bladder cancer risks associated with Actos. And, just last week, a federal judge issued a 115-page order outlining how, between 2002 and 2011, Takeda intentionally destroyed documents and evidence regarding Takeda's conduct in concealing bladder cancer risks. *In re: Actos (Pioglitazone) Prod. Liab. Litig.*, Final Memorandum and Ruling (Takeda Only), 11-MD-2299, Dkt. 4356 (W.D. La.). Moreover, private third-party payors have started filing claims against Takeda, mirroring the claims Dr. Ge raised on behalf of public third-party payors, i.e., Medicare and Medicaid. *E.g.*, *In*

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district court nor the court of appeals has held that amendment would be futile. Takeda is the *only* one making that claim, both here and before the court of appeals. And yet, despite this issue being presented and briefed, Dr. Ge has never been given the opportunity to have the merits addressed. Should *certiorari* be granted and Dr. Ge succeeds on her appeal, this case will be remanded with instructions to allow amendment.

IV. THE FACT THAT THIS IS A *QUI TAM* CASE DOES NOT MAKE IT A POOR VEHICLE TO REVIEW THIS IMPORTANT PROCEDURAL CIRCUIT SPLIT

Takeda argues that, because this lawsuit is brought as a whistleblower claim on behalf of the United States, it lacks "systemic importance." (App. 32.) According to Takeda, since the FDA has taken no policing action against Takeda as a result of its conduct (other than force Takeda to issue new warnings for the drugs), "[t]his Court need not be concerned with [Dr.] Ge's inability to 'have [her] case decided on the merits.'" (App. 33.) Takeda's argument, however, while conceding that Dr. Ge did not have her case decided on the merits, ignores the fact that the FDA does not enforce the False Claims Act.

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re: Actos (Pioglitazone) Prod. Liab. Litig., Bundled Complaint, 14-cv-01151, Dkt. 1 (W.D. La.). Should this Court allow Dr. Ge to proceed with her claims, she will be armed with substantial evidence sufficient to meet *any* pleading standard.

It also ignores the purpose of the False Claims Act's *qui tam* provisions, which were enacted "to stimulate actions by private parties should the prosecuting officers be tardy in bringing the suits." *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 547 (1943). Giving a *qui tam* case less importance because it is brought on behalf of the United States would undermine the very purpose of the *qui tam* provisions.

CONCLUSION

The petition for writ of *certiorari* should be granted.

Dated: June 27, 2014

Respectfully submitted,

MICHAEL L. BAUM
Counsel of Record
R. BRENT WISNER
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, California 90025
Telephone: (310) 207-3233
Facsimile: (310) 207-4204
MBaum@baumhedlundlaw.com

MICHAEL SULLIVAN
THE ASHCROFT GROUP
1 Post Office Square, Suite 3750
Boston, Massachusetts 02109
Telephone: (617) 573-9400
Facsimile: (617) 933-7607
MSullivan@ashcroftlawfirm.com