

No. 13-1085

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT**

In re GENZYME CORP. SECURITIES LITIGATION

DEKA INTERNATIONAL S.A. LUXEMBOURG; CITY OF EDINBURGH COUNCIL,
as administering authority of the Lothian Pension Fund;
GOVERNMENT OF GUAM RETIREMENT FUND,

Plaintiffs-Appellants,

VIVIAN OH, individually and on behalf of all others similarly situated;
JON RAHN, individually and on behalf of all others similarly situated;
and GENZYME INSTITUTIONAL INVESTORS,

Plaintiffs,

v.

GENZYME CORP., HENRI A. TERMEER, DAVID P. MEEKER, MICHAEL S. WYZGA,
ALISON LAWTON, MARK R. BAMFORTH, and GEOFFREY MCDONOUGH,

Defendants-Appellees.

**On Appeal from the United States District Court
for the District of Massachusetts**

**BRIEF OF WASHINGTON LEGAL FOUNDATION AS
AMICUS CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES
SUPPORTING AFFIRMANCE**

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed.R.App.P. 26.1, the Washington Legal Foundation (WLF) states that it is a nonprofit corporation organized under § 501(c)(3) of the Internal Revenue Code. WLF has no parent corporation, nor has it issued any stock owned by a publicly held company.

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IDENTITY AND INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF)¹ is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

To that end, WLF has appeared before this and other federal courts in numerous cases related to the proper scope of the federal securities laws. *See, e.g., Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011); *Stoneridge Inv. Partners, LLC v. Scientific Atlanta, Inc.*, 552 U.S. 148 (2008); *Tellabs, Inc. v. Makor Issue & Rights, Ltd.*, 551 U.S. 308 (2007).

As the Supreme Court has recognized, private securities fraud actions, “if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law.” *Tellabs*, 551 U.S. at 313. “As a check against abusive litigation by private parties,” *id.*, Congress adopted the Private Securities Litigation Reform Act of 1995 (PSLRA), 109 Stat. 737, which among other things imposed exacting pleading requirements upon “any private action” arising from the Securities Exchange Act. *See* 15 U.S.C.

¹ Pursuant to Fed.R.App.P. 29(c)(5), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief. All parties have consented to the filing of this brief.

§ 78u-4(b). They included a requirement that the plaintiff “state with particularity facts giving rise to a strong inference” that the defendant acted with the requisite scienter – an intent to deceive, manipulate, or defraud. 15 U.S.C. § 78u-4(b)(2)(A). WLF is concerned that the position espoused by Appellants, if adopted by this Court, would effectively nullify the heightened pleading requirement with respect to scienter.

WLF is filing this brief to promote the interests of the investment community and the public at large. It has no direct interest, financial or otherwise, in the outcome of this lawsuit. Because of its lack of direct interest, WLF believes that it can assist the Court by providing a perspective distinct from that of any party.

WLF supports each of the arguments raised by Appellees in their briefs. WLF writes separately to focus exclusively on the first argument raised by Appellee Genzyme: that neither Appellants’ complaint nor their proposed amended complaint meets the PSLRA’s exacting requirements for pleading scienter.

INTRODUCTION AND SUMMARY OF ARGUMENT

This litigation involves precisely the sort of abusive, lawyer-driven securities fraud claims that the PSLRA was intended to curb. SEC Rule 10b-5 has

long upheld the right of buyers and sellers of securities to recover losses incurred as a result of their reliance on fraudulent statements by publicly traded corporations. But in adopting the PSLRA's heightened pleading requirements, Congress recognized that all too often, the "fraud" alleged in a securities fraud action amounted to nothing more than "fraud by hindsight" – a complaint that "simply contrast[s] a defendant's past optimism with less favorable actual results." *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 62 (1st Cir. 2008). Congress determined that such suits, when combined with "vexatious discovery requests," and "manipulation by class action lawyers of the clients whom they purportedly represent," had "resulted in extortionate settlements, chilled any discussion of issuers' future prospects, and deterred qualified individuals from serving on boards of directors." *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 81 (2006).

The claims asserted by Appellants fall squarely within the "fraud by hindsight" model. They target a company, Genzyme, whose shareholders profited over the years from its expanding profits and rising stock price. Genzyme suffered a number of reverses during 2009: its application for FDA approval of a new product took longer than initially anticipated, the outbreak of a viral contamination at two of its production facilities hampered its ability to produce sufficient

products to meet customer demand, and FDA findings that one of Genzyme's production facilities was not conforming to current Good Manufacturing Practices (cGMP) further hampered production. When each of those adverse events occurred, Genzyme *promptly* disclosed them, and the price of its stock fell. Appellants fault Appellees (collectively, "Genzyme") for having failed to warn investors in advance that these adverse events were likely to occur and for providing unrealistic assessments regarding future earnings and future product approvals. While not seriously disputing that cited corporate statements were forward-looking in nature, Appellants contend that the statements: (1) were materially misleading in nature due to Genzyme's omission of other information that would have painted a less optimistic picture of the corporation; and (2) were uttered with an intent to deceive. Appellants Br. 24-26.

The district court correctly determined that the allegations regarding the defendants' state of mind "amount[ed] to fraud by hindsight, asking the Court to essentially infer earlier knowledge based only on the situation that later came to pass, which the First Circuit has consistently rejected." ADD-20 (citations omitted). While noting that Genzyme had withheld some information that Appellants asserted was "material," the district court concluded that the complaint failed to satisfy the PSLRA's requirement that a securities fraud complaint "state

with particularity facts giving rise to a strong inference” that the defendant acted with scienter. ADD-21.² In particular, the court determined that the inference that Appellants sought to draw from Genzyme’s failure to disclose information about approval of a new product – an inference that Genzyme was seeking to suppress information about its product approval application because it feared that the information would drive down Genzyme’s stock price – was less compelling than the nonculpable explanation advanced by Genzyme:

[M]ore compelling instead is the inference that Genzyme was attempting to develop a biologic that the defendants considered to be beneficial and that they believed was progressing, if fitfully at times, toward FDA approval for Lumizyme, and that they did not expect that the setbacks the company experienced in various ways would have a significant impact on the ultimate approval so as to require more disclosure than there had been.

Id.

The district court’s conclusion regarding scienter is unassailable in light of Genzyme’s prompt disclosure of adverse information throughout 2009. All of FDA’s major actions in 2009 – the February 2009 Warning Letter and Complete

² To establish liability under § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, a private plaintiff must prove that the defendant acted with scienter, “a mental state embracing intent to deceive, manipulate, or defraud.” *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193-94 & n.12 (1976). This Court has broadened the definition of scienter somewhat, so as also to include defendants who act “with a high degree of recklessness.” *City of Dearborn Heights v. Waters Corp.* [Waters], 632 F.3d 751, 757 (1st Cir. 2011).

Response Letter, the May 2009 announcement of the delay of the PDUFA date, its July 2009 letter, and the November 2009 Complete Response Letter and Form 483 – were disclosed by Genzyme immediately after it learned of them. In June 2009, it disclosed the cause of its bioreactor contaminations as soon as it determined the cause, and immediately disclosed its determination that addressing the contaminations would require a temporary shutdown of its Allston manufacturing facility – as well as that the shutdown would create product shortages. Such full and timely disclosure of adverse information is inconsistent with Appellants’ proposed inference of scienter; it makes little sense to conclude that a company that promptly disclosed highly material adverse information was simultaneously attempting to hide information of far lesser materiality, information that bore only on the likelihood that *future* events would come to pass. Indeed, Appellants’ failure to allege facts supporting *any* plausible motive for Genzyme to attempt to hide information that (Appellants assert) was inevitably going to have a near-term adverse impact on the company undermines any plausible basis for inferring scienter.

Appellants assert that the district court based its dismissal on an improper determination as a matter of law that the withheld information was not material. Appellants Br. 36-44. Not true. Dismissal was based solely on the district court’s

determination that the facts alleged in the complaint failed to give rise to a “strong inference” that Genzyme acted with scienter. The district court’s observations regarding materiality are highly relevant to this appeal, however, and lend considerable support to its conclusions regarding scienter.

Appellants rely heavily on Genzyme’s nondisclosure of the Form 483 issued by FDA in October 2008 following its inspection of Genzyme’s Allston manufacturing facility; the “observations” in the Form 483 identified 16 deviations at Allston from cGMP. Although it made no definitive finding regarding whether Appellants had adequately alleged materiality, the district court stated that it was “doubtful” whether Genzyme’s failure to mention the Form 483 in subsequent public statements constituted a material omission. ADD-17.

The district court’s statement was unquestionably accurate, given the relatively modest importance of Forms 483 in the dealings between FDA and regulated entities. A Form 483 is used to record the observations of FDA inspectors. While those observations can be very helpful both to the regulated company (which can use the observations to identify and eliminate potential deficiencies in its manufacturing practices) and to more senior FDA officials (who can use the observations to decide what, if any, future course to take), FDA makes absolutely clear that Form 483 inspectional observations do not represent any sort

of final agency determination. Indeed, observations contained in a Form 483 can lead to no further action whatsoever, a warning letter, or actual administrative proceedings (including consent decrees, cease and desist orders, etc.). But given that the *vast majority* of Forms 483 issued by FDA do not result in enforcement action, not even so much as a Warning Letter, it is questionable whether prompt disclosure of the October 2008 Form 483 would have been viewed by the reasonable investor as “material” – that is, as having “significantly altered the total mix of information made available.” *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1318 (2011).

Appellants assert that approval of Genzyme’s pending Biologic License Application (BLA) for Lumizyme was “precluded” until FDA concluded that all 16 observations on the Form 483 had been fully “corrected,” Appellants Br. 38, and that Genzyme knew that FDA would not approve the BLA until corrections had been completed. *Id.* at 45-47. But the complaint alleges no facts to support either assertion. As noted above, the October 2008 Form 483 observations did not constitute an FDA finding that the Allston plant was not in compliance with cGMP, and Appellants have alleged no facts suggesting that during the relevant time period (October 2008 through February 27, 2009), Genzyme believed that “corrections” had to be completed before the BLA could be approved.

When, as here, a Rule 10b-5 plaintiff focuses on alleged omissions from statements that involve speculative judgments about future events, the materiality of those omissions involves a balancing of two independent factors: (1) the indicated probability that the event will occur; and (2) the anticipated magnitude of the event in light of the totality of the company activity. *Hill v. Gozani*, 638 F.3d 40, 57 (1st Cir. 2011). Both factors call into serious question the materiality of Genzyme's omission of information about the October 2008 Form 483. FDA's own statistics demonstrate that the probability that any given Form 483 will result in so much as a Warning Letter is quite low. Moreover, while Genzyme's financial projections were based in part on its prediction that FDA would approve its BLA in a timely manner, the increased sales that Genzyme anticipated would be generated by that approval constituted a relatively minor part of its overall sales. This Court has been far less willing to find that an omission "significantly altered the total mix of information made available" to investors when, as here, the omission was relevant to at most a small portion of the corporation's overall sales and raised no issues regarding the company's continued viability. While the later disruption in production at the Allston plant that arose in the aftermath of the bioreactor contamination had the potential to disrupt a larger percentage of Genzyme's sales, Appellants have alleged no plausible connection between the October 2008 Form

483 and the contamination.

The district court's accurate conclusion that the omission of the October 2008 Form 483 from later company communications was of "doubtful" materiality strongly supports its holding that the complaint failed to meet the PSLRA's heightened standard for pleading scienter. A finding that materiality is "questionable" "tends to undercut the argument that defendants acted with the requisite intent or extreme recklessness in not disclosing the fact." *Waters*, 632 F.3d at 757. Thus, the district court's finding that Genzyme's omission was of "doubtful" and "questionable" materiality strengthens its conclusion that the inference that Appellants seek to draw – that Genzyme omitted mention of the Form 483 because it intended to deceive investors – is not as strong as the competing, nonculpable inference put forward by Genzyme. Under those circumstances, Appellants have failed to "state with particularity facts giving rise to a strong inference" of scienter, as required by 15 U.S.C. § 78u-4(b)(2)(A).

ARGUMENT

I. THE DISTRICT COURT'S FINDING THAT MATERIALITY IS "DOUBTFUL" BUTTRESSES ITS CONCLUSION THAT APPELLANTS HAVE INADEQUATELY PLEADED SCIENTER

To state a claim under Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, a plaintiff must allege "(1) a material misrepresentation or

omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Matrixx*, 131 S. Ct. at 1317. The district court dismissed the complaint on the pleadings based on the second requirement: it held that the complaint alleged insufficient facts to meet the PSLRA’s heightened pleading standards for scienter. ADD-21. That holding was well supported by the district court’s thorough analysis of the pleadings and of the appropriate inferences to be drawn therefrom. In particular, the court correctly determined that Genzyme’s alleged omissions were of “doubtful” materiality, and that “if the materiality of a particular fact is in question, that ‘tends to undercut’ an inference that a defendant acted with the requisite scienter.” ADD-14 (quoting *Waters*, 632 F.3d at 757). *See also Automotive Indus. Pension Trust Fund v. Textron, Inc.*, 682 F.3d 34, 39 (1st Cir. 2012); *In re Boston Scientific Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012).

Appellants insist that “the Complaint ‘plausibly suggests’ the materiality” of the October 2008 Form 483 because the cGMP “violations” observed therein “would not have been so obviously unimportant to a reasonable investor.” Appellants Br. 38-41. But the materiality of the Form 483 is not appropriately determined in isolation. Indeed, a corporation is not required to release

information simply because some investors might wish to learn of it in connection with their investment decisions; the information's Rule 10b-5 "materiality" can only be determined in the context of the entire package of information available to investors:

[I]t bears emphasis that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary "to make . . . statements made, in the light of the circumstances under which they were made, not misleading."

Matrixx, 131 S. Ct. at 1321 (quoting 17 C.F.R. § 240.10b-5(b)).

The Supreme Court in *Basic, Inc. v. Levinson*, 485 U.S. 224 (1988), established the rule for determining when the omission of a fact meets the Rule 10b-5 "materiality" requirement. *Basic* held that the requirement is satisfied when there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." 485 U.S. at 231-32. Importantly, this Court has explained that a complaint fails to satisfy the Rule 10b-5 "materiality" requirement if it does not satisfy *Basic*'s "total mix" standard – *i.e.*, if "the total mix of statements in [a corporation's] disclosures was not skewed to present a rosy picture" – even when "the alleged omissions are material" when considered in isolation. *Hill*, 638 F.3d at 61.

The district court was well advised not to dismiss the complaint on the basis of a finding that Appellants failed to plead sufficient facts to support a materiality claim. Rather than find the 483 immaterial as a matter of law, the court used its finding of relative immateriality as a factor in its scienter analysis. Nonetheless, numerous factors support the district court's conclusion that it was "doubtful" that Genzyme's alleged omissions from its public statements met the Rule 10b-5 materiality standard.

A. FDA's Issuance of a Form 483 Is an Everyday Occurrence That Only Rarely Leads to FDA Enforcement Action

Following the close of FDA's inspection of Genzyme's Allston plant in September and October 2008, investigators issued a Form 483 that listed 16 "inspectional observations" regarding "significant deviations" from FDA regulations regarding cGMP. The routine inspection coincided with Genzyme's BLA for Lumizyme,³ which Genzyme intended to manufacture in the Allston plant. Appellants allege that the Form 483 indicates that Genzyme "flunked" the

³ Lumizyme is a biologic approved by FDA for treatment of Pompe disease. Since 2006, it has been approved for marketing in the United States under the name Myozyme when produced in 160-liter ("160L") bioreactors. When Genzyme sought to increase production capability for the U.S. market by producing it in 2000-liter ("2000L") bioreactors at the Allston plant, FDA directed it file a new BLA covering 2000L production. Genzyme assigned the name Lymozyme to the Myozyme that was to be produced in 2000L reactors for sale in the United States.

inspection and that approval of the BLA for Lumizyme was “precluded” until Genzyme could correct all deficiencies cited in the Form 483.

Those allegations significantly misinterpret the nature of a Form 483 and the consequences that attach to “observations” listed on the form. Most importantly, a Form 483 does not constitute any sort of FDA enforcement action and does not even represent an FDA determination that a regulated entity is not in compliance with FDA regulations. Rather, a Form 483 is simply the means by which FDA inspectors can convey to more senior FDA officials their “significant” inspection findings. Based on those findings, those more senior officials determine what, if any enforcement proceedings to undertake. *See* FDA Compliance Program Guidance Manual, Chapter 45, “Biological Drug Products” (2012) at 24-25. A Form 483 is also “intended for use in notifying the inspected establishment’s top management in writing of significant objectionable conditions.” *See* FDA Investigations Operational Manual (2012), § 5.2.3. “Observations” are to be made “when in the investigator’s ‘judgment’, conditions or practices observed, indicate that any food, drug, device, or cosmetic have been adulterated or are being prepared, packed, or held under conditions whereby they may become adulterated or rendered injurious to health.” *Id.* The limited nature of Forms 483 was cogently explained by the district court:

The [October 2008] Form 483 itself includes statements that tend against a conclusion of materiality. The October 2008 Form 483 stated in bold, capitalized lettering that it was setting forth merely “INSPECTIONAL OBSERVATIONS” that “DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING . . . COMPLIANCE.” . . . The language was added to Form 483 by the FDA to minimize any perceived ambiguity that might result in inaccurate conclusions about the compliance of an inspected firm. . . . Because the Form 483 observations “do not represent a final agency determination,” they are necessarily interim statements, subject to revision.

ADD-17-18 (citations omitted).

That a Form 483 is solely informational and does not represent either a final FDA determination or a type of enforcement action is underscored by FDA listings of the types of “enforcement actions” they ordinarily undertake. Such lists include “Warning Letters,” but they do not include Forms 483.⁴

In other words, FDA’s explanation of the purpose of a Form 483 does not support Appellants’ contention that the October 2008 Form 483 constituted an FDA determination that the Allston plant had “flunked” the FDA inspection, or that the BLA for Lumizyme could not be approved until Genzyme had “corrected”

⁴ For example, FDA’s Center for Biologics Evaluation and Research (CBER) has issued a guidance document entitled, “Enforcement Actions” that lists five types of “regulatory action letters” that it issues “to biological product manufacturers in the effort to stop practices found to be in violation of the regulations and to promote corrective action.” The five types of “regulatory action letters” include Warning Letters; they do not include Forms 483. See www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/default.htm.

the 16 listed observations.

Appellants insist that Genzyme's omissions of information about the October 2008 Form 483 constituted "material omissions" because the deficiencies listed in the form had such serious repercussions for Genzyme in the following 18 months:

Indeed, the violations [cited in the October 2008 Form 483] caused Genzyme key products to be contaminated with foreign matter, and to be produced at low fill volumes, which affected their strength and potency. The violations that existed unremedied throughout the Class Period caused the FDA to reject the Lumizyme BLA a second time, impose a \$175 million fine on Genzyme, and require Genzyme and Termeer to consent to a permanent injunction barring them from manufacturing drugs at Allston until the violations were corrected.

Appellants Br. 38-39. But such arguments are classic "fraud by hindsight" arguments of the sort routinely rejected by this Court as sufficient to support a Rule 10b-5 claim. *See, e.g., ACA Fin. Guar. Corp.*, 512 F.3d at 62. Genzyme is being faulted for failing to report information that later mushroomed into significant, unanticipated adverse events. Appellants cannot reasonably assert that Genzyme should have known, based on the Form 483, that soon it would be facing a massive fine from FDA. At most, Genzyme can be faulted for a deficient response to the Form 483; but such deficiencies are evidence of inattention, not fraud.

Indeed, based on FDA's own statistics, neither Genzyme nor its potential investors had reason to believe that the October 2008 Form 483 would lead to any FDA enforcement action. Those statistics indicate that only a small percentage of Forms 483 issued by FDA are followed by enforcement action. For example, in Fiscal Year 2010, FDA issued 6,303 Forms 483. *See* www.fda.gov/ICECI/EnforcementActions/ucm255532.htm. But in the same fiscal year, it issued only 673 Warning Letters, by far the most common form of FDA enforcement action. *See* www.fda.gov/downloads/ICECI/EnforcementActionsUCM247845.pdf. In other words, FDA's statistics indicate that only a very small percentage of Forms 483 are followed by any sort of enforcement action. In light of those statistics, dissemination of information that Genzyme had received a Form 483 in October 2008 was unlikely to have "significantly altered the total mix of information" available to Genzyme investors in the ensuing months regarding Genzyme's financial prospects.

B. Overly Expansive Definitions of Materiality Impose Unwarranted Burdens on Corporations and Disserve the Interests of Investors

The Rule 10b-5 "materiality" of statements and omissions of publicly traded corporations must be considered within the context of the business environment within which highly-regulated corporations operate. The reality is that a

corporation regulated by FDA is in daily contact with the agency, and a massive quantity of information flows back and forth between the entities on a regular basis. Appellants are pushing for a rule that would label much of that information “material” for purposes of Rule 10b-5 and would, for example, require disclosure of all or virtually all Forms 483.⁵ Both the Supreme Court and this Court have cautioned against adoption of such overly expansive definitions of materiality, for fear that such definitions would prove extremely burdensome for publicly traded corporations and would, in the end, make it more difficult for investors to discern which information released by a corporation is highly relevant to its future financial well-being.

Thus, the Supreme Court noted in *Matrixx* that its earlier decision in *Basic* was “‘careful not to set too low a standard of materiality’ for fear that management would ‘bury the shareholders in an avalanche of trivial information.’” *Matrixx*, 131 S. Ct. at 1318 (quoting *Basic*, 485 U.S. at 231). *See also TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976) (“[I]f the standard of materiality is

⁵ Appellants assert that the “observations” in the October 2008 Form 483 were “significant” and thus material. But *all* observations in any Form 483 are “significant” in that same sense; FDA instructs its inspectors not to include observations of “objectionable conditions” unless the inspectors deem the observations to be “significant.” *See* FDA Investigations Operational Manual (2012), § 5.2.3.

unnecessarily low, not only may the corporation and its management be subjected to liability for insignificant omissions or misstatements, but also management's fear of exposing itself to substantial liability may cause it simply to bury shareholders in an avalanche of trivial information, a result that is hardly conducive to informed decisionmaking.""). This Court has also explained why adopting an overly expansive definition of materiality not only would impose unwarranted burdens on corporations, but also could inflict competitive harm:

Why companies do not have to disclose immediately all information that might conceivably affect stock prices is apparent: the burden and risks to management of an unlimited and general obligation would be extreme and could easily disadvantage shareholders in numerous ways (*e.g.*, if a new invention were prematurely disclosed to competitors or a take-over plan to the target company). So the securities laws forbid false or misleading statements in general but impose more specific disclosure obligations only in particular circumstances.

In re Boston Scientific Corp. Sec. Litig., 686 F.3d at 27-28.

The Securities and Exchange Commission is also mindful of the need to avoid disclosure requirements that end up providing investors with more information than they can meaningfully digest. In a recent speech, SEC Commissioner Troy A. Parades stated:

In fashioning the disclosure regime at the core of the federal securities laws, we must account for the fact that too much disclosure, particularly when it is too complex, can be counterproductive. We need to recognize the impact on investor decision making as investors find themselves having to confront

expanding volumes of information, some of which can be a challenge to understand with the kind of clarity that one might hope for. It would be better for investors to be provided with shorter, more manageable SEC filings, for example, rather than the lengthy documents they receive today.

Commissioner Troy A. Paredes, *Remarks at the SEC Speaks in 2013* (Feb. 22, 2013).

The district court's conclusion that Genzyme's omission of the October 2008 Form 483 from subsequent public statements was of doubtful materiality was similarly mindful of the need to avoid too expansive a definition of materiality.

The court said:

It simply cannot be that every critical comment by a regulatory agency – even about matters as important as good manufacturing practices – has to be seen as material for securities law reporting purposes, especially in an industry like Genzyme's, where there is a constant and close supervision by the FDA. *See Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 52-53 (2d Cir. 1995). Indeed, to think otherwise would be to insist on a flood of data that would overwhelm the market and would ironically be, in the end, actually uninformative.

ADD-18.

Appellants take issue with the district court's reliance on *Acito*, noting that the omitted information at issue in *Acito* involved only a small portion of the defendants' overall business. Appellants Br. at 44 n.9. But as noted below, the same can be said here: even if Appellants could allege facts demonstrating a link in October 2008 between the Form 483 and Genzyme's BLA for Lumizyme (and

to date no such link has been pleaded), it remains true that projected future sales for Lumizyme constituted only a modest portion of Genzyme's overall sales.

More importantly, given the tremendous volume of information that flowed daily between Genzyme and FDA, the district court was correct to question materiality; *i.e.*, to question whether the disclosure of "observations" on a Form 483 – observations that FDA repeatedly tells corporations do not represent any sort of "final agency determination" – would "significantly alter[] the total mix of information" available to investors. *Matrixx* rejected assertions that the "total mix" standard requires a pharmaceutical company to "disclose all reports of adverse events" arising from use of its products; noting that FDA "entered nearly 500,000 such reports into its reporting system" in 2009, *Matrixx* concluded that individual reports are unlikely to meet the Rule 10b-5 "materiality" standard because "[t]he fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event." *Matrixx*, 131 S. Ct. at 1321. The materiality of an individual Form 483 is similarly subject to question, given that "observations" on the form do not represent an official FDA determination that the manufacturer has violated FDA regulations and that the vast majority of the thousands of Forms 483 issued each year do result in any FDA enforcement action. The contrary rule espoused by Appellants would impose tremendous reporting

burdens on corporations regulated by FDA, while flooding investors with data whose significance they will have great difficulty discerning.

C. The Materiality of Genzyme's Omissions Is Weakened Considerably Because They Arise In the Context of Speculative Judgment About Future Events

Appellants contend that the October 2008 Form 483 was material because it was an omen of bad things to come. They contend that a reasonable investor might have concluded, based on the Form 483, that Genzyme was likely to face: (1) significant future FDA enforcement action with respect to its Allston plant; (2) delays in approval of its BLA for Lumizyme because that product was scheduled for production at the Allston plant; and (3) future contamination problems with its bioreactors at the Allston plant because failure to comply with cGMP can lead to such contamination. They further contend that the omission of any reference to the Form 483 in subsequent public statements by Genzyme was a material omission because mentioning the Form 483 would have “significantly altered the total mix of information” available to investors with respect to all three topics.

When, as here, a Rule 10b-5 plaintiff focuses on alleged omissions from statements that involve speculative judgments about future events, demonstrating materiality is an especially demanding task. Courts evaluating the materiality of such omissions must weigh several factors not relevant when the information is

omitted from statement involving current conditions at the company:

[I]f an alleged omission involves speculative judgments about future events, . . . materiality will depend at any given time upon a balancing of both the *indicated probability* that the event will occur and the *anticipated magnitude of the event* in light of the totality of the company activity.

Hill, 638 F.3d at 57 (quoting *Milton v. Van Dorn Co.*, 961 F.2d 965, 969-70 (1st Cir. 1992) (emphasis in original)). Both factors call into serious question the materiality of Genzyme's omission of information about the October 2008 Form 483.

With respect to the claim that the Form 483 was a harbinger of future FDA enforcement action, FDA's own statistics (as noted above) demonstrate that the probability that any given Form 483 will result in so much as a Warning Letter is quite low. With respect to claims that the Form 483 indicated a probable delay in approval of the BLA for Lumizyme, that inference is difficult to draw from a document that made no mention of the BLA and stated IN CAPITAL LETTERS that none of the 16 observations represented "a final agency determination regarding . . . compliance." There is little reason to infer that observations that FDA was unlikely to invoke as a basis for restricting existing production at the Allston plant would nonetheless be used to block *future* production at the plant. Finally, there is absolutely no evidentiary support for Appellants' assertion that the

Form 483 would have suggested to reasonable investors that the Allston plant might face future bioreactor contamination issues that could lead to costly shutdowns of the plant. Indeed, as Appellees spell out in considerable detail in their briefs, the observations contained in the Form 483 were unrelated to operation of the bioreactors and thus were unrelated to the contamination issues later experienced at the Allston plant.

The second factor identified by *Hill* – the anticipated magnitude of speculative future events in light of the totality of the company activity – also calls into question the materiality of the Form 483. Appellants contend that the Form 483 might have caused a reasonable investor to infer that FDA approval of Genzyme’s BLA for Lumizyme would be delayed. Even if that inference were plausible, it would be unlikely to “significantly” alter the total mix of information available to investors in light of the relatively modest role that Lumizyme sales played in Genzyme’s forward-looking sales projections.

In sum, the district court had good reason to question the materiality of Genzyme’s omission of the October 2008 Form 483 from subsequent forward-looking statements regarding the corporation’s financial prospect. The “doubtful” and “questionable” materiality of that omission lend considerable additional support to the district court’s already well-supported holding that the complaint

failed to state with particularity facts giving rise to a strong inference that Genzyme acted with scienter.

II. NEITHER THE COMPLAINT NOR AMENDED COMPLAINT STATES WITH PARTICULARITY FACTS GIVING RISE TO A STRONG INFERENCE OF SCIENTER

The Supreme Court had occasion in *Tellabs* to construe the PSLRA's heightened pleading standards regarding scienter. The Court observed that § 78u-4(b)(2)(A)'s "strong inference" language "unequivocally raised the bar for pleading scienter." *Tellabs*, 551 U.S. at 321. It held that "Congress required plaintiffs to plead with particularity facts that give rise to a 'strong' – *i.e.*, a powerful or cogent – inference" of scienter. *Id.* at 323.

Moreover, the Court explained:

The strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts? To determine whether the plaintiff has alleged facts that give rise to the requisite "strong inference" of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. . . . [T]he inference of scienter must be more than merely "reasonable" or "permissible" – it must be cogent and compelling, thus strong in light of other explanations.

Id. at 323-24. The Court held that a complaint cannot survive a Rule 12(b)(6) motion to dismiss for failure to state a claim unless "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing

inference one could draw from the facts alleged.” *Id.* at 324.

While absence of allegations regarding the defendants’ motives for intentionally deceiving investors “is not fatal,” the Supreme Court stated that motive can be a relevant consideration in determining whether the inference of scienter is sufficiently strong. *Id.* at 325.

The district court’s faithfully applied *Tellabs* in arriving at its determination that Appellants had inadequately pleaded scienter. The court determined that the inference that Appellants sought to draw from Genzyme’s failure to disclose information about the October 2008 Form 483 – an inference that Genzyme was seeking to suppress information about the Form 483 because it feared that the information would cause concern among investors about possible delays in FDA approval of its BLA for Lumizyme and thus would drive down Genzyme’s stock price – was less compelling than the nonculpable explanation advanced by Genzyme:

[M]ore compelling instead is the inference that Genzyme was attempting to develop a biologic that the defendants considered to be beneficial and that they believed was progressing, if fitfully at times, toward FDA approval for Lumizyme, and that they did not expect that the setbacks the company experienced in various ways would have a significant impact on the ultimate approval so as to require more disclosure than there had been.

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The district court's conclusion regarding scienter is unassailable in light of Genzyme's prompt disclosure of adverse information throughout 2009. All of FDA's major actions in 2009 – the February 2009 Warning Letter and Complete Response Letter, the May 2009 announcement of the delay of the PDUFA date, its July 2009 letter, and the November 2009 Complete Response Letter and Form 483 – were disclosed by Genzyme immediately after it learned of them. In June 2009, it disclosed the cause of its bioreactor contaminations as soon as it determined the cause, and immediately disclosed its determination that addressing the contaminations would require a temporary shutdown of its Allston manufacturing facility – as well as that the shutdown would create product shortages. Such full and timely disclosure of adverse information is inconsistent with Appellants' proposed inference of scienter; it makes little sense to conclude that a company that promptly disclosed highly material adverse information was simultaneously attempting to hide information of far lesser materiality, information that bore only on the likelihood that *future* events would come to pass. Indeed, Appellants' failure to allege facts supporting *any* plausible motive for Genzyme to attempt to hide information that (Appellants assert) was inevitably going to have a near-term adverse impact on the company undermines any plausible basis for inferring scienter.

Nor have Appellants convincingly alleged facts creating a strong inference that Genzyme acted with extreme recklessness. This Court defines “recklessness” as “a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it.” *In re Smith & Wesson Holding Corp. Sec. Litig.*, 669 F.3d 68, 77 (2012). Given that the October 2008 Form 483 stated on its face that the observations in the document “d[id] not represent a final agency determination regarding compliance,” as well as FDA statistics demonstrating that most Forms 483 do not result in any sort of enforcement action, Appellants cannot plausibly argue that Genzyme’s failure to publicly disclose the Form 483 constituted “an extreme departure from the standards of ordinary care” and that the danger of misleading investors was “so obvious” that Genzyme “must have been aware” of the danger.

Appellants contend that Genzyme must have known in the fall of 2008 (contrary to public statements) that the BLA would not be approved in February 2009, given that it was not scheduled to implement all of its corrective actions (in response to the Form 483) by that date. But Appellants have pleaded no facts suggesting that FDA followed a rule that prohibited approval of a BLA while

responses to a Form 483 were still being implemented – a rule that would be surprising in light of FDA’s insistence that observations contained in a Form 483 do not represent a final agency determination regarding compliance. Moreover, as Genzyme points out, on November 17, 2008, FDA set a PDUFA of February 28, 2009, even though it knew full well by November 17 that Genzyme was not expected to complete its Form 483 remediation until late March – thereby indicating that Genzyme had no reason to believe that there was no possibility that its BLA could not be approved on the PDUFA date. Genzyme Br. 23.

Furthermore, when FDA inspectors issued their 16 “observations” in October 2008, the Allston plant was working at full capacity to produce several of Genzyme’s most profitable biologics, including Cerezyme and Fabrazyme. At no time in the months following issuance of the Form 483 did FDA officials indicate that the cGMP issues raised by the inspectors would likely lead to a shutdown of all production at the Allston plant. The absence of any such statements suggests that Genzyme’s belief that the BLA would be approved on schedule was reasonable. After all, if FDA officials believed that manufacturing conditions at the Allston plant were adequate to justify on-going manufacturing activities, Genzyme would have had little reason to believe that FDA would not authorize future manufacturing of Lumizyme – particularly in light of Genzyme’s

commitment to address the deficiencies identified by FDA inspectors.

Finally, Appellants' failure to articulate any plausible motive for Genzyme to have engaged in fraud weighs heavily against the cogency of their proposed inference. There is no evidence of insider trading, and thus Genzyme could not have been motivated by a desire to inflate the stock price until such sales could be completed. Nor is there evidence that Genzyme might have been motivated to delay the bad news (which, if Appellants' allegations are to be believed, could not have been suppressed for more than a matter of months) in order to ensure that some important business transaction could be completed. Nor is there evidence that the bad news was so bad that Genzyme and its directors were motivated by a desire to preserve their positions by staving off an inevitable bankruptcy as long as possible. *See, e.g., In re Stone & Webster, Inc. Sec. Litig.*, 414 F.3d 187, 210-211 (2005). Indeed, even in *Stone & Webster*, the Court concluded that Rule 10b-5 scienter had been adequately pleaded only with respect to statements regarding the *current condition* of a corporation facing imminent bankruptcy, not with respect to statements that focused on future events. *See, e.g., id.* at 205.

In sum, the inference of scienter is far less cogent than the inference that Genzyme possessed nonculpable motivations when it chose not to disclose the Form 483 between October 2008 and the end of February 2009. That conclusion

becomes unassailable when one adds to the equation the district court's reasonable conclusion that the omission of the Form 483 from post-October 2008 public statements was of "doubtful" and "questionable" materiality.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court affirm the judgment of the district court.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amici curiae* Washington Legal Foundation (WLF), *et al.* Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect X5), the word count of the brief is 6,994, not including the corporate disclosure statement, table of contents, table of authorities, certificate of service, certificate of bar membership, and this certificate of compliance. The hard copy and the electronic copy of this brief are identical.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I hereby certify that on July 3, 2013, and again on July 8, 2013, I electronically filed the brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court of the U.S. Court of Appeals for the First Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp
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