

IN THE
Supreme Court of the United States

MENORAH MIVTACHIM INSURANCE LTD., *et al.*,

Petitioners,

v.

JOHN D. SHEEHAN, *et al.*,

Respondents.

**ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED
STATES COURT OF APPEALS FOR THE SECOND CIRCUIT**

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Second Circuit Court of Appeals and the district court adequately set out their reasons for dismissing and/or affirming the dismissal of Petitioners' claims by clearly describing them in written decisions.
2. Whether the Second Circuit Court of Appeals and the district court properly rejected Petitioners' generic drug claims for failure to adduce adequate evidence of loss causation, where Petitioners failed to disaggregate losses caused by changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions or other events, from disclosures of the truth behind the alleged misstatements.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondents state the following: Mylan Inc. is a wholly owned subsidiary of Viatris Inc., a publicly held corporation. Mylan N.V. was formerly the parent company of Mylan Inc. but ceased to exist upon the closing of a business combination of Mylan N.V. and Upjohn Inc., which resulted in the creation of Viatris Inc. Viatris Inc. does not have a corporate parent and no publicly held corporation owns 10% or more of its stock.

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STATEMENT OF THE CASE

This is a securities case in which Petitioners cobbled together allegations from other lawsuits and investigations and dressed them up as claims for securities fraud. After the case was substantially narrowed through the dismissal of other unsupported allegations, the crux of the case that went forward was that Mylan N.V. and Mylan Inc. (collectively, “Mylan”) (and certain officers and employees) allegedly failed to disclose to shareholders that the company offered anticompetitive rebates on the EpiPen, classified it incorrectly for purposes of Medicaid rebates, and fixed prices and allocated markets for certain generic drugs—thus inflating artificially the price of Mylan’s stock. Petitioners survived several motions to dismiss after three amendments based on the promise that their allegations would be supported by confidential witnesses and evidence from a pending criminal investigation. That never happened.

After nearly seven years of litigation, Petitioners’ purported confidential witnesses never materialized, and an industry-wide criminal investigation by the U.S. Department of Justice involving generic drug pricing (“DOJ Generic Pricing Investigation”) never resulted in any charges against Mylan. On the contrary, the undisputed evidence showed that Mylan’s rebates were pro-competitive, the EpiPen was properly classified for Medicaid purposes, and Mylan acted independently (not as part of a cartel) in marketing and selling its generic drug products. Thus, the district court properly found Petitioners’ allegations to lack support and entered summary judgment in favor of Respondents.

The Second Circuit affirmed the district court’s decision and denied Petitioners’ request for a rehearing and a rehearing en banc.

Although they abandoned the bulk of their case by not appealing significant parts of the district court’s ruling, Petitioners now seek to conjure up “cert-worthy” issues for review by this Court. They claim that both the district court and the Second Circuit: (1) failed to explain adequately their dismissal of two aspects of Petitioners’ Medicaid-related claims (what Petitioners call their “Rebate-Rate Claims” and their “Government Investigation Claims”); and (2) applied an overly demanding standard in finding that Petitioners failed to adduce adequate evidence of loss causation concerning their allegations of price-fixing and market allocation in the generic pharmaceutical drug industry (the “Generic Drug Claims”). According to Petitioners, the lower courts require guidance on these issues. In fact, the law is clear on both points: the district court and the Second Circuit explained their reasons for rejecting Petitioners’ claims; and the lower courts properly applied the law concerning loss causation. Petitioners’ application for certiorari should be denied.

A. The Parties

During the relevant period (February 21, 2012 to May 24, 2019, both dates inclusive), Mylan N.V. was a publicly traded company. Mylan entities develop, license, manufacture, market and distribute brand-name and generic pharmaceuticals worldwide. (A-103 ¶ 4.)¹ These

1. Citations to the Deferred Joint Appendix filed in the Appeal below are designated “A-__” with appropriate page references.

products include EpiPen, as well as thousands of generic drugs. (A-103-104 ¶¶ 6-8.) The Individual Respondents are Heather Bresch, Paul Campbell, Robert Coury, Rajiv Malik, Kenneth Parks, John Sheehan and James Nesta. (A-104-111 ¶¶ 9-47.) Petitioners are purchasers of Mylan common stock between February 21, 2012 and May 24, 2019. (A-102-103 ¶ 3.)

B. This Litigation

Petitioners filed four complaints from March 20, 2017 to June 17, 2019, culminating in the Third Amended Complaint (the “TAC”). The TAC asserts claims under §§ 10(b), 14(e) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. (TAC ¶ 30.)

Petitioners crafted the TAC by copying allegations from three sets of non-securities litigations and/or investigations: (1) litigation accusing Mylan of misconduct in the sale of EpiPen, an auto-injector used to deliver epinephrine (the “EpiPen Antitrust Claims”); (2) a DOJ investigation concerning the classification of EpiPen for purposes of the Medicaid Drug Rebate Program (“MDRP” and the “MDRP Claims”); and (3) litigation/investigations concerning the Generic Drug Claims. (App. 11a-12a).²

C. Petitioners’ Claims

Petitioners claimed that Respondents made statements explaining the market, regulatory risk and Mylan’s income that were materially misleading because Mylan did not

2. Citations to Petitioners’ Appendix are designated “App. __” with appropriate page references.

disclose the alleged misconduct underlying each of the EpiPen Antitrust Claims, MDRP Claims or Generic Drug Claims. (TAC ¶¶ 5-29.)

Petitioners' EpiPen Antitrust Claims alleged that what Mylan said was materially misleading because it failed to disclose that the company offered rebates on EpiPen as part of an unlawful scheme to exclude a competing product from the market. (*Id.* ¶¶ 12-14.) Petitioners also alleged Mylan engaged in anticompetitive conduct by imposing vertical restraints on pharmacy benefit managers ("PBMs"), and by bribing PBMs to eliminate a competitor. (A-325-326.)

Petitioners' MDRP Claims were predicated primarily on allegations that Mylan knowingly misclassified EpiPen as an "N Drug". (TAC ¶ 70.) The MDRP requires drug manufacturers to pay rebates to Medicaid, depending upon a drug's classification: rebates for so-called "S Drugs" and "I Drugs" are higher than rebates for N Drugs. 42 U.S.C. § 1396r-8(c). Petitioners also alleged that Mylan misrepresented that: (1) EpiPen was rebated at 23% Average Manufacturer's Price ("AMP") (instead of 13% AMP, the rate at which N Drugs are rebated), (2) a governmental agency had *not* taken a position contrary to Mylan's on EpiPen's classification and (3) a government investigation was *not* in progress. (TAC ¶¶ 88-94; Dkt. 350 at 1-2.)

Petitioners' Generic Drug Claims were based on allegations that Mylan entered into agreements with its competitors to allocate the markets for six generic drugs (A-371) and to fix the list prices of 14 others (A-388).

D. Summary Judgment Decision

Following class certification and extensive discovery, Respondents moved for summary judgment on all of Petitioners' claims. Petitioners cross-moved for partial summary judgment as to elements of their MDRP Claims.

On March 30, 2023, the district court entered an order granting Respondents' motion and denying Petitioners' motion (the "Summary Judgment Ruling"). (App. 111a.) The court followed four other federal judges in rejecting Petitioners' EpiPen Antitrust Claims,³ acknowledged that multiple government agencies had found EpiPen was properly classified under the MDRP and found Petitioners' Generic Drug Claims to be unsupported.

E. The Second Circuit Appeal

Petitioners did not appeal the portion of the Summary Judgment Ruling dismissing their EpiPen Antitrust Claims. They also did not appeal the dismissal of their primary MDRP Claim: that Mylan knowingly misclassified EpiPen. (Appeal Op. Br. 19 n.14).⁴ And they did not appeal their

3. *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 507 F. Supp. 3d 1289 (D. Kan. 2020); *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-MD-2785-DDCTJJ, 2021 WL 2585065 (D. Kan. June 23, 2021); *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 44 F.4th 959 (10th Cir. 2022), cert. denied sub nom. *Sanofi-Aventis U. S., LLC v. Mylan, Inc.*, 143 S. Ct. 1748, 215 L. Ed. 2d 649 (2023).

4. Citations to the Petitioners' Opening Brief filed in the Appeal below are designated "Appeal Op. Br. __" with appropriate page references.

primary claims against the Individual Respondents; Petitioners made no specific mention of their primary claims against any particular Individual Respondent.

Petitioners purported to appeal the portion of the Summary Judgment Ruling rejecting the remaining MDRP Claims (those as to which Petitioners cross-moved for summary judgment) for failure to show falsity and materiality. (*Id.* 17-25.) But they did not appeal the district court's holding that Petitioners failed to adduce evidence sufficient to prove scienter as to these claims, a failure that was independently dispositive, foreclosing altogether Petitioners' appeal of their MDRP Claims. (*Id.* 24-25; App. 59a-75a.)

Petitioners also appealed the dismissal of the Generic Drug Claims. However, their arguments as to these claims (and their MDRP Claims) misstated the district court's ruling, misrepresented the undisputed evidence and ignored alternative grounds for affirmance. (Appeal Op. Br. 25-56.)

Finally, Petitioners appealed the dismissal of their Section 20(a) claims but rested it entirely on their mistaken arguments regarding primary liability; they failed to mention the undisputed evidence that the Individual Respondents acted in good faith. (*Id.* 62.) Indeed, they failed to mention most of the Individual Respondents at all.

The Second Circuit held oral argument on Petitioners' appeal on March 14, 2024. Both sides presented argument (and the Second Circuit asked questions) on the issues Petitioners now claim the Second Circuit ignored.

F. The Second Circuit Decisions

In an order dated April 15, 2024, the Second Circuit affirmed the district court’s decision. (App. 1a.) With respect to Petitioners’ MDRP Claims, the Second Circuit concluded that “[t]he district court expressly considered each of the alleged misstatements underlying the MDRP Claims and concluded that Appellants failed to adduce sufficient evidence of scienter on any of them. Accordingly, by failing to adequately brief scienter, Appellants have waived any challenge to the district court’s rulings on that issue”. (*Id.* 4a-5a.)

With respect to Petitioners’ Generic Drug Claims, the Second Circuit (like the district court) concluded that Petitioners had failed to demonstrate loss causation. The Second Circuit also agreed with the district court “that Appellants failed to disaggregate the losses caused by Mylan’s alleged agreements to allocate markets and fix prices of specific generic drugs from losses caused by negative news relating to Mylan, generic drugs, and antitrust generally”. (*Id.* 6a.)

Petitioners sought a panel rehearing or, in the alternative, a rehearing en banc. On May 20, 2024, the Second Circuit denied Petitioners’ request. (*Id.* 112a.)

REASONS FOR DENYING THE PETITION

Nothing in Petitioners’ application justifies the granting of a writ of certiorari. Contrary to their contention, there is no uncertainty about what a district court should do in deciding a motion for summary judgment. Rule 56(a) expressly provides that, when a

court decides a summary judgment motion, the court should state on the record the reason for granting or denying the motion. Fed. R. Civ. P. 56(a). That is exactly what the district court did here, as the Second Circuit recognized in rejecting Petitioners' argument that the district court failed to provide a rationale for its decision.

Petitioners' contention that there is a significant need for guidance from this Court on the standard for loss causation is similarly without merit. There is no question that loss causation is an essential element of Petitioners' claim. Nor is there any question that a plaintiff must disaggregate those losses caused by changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions or other events, from disclosures of the truth behind the alleged misstatements. The Second Circuit properly found that Petitioners failed adequately to disaggregate.

Finally, Petitioners contend that the Second Circuit's decision "has far reaching implications which must be addressed". (Br. 21.) That is simply not true. The Second Circuit resolved the case in a summary order that by definition lacks precedential effect. Moreover, its order does not: (1) decide any question of federal law that has not been, but should be, settled by this Court; (2) so far depart from the accepted usual course of judicial proceedings, or sanction such a departure by the district court, as to call for an exercise of this Court's supervisory power; or (3) decide an important federal question in a way that conflicts with relevant decisions of this Court.

I. THE SECOND CIRCUIT PROPERLY AFFIRMED THE DISMISSAL OF PETITIONERS’ MDRP CLAIM BASED UPON A CLEAR EXPLANATION OF THE FLAWS IN PETITIONERS’ CASE

Contrary to Petitioners’ contention, the law is firmly established that a district court should state on the record the reasons for granting or denying summary judgment. The district court clearly set out the reasons for rejecting Petitioners’ claims in a lengthy order, following extensive briefing and oral argument. Thus, Petitioners’ request for review is misplaced.

A. Nothing About Rule 56(a) Requires Clarification

Petitioners ask this Court to use this case “to clarify that dismissing a party’s claim on summary judgment without providing any substantive explanation violates the requirement of Federal Rule of Civil Procedure 56(a) to provide reasons for that dismissal”. (Br. 8.) But there is nothing about Rule 56(a) that requires clarification: the rule and the caselaw applying it are clear.

Starting with the rule itself, Rule 56(a) directly states that a court “should state on the record the reasons for granting or denying the [summary judgment] motion”. Fed. R. Civ. P. 56(a). This specific sentence was added when the rule was amended in 2010, codifying a practice that was already common among courts. *See* Fed. R. Civ. P. 56(a) Advisory Committee’s note to 2010 amendment (noting that “[m]ost courts recognize this practice”). Along with this guidance, the Advisory Committee also noted that, under the rule, “[t]he form and detail of the statement of reasons are left to the court’s discretion”. (*Id.*)

The caselaw applying Rule 56(a) is equally clear and consistent across circuits. As Petitioners themselves acknowledge, courts of appeals take the approach that a district court should “state the reasons for granting summary judgment . . . on the record, as is required by Rule 56(a)” and, if no reasons are stated, a court of appeals will remand the case to the district court to do so. (Br. 8-9 (citing *D’Onofrio v. Vacation Publ’ns, Inc.*, 888 F.3d 197, 210 n.13 (5th Cir. 2018); *Certain Underwriters at Lloyd’s v. Axon Pressure Prods.*, 951 F.3d 248, 272-273 (5th Cir. 2020)); *see also Jackson v. Fed. Express*, 766 F.3d 189, 196-97 (2d Cir. 2014).)

Thus, while Petitioners claim that lower courts need guidance to apply Rule 56(a), nothing in their cited cases supports such a contention. There is no circuit split. And there is no uncertainty among courts in understanding what the rule requires. Instead, as Petitioners effectively concede, courts of appeals have ruled that a district court must state on the record the reasons for granting or denying summary judgment, and where district courts have not, appellate courts have remanded. Clarification by this Court is not needed.

B. The Lower Courts Explained Their Rejection of the Rebate-Rate Claim

Petitioners argue that “neither the district court nor the Second Circuit *ever* provided *any explanation* for why Plaintiffs’ claim that Defendants misrepresented the rebate rate for EpiPen should be dismissed on summary judgment”. (Br. 2 (emphases in original).) That is wrong.

As an initial matter, the district court afforded Petitioners ample opportunity to present their Rebate-

Rate Claim. It permitted a 90-page brief, allowed thousands of pages of 56.1 contentions and held oral argument.

Against that backdrop, the district court rejected the claim for failure to adduce evidence sufficient to permit an inference of scienter. The district court expressly referenced Petitioners' Rebate-Rate Claim at App. 58a:

Plaintiffs challenge certain statements and communications by Mylan considered together. Mylan at various points made claims to the effect of, "If ANDA, then 13%." ... This is said to be misleading because Mylan failed to also disclose that the EpiPen, according to Plaintiffs but contested by Defendants, was also rebated at 13% but was not approved pursuant to an ANDA.

On the following page, from App. 59a-60a, the district court held that the record did not support an inference of scienter:

Much of Plaintiffs' argument turns on construing the MDRP. But even if Plaintiffs are correct in their reading of the statutory text, liability could only exist if they established the clarity of textual meaning sufficiently to also impute knowledge (scienter) to Defendants.[] *The record supports no such inference*; rather, it is replete with evidence tending to significant confusion or disagreement among and within the regulatory agencies. There simply was not a single, clear interpretation of the MDRP

statute rendering all the rest unreasonable. Even if Defendants' view of the MDRP was unreasonable, that would not support a reasonable inference of scienter – requiring evidence of 'extreme' recklessness, not mere negligence or unreasonableness

The Court concludes that this degree of regulatory uncertainty and confusion, overlaid with the existing factual record, is insufficient to permit a reasonable juror to infer that Mylan knowingly made misleading statements about its classification of the EpiPen. (emphasis added.)

Moreover, the district court addressed scienter concerning this claim in disposing of Petitioners' classification claim. The district court found that Mylan acted reasonably in classifying the EpiPen as an N-drug at App. 78a-79a: "Mylan may well have thought it was – and, indeed, reasonably thought it was – in the right regarding how it classified the EpiPen". It necessarily follows from this ruling of Mylan's reasonableness in how it *classified* the EpiPen – which Petitioners did not appeal (Appeal Op. Br. 19 n.14) – that it acted reasonably in how it *rebated* the EpiPen. The appropriate rebate rate depends upon the classification of EpiPen; the rate is derived directly from the classification. 42 U.S.C. §1396r-8(c).

While Petitioners did not raise the district court's alleged failure to rule on scienter until they submitted their reply brief in the Second Circuit, they briefed the issue, it was argued orally and the Second Circuit asked questions about it during oral argument. It was also

addressed in Petitioners' request for rehearing and/or rehearing en banc. Thus, this is not a case in which the district court's alleged failure to address a claim impaired appellate review. In affirming the district court's decision, the Second Circuit stated it "disagree[d]" with Petitioners, and, in fact, "[t]he district court expressly considered each of the alleged misstatements underlying the MDRP Claims and concluded that Appellants failed to adduce sufficient evidence of scienter on any of them". (App. 4a-5a.)

None of the arguments Petitioners now advance supports granting their request. This is not a case in which the lower courts were silent as to the facts or legal grounds or where the record was unclear. (See Br. 12.) It is also not a case in which the Second Circuit's decision was "based on the solitary celebration of the trial court". (*Id.* (citation omitted).) Rather, the district court handed down a 62-page opinion that identified and addressed Petitioners' Rebate-Rate Claim. The Second Circuit heard Petitioners' arguments that they did not waive their Rebate-Rate Claim and dismissed them, referring to the pertinent parts of the district court's opinion, as well as setting out the well-established law that it applied to affirm the district court's decision. (App. 4a-5a.)

C. The Lower Courts Explained Their Rejection of the Government Investigation Claim

Petitioners' claim that the district court also failed to explain its rejection of their Government Investigation Claim is also without merit. (Br. 2-3.)

Just as it expressly rejected Petitioners' Rebate-Rate Claim, the district court expressly rejected their

Government Investigation Claim. The district court introduced the claim at App. 78a:

Plaintiffs also argue that the same Statements of Regulatory Risk were misleading because they purportedly implied that Mylan was not yet being investigated by a regulator when, in fact, Mylan had received a federal subpoena related to the EpiPen’s rebate classification.

Then, at App. 78a-79a, the district court found no scienter:

[A]ll of the reasons that Mylan may well *have thought* it was—and, indeed, *reasonably thought* it was—in the right regarding how it classified the EpiPen are also reasons why no one at Mylan would have had *reason to think* the subpoena material. That is, if, as the Court has held, Mylan acted reasonably in its reliance on CMS statements and other communications in determining how to rebate the EpiPen, then *there is no reasonable basis for Mylan to have regarded the subpoena material.* (emphases added) (citation omitted).

Petitioners seek to dismiss this language as referring only to materiality, not scienter. (Br. 15.) But that assertion is belied by the plain language of the district court’s order. The district court referred to what Mylan “thought”, what Mylan “reasonably thought” and what Mylan would have “reason to think”. (App. 78a-79a.) This is the language of scienter. It concerns the company’s state of mind, including whether knowledge of falsity or recklessness can be imputed to it.

Even if this language related to materiality, it would not further Petitioners' contention, as there is a clear connection in this context between materiality and scienter. If, as the district court found, Mylan reasonably believed the subpoena was immaterial, then it could not have acted with scienter in deciding not to disclose it. Companies receive subpoenas all the time, and there is no general legal requirement to disclose them. *See Ont. Tchrs.' Pension Plan Bd. v. Teva Pharm. Indus. Ltd.*, 432 F. Supp. 3d 131, 167, 168 (D. Conn. 2019).

Here again, Petitioners argued to the Second Circuit that the district court failed to address scienter as to this claim, and the Second Circuit expressly rejected the argument. The Second Circuit stated that “[t]he district court expressly considered each of the alleged misstatements underlying the MDRP Claims and concluded that Appellants failed to adduce sufficient evidence of scienter on any of them”. (App. 4a-5a.)

II. THE SECOND CIRCUIT PROPERLY REJECTED PETITIONERS' CLAIMS FOR FAILURE TO PROVE LOSS CAUSATION, THE STANDARD FOR WHICH IS CLEAR

Like their claims about there being uncertainty concerning the degree to which district courts must explain their reasoning, Petitioners' argument that the lower courts need guidance on the standard for loss causation is off base. The law is clear and the Second Circuit properly applied it here.

A. The Law of Loss Causation Is Clear

As Petitioners acknowledge, the Private Securities Litigation Reform Act of 1995 (“PSLRA”) provides that “the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages”. (Br. 17-18 (quoting 15 U.S.C. § 78u-4(b)(4).) This Court, in interpreting the PSLRA, has explained that, to prove loss causation, plaintiffs must “prove that the defendant’s misrepresentation (or other fraudulent conduct) proximately caused the plaintiff’s economic loss”, *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346 (2005), which involves distinguishing the alleged fraud from the “tangle of [other] factors” that affect a stock’s price. *Id.* at 343.

Based on the text of the PSLRA, and this Court’s decision in *Dura*, the Second Circuit has explained the standard in the following clear terms:

To establish loss causation, a plaintiff must show that the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered, *i.e.*, that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security. *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005)

In doing so, a plaintiff must disaggregate those losses caused by ‘changed economic circumstances, changed investor expectations, new industry-specific or firm specific facts,

conditions, or other events,’ from disclosures of the truth behind the alleged misstatements. *In re Flag Telecom Holdings, Ltd. Sec. Litig.*, 574 F.3d 29, 36 (2d Cir. 2009) (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 343 (2005)); *see also Lentell*, 396 F.3d at 177 (requiring a plaintiff to ‘allege (i) facts sufficient to support an inference that it was defendant’s fraud—rather than other salient factors—that proximately caused plaintiff’s loss; or (ii) facts sufficient to apportion the losses between the disclosed and concealed portions of the risk that ultimately destroyed an investment’). (App. 5a-6a (cleaned up).)

Petitioners do not point to any decision of any court anywhere taking a different view. On the contrary, courts across the country are consistent in how they apply the principles set out by this Court in determining whether a plaintiff has proved loss causation. *See, e.g., Bricklayers & Trowel Trades Int’l Pension Fund v. Credit Suisse Sec. (USA) LLC*, 752 F.3d 82, 95 (1st Cir. 2014); *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 433 (3d Cir. 2007); *Glaser v. Enzo Biochem, Inc.*, 464 F.3d 474, 477-79 (4th Cir. 2006); *Catogas v. Cyberonics, Inc.*, 292 F. App’x 311, 314 (5th Cir. 2008); *D.E. & J. Ltd. P’ship v. Conaway*, 133 F. App’x 994, 1000-01 (6th Cir. 2005); *Ray v. Citigroup Glob. Mkts.*, 482 F.3d 991, 994-95 (7th Cir. 2007); *Rand-Heart of N.Y., Inc. v. Dolan*, 812 F.3d 1172, 1179-80 (8th Cir. 2016); *Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1122-23 (9th Cir. 2013); *In re Williams Sec. Litig. - WCG Subclass*, 558 F.3d 1130, 1136-37 (10th Cir. 2009); *MacPhee v. MiMedx Grp., Inc.*, 73 F.4th 1220, 1242 (11th Cir. 2023); *Ark. Pub. Emps. Ret.*

Sys. v. Harman Int'l Indus. Inc. (In re Harman Int'l Indus., Inc. Sec. Litig.), 791 F.3d 90, 111 (D.C. Cir. 2015).

Thus, Petitioners' claim that the law must be clarified falls flat.

B. The District Court and the Second Circuit Properly Rejected Petitioners' Generic Drug Claims for Failure To Show Loss Causation

After setting out the correct standard for loss causation, the district court and Second Circuit properly rejected Petitioners' Generic Drug Claims for failing to meet that standard. The district court found Petitioners' loss causation arguments wanting for two primary reasons: (1) they failed to "isolate the effect" of the alleged corrective disclosures (*i.e.*, failed to disaggregate price declines attributable to alleged fraud from declines attributable to non-fraud events) (App. 103a (citation omitted)); and (2) they failed to show, for multiple reasons, a correlation between any of the alleged triggers and the alleged fraud. (*Id.* 104a-110a.)

On appeal, Petitioners offered no basis to disturb the district court's decision. They effectively ignored the district court's disaggregation holding (summarized in (1), above). (Appeal Op. Br. 56-62.) Although it was the district court's lead rationale and related to each of the disclosures at issue (App. 103a), Petitioners mentioned disaggregation only concerning the May 2019 disclosure and only to argue that "disaggregation between drugs" was "inappropriate because the losses largely represented general reputational harm". (Appeal Op. Br. 61.) Petitioners cited no case relieving them of the obligation

to disaggregate declines from alleged fraud events and non-fraud events, and there is none. Nor did they point to any showing of disaggregated declines. On the contrary, Petitioners conceded they “were unable to sufficiently disaggregate the effect of [disclosures concerning an investigation of Mylan] from other confounding factors”.⁵ (*Id.* 58 n.36.)

In any case, the Second Circuit properly concluded that Petitioners “failed to disaggregate the losses caused by Mylan’s alleged agreements to allocate markets and to fix prices of specific generic drugs from losses caused by negative news relating to Mylan, generic drugs, and antitrust generally”. (App. 6a.) And that is true as to each of the alleged corrective disclosures identified by Petitioners.

November 3, 2016. Petitioners sought to show loss causation from a November 3, 2016 *Bloomberg* article

5. Petitioners also had no response to the other grounds on which the district court found a failure of proof of loss causation. Rather than deal with the district court’s rulings head on, Petitioners claimed on appeal for the first time that Respondents sought to conceal that Mylan’s “seemingly lucrative business model (upon which its valuation was based) was unsustainable, resting in material part on a conspiracy that could be broken up by law enforcement or fall apart on its own at any time”. (Appeal Op. Br. 57.) But that was not the theory Petitioners presented to the district court; it did not correlate to the disclosures Petitioners identified; and it was incompatible with the undisputed evidence, *e.g.*, Petitioners have not shown the DOJ Generic Pricing Investigation has resulted in any action involving Mylan or any of its employees or any damage to Mylan’s business.

reporting on the DOJ Generic Pricing Investigation into generic drug companies, including Mylan. As the district court held, however, the article did not disclose “anything ‘new’”; it merely repackaged existing information (as confirmed by Petitioners’ own evidence). (App. 105a.) *See In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 514 (2d Cir. 2010) (holding that “[t]he securities laws require disclosure that is adequate to allow investors to make judgments about a company’s intrinsic value. Firms are not required . . . to speculate about distant, ambiguous, and perhaps idiosyncratic reactions by the press” to escape 10b-5 liability).⁶

Petitioners did not dispute that the fact “Mylan was a target of the [DOJ] investigation” had been “disclosed”, at least, on December 4, 2015, February 16, 2016, May 3, 2016, and August 9, 2016, “all well before the *Bloomberg* article was published” on November 3, 2016. (App. 105a; A-299-300 ¶¶ 1109-12.) Instead, they argued that the *Bloomberg* article revealed “that [the] scope of the investigation had increased” and that DOJ was considering charges. (Appeal Op. Br. 58.) But the article revealed nothing new about Mylan; instead, it referred to the DOJ Generic Pricing Investigation expanding to cover additional companies and additional drugs unconnected

6. A “generalized investor reaction of concern causing a temporary share price decline . . . is far too tenuously connected . . . to the [challenged] transaction[s] to support liability”. *In re Omnicom*, 597 F.3d at 514. A holding “otherwise would expose companies . . . to expansive potential liabilities for events later alleged to be frauds, the facts of which were known to the investing public at the time but did not affect share price, and thus did no damage at that time to investors”. *Id.*

to Mylan or its personnel. (CA31 ¶ 101.)⁷ Petitioners' assertion that investors "reasonably viewed the news that the investigation was heading towards indictments, and had expanded in scope, as showing that the risk to Mylan was materially greater than previously revealed" was pure speculation (Appeal Op. Br. 58). DOJ never brought any charges against Mylan. Moreover, Petitioners failed to isolate the effect of the allegedly corrective information on Mylan's stock price from that of the negative reporting on the investigation's expansion. (*Id.* 58 n.36.)

January 11, 2017. Petitioners also sought to show loss causation from remarks by President-elect Trump at a press conference where he called for changes to the drug industry's pricing practices. Petitioners argued the remarks reflected the materialization of a concealed risk of "government scrutiny". (Appeal Op. Br. 59.) But they mistakenly asserted that "[t]he only reason the District Court gave for rejecting [their] proof was that President Trump did not single out *generic* drugs or reference Mylan or any of its drugs by name". (*Id.*) In fact, the district court also rejected Petitioners' contention because regulatory scrutiny was already known to the market, such that Mr. Trump's "statements are parallel to similar posturing by politicians that has been rejected in this district as a sufficient means by which to survive summary judgment". (App. 104a.) Having ignored the point, Petitioners waived any challenge to this ruling. *Casciani v. Nesbitt*, 392 F. App'x 887, 889 (2d Cir. 2010).

7. Citations to the Confidential Joint Appendix filed in the Appeal below are designated "CA--" with appropriate page references.

Even if the district court had focused solely on the fact that Mr. Trump did not single out *generic* drugs or reference Mylan or any of its drugs by name, the district court got it exactly right. Mr. Trump had long criticized pharmaceutical pricing, and his remarks simply repeated the criticisms he made at a rally on May 1, 2016. (A-298-299 ¶ 1106.) The market was well aware of the specific risk of mounting political scrutiny over drug pricing in the lead-up to the 2016 election long before this alleged disclosure. (A-298 ¶¶ 1104-05.) Petitioners asserted that “the market was reacting to *Mylan’s* response to the comments” and not to Mr. Trump’s posturing. (Appeal Op. Br. 59.) But that argument failed because it lacked evidentiary support and did nothing to: (1) establish that the risk that caused the alleged loss was within the zone of risk concealed by the alleged misrepresentation; or (2) disaggregate the alleged declines.

October 31, 2017. Petitioners point to a proposed amended complaint filed by the attorneys general of multiple states (“AGs”) in a civil antitrust lawsuit against many generic drug companies, including Mylan. But as the district court held, Petitioners failed to establish loss causation for three independent reasons: (1) the AGs’ amended complaint did not adduce new information showing a connection between anything Mylan said and new facts; (2) Petitioners failed to disaggregate losses caused by an earlier AG complaint; and (3) “to the extent that the amended AG complaint disclosed new information, it was new information that [the district court had] already dismissed in this case”. (App. 107a-108a.) On appeal, Petitioners made no mention of the district court’s second and third points, which necessarily foreclosed their loss-causation argument as to the AGs’ amended complaint.

Petitioners did argue that the amended complaint “newly implicated Mylan’s President Respondent Malik by name in the Doxy DR scheme”. (Appeal Op. Br. 59-60.) However, Petitioners did not dispute that the AGs had previously disclosed (no later than December 2016) the alleged involvement of an unnamed Mylan executive in alleged antitrust misconduct. (A-301-302 ¶¶ 1115-18.) Petitioners argued that the district court overlooked evidence that it was the disclosure of Mr. Malik’s name that moved Mylan’s stock price but offered no supporting evidence. And even if they had, Petitioners failed to disaggregate the information about Malik from other information contained in the amended complaint. Indeed, Petitioners had previously argued that the “breadth and ongoing nature of the investigation” was “important revelatory information” contained in the amended complaint, and Petitioners’ expert attributed the stock price decline to both the expanded breadth of the investigation and the revelation of Malik’s involvement. (Class Representatives’ Statement Pursuant to Local Civil Rule 56.1 ¶ 2318; CA-34 ¶ 121.)

May 13, 2019. Finally, Petitioners pointed to disclosures on May 10, 2019 regarding a State AG’s announcement that they were filing a new lawsuit against 20 companies and 15 individuals, including Mylan and Mr. Nesta (an Individual Defendant), and including additional drugs. (Appeal Op. Br. 60.) The district court correctly found the disclosures insufficient to establish loss causation because: (1) the “lawsuit exclusively concerned drugs that this Court ha[d] already rejected in the context of this litigation” and (2) “there has been no proof adduced that the risk materialized and that [Respondents] knew or should have known what that risk was (here, uncharged

antitrust allegations)”. (App. 109a.) On appeal, Petitioners addressed only part of the district court’s ruling, leaving dispositive elements unchallenged.

In any case, none of Petitioners’ assertions undermined the district court’s decision. Petitioners argued the district court did not dismiss Petitioners’ allegations regarding Levothyroxine (Appeal Op. Br. 60-61), but they ignored the fact that the drug was already at issue in lawsuits making similar allegations, which Petitioners made no effort to disaggregate. Petitioners asserted “the expanded scope of the investigation and the extensive participation of [Respondent] Nesta in the scheme made the prospect that Mylan would face penalties and regulatory scrutiny more likely”. (*Id.*) But there was no evidence of that, and neither Mylan nor Mr. Nesta was criminally charged or required to pay any penalties concerning generic drug pricing. Petitioners argued the district court “erred in limiting [their] proof to evidence directly relating to 21 specific drugs” (*id.*), but that argument failed for multiple reasons, including that Petitioners offered no evidence of collusion as to any drug. And although Petitioners asserted that “disaggregation between drugs is particularly inappropriate because the losses largely represented general reputational harm” (*id.*), they presented no legal or factual support for that assertion.

Petitioners’ arguments, and Respondents’ rebuttals, were discussed at length during oral argument. And in its summary order, the Second Circuit agreed with the district court’s overall finding that Petitioners “failed to disaggregate the losses caused by Mylan’s alleged agreements to allocate markets and fix prices of specific generic drugs from losses caused by negative news

relating to Mylan, generic drugs, and antitrust generally”. (App. 6a.) As to each of the alleged disclosure events, the Second Circuit concluded that none of the disclosures could support loss causation. According to the Second Circuit, the November 3, 2016 disclosure “was merely a ‘negative characterization of already-public information’ and could not support loss causation, even if a ‘generalized investor reaction of concern caus[ed] a temporary share price decline.’” (*Id.*) (quoting *In re Omnicom*, 597 F.3d 501, 512-14.) And, for the other alleged disclosures, the “events revealed little, if any, new information about Mylan, and ‘it was essential for [Petitioners] to disaggregate new effects and the effects of a new characterization of already filed documents.’” (*Id.* at 7a (quoting *In re Mylan N.V. Sec. Litig.*, 666 F. Supp. 3d 266, 328 (S.D.N.Y. 2023).)

III. PETITIONERS MISSTATE THE IMPLICATIONS OF THE SECOND CIRCUIT’S DECISION AND THE NEED FOR FURTHER REVIEW

Finally, and despite Petitioners’ rhetoric, the Second Circuit’s decision is not one that has “far-reaching and highly problematic implications”. (Br. 21-22.)

First, the Second Circuit acted by summary order. As the Second Circuit’s local rules explain, “[r]ulings by summary order do not have precedential effect”. *See* Local Rule 32.1.1(a). Therefore, even if Petitioners’ claims of error were true (and they are not), the implications of the Second Circuit’s decision are quite limited.

Second, nothing in the Second Circuit’s decision would allow district courts to ignore claims by plaintiffs or any other party. (Br. 21.) There is no holding or dicta for that

point anywhere in the decision. On the contrary, both the district court and Second Circuit carefully considered Petitioners' claims and expressly explained why they dismissed them. Petitioners' point is especially misplaced where the district court permitted them to submit a brief and Rule 56.1 contentions (excluding exhibits) in excess of 1,300 pages.

Third, nothing in the Second Circuit's decision would render proof of loss causation impossible in securities cases. (*Id.* 22.) The decision did not turn on a change in the prevailing standard; it turned on Petitioners' failure to meet that standard by electing not to disaggregate. That this was a question of evidence and not law is highlighted by the district court's motion to dismiss ruling, in which it stated that, at the motion to dismiss stage, Petitioners "[had] sufficiently pleaded loss causation", but "defer[red] questions about the robustness of [Petitioners'] selection of corrective disclosures to a later stage of litigation, after the aid of discovery". *In re Mylan N.V. Sec. Litig.*, No. 16-CV-7926 (JPO), 2020 WL 1673811, at *6 (S.D.N.Y. Apr. 6, 2020). Despite extensive discovery, Petitioners were unable to show that those alleged disclosures caused the harm they claimed occurred. The disagreement about factual findings, for which this Court "rarely grant[s]" review. Sup. Ct. R. 10.

Fourth, there is nothing unjust about the Second Circuit's decision. The generic pricing investigations to which Petitioners refer resulted in no actions involving Respondents. And the settlements with DOJ and the Securities Exchange Commission included MDRP claims different from those at issue here and did not include any admissions of wrongdoing. That Petitioners claimed damages in this case, and pointed to other

cases involving other defendants that resulted in guilty pleas and settlements is irrelevant. Petitioners failed to establish any basis for damages here. The only injustice in this case is that Petitioners have forced Respondents to defend baseless claims for more than seven years and at great expense.

Fifth, none of the reasons for review offered by Petitioners survives scrutiny. This is not a case in which the Second Circuit “decided a question of federal law that has not been, but should be, settled by this Court”. (Br. 7 (quoting Sup. Ct. R. 10(c)).) It is not a case in which the Second Circuit “so far departed from the accepted and usual course of judicial proceedings, or sanctioned such a departure by a lower court, as to call for an exercise of this Court’s supervisory power”. (*Id.* (quoting Sup. Ct. R. 10(a)).) And it is not a case in which the Second Circuit “decided an important federal question in a way that conflicts with relevant decisions of this Court”. (*Id.* (quoting Sup. R. 10(c)).) Nothing in Petitioners’ brief in any way supports the characterization of this case in these ways. The Second Circuit rightly rejected Petitioners’ claims.

CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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