No. 13-1236

IN THE

# Supreme Court of the United States

UNITED STATES EX REL. HELEN GE,
*Petitioner,*

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED AND
TAKEDA PHARMACEUTICAL NORTH AMERICA, INC.,
*Respondents.*

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

## BRIEF IN OPPOSITION


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## QUESTION PRESENTED

Should 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, or should this Court announce a new rule that would categorically prohibit district courts from denying leave to amend, even when the plaintiff could have made the same request before judgment?

## CORPORATE DISCLOSURE STATEMENT

Respondent Takeda Pharmaceutical Company Limited, a Japanese corporation with its principal place of business in Japan, is publicly traded on the Tokyo Stock Exchange. Takeda Pharmaceutical Company Limited has no parent company and no publicly traded company owns 10 percent or more of its stock.

Respondent Takeda Pharmaceuticals U.S.A., Inc. (formerly known as Takeda Pharmaceuticals North America, Inc.), a Delaware corporation with its principal place of business in Illinois, is wholly owned by Takeda America Holdings, Inc., which is wholly owned by Respondent Takeda Pharmaceutical Company Limited.

Both Respondents are collectively referred to as "Takeda" in this brief.

## TABLE OF CONTENTS

## TABLE OF CONTENTS
(continued)

# TABLE OF AUTHORITIES

Page(s)

CASES

## TABLE OF AUTHORITIES
(continued)

Page(s)

## TABLE OF AUTHORITIES
(continued)

## TABLE OF AUTHORITIES
(continued)

## BRIEF IN OPPOSITION

As a matter of well-settled law, all circuits distinguish between motions for leave to amend filed before the entry of judgment, on one hand, and after the entry of judgment, on the other. In both instances, motions for leave invoke the district courts' discretion. But there is a key difference in the standard of review applied to these distinct motions. Before judgment, such motions are governed entirely by the Federal Rule of Civil Procedure 15(a)(2), which provides that courts "should freely give leave when justice so requires." After judgment, on the other hand, when additional interests of finality and repose enter into the calculus, courts also consider grounds for reconsideration and reopening under Rules 59 and 60. In particular, courts in *every circuit* may exercise their discretion to deny leave to amend when a post-judgment request is based on information that plaintiffs could have gathered and deployed to support the same request before judgment.

That is what the district court did here, and the First Circuit correctly affirmed. Relator Helen Ge, despite two prior opportunities to amend her complaints, still could not state a fraud claim with requisite specificity, and the district court dismissed her complaints under Rules 9(b) and 12(b)(6). Having squandered her pre-judgment opportunity to seek leave to amend a third time on two sentences of boilerplate tucked away in her opposition to the motion to dismiss (which the district court properly disregarded), Ge collected more information and sought leave to amend *after* the judgment on the basis of the so-called "newly discovered evidence." The district court denied the motion without opinion,

and the First Circuit affirmed because Ge's information could have been used before judgment. It was not "new" in the relevant sense of "not previously obtainable." That application of well-settled law, on which all circuits are uniform, does not remotely warrant further review.

Against that backdrop of uniformity in the circuits, Ge tries to manufacture a circuit split. Focusing on snippets from circuit courts' opinions, Ge argues that her motion would have been favorably resolved in several other circuits. But she is wrong. Even apart from the difficulty of predicting how a *discretionary* request would be resolved in any particular case, a closer look reveals that Ge is mistaken on the law. Despite small differences in wording, all circuits permit the result that the First Circuit affirmed. Many circuits, including the circuits where Ge predicts her post-judgment motion would have been granted, have affirmed denials of similar motions precisely because, as here, the plaintiffs' "newly discovered evidence" was not new at all.

It becomes clear that, in the absence of any real circuit split, and contrary to her own arguments below, Ge is now trying to move the law in a radically new direction by seeking to prohibit categorically the district courts from considering the post-judgment interests of finality and repose. Under Ge's preferred rule, a plaintiff can defend a faulty pleading while holding potential grounds for an amendment in her pocket, see how a motion to dismiss is resolved, and then spring a new amendment request on the court and other litigants. Or the same plaintiff can hold onto the initial flawed pleadings, wait for the district court to explain the deficiencies, and then use that

free education to search for additional evidence. That type of gamesmanship shifts the costs of faulty pleadings to the courts and other litigants and is precisely why Rules 59 and 60 make it somewhat harder to obtain leave to amend after the entry of judgment. Ge's proffered rule cannot be squared with this sound policy.

Finally, there are other problems with Ge's arguments, for even under Ge's preferred rule, her case would turn out the same way. As she concedes, leave to amend need not be given under Rule 15(a) when the amendment would be futile. Her proposed amendment, attempting to cure the 9(b) but not 12(b)(6) deficiencies would have been futile, and so leave could still be denied for that reason. This and numerous other vehicle objections further counsel against this Court's review.

Accordingly, for any and all of these reasons, certiorari should be denied.

## BACKGROUND

### A. Complex FDA Rules Governing Adverse Event Reporting, Drug Labeling, And Enforcement

To provide context for Ge's twice amended complaints and her request for an additional amendment, the following is a brief summary of the legal framework for FDA adverse event reporting requirements.

1. By Act of Congress, FDA is the exclusive expert agency charged with regulating prescription drugs. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). FDA oversees the Federal Food, Drug, and Cosmetic Act ("FDCA") and its

implementing regulations, which together form a complex and comprehensive framework governing the development, approval, and ongoing review of pharmaceutical products. *See* 21 U.S.C. § 301 *et seq.*; 21 C.F.R. § 1.1 *et seq.*

Under this framework, a drug manufacturer may not market a new drug unless it has submitted a New Drug Application ("NDA") to FDA and received the Agency's approval. 21 U.S.C. § 355(a). FDA "will approve an [NDA] after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(c), (d).

After NDA approval, FDA remains responsible for monitoring the drug's safety and efficacy. Manufacturers must review and file post-marketing reports of "[a]dverse drug experience[s]" with the agency. 21 C.F.R. § 314.80. This requirement is broad: reportable "adverse drug experiences" include "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related[.]" *Id.* § 314.80(a) (emphasis added). Thus, the submission of an adverse event report does not establish either that an adverse event actually occurred or that the event was caused by a drug. *See, e.g., N.J. Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 53 (1st Cir. 2008); S. Rep. No. 109-324, at 6 (2006) ("The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product.").

2. FDA also regulates the labeling of prescription drugs. Under 21 C.F.R. § 201.57(c)(7), for example, the "adverse reactions" section of the label must

"describe the overall adverse reaction profile of the drug based on the entire safety database." The meaning of a labeled "adverse reaction," however, is narrower than an "adverse event" for reporting purposes: "This definition does not include all adverse events observed during use of a drug." *Id.* Instead, the "adverse reactions" include only "those adverse events for which there is some basis to believe there is *a causal relationship* between the drug and the occurrence of the adverse event." *Id.* (emphasis added). Similarly, 21 C.F.R. § 201.80(e) requires that a manufacturer revise its labels to "include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug."

3. The United States has the exclusive authority to enforce the FDCA. 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352 (2001). And FDA exclusively is authorized to investigate violations of the FDCA. 21 U.S.C. § 372. When it finds such violations, FDA is authorized to pursue a variety of sanctions, including withdrawing its approval of a drug, injunctive relief, civil monetary penalties for submission of false or misleading information, and even criminal prosecution of the manufacturer. 21 U.S.C. §§ 332, 333(a), 333(f)(3)(A), 355(e); 21 C.F.R. § 314.80(j). In short, FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration." *Buckman*, 531 U.S. at 349.

As important, these enforcement provisions "commit complete discretion to the Secretary to decide how and when they should be exercised."

*Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Accordingly, the Agency's decision not to take enforcement action is not subject to judicial review under the Administrative Procedure Act. *See id.*

### B. Ge's Two Lawsuits, Twice Amended

Beginning in September 2008, for a little over a year Ge worked for Takeda as an outside contract physician. Cert. Pet. App. ("App.) 5. She performed medical reviews of adverse event reports for, among others, the subject drugs in this litigation: Actos® (used to treat type 2 diabetes), Uloric® (gout), Dexilant® (gastroesophageal reflux disease), and Prevacid® (same) (collectively, the "subject drugs"). *Id.* Takeda has obtained FDA approval for these four drugs and sells them. *Id.* Ge's job required her to ascertain the seriousness of a reported event, determine whether the associated drug caused the event, and decide whether the event called for additional safety warnings. *Id.* None of the four subject drugs has ever had its FDA approval suspended or withdrawn.

If Ge were concerned with Takeda's adverse event reporting or drug labeling practices, she could have notified FDA. Any person who believes that a pharmaceutical company is violating the FDCA can petition FDA to bring an action against the offender. 21 C.F.R. § 10.30. But Ge did not do this.

Instead, since all four of the subject drugs are reimbursable by the federal government under Medicare and Medicaid, C.A. App. 27-28, 184-85, Ge brought two parallel lawsuits against Takeda: the June 18, 2010 action pertaining to Actos® and the March 1, 2011 action pertaining to the remaining three subject drugs. App. 6. In each lawsuit, Ge

attempted to bring claims under the False Claims Act ("FCA") on behalf of the United States.[1] *Id.* To that end, she alleged violations of 31 U.S.C. § 3729(a)(1)(A) ("knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"), § 3729(a)(1)(B) ("knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"), and § 3729(a)(1)(C) (conspiring to commit a violation of, among other things, § 3729(a)(1)(A) or § 3729(a)(1)(B)). App. 6.

Ge did not rest on her two initial complaints. In 2011 and 2012, while both complaints were still under seal (a requirement under the FCA), Ge amended them, filing the third and fourth complaints in this case. App. 7. That was not all. Between March and April 2012, after unsealing, Ge filed a second set of amended complaints—her fifth and sixth attempts at pleading. *Id.*

In her second amended (and operative) complaints, Ge "alleged Takeda had failed to report promptly and accurately to the FDA a number of post-approval adverse events associated with the four subject drugs." *Id.* For the drug Actos®, she alleged that Takeda asked her to misreport several adverse events associated with the drug, including bladder cancer. *Id.* Ge also alleged to have discovered several instances of Takeda's under-reporting related

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[1] She also attempted to sue Takeda on behalf of twenty-five States, alleging various violations of state FCA analogs. App. 6 n.1. Ge did not, however, appeal the district court's dismissal of her state-law claims, App. 43-44, and does not put them at issue before this Court, limiting her petition for certiorari only to her federal claim on behalf of the United States.

to the incidence of bladder cancer. App. 8. FDA did, however, eventually receive information on the bladder cancer risk associated with Actos®. *Id.* In response, FDA issued an official warning and required a label change, but it also issued a supplemental approval of Actos® after learning of that risk. *Id.*

As for the other three subject drugs, Ge alleged that Takeda interfered with her independent analysis of reported adverse events. App. 8-9. She alleged that Takeda, wanting to avoid the 15-day reporting requirement in 21 C.F.R. § 314.80(c)(1)(i), pushed her to classify events as "non-serious" and to record her causality assessment as "unrelated." App. 8. And on several occasions, Ge alleged, Takeda altered Ge's assessments of reported adverse events. App. 9. As with Actos®, Takeda eventually submitted a Supplemental New Drug Application to update the "Adverse Reactions" section of the Uloric® label. *Id.* That application, too, met with FDA's approval. *Id.*

In sum, according to Ge's allegations, Takeda resisted label changes for the four subject drugs by failing to report adverse events promptly and by generally under-reporting them. There is no allegation that any adverse event at issue in Ge's complaints went completely unreported; Ge just thinks reporting should have gone faster.

### C. Takeda's Motion To Dismiss, And Ge's Pre-Judgment Request For Leave To Amend A Third Time

1. Takeda moved to dismiss both complaints under Rules 9(b) (failure to plead fraud with particularity) and 12(b)(6) (failure to state a claim). App. 30.

In opposing Takeda's motion, Ge relied on two theories of liability under the FCA, which the district court summarized as follows. *First*, "[h]ad Takeda properly reported the serious adverse events, FDA might never have approved or, in the alternative, it might have withdrawn approval for the subject drugs." App. 32. *Second*, proper reporting "might have" yielded drug label amendments and perhaps also additional information posted in FDA databases, which in turn "might have prompted physicians to prescribe the subject drugs less often, resulting in a decrease in claims for reimbursement." *Id.*

In her opposition papers, Ge also half-heartedly sought a third opportunity to amend her complaints. Essentially a throwaway boilerplate request, stated conditionally, it consisted in its entirety of two sentences: "If the Court were to determine that Relator's Complaints are deficient in any regard, Relator respectfully requests that this Court afford her an opportunity to amend her complaint. Federal Rule of Civil Procedure 15(a) provides that leave to amend a pleading shall be freely given when justice so requires, and reflects a liberal amendment policy." App. 66 (internal quotation omitted).

Ge did not explain how her proposed amendment would cure the fatal pleading problems under Rules 9(b) and 12(b)(6) that Takeda raised in its motion. She did, however, attempt to support her opposition brief with a declaration from one of her counsel, "which included an attachment providing the total expenditures by the federal government for Actos." App. 39. Takeda moved to strike the declaration and attached exhibits. Dist. Ct. (10-cv-11043) No. 41. In opposition to Takeda's motion to strike, Ge explained

that she would seek to amend her pleadings to include the "newly discovered evidence" attached to her counsel's declaration. Dist. Ct. No. 43 at 2 n.2.

2. On November 1, 2012, the district court granted Takeda's motion and dismissed Ge's FCA claims under Rules 12(b)(6) and 9(b). App. 29-44. With respect to Rule 12(b)(6), the district court found that the complaints adequately alleged that Takeda knowingly caused providers to submit claims for payment of the subject drugs. App. 41. The issue thus turned on whether Ge sufficiently alleged that the claims at issue were false or fraudulent within the meaning of the FCA. *Id.* And because the claims were not facially false (*e.g.*, did not misrepresent quantities of drugs for which reimbursement was sought), the issue was whether they "misrepresented compliance with a material precondition of payment," which would render them false under the FCA. *Id.*

That, the court held, was where the complaints failed under Rule 12(b)(6). The complaints did not explain how providers' claims for payment for the subject drugs misrepresented Takeda's compliance with FDA reporting requirements. *Id.* Nor could Ge show that Takeda's compliance with adverse-event reporting requirements was an implied material precondition of payment. Ge's assertions that, but for the alleged misreporting and mislabeling, FDA would have withdrawn approval required too many layers of speculation—as "FDA exercises discretion in its enforcement procedures for such types of violations, and does not always prosecute them, let alone enforce the harshest penalty available." App. 42-43.

Moreover, the complaints failed for the independent reason that they did not plead fraud

with the specificity that Rule 9(b) requires. The court concluded that Ge "failed to allege the specific details of any claims that were allegedly rendered 'false' as a result" of Takeda's purported misreporting or mislabeling. App. 39. Nor had Ge identified providers who submitted false claims; the rough time periods, locations, or amounts of the claims; or the specific government programs to which the claims were made. *Id.* The court specifically rejected Ge's theory that all of the claims for the subject drugs were false based on Takeda's adverse event reporting, and further found that she failed to specifically allege that FDA would have withdrawn approval for the drugs after learning of the adverse events. App. 40. In any event, the court reasoned, Ge had not explained how any fraudulent reporting could render false any reimbursement claims that were filed prior to the occurrence of the alleged adverse events. *Id.*

3. The district court did not separately address Ge's request to amend her complaints a third time. But in the course of discussing Ge's failure to satisfy the heightened pleading requirement of Rule 9(b), the court explained that even with the additional information on the drug Actos® that Ge wished to add to her complaints (to the extent that the court discussed and relied on that information, it denied Takeda's motion to strike it, App. 31 n.1), Ge still would fail to satisfy Rule 9(b). App. 39. The only claim details provided in those attachments were "for one of the four drugs at issue, presented in aggregate form, and identif[ied] no specific claimants or government program payors." *Id.* In other words, allowing Ge to amend her complaints with that information would have been futile. App. 24.

### D. Ge's Motion To Reconsider And, In The Alternative, For Leave To Amend

Ge sought reconsideration of the court's dismissal under Rules 59(e) and 60(b) and, in the same motion but in the alternative, requested leave to amend under Rule 15(a). Dist. Ct. No. 47. In support, Ge relied for the first time on several declarations and other documents never disclosed in her three sets of complaints or in opposition to Takeda's motion to dismiss. Dist. Ct. No. 48. The declarations fell into two groups. *First*, Ge attached an economic model by a pharmaceutical economics professor that purported "to show the amount of claims for Actos that would not have been submitted for government payment but for Takeda's alleged misconduct." App. 12. *Second*, Ge attached declarations from eight individual patients attesting that they would not have submitted their claims "if Takeda had promptly and accurately disclosed the link between Actos and bladder cancer." App. 12-13.

The additional information attached in support of Ge's motion purportedly addressed the district court's dismissal under Rule 9(b) but not under Rule 12(b)(6). As Ge argued in the motion itself, "Relator believes the newly discovered evidence cures the deficiencies the Court found when it dismissed Dr. Ge's complaints on Rule 9(b) grounds." Dist. Ct. No. 47 at 2; *see also* App. 63 ("Through the newly discovered evidence, Dr. Ge has cured these [Rule 9(b)] deficiencies . . . ."). To overcome the district court's Rule 12(b)(6) analysis, on the other hand, Ge contended that the court "misapprehended her arguments by focusing solely on the impact of Takeda's fraud on the FDA (which does not purchase

nor fill prescriptions) and overlooking the impact that Takeda's fraud had on physicians and patients who prescribe Actos, take Actos and initiate the submission of Actos claims to government-funded health plans." Dist. Ct. No. 47 at 2. For these reasons, Ge argued that if reconsideration is denied, she should have the opportunity to amend her complaints on the basis of the new information, contending that the amendment would not be futile and attaching the proposed *fourth* version of her complaints. Dist. Ct. No. 47 at 2-3; Dist. Ct. No. 49.

Opposing Ge's motion, Takeda specifically pointed to the disconnect between Ge's proposed amended complaints and the Rule 12(b)(6) grounds for dismissal. Takeda argued, "even if Relator cured her Rule 9(b) pleading deficiencies, amendment would be a futile act in light of this Court's Rule 12(b)(6) ruling." Dist. Ct. No. 50 at 19.

On December 18, 2012, the district court denied without opinion Takeda's motion to reconsider or amend. App. 13.

### E. The First Circuit Appeal

Ge timely appealed to the First Circuit. She argued that (1) her complaints contained enough specificity to satisfy Rule 9(b); (2) the district court abused its discretion in denying Ge's pre- and post-judgment requests for leave to amend her complaints a third time; and (3) the district court misconstrued the nature of FCA liability in dismissing Ge's complaints under Rule 12(b)(6). App. 4-5. Because the First Circuit affirmed the district court's judgment on the basis of the first two issues, it declined to reach Ge's arguments on Rule 12(b)(6).

App. 5. Rule 12(b)(6) remains a valid ground for affirming the district court's final judgment.

In a careful opinion, a unanimous panel of the First Circuit affirmed the district court's Rule 9(b) and denial of amendment rulings. On Rule 9(b), the court concluded that Ge "made no attempt in her complaints to allege facts that would show that some *subset* of claims for government payment for the four subject drugs was rendered false as a result of Takeda's alleged misconduct." App. 17. No more persuasive was Ge's attempt to argue for a "per se rule that if sufficient allegations of misconduct are made, it necessarily follows that false claims and/or material false information were filed." *Id.* The court rejected that approach as inconsistent with Rule 9(b)'s specificity requirements. *Id.* The rest of Ge's arguments relied on three theories of FCA liability that Ge had failed to raise at the district court. The court concluded that "Ge waived all of her new arguments to the effect that the four subject drugs were per se ineligible for government reimbursement during the relevant period on these varying theories." App. 23.

Turning to the district court's rulings on Ge's pre- and post-judgment requests for leave to amend, the First Circuit carefully explained the slight but important difference in the standards governing the two requests. If a motion to amend is properly made before judgment, "the district court is to evaluate that motion under the liberal standard of Fed. R. Civ. P. 15(a)." App. 24 (internal quotation omitted). No other considerations enter into that analysis. Post-judgment requests to amend, however, cannot be allowed "unless that judgment is first set aside or

vacated pursuant to Fed. R. Civ. P. 59 or 60." App. 25 (internal quotation omitted). And a motion for reconsideration under Rules 59 or 60 itself calls for "an extraordinary remedy which should be used sparingly." *Id.* (internal quotation omitted). Thus, post-judgment motions to amend implicate some analysis in light of the interests of finality and repose that come into play after the final judgment. *See, e.g.*, *Palmer v. Champion Mortg.*, 465 F.3d 24, 30 (1st Cir. 2006), *cited in* App. 25.

Applying the above principles, the First Circuit held that the district court did not abuse its discretion in rejecting both requests for leave to amend. Ge's pre-judgment request was not properly presented to the district court because it consisted of two boilerplate sentences that leave to amend is to be freely given. App. 26. The district court was thus within its discretion to disregard Ge's pre-judgment request, but the district court actually went further and considered *arguendo* the attached material on which Ge purported to rely in connection with her pre-judgment request to amend. App. 26-28. In her petition for certiorari, Ge does not challenge the First Circuit's ruling regarding her pre-judgment request to amend.

As for Ge's post-judgment request, the First Circuit found no abuse of discretion because the new information at the heart of Ge's motion was not "new" in the relevant sense. App. 27. Ge "could hardly contend that the so-called newly discovered evidence accompanying her second request was not previously available." *Id.* (internal quotation omitted). And because Ge more generally failed to satisfy any of the standards for reconsideration, the district court did

not abuse its discretion in denying leave to amend after the final judgment. *Id.*

The First Circuit subsequently denied Ge's petition for panel rehearing and rehearing en banc, noting no dissent from either denial. App. 47.

## REASONS FOR DENYING THE WRIT

This case does not warrant the Court's review. The First Circuit below applied settled law to the unique facts of this case. No real circuit split exists. And even if it did, and Ge's preferred rule were adopted, there would still be no reason to grant her request to amend a third time, which would be futile. That, along with other vehicular problems, makes this an especially poor candidate for breaking new ground. Accordingly, certiorari should be denied.

### I. THE FIRST CIRCUIT'S CAREFUL DECISION DOES NOT CONFLICT WITH DECISIONS OF ANY OTHER APPELLATE COURT OR THIS COURT

The First Circuit's decision is in line with all other federal appellate courts. Any purported differences in the wording of the standards by various circuits courts are, on the facts here, of no moment. The First Circuit also faithfully applied this Court's precedent in *Foman v. Davis*, 371 U.S. 178 (1962). Ge's arguments to the contrary are unconvincing.

#### A. No Conflict Exists Among Circuit Courts Addressing The Question Presented Here

1. All circuits agree that motions for leave to amend after the final judgment implicate considerations besides Rule 15. "Once a final judgment has been entered, the district court lacks power to rule on a motion to amend unless the party

seeking leave first obtains relief under Rule 59(e) or 60." Moore's Federal Practice § 15.13[2]; *see also* Wright & Miller, Federal Practice and Procedure § 1489. In that procedural posture, "a plaintiff may be granted leave to amend by the district court only if that court agrees to alter or reopen the judgment under Rule 59, that court agrees to set it aside under Rule 60, or there is a timely appeal and the judgment is set aside on appeal." Moore's § 15.13[2] & n.8. Accordingly, after final judgment, courts look at Rule 15(a) and Rule 59(e) (or similar device to obtain reconsideration or reopening) in deciding whether to grant leave to amend. The rule makes ample sense as a policy matter because "[t]o hold otherwise would enable the liberal amendment policy of Rule 15(a) to be employed in a way that is contrary to the philosophy favoring finality of judgments and the expeditious termination of litigation." Wright & Miller § 1489 at 694. It is also well-settled law, on which all circuits stand united.

Both Rule 59(e) and Rule 15(a) call for the exercise of the district courts' discretion. *See, e.g.*, *Foman*, 371 U.S. at 182; Wright & Miller § 2818. Not surprisingly, because any given set of facts may support several outcomes, all evincing the sound exercise of discretion, while the circuits 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.[2] *See, e.g.*, *Ahmed v. Dragovich*, 297 F.3d 201,

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[2] Ge thus accomplishes nothing by noting that, in the three months preceding the filing of her petition, a number of district

207-08 (3d Cir. 2002) ("Although Rule 15 vests the District Court with considerable discretion to permit amendment 'freely . . . when justice so requires,' Fed. R. Civ. P. 15(a), the liberality of the rule is no longer applicable once judgment has been entered."); *Laber v. Harvey*, 438 F.3d 404, 428 (4th Cir. 2006) (en banc) (citing, among others, the language used by the Third and Fifth Circuits and granting motion to amend "under the unusual circumstances presented here"); *id.* at 432-33 (Wilkinson, J., concurring) (explaining that "motions filed post-judgment for leave to amend a complaint are not favored under law," noting "the interest in finality that attaches to every judgment," and highlighting the "special" and "unique" circumstances justifying post-judgment amendment in that case); *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 865 (5th Cir. 2003) (affirming the district court's denial in part because "the motion to amend hardly presents any new information"); *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002) ("[W]hile Rule 15 plainly embodies a liberal amendment policy, in the post-judgment context, we must also take into consideration the competing interest of protecting the finality of judgment and the expeditious termination of litigation." (internal quotation omitted)); *The Tool Box, Inc. v. Ogden City Corp.*, 419 F.3d 1084, 1087 (10th Cir. 2005) (describing a rule, "the same in our sister circuits," that "a judgment generally will be set

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(continued...)

courts had reached a number of decisions in the exercise of their discretion. Pet. 34 n.20. The opposite—all district courts reaching the same result and describing it using the same words—would have been noteworthy.

aside only to accommodate some new matter that could not have been asserted during the trial").

In particular, and directly dispositive of the question presented here, circuit courts agree that district courts do not abuse their discretion in denying leave to amend after final judgment if the motion is based on information that could have been obtained and deployed before the judgment. When, in other words, either by strategy or oversight, a plaintiff waits until after final judgment to amend when the same amendment could have been pursued before judgment, courts find no abuse of discretion in denying leave. *See, e.g.*, *Palmer*, 465 F.3d at 30-31 (1st Cir.) (well within the district court's discretion to deny leave to amend even under Rule 15(a) when plaintiff had no valid reason to wait until after dismissal); *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267, 280 (3d Cir. 2004) ("District Court did not err in refusing to open the judgment of dismissal when plaintiffs clearly relied on 'misplaced confidence' in their original pleading."); *Schiller v. Physicians Resource Grp. Inc.*, 342 F.3d 563, 569 (5th Cir. 2003) (no abuse of discretion in denying leave to amend "[b]ecause the Fourth Amended Complaint was not based on newly discovered evidence that was unavailable prior to the district court's judgment"); *Leisure Caviar, LLC v. US Fish & Wildlife Serv.*, 616 F.3d 612, 617-18 (6th Cir. 2010) ("The district court did not exceed its discretion in concluding that plaintiffs provided nothing" to explain why they waited until they lost to seek amendment); *Tool Box*, 419 F.3d at 1088 ("Courts have refused to allow a postjudgment amendment when, as here, the moving party had an opportunity to seek the amendment

before entry of judgment but waited until after judgment before requesting leave.").

2. Ge tries to carve up the federal appellate courts into a three-way split. She argues that only the First, Seventh, and Eleventh Circuits would affirm the district court's denial of her post-judgment motion to amend. Pet. 24. Five other courts—the Third, Fourth, Fifth, Sixth, and Tenth Circuits—would, on her account, require that she be granted leave to amend her complaints post-judgment. *Id.* at 24-25. And two others—the Second and Eighth Circuits—would "probably" support Ge's preferred result. *Id.* at 25-29, 31. Regarding the Ninth Circuit, Ge does not want to commit, placing it initially in the category that Ge does not like (along with the First, Seventh, and Eleventh Circuits), *id.* at i, 4, only to move it into the "maybe" bucket (along with the Second and Eighth Circuits) later in the petition, *id.* at 31.

Circuit-level case law, however, erases Ge's imaginary boundaries. As an initial matter, the abuse of discretion standard of review is an awkward companion to bold pronouncements of what other circuits would *necessarily* do under any given set of unique procedural and factual circumstances. Ge's fundamental mistake is failing to recognize that district courts can exercise their discretion to grant *or* deny leave to amend, *both* of which might be supportable on appeal.

But in any event, there is no conflict among the circuit courts on the sole issue presented here: whether courts are categorically prohibited from considering whether the proposed post-judgment amendment could have been requested before judgment. As discussed above, the Third, Fourth,

Fifth, Sixth, and Tenth Circuits would not categorically allow Ge's post-judgment amendment. Indeed, decisions from this group of circuits explain that the district courts do not abuse their discretion in denying such belated motions for leave to amend. *See Adams*, 381 F.3d at 280 (3d Cir.); *Laber*, 438 F.3d at 428 (4th Cir.); *id.* at 432-33 (Wilkinson, J., concurring); *Schiller*, 342 F.3d at 569 (5th Cir.); *Leisure Caviar*, 616 F.3d at 617-18 (6th Cir.); *Tool Box*, 419 F.3d at 1088 (10th Cir.). Ge's argument necessarily rests on the premise that her motion would have been granted in these circuits. Pet. 31-32. Alas, there is no support for that premise. It actually gets even worse for Ge, because the Third, Fifth, and Sixth Circuit decisions cited above explicitly reference the earlier decisions of those courts on which Ge relies. Pet. 24-25.[3]

Ge's arguments regarding the Second and Eighth Circuits are no more persuasive. She argues a post-judgment motion to amend "probably" would be granted in these circuits, no matter that it relies on information that could have been brought up before judgment. Pet. 31. But here, too, the circuits' cases reveal a fact-intensive, individualized determination;

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[3] *See Adams*, 381 F.3d at 280 (citing *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267 (3d Cir. 2001)); *Schiller*, 342 F.3d at 568-69 (discussing *Rosenzweig*, 332 F.3d 854 (5th Cir.)); *Leisure Caviar*, 616 F.3d at 616-18 (citing *Morse*, 290 F.3d at 799 (6th Cir.)); *accord Vielma v. Eureka Co.*, 218 F.3d 458, 468 (5th Cir. 2000) ("[W]e have consistently upheld the denial of leave to amend where the party seeking to amend has not clearly established that he could not reasonably have raised the new matter prior to the trial court's merits ruling." (internal quotation omitted)).

predicting what district courts applying these standards would do is a fool's errand. *See Williams v. Citigroup Inc.*, 659 F.3d 208, 213 (2d Cir. 2011) (per curiam) (explaining that post-judgment, "Rule 15's liberality must be tempered by considerations of finality"); *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 823 (8th Cir. 2009) (affirming the denial because the plaintiff's excuse for waiting until after dismissal was "balderdash" and the plaintiff simply "adopted a strategy of vigorously defending his initial Complaint, despite its numerous and obvious Rule 9(b) deficiencies"). Plainly, these standards are compatible with the standards in other circuits, like the First Circuit, where finality and repose interests play a significant—sometimes overriding, sometimes not—role in deciding post-judgment motions to amend.[4]

The final circuit that, according to Ge (but only in some portions of her petition), splits with the First is the Ninth Circuit. Again, not so. *See Lindauer v. Rogers*, 91 F.3d 1355, 1357 (9th Cir. 1996) (relying on decisions from the Fifth, Seventh, Eighth, and Tenth Circuits and holding that the district court did not err in denying amendment when plaintiffs did not

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[4] As further evidence that any differences in how a discretionary legal standard is formulated do not necessarily translate into incompatible applications, the Eighth Circuit case on which Ge relies contradicts Ge's categorical description of the supposed split. Recall that Ge puts the Fifth and Sixth Circuits on the same side of her alleged split. Pet. 24-25. The Eighth Circuit, however, saw a slight difference between the two, which nonetheless produced no difference in outcomes. *See Roop*, 559 F.3d at 823. All standards are compatible.

satisfy the requirements for reopening the judgment under Rules 59 or 60). There is no split here, either.[5]

Finally, had there been a real split in the circuits, one would not expect to see approving references that cross the split's boundaries. But as it turns out, Ge's alleged split supplies such cross-references aplenty. *See, e.g.*, *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1361-62 n.22 (11th Cir. 2006) (citing with approval decisions from the Third and Fifth Circuits); *supra* at 22 n.4 (noting the Eighth Circuit's references to the Third and Fifth Circuits' decisions); *Morse*, 290 F.3d at 800 (6th Cir.) (approvingly citing decisions from the Second, Fifth, and Seventh Circuits). The frequent cross-references do not bespeak confusion in the courts. Rather, they confirm that the circuits, even if employing different words, are uniform in their treatment of post-judgment motions to amend.

In sum, circuit courts' decisions on both sides of Ge's alleged split are compatible. Ge has identified no circuit where a district court judge was categorically prohibited from considering why the plaintiff's request was delayed until after the final judgment. This non-split does not remotely merit the Court's review.[6]

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[5] Ge does not categorize the D.C. Circuit, but it also follows its sister circuits' uniform approach that blends considerations of finality and liberal amendment embedded in Rule 59(e) and Rule 15(a) when analyzing post-judgment motions to amend. *See Ciralsky v. CIA*, 355 F.3d 661, 672-73 & n.12 (D.C. Cir. 2004) (citing, among others, *Ahmed*, 297 F.3d at 207-08 (3d Cir.)).

[6] This likely explains why the Court has consistently denied petitions for certiorari raising similar issues. *See, e.g.*, Cert. Pet.

3. Having identified no real circuit split, Ge is simply trying to move the law in a new, radical direction. She wants courts to erase the difference between pre- and post-judgment motions to amend, nullifying the interests of finality and repose prominent in the latter and absent in the former. In her vision, a plaintiff should be able to cling stubbornly to the original (or, in her case, *twice-amended*) complaint in opposition to a motion to dismiss. Then, the same plaintiff should have a free shot at a do-over under Rule 15, which, according to Ge, takes on a special importance after this Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), that "ushered in a new standard for fact pleading in federal court." Pet. 33-34. One might quibble with

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(continued...)

at i, *Horras v. Am. Capital Strategies, Ltd.*, 134 S. Ct. 1346 (2014), No. 13-843 (denying certiorari on whether "a denial of a Motion for Leave to Amend a Complaint [is] appropriate under Rule 15 when the Court unexpectedly applied a new pleading standard and granted a motion to dismiss the original complaint"); Cert. Pet. at i, *Jung v. Ass'n of Am. Med. Colleges*, 549 U.S. 1156 (2007), No. 06-567 (denying certiorari on "[w]hether all federal district and circuit courts should apply the same standard for post-judgment leave to amend a complaint where it has been dismissed *on the pleadings*, specifically the standard established by this Court in *Foman,* 317 U.S. at 182, or whether courts in the D.C., Seventh, Eighth, and Ninth Circuits may apply a conflicting standard that permits rejecting amended complaints that would be allowed in all other circuits"); Cert. Pet. at i, *Segal v. Massachusetts Mutual Life Ins. Co.*, 534 U.S. 1041 (2001), No. 01-0494 (denying certiorari on whether it was "error for the court to prohibit amendment of the complaint by refusing to follow this Court's decisional law relating to" Rules 59(e) and 15(a)).

the use of *Iqbal* and "fact pleading" in the same sentence. But academic debate aside, Ge's preferred rule would be unsound as a policy matter.

*First*, as courts overwhelmingly agree, "[i]f a permissive amendment policy applied after adverse judgments, plaintiffs could use the court as a sounding board to discover holes in their arguments, then 'reopen the case by amending their complaint to take account of the court's decision.'" *Leisure Caviar*, 616 F.3d at 616 (6th Cir.) (quoting *James v. Watt*, 716 F.2d 71, 78 (1st Cir. 1983) (Breyer, J.)). Allowing that sort of gaming "would sidestep the narrow grounds for obtaining post-judgment relief under Rules 59 and 60, make the finality of judgments an interim concept and risk turning Rules 59 and 60 into nullities." *Id.* (citing Wright & Miller § 1489). Ge does not even acknowledge the important interests of finality and repose, much less explain why they should yield, permitting plaintiffs to engage in this type of tails-I-win-heads-you-lose strategy at the expense of courts and other litigants. Rather, she blithely asserts that "there is no indication that Takeda would suffer any prejudice should Dr. Ge be permitted to file amended complaints." Pet. 35. One would think there is at least some prejudice that comes from upsetting Takeda's repose following the final judgment.

*Second*, Ge's preferred rule—permitting plaintiffs to hold a potential amendment in their pockets only to spring it on the district court and other parties after final judgment—relies on a faulty premise. She argues that requiring plaintiffs to amend before judgment would force plaintiffs to "plead with forked tongue." *Id.* at 23 n.17. Plaintiffs, she argues, would

be required to oppose a motion to dismiss on one hand, but then on the other seek an amendment that recognizes the inherent merit in the dismissal. *Id.* There is another choice, though: abandon the deficient complaint and seek an amendment, which would be "freely give[n]" under Rule 15. Why should the judicial system prefer a rule that encourages plaintiffs to fight every motion to dismiss, secure in the knowledge that a post-judgment amendment is available to cure whatever flaws the district court identifies? Indeed, some district courts expressly require every plaintiff to state in response to every motion to dismiss whether the plaintiff intends to amend or rely on the pleadings under attack. *See, e.g.*, Individual Practices of Judge Harold Baer, Jr. at 5, *available at* www.nysd.uscourts.gov. And the choice has real consequences. "If the non-moving party elects not to amend its complaint, *no further opportunities to amend* will be granted and the motion to dismiss will proceed in the regular course." *Id.* Thus putting plaintiffs to a choice discourages the waste of judicial resources inherent in a rule that Ge would prefer. Ge's rule, in contrast, would cultivate "misplaced confidence" in the challenged pleadings, *Adams*, 381 F.3d at 280 (3d Cir.), by removing some incentive for plaintiffs to think critically about their soundness.

Without any real conflict, this Court's review is unwarranted. And that is doubly so when the petitioner is urging this Court to break new ground in a settled area and in a way that contradicts sound policy.

### B. The First Circuit's Decision Does Not Conflict With This Court's Precedent

Having failed to identify a real conflict among circuit court decisions, Ge next argues that the First Circuit's decision conflicts with *Foman*, 371 U.S. at 178. Pet. 29-31. Ge is incorrect, for she misapprehends both *Foman* and the First Circuit's decision in this case.[7]

*First*, Ge argues that the district court committed "reversible error" when it "summarily denied Dr. Ge's request and provided no explanation," by which Ge must mean that the *Foman* decision required the First Circuit to reverse the district court. *Id.* at 31. The actual holding in *Foman* is narrow—leave to amend should be given freely, absent any "apparent or declared reason" not to, and the district court's denial "without any justifying reason appearing for the denial" is an abuse of discretion. 371 U.S. at 182. It is clear from this language that "any justifying reason" for the denial need not be "declared" by the district court, but can be "apparent" to the reviewing court. This rule makes a great deal of sense, sparing district courts from expending judicial resources on stating the obvious and relieving reviewing courts from reversing summary denials of post-judgment motions to amend when the result below would not change after the district court "declares" what has been "apparent" all along.

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[7] Even if Ge were correct and the First Circuit, as she argues, clearly ran afoul of *Foman*, she forgets that "[a] petition for a writ of certiorari is rarely granted when the asserted error consists of . . . the misapplication of a properly stated rule of law." Sup. Ct. R. 10.

As for the possible grounds for denying leave to amend post-judgment, *Foman*'s non-exhaustive list included "undue delay." *Id.* *Foman* thus does not stand for the proposition that a plaintiff's decision to delay amendment until after judgment is an invalid reason to deny leave to amend. The First Circuit did not run afoul of *Foman* by affirming the district court's denial on that "apparent" basis. *See* Part II *infra*.

*Second*, Ge argues that the First Circuit erred in stating that "the liberal leave to amend language of Rule 15(a) does not apply" after judgment. Pet. 30 (quoting App. 27). Ge interprets this statement as saying that "the liberal spirit of Rule 15 necessarily dissolves as soon as final judgment is entered." *Id.* (internal quotation omitted). But that is not what the First Circuit had in mind. Rather, just a couple of pages earlier, the court restated well-settled law that post-judgment motions must *begin* under Rules 59 or 60, before getting to Rule 15. App. 25. In this context, the statement that Rule 15 does not apply simply means that it does not apply without first reopening the case. *Foman* does not preclude circuit courts from fashioning rules for post-judgment motions to amend that give meaning to all the relevant Rules—59, 60, and 15. There is no basis to conclude the First Circuit wholly ignored Rule 15 in this case.

For this reason, too, the denial of Ge's post-judgment motion to amend does not present this Court with an issue worthy of certiorari.

## II. THE FIRST CIRCUIT'S DECISION IS CORRECT UNDER ANY STANDARD

This case is also a poor vehicle for review because whatever rule caries the day, the result will not necessarily change.

To begin, in light of the foregoing, the First Circuit here properly applied well-settled law when it concluded that the district court did not abuse its discretion in denying Ge's post-judgment request to amend. Presented with a motion to dismiss her *third* set of complaints under Rules 9(b) and 12(b)(6), Ge made a strategic choice to hold firm and place all confidence in her complaints, mentioning a possible amendment in only the most cursory, boilerplate fashion. App. 66. When that choice backfired—with the complaints dismissed under Rules 9(b) and 12(b)(6) and with Ge's futile request to amend disregarded— Ge chose to do some legwork. She collected several declarations from individual patients and engaged an economist to prepare a study purportedly in support of her claims. Then, 28 days after the final judgment, she timely moved for reconsideration or, in the alternative, to amend her complaints a third time. Dist. Ct. No. 47. She supported both requests with her new materials, labeling them "the newly discovered evidence." App. 63; Dist. Ct. No. 48. The district court denied the motion without opinion. Dist. Ct. No. 52.

In affirming the denial, the First Circuit examined all factual and procedural circumstances and properly concluded that they supported the district court's decision. The First Circuit's precedent, as everywhere else, required that it first decide whether the final judgment should be vacated under Rules 59

or 60 and then apply Rule 15 to the amendment issue. App. 25 (citing circuit precedent). Focusing on the asserted reason for the amendment, the court explained that Ge's "newly discovered evidence" was hardly new in the sense of "previously unavailable." App. 27. Just the opposite. "Ge could have sought the testimony of an expert witness and/or subject drug users much earlier." *Id.* Moreover, Ge had already twice amended her complaints and, for whatever reason, was confident in the result. *Id.* It was not an abuse of discretion for the district court to hold Ge to her own strategy without permitting a post-judgment do-over. App. 27-28. The First Circuit explained that Ge's "practice would dramatically undermine the ordinary rules governing the finality of judicial decisions, and should not be sanctioned in the absence of compelling circumstances." App. 28 (quoting *James*, 716 F.2d at 78 (Breyer, J.)). Ge offered no compelling circumstances to excuse her delay.

But the result would have been the same even under Ge's preferred approach of focusing solely on Rule 15(a). As *Foman* held, leave to amend under that Rule need not be given when there exists an "apparent or declared reason" against granting leave. 371 U.S. at 182. "Futility of amendment" is, of course, one such reason. *Id.* In her post-judgment motion, Ge did not explain how her proposed amendment would cure the *Rule 12(b)(6)* deficiencies with her operative set of complaints. Her argument on that score relied solely on the district court's supposed misapprehension of Rule 12(b)(6) and Ge's arguments. Dist. Ct. No. 47 at 2. Thus, the only way to overcome Rule 12(b)(6) objections would have been to secure reconsideration under Rule 59(e). Without it, the

proposed amendment alone would have been futile. And that is exactly what Takeda explained in opposing Ge's motion: "even if Relator cured her Rule 9(b) pleading deficiencies, amendment would be a futile act in light of [the district court's] Rule 12(b)(6) ruling." Dist. Ct. No. 50 at 19.

Takeda repeated the same point in its First Circuit response brief, arguing that "no matter how Ge might try she cannot jam the square peg of her allegations against Takeda into the round hole of the FCA. That required dismissal under Rule 12(b)(6), and nothing she could plead would change that." Ct. App. Br. for Defs.-Appellees 71. Astonishingly, Ge offered no response to that point in her reply brief. In her petition for certiorari, she asserts "the underlying record demonstrates that Dr. Ge would have been able to cure the deficiencies identified by the district court with an amended complaint." Pet. 36. As to Rule 12(b)(6) deficiencies, however, the underlying record demonstrates no such thing.

This "apparent" futility under Rule 12(b)(6), *Foman*, 371 U.S. at 182, thus dooms Ge's post-judgment request to amend even under her preferred standard that categorically ignores the belated nature of her grounds for the amendment.

Even if this Court does not reach the futility question, it will be left for the First Circuit to address in the first instance. Either way, Ge is incorrect that "this case would be remanded to the district court" from this Court. Pet. 36. Ge may never return to the district court to effect her stated desire to cure the many waiver problems that the First Circuit recognized in her theory of liability. *Id.* "[A] procedural quagmire," *id.*, in which she finds herself

is of her own making—remember, she could have avoided the whole issue by supplying her proposed amended complaints before judgment, as opposed to relying on a boilerplate request tucked away in opposition to the motion to dismiss. For this reason alone, this case is a poor vehicle in which to expend this Court's resources.

## III. ADDITIONAL REASONS MAKE THIS CASE A POOR VEHICLE FOR REVIEW

Ge's petition faces several additional vehicular problems that render this case a poor candidate for the Court's review.

*First*, Ge waived her argument that Rule 15 trumps all considerations under Rules 59 and 60 in the post-judgment world. In support of her motion for leave to amend after the final judgment, she argued that her "newly discovered evidence" purportedly cured the second amended complaints' pleading problems. App. 63. That argument correctly recognized that leave to amend after the final judgment would depend, in part, on whether the new information is "newly discovered." In making that argument—as opposed to, say, arguing that the amendment had to be allowed regardless whether she could have requested the same amendment before judgment—Ge waived the sole question presented in her petition for certiorari.

*Second*, this case lacks the kind of systemic importance that may exist when vindication of the underlying interests depends entirely on the lawsuit at hand. Ge is a relator, trying to stand in the shoes of the United States in policing compliance with the FDCA. But the United States hardly requires her services. The responsibility to investigate violations

of the FDCA sits squarely with FDA. 21 U.S.C. § 372; *see supra* at 5-6. As this Court knows, FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration." *Buckman*, 531 U.S. at 349. That FDA made no such moves here is of no moment; prosecutorial discretion lies with FDA. *See Chaney*, 470 U.S. at 835. This Court need not be concerned with Ge's inability to "have [her] case decided on the merits." Pet. 34.

*Third* and finally, the fact-intensive nature of the nuances involved in the question presented counsels against this Court's review. Whichever way the Court goes would require an analysis of the factual circumstances of Ge's alleged theories of liability, of the dual reasons—under Rules 9(b) and 12(b)(6)—for dismissing her second amended complaints, and of the explanation why she could not have sought leave before judgment to file the proposed third amended complaints. Ge incorrectly maintains that "resolution of the issue presented in this case does not turn on the specific facts of Dr. Ge's claims." Pet. 36. She is again forgetting that this case is ultimately about the exercise of the district courts' discretion, which cannot be facilely dismissed as a pure question of law. The factual complexities are unavoidable.

* * *

In sum, all circuits agree on the standard for deciding post-judgment motions to amend on the basis of evidence and reasoning that could have been deployed before judgment. The First Circuit faithfully applied that standard in this case. Ge lost because of her own delay in bringing the inaptly

labeled "newly discovered evidence" to the district court's attention. But the result would not change even under Ge's own preferred test, because her proposed amendment would have been futile. All legal principles at issue are, and for some time have been, settled. Nothing here calls for the expenditure of this Court's limited resources on yet further review.

## CONCLUSION

The petition for writ of certiorari should be denied.

Respectfully submitted,

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