No. 12-1457

IN THE

Supreme Court of the United States

AMAG PHARMACEUTICALS, INC.; BRIAN J.G. PEREIRA, M.D.; DAVID A. ARKOWITZ; JOSEPH V. BONVENTRE, M.D.; MICHAEL NARACHI; ROBERT J. PEREZ; LESLEY RUSSELL, M.D.; DAVEY S. SCOON; RON ZWANZIGER; MORGAN STANLEY & CO. INCORPORATED; J.P. MORGAN SECURITIES LLC.; GOLDMAN, SACHS & CO.; LEERINK SWANN LLC; ROBERT W. BAIRD & CO. INCORPORATED; CANACCORD GENUITY INC.,

Petitioners,

v.

SILVERSTRAND INVESTMENTS; BRIARWOOD INVESTMENTS, INC.; SAFRON CAPITAL CORPORATION, on behalf of themselves and all others similarly situated,

Respondents.

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

BRIEF IN OPPOSITION

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August 16, 2013

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CORPORATE DISCLOSURE STATEMENT

Silverstrand Investments, Briarwood Investments, Inc., and Safron Capital Corporation ("Respondents") have no parent corporations. No publicly-held corporation owns 10% or more of the stock of any Respondent.

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Respondents respectfully request that this Court deny Petitioners' request for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case, *Silverstrand Investments et al. v. AMAG Pharmaceuticals, Inc. et al.*, No. 11-2063, which followed well settled practice and did not conflict with any circuit court or Supreme Court decision.[1]

INTRODUCTION

Petitioners have presented no "compelling reason" for this Court to grant their Petition for a Writ of Certiorari ("Petition"). *See* Sup. Ct. R. 10. The touchstone of the Petition is a purported conflict between the First Circuit's opinion below (the "Opinion") and decisions of five other Circuits pertaining to liability to investors for violations of Section 11 of the Securities Act of 1933 ("Securities Act"), 15 U.S.C. § 77k(a), premised on violations of Items 303 and 503 of Regulation S-K, 17 C.F.R. § 229.303(a)(3)(ii) and 17 C.F.R. § 229.503(c). No such conflict exists.

Under Section 11, Congress granted investors an express right to recover for violations of the disclosure requirements of the Securities Act, including for

1. The 'AMAG Petitioners' are comprised of AMAG Pharmaceuticals, Inc. ("AMAG" or the "Company"), the Chief Executive Officer, Brian J.G. Pereira, the Chief Financial Officer, David A. Arkowitz, and directors Joseph V. Bonventre, Michael Narachi, Robert J. Perez, Lesley Russell, Davey S. Scoon, and Ron Zwanziger. The "Underwriter Petitioners" are comprised of Morgan Stanley & Co. Incorporated, J.P. Morgan Securities Inc., Goldman, Sachs & Co., Inc., Leerink Swann LLC, Robert W. Baird Co. Incorporated and Canaccord Genuity Inc. The AMAG Petitioners and the Underwriter Petitioners will collectively be referred to as "Petitioners."

violations of Items 303 and 503 of Regulation S-K. As is relevant here, Items 303 and 503 of Regulation S-K instruct registrants to describe or discuss in their registration statement or other Offering Documents "… any known trends or uncertainties that have had or that the registrant reasonably expects will have a ***material*** favorable or unfavorable impact on net sales or revenues," 17 C.F.R. § 229.303(a)(3)(ii) (emphasis added), and "… the most significant factors that make the offering speculative or risky." 17 C.F.R. § 229.503(c).

The First Circuit found that Respondents stated Section 11 claims premised on violation of Items 303 and 503 of Regulation S-K because Petitioners did not disclose 23 serious adverse event ("SAE") reports concerning the Company's (*i.e.*, AMAG's) make-or-break drug, Feraheme. App. 3-4.[2] In making this finding, the First Circuit performed a *de novo*, detailed and factbound analysis of the materiality of the 23 SAE reports. App. 14. The First Circuit analyzed the materiality of the 23 SAE reports in line with relevant precedents, as well as the well-accepted meaning of the statutory language.

The First Circuit did not rely upon *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988), but nonetheless performed a materiality analysis that shows that Petitioner's non-disclosure of the 23 SAE reports significantly altered the "total mix" of information available to investors, thereby satisfying the test set out in *Basic*. Taking as true a list of seven factual allegations

2. The Appendix for Plaintiffs-Appellants filed in the First Circuit will be cited as "A ___." The Appendix to the Petition for Writ of Certiorari will be cited as "App. ___."

that set forth the source, content and context of the 23 SAE reports, the First Circuit found that investors would have been "less likely" to invest in the Company if they knew of the death, two life-threatening reactions and 14 other hospitalizations that were described in the SAEs and not disclosed to investors before the Offering. App. 19.

In this Section 11 case, the First Circuit did not rely upon *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), noting that *Matrixx* "addressed claims of omissions under § 10(b) of the Securities and Exchange Act of 1934, which imposes completely different exigencies than those of Items 303 and 503." App. 24 n. 9. In short, for the implied right of action under Section 10(b), plaintiffs must plead more elements than they must plead for the express right of action under Section 11. For example, scienter and reliance are elements of a Section 10(b) claim but not of a Section 11 claim. App. 15 (citing *In re Morgan Stanley Info. Fund Secs. Litig.*, 592 F.3d 347, 359 (2d Cir. 2010) and *Glassman v. Computervision Corp.*, 90 F.3d 617, 628 n. 13 (1st Cir. 1996).

Even without relying upon *Matrixx*, the First Circuit acted in line with *Matrixx* and considered the source, content and context of the SAEs to evaluate whether or not they were material. *See* App. 18-25. The First Circuit employed the relevant holdings from *Basic* and *Matrixx* to determine the materiality of the 23 SAE reports. The First Circuit permitted the Section 11 claim to proceed after finding that the omitted information was indeed material.

The materiality analysis that the First Circuit performed places it in line with relevant precedent from

the five Circuits with which Petitioners claim there is a conflict (the Second, Third, Fifth, Eighth and Eleventh Circuits). Petitioners claim that the First Circuit permitted a Section 11 claim "to proceed regardless of whether the information allegedly omitted was material under *Basic* and *Matrixx*". Pet. at 5. To the contrary, the analysis conducted by the First Circuit in evaluating the materiality of the 23 SAE reports more than satisfies the tests and standards stated in *Basic* and *Matrixx*.

Moreover, even if Petitioners were able to demonstrate that the First Circuit should have explicitly relied upon *Basic*, 485 U.S. at 232, via citation and quotation of its "total mix" shorthand, the finding that Respondents sufficiently alleged violations of Section 11 would not change because the First Circuit analyzed the materiality of the omitted information and found the information to be material. In the same vein, even if Petitioners could demonstrate that the First Circuit should not have distinguished *Matrixx Initiatives, Inc.*, 131 S. Ct. at 1309 as a Section 10(b) case with "different exigencies" from a Section 11 case, the materiality analysis and the result would not change because the First Circuit analyzed the source, content and context of the 23 SAE reports. Moreover, in its analysis, the First Circuit drew fact-based inferences about the significance of the SAEs in line with *Matrixx* – without affording inferences of scientific or medical "causation" which Petitioners mistakenly argue are impermissible under *Matrixx*. Accordingly, the question presented in the Petition is immaterial to the outcome of the case.

STATEMENT OF THE CASE

I. NATURE OF THE CASE

Respondents Silverstrand Investments, Briarwood Investments, Inc. and Safron Capital Corporation, the court-appointed Lead Plaintiffs in this putative class action, have asserted claims for damages against AMAG, its Chief Executive Officer and its Chief Financial Officer as well as its directors, and certain underwriters pursuant to Sections 11, 12(a)(2) and 15 of the Securities Act, on behalf of a putative class of purchasers of the common stock of AMAG pursuant or traceable to a secondary offering held on January 21, 2010. The district court dismissed the claims.[3] The First Circuit affirmed in part and reversed in part, permitting the claims to proceed. The First Circuit also denied a petition for panel rehearing and rehearing *en banc*.

II. RELEVANT FACTUAL BACKGROUND

A. Feraheme and Its Competitor

Feraheme is a powerful intravenous iron-replacement drug that rapidly administers a high quantity of iron directly into the bloodstream. App. 60 (SAC ¶2). The drug is marketed by AMAG, a small biopharmaceutical company that markets only two products, with Feraheme accounting for 97.5% of AMAG's revenues during the time

3. The Memorandum and Order is reproduced in Appendix B of the Petition and is also available at *Silverstrand Investments v. AMAG Pharmaceuticals, Inc.*, No. 10-10470-NMG, 2011 U.S. Dist. LEXIS 90166 (D. Mass. Aug. 11, 2011).

period relevant to this action. A 422; A 425, 426 (AMAG Form 8-K filed Oct. 29, 2009 at 1 (Skovron Decl. Ex. 4); AMAG Form 8-K filed Mar. 1, 2010 at 2 (Skovron Decl. Ex. 5)).

Feraheme is narrowly indicated and may only be prescribed for the treatment of iron-deficiency anemia in adult patients with chronic kidney disease. App. 60-61 (SAC ¶3).

Feraheme's primary market competitor is Venofer® ("Venofer"), which is also an intravenous iron-replacement drug and has the same indication as Feraheme. Feraheme and Venofer, along with a third similar drug, Ferrlecit® ("Ferrlecit"), provide essentially the same therapeutic benefit to patients; however the supposed benefit of Feraheme is that it can be administered at a faster rate, and in higher dosages. App. 75 (SAC ¶56). At the time of Feraheme's entry onto the market, Venofer had been on the market for over ten years, without any major safety concerns. App. 113-114 55 (SAC ¶109). According to analysts, clinicians' experience with Venofer had been "excellent." *Id.*

B. The Relevant Market

To increase the use of Feraheme, and in consideration of its limited indication, AMAG marketed the drug primarily to nephrologists and nephrology clinics, a relatively small, highly specialized segment of the medical community. *See* App. 119 (SAC ¶113)). As the AMAG Petitioners acknowledged, the nephrology community was "close-knit." App. 119 (SAC ¶113).

C. Nephrologists Changed Their Prescribing Practices Due to Safety Concerns Arising From Serious Adverse Events Linked to Feraheme, Materially Impacting AMAG's Business

When Feraheme was introduced to the market on June 30, 2009, nephrologists were particularly focused on adverse events resulting from the drug's use because the drug was relatively untested, and there was already an established, safe alternative in Venofer, as well as Ferrlecit. The heightened concern and increased scrutiny of the nephrology community is evidenced by an immediate decline in the use of Feraheme after safety concerns arose from post-marketing serious adverse events linked to use of the drug.

As conceded by AMAG's chief commercial officer during an earnings call attended by both the Company's CEO and its CFO on October 28, 2010, "when nephrologists have an experience, a bad experience and maybe have not had a significant experience up to that point in time using a relatively new product, they become concerned and in several cases clinics *stopped using Feraheme and moved [on] to other products*." App. 119 (SAC ¶113) (emphasis added). The "immediate impact" on AMAG's financials due to safety concerns arising from the post-marketing SAEs was acknowledged by the Company, which further stated that there were "specific examples" where the safety of Feraheme had "*played a role in impacting the business in the third quarter . . .*" App. 120 (SAC ¶113) (emphasis added).

D. Feraheme Was Linked to Serious Adverse Events in Clinical Trials, Which Impacted the FDA's Approval of the Drug

During clinical trials of Feraheme, a number of serious adverse events occurred following administration of the drug at its indicated dosages.[4] App. 76 (SAC ¶57). Additionally, at least one patient suffered an anaphylactic[5] reaction during clinical trials, which was a cause for concern for the FDA during the drug approval process. App. 61 (SAC ¶5). Anaphylaxis is a serious adverse event because it can result in death. App. 76 (SAC ¶58). FDA inspectors discovered that the Company had "inconsistently and inaccurately" reported these adverse events. App. 70 (SAC ¶60). Specifically, as set forth in its October 17, 2008 letter to AMAG, the FDA stated:

> The inspectors determined that adverse events, including serious adverse events, were not consistently reported. . . . Additionally, drug disposition records were inaccurate for four subjects and our inspectional team

4. "The FDA defines an 'adverse drug experience' as '[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related.'" *Matrixx*, 131 S. Ct. at 1319 n.5 (quoting 21 C.F.R. § 314.80(a) (2010)).

5. Anaphylaxis is a life-threatening whole-body allergic reaction to a drug or allergen. App. 76 (SAC ¶58). For example, anaphylaxis may result from a severe allergy to bee venom or peanuts. Id. Within seconds or minutes of exposure to the drug or allergen, the immune system releases a flood of chemicals that can cause the body to go into shock, and causes, among other things, a sudden drop in blood pressure (hypotension) and a narrowing of airways that blocks normal breathing. *Id.*

> recommended elimination of the clinical data from these four subjects. . . . .

Id. In light of the Company's inaccurate reporting of serious adverse events, along with the occurrence of one anaphylactic reaction in a patient, the FDA twice declined to approve Feraheme. App. 76-77 (SAC ¶¶ 58-61).

E. AMAG Offered Its Stock to Investors But Failed to Disclose Post-Marketing Adverse Event Reports, Including Two Cases of Life Threatening Anaphylaxis And One Death, Linked to Feraheme

On January 21, 2010, AMAG conducted a secondary offering of 3.6 million shares at $48.25 per share, netting the Company proceeds of approximately $173.7 million (the "Offering"). However, in the Registration Statement dated January 21, 2010 filed on Form S-3 and the Prospectus incorporated therein (the "Offering Documents"), Petitioners did not disclose the occurrence of (1) twenty-three serious adverse events, (2) two cases of anaphylaxis, and (3) a death, all of which had occurred after FDA approval on June 30, 2009 but prior to the Offering (collectively, the "Post Marketing Events"), although the Company explicitly stated that no cases of anaphylaxis and no deaths attributable to Feraheme had occurred during clinical trials. App. 93-94 (SAC ¶86) ("Across all phases of the Feraheme clinical development program with approximately 2,800 total administered doses of Feraheme, there were no cases of anaphylaxis and no deaths determined by the investigator to be drug-related.").[6]

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6. As reported in the Company's Form 10-K for the fiscal year ended December 31, 2008 at 6, which was expressly incorporated by reference in the Offering Documents. App. 90 (SAC ¶85).

The two post-marketing cases of anaphylaxis had occurred in women ages 38 and 51, and had been reported to the Company and FDA as "life-threatening" and requiring hospitalization. They were reported to the Company in October and November 2009, *i.e.*, prior to the Offering. App. 80 (SAC ¶71). Also, a post-marketing, pre-Offering death had been reported by a physician identifying Feraheme as the "Primary Suspect" in the fatality. App. 78 (SAC ¶64). The SAC describes these events in further detail. App. 78, 79-80 (SAC ¶¶64, 68, 71).

It is clearly alleged, and undisputed that AMAG received the reports of the Post Marketing Events between June 30, 2009, the date that Feraheme was approved by the FDA, and January 21, 2010, the date of the Offering, App. 78 33, 80 (SAC ¶¶64, 65, 71). Nonetheless, the Offering Documents did not disclose the existence of any of the Post Marketing Events. App. 78, 81 (SAC ¶¶65, 73).

In the Offering Documents, AMAG warned only that "[s]ignificant safety or drug interaction problems could arise with respect to Feraheme even after FDA approval . . ." and "New safety or drug interaction issues may arise as Feraheme is used over longer periods of time . . ." App. 99-100 (SAC ¶94). The Company also alluded to "[t]he development of unanticipated adverse reactions to Feraheme resulting in safety concerns among prescribers." App. 97-98 (SAC ¶91). AMAG did not disclose that these risks had already materialized.

F. AMAG's Stock Price Drops Significantly on Reports of "Several" Anaphylactic Reactions Linked to Feraheme

On February 4, 2010, just two weeks after the Offering, an analyst report issued by Summer Street revealed to investors that "several" patients using Feraheme during the post-marketing period had anaphylactic reactions to the drug that resulted in hospitalization, and that at least one patient died. That day, the price per share of AMAG stock fell $7.13, or 15.7%, to $38.12, from its previous close of $45.25, on near record volume.

The next day, on February 5, 2010, the Company issued a press release revealing that as of February 5th, there had been forty (40) serious adverse events linked to Feraheme since the drug had received FDA approval. App. 107-108 (SAC ¶103). This disclosure was the first to quantify the number of serious adverse events that had occurred post-marketing. In the press release, the Company maintained that the forty SAEs were not statistically significant, and were being reported at a rate consistent with the safety rate contained in the drug's package insert.

The next business day, on February 8, 2010, analysts at Summer Street issued a follow-up report entitled "Feraheme Safety Update Raises More Questions than Answers." App. 112-113 (SAC ¶109). The report questioned the Company's claim that the actual rate of reported post-marketing serious adverse events was consistent with the rate disclosed on the drug's packaging insert as required by the FDA. App. 112-113 (SAC ¶109). As noted by the Summer Street report, AMAG previously (and

in its package insert) calculated the SAE rate on a "per patient" basis. App. 112-113 (SAC ¶109). In calculating the post-marketing SAE report rate, however, the Company calculated the rate based on each dose administered, which at minimum, approximately doubled the denominator and necessarily resulted in a significantly lower SAE rate, considering that the drug is indicated for use in at least two doses, and as many as four doses, per treatment, and that adverse events are far more likely to occur upon administration of the first dose. App. 111 (SAC ¶106), App. 111-112 (SAC ¶107), App. 112 (SAC ¶108), App. 112-113 (SAC ¶109) (quoting the Summer Street analyst report: "The rate we really want to know is the number of SAEs/ the number of patients.")

The Summer Street report also noted Feraheme's poor safety record in comparison to Venofer:

> AMAG's safety update reveals 40 SAEs in 35K patient exposures. Their calculated rate is 0.1% and the label's is 0.2%. However the two rates are calculated differently: 3/1726 patients vs 40/35,000 exposures, ***thus is not a valid comparison***. Exposures count patients that safely received multiple Feraheme doses. ***The rate we really want to know is the number of SAEs/ the number of patients*** . . . .
>
> ***Feraheme's perceived safety profile is key***. . . . . ***Our conversations with clinicians reveal their experience with Venofer is excellent: we have heard of one SAE and one death in 10 years of Venefor [sic] use***. It is in best interest of AMAG and Feraheme to be accurate and proactive in

> providing details surrounding the SAEs to the medical community.

App. 112-113 (SAC ¶109) (emphases added).

The February 8, 2010 Summer Street report affirmed the market's understanding of the significant commercial risks and uncertainties presented by the post-marketing SAEs. Accordingly, the day of the report, the price per share of AMAG stock fell another $1.10, or approximately 3%, on unusually heavy trading volume. App. 115 (SAC ¶110).

In total, between January 21, 2010, the day the Offering commenced, and February 8, 2010, the price per share of AMAG stock fell $11.58, or 24%. *See* App. 62 (SAC ¶8) (Offering price on January 21, 2010 of $48.25 per share) and compare with App. 115 (SAC ¶110) (closing price on February 5, 2010 of $36.67 per share).

G. The FDA Forces AMAG to Re-Label Feraheme with a Warning Regarding Anaphylaxis and SAEs

In or around August 2010, the FDA created a Tracked Safety Issue for Feraheme as a result of the post-marketing SAEs that occurred. App. 82 (SAC ¶76). On September 23, 2010, the FDA met with several high level officers of AMAG, including CEO Pereira. App. 82-83 (SAC ¶¶76, 77); A 415 (FDA Meeting Minutes for September 23, 2010 (Skovron Decl. Ex. 2)). The FDA rejected AMAG's arguments that the post-marketing SAEs were consistent with the rate reported during clinical trials:

> [AMAG]: Does the Agency agree that the reporting rate of cardiovascular serious adverse events is consistent with that observed in clinical trials . . . ?
>
> FDA Response: ***We disagree. Your comparison of the adverse event rates between the clinical trials and the spontaneous post-marketing reports is inappropriate*** . . . . The majority of serious and unlisted adverse events including cardiac events from spontaneous post-marketing reports occurred during, immediately, or shortly after Feraheme administration.

A 416 (Skovron Decl. Ex. 2 at 3) (emphasis added.)

Ultimately, the FDA took the extraordinary measure of requiring that Feraheme be relabeled to include specific warnings regarding the occurrence of anaphylaxis and other serious adverse events associated with Feraheme use. App. 85-86 (SAC ¶79). The fact of the relabeling showed yet again the significance of the post-marketing SAEs, which were already undermining the viability of AMAG and Feraheme.

Petitioners' failure to disclose the true efficacy and risk profile of Feraheme in the Offering Documents, particularly the Post Marketing Events, is supported by an FDA "Warning Letter" sent to AMAG on October 18, 2010 regarding the same information being omitted from the Company's website. The October 18, 2010 Warning Letter noted that "[t]he webpages [for Feraheme] present numerous efficacy claims for [] Feraheme, but

fail to communicate any of the risks associated with the drugs . . . . By omitting the most serious and frequently occurring risks associated with these drugs, the webpages misleadingly suggest that [] Feraheme [is] safer than has been demonstrated and therefore place the public at risk."

The FDA further stated that the website links to the Feraheme package insert that are "buried in the second sentence of the Feraheme webpage . . . do not mitigate the complete omission of risk information . . ." and that the Company's "statements thus misbrand Feraheme . . . ." App. 87-88 (SAC ¶81). The FDA determined that the Company had violated the FDCA, 21 U.S.C. §§352(a), (f)(1) & (n), and applicable FDA regulations. App. 89 (SAC ¶¶82, 83).

H. AMAG's Revenues Are Dependent Upon Feraheme's Commercial Success

By failing to disclose the occurrence of the Post Marketing Events, Petitioners did not disclose a risk to at least a substantial portion of 97.5% of its revenues.[7] App. 61 (SAC ¶4) (97.5% of revenues derived from Feraheme). As stated in the Prospectus:

> Our ability to generate future revenues is solely dependent on our successful commercialization and development of Feraheme . . . . Accordingly, if we are unable to generate sufficient revenues from sales of Feraheme, we may never be

7. Gastromark is the other drug marketed by AMAG during the time period relevant to this action. It admittedly did not contribute materially to AMAG's revenues. App. 61 (SAC ¶4).

> profitable, our financial condition will be materially adversely affected, and our business prospects will be limited.

Id.

At the core of this action, Respondents allege that the Offering Documents did not disclose the material Post Marketing Events that occurred between the time that Feraheme was approved by the FDA on June 30, 2009 and the date of the Offering on January 21, 2010. As the First Circuit found, the Post Marketing Events should have been disclosed in light of the contextual facts pled in the SAC concerning among other things the serious nature of the Post Marketing Events, which included cases of life-threatening shock and death , the availability of a safe alternative, and the undisputed importance of Feraheme to the financial results of AMAG.

Respondents more than amply alleged that the Post Marketing Events were material because of the impact they would – and did – have on Feraheme's commercial prospects, independent of any "statistical significance" of the SAEs or any action by the FDA. Indeed, the materiality of the SAEs was confirmed by the 24% drop in AMAG's stock price after the information was revealed to the market and the effect these events had on the nephrology community. Furthermore, the materiality of the information was reaffirmed when the FDA later required AMAG to issue a new safety warning on Feraheme's label, ensuring that the commercial prospects of Feraheme, and with it, AMAG's stock price, never improved. Respondents' claim that the Post Marketing

Events were material information to investors and that Petitioners had a duty to disclose such information under Section 11 are well-pled and the First Circuit was correct to allow the case to proceed.

OBJECTION TO CONSIDERATION OF THE QUESTION PRESENTED IN THE PETITION BASED ON WHAT OCCURRED IN THE PROCEEDINGS BELOW

Respondent objects to consideration of the question presented in the Petition "based on what occurred in the proceedings below." Sup. Ct. R. 15.2. Petitioners pose their question presented as an inquiry into whether, in Section 11 claims based on an alleged violation of SEC regulations, plaintiffs must "plead facts establishing that the allegedly omitted information is material under *Basic* and *Matrixx*." *See* Pet. at i. But that question is animated by Petitioners' incorrect contention that the First Circuit wrote "the word 'material' out of Section 11" and eliminated "the materiality requirement in Section 11 claims premised on violations of SEC regulations." *See* Pet. at 35, 36. Neither the district court nor the First Circuit wrote materiality out of Section 11, and this Court's consideration of the Petition therefore is not warranted.

REASONS FOR DENYING THE PETITION

I. THE FIRST CIRCUIT EVALUATED THE MATERIALITY OF THE OMITTED INFORMATION USING THE RELEVANT LEGAL AUTHORITY AND FACTS

A. The First Circuit Based Its Opinion on Relevant Legal Authority That Embodies Materiality

As recognized by the First Circuit below, "Section 11 is an enforcement mechanism for the mandatory disclosure requirements of the Securities Act." App. 15, quoting *Glassman v. Computervision Corp.*, 90 F.3d 617, 623 (1st Cir.1996). "As relevant here, § 11 is triggered 'in case any part of [a] registration statement, when such part became effective ... omitted to state a ***material*** fact required to be stated therein....'" *Id.*, quoting 15 U.S.C. § 77k(a) (emphasis added). "Information is material when there is a reasonable likelihood that a reasonable investor would consider it important." *Glassman*, 90 F.3d at 632 (assessing a claim under Item 101 of Regulation S-K).

Item 303 requires the disclosure of any known trends or uncertainties that "the registrant reasonably expects will have a ***material*** ... unfavorable impact on net sales[,] revenues[,] or income from continuing operations." App. 16-17 (emphasis added), quoting 17 C.F.R. § 229.303(a)(3)(ii). To plausibly plead an Item 303 failure to disclose claim, a complaint must allege, among other things, "that the known uncertainty is 'reasonably likely to have ***material*** effects on the registrant's financial condition or results of operation.'" App. 17 (emphasis added), quoting Mgmt.'s Discussion and Analysis of Fin. Conditions and

Results of Operations, SEC Release No. 6835, 1989 WL 1092885, at *4.

B. The First Circuit Made Factbound Determinations of Materiality

Petitioners argue that the First Circuit imposed "what is, in effect, absolute strict liability to investors for the omission of information called for by Item 303 no matter how immaterial that information may be to shareholders' investment decisions." *See* Pet. at 36. That characterization does not square with the Opinion. Taking up the question of materiality *de novo*, the First Circuit performed a robust and thorough analysis of materiality before finding that the 23 SAEs were material and that Respondents sufficiently plead Petitioners violation of Section 11 premised on their violation of Item 303.

The First Circuit began its analysis with seven relevant factual allegations, concluding with the allegation that the "Offering Documents did not disclose either the death, the 'life-threatening' incidents, or the fourteen hospitalizations attributed to Feraheme." App. 18-19. Taking those factual allegations as true, the First Circuit had "no trouble drawing the reasonable inference that before the Offering AMAG knew that a death, two life-threatening reactions, and fourteen hospitalizations would have been relevant to consumers when deciding whether to use Feraheme, as opposed to another proven and safer alternative." App. 19.

The First Circuit further found that "the allegations also allow the reasonable inference that, before the Offering, AMAG knew that the 23 SAEs could have

prompted FDA action in connection with Feraheme." App. 19 ("because the FDA investigators had found no drug-related deaths as of the time of Feraheme's approval, we can reasonably infer that the FDA could have sprung into action due to a Feraheme-related death."). "Similarly, the allegations allow us to reasonably infer that FDA intervention due to the 23 SAEs would have meant trouble for AMAG." App. 19-20.

The First Circuit tied the reasonable inferences together into a succinct statement that shows its understanding of the importance to investors of the 23 SAEs that Petitioners failed to disclose to investors in their Offering Documents: "Common sense also dictates that AMAG knew that the riskier Feraheme appeared, the less attractive the drug would be as a method of treatment, and ***the less likely an investor would be to invest in AMAG***, whose profits entirely depended on Feraheme's commercial success." App. 19 (emphasis added).

C. Considering Materiality and Other Issues, the First Circuit Overturned the District Court on Item 303 "Known Trend"

Based on a faulty conclusion that the 23 post-marketing SAEs were consistent with prior disclosures from the clinical trials, the district court found that the 23 SAEs were not required to be disclosed under Item 303. App. 20. The First Circuit disagreed with the district court's factual findings on three grounds. First, the district court got the quantitative analysis wrong (due at least in part to the fact that Petitioners did not provide the district court with all of the information necessary to make accurate

computations) – there was a classic apples and oranges problem in calculating the rate of post-marketing SAEs. App. 21-22. Second, the district court improperly credited as a prior disclosure a press release that the Company made two weeks ***after*** the offering. App. 22. Third, the district court failed to grasp the qualitative significance of the 23 SAEs. At this point in its critique of the district court's finding that the 23 SAEs were not required to be disclosed, the First Circuit considered the materiality of the SAEs. As the First Circuit explained, "[l]ast but not least, ***our analysis under Items 303 and 503 cannot be limited to simple arithmetical computations***." App. 22 (emphasis added). "Item 303's disclosure obligations, like materiality under the federal securities laws' anti-fraud provisions, do not turn on restrictive mechanical or quantitative inquiries." App. 24, quoting *Panther Partners, Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 120, 122 (2d Cir. 2012) and noting *Panther's* citation to *Matrixx*.

In wrapping up its analysis, the First Circuit emphasized the allegation that, "when the Offering took place, the news that Feraheme had possibly caused a death, as well as the other serious side effects reported in the 23 SAEs, was already circulating within the medical community AMAG needed to win over ***to remain as a going concern***." App. 25 (emphasis added). There can be no doubt that undisclosed information that jeopardizes the ability of a company "to remain as a going concern" is material to investors.

II. THE ANALYSIS OF MATERIALITY SET FORTH IN THE OPINION FOLLOWED WELL SETTLED PRACTICE AND DID NOT CONFLICT WITH ANY CIRCUIT COURT OR SUPREME COURT DECISION

A. The First Circuit Is In Line With the Second Circuit

Petitioners argue that in the Second Circuit there is, in effect, a *per se* requirement in every Section 11 case premised on a violation of Item 303 for a materiality analysis under *Basic* apart from the finding of a violation of Item 303 – *i.e.*, that a court must perform a separate *Basic* "total mix" materiality analysis after finding a violation of Item 303. *See* Pet. at 24-25. Petitioners' mistaken belief that the Second Circuit imposes this requirement underpins the conflict (*i.e.*, the false conflict) that Petitioners rely upon in seeking review. As it did in *Panther Partners, Inc.*, 681 F.3d 114, the Second Circuit can and does find Section 11 liability premised on a violation of Item 303 without performing a separate analysis under *Basic*. The purported requirement that Petitioners imagine as a mandatory two-part materiality analysis in every Section 11 case premised on violations of SEC regulations does not exist; therefore, the conflict that they imagine does not exist.

In *Panther*, the Second Circuit found that defendants violated Section 11 based on "an omission in contravention of an affirmative legal disclosure obligation" that arose under Item 303 of SEC Regulation S-K. *See Panther*, 681 F.3d at 120-121. "[V]iewed in the context of Item 303's disclosure obligations," the Second Circuit found

that uncertainty surrounding an undisclosed defect issue that generated "an increasing flow of highly negative information from key customers … might reasonably be expected to have a ***material*** impact on future revenues." *Id*. at 120 (emphasis added). The Second Circuit found that the company did not fulfill its "duty to inform the investing public of the particular, factually-based uncertainties of which it was aware in the weeks leading up to the Secondary Offering." *Id.* at 122. In *Panther*, the Second Circuit found that the company "jeopardized its relationship with clients who at that time accounted for the vast majority of its revenues" and that "[i]t goes without saying that such 'known uncertainties' could ***materially*** impact revenues." *Id.* at 121-122 (emphasis added), citing *Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 722 (2d Cir. 2011). In *Panther*, the Second Circuit found that the company violated Item 303 and therefore that the company also violated Section 11 – the Second Circuit did not separately consider materiality under *Basic*.

The Second Circuit decided *Panther* in May 2012, after it decided two other cases that Petitioners rely upon for the mistaken notion that the Second Circuit requires plaintiffs to allege both a violation of Item 303 and separately to allege that the omitted information is material under *Basic*. *See* Pet. at 24-25, citing *Hutchison v. Deutsche Bank Secs. Inc.*, 647 F.3d 479, 485-89 (2d Cir. 2011) and *Litwin*, 634 F.3d at 723. *Panther* shows the opposite of what Petitioners contend to be required: the Second Circuit does not require a separate analysis of materiality under *Basic*. In *Panther*, the Second Circuit found that the company violated Item 303. *Panther* 681 F.3d at 121. But the Second Circuit did not perform a separate analysis (or any analysis) under *Basic*.

Like the Second Circuit in *Panther*, the First Circuit in the Opinion below did not perform a separate analysis of materiality under *Basic* or employ the specific mantra advocated by Petitioners in conducting its materiality analysis. Further, neither court held what Petitioners incorrectly claim is the holding of the Ninth Circuit in *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293 (9th Cir. 1998). Although Petitioners assert otherwise, the Ninth Circuit in *Steckman* did not hold that there is Section 11 liability premised on Item 303 for omissions of facts "regardless of whether those facts would significantly alter the total mix of available information." *See* Pet. at 29. The Ninth Circuit neither found liability in the *Steckman* action nor reached that conclusion – and thus the First Circuit could not have "effectively joined" that conclusion as argued by Petitioners. Instead, in *Steckman*, the Ninth Circuit found that the omitted information was neither a trend nor material, and therefore dismissed a Section 11 claim premised on Item 303. *See Steckman*, 143 F.3d at 1298. Unlike the Ninth Circuit in *Steckman*, the First Circuit found that plaintiffs sufficiently alleged Section 11 claims premised on the failure to disclose information required under Item 303 – after completing a rigorous analysis of the materiality of the omitted risks and uncertainties.

Finally, in its effort to fabricate a conflict with the Second Circuit, Petitioners offer the Summary Order (which has no precedential effect) in *Arfa* as a case that "perhaps best illustrated" the "proper analysis" as beginning with Item 303 and then proceeding to *Basic*. *See* Pet. at 25, quoting *Arfa v. Mecox Lane, Ltd.*, 504 F. App'x 14, 16 (2d Cir. 2012). But the Second Circuit in *Arfa* did not do what Petitioners describe, and the supposed

conflict with *Arfa* is illusory. In *Arfa*, the Second Circuit found the existence of a trend that could materially impact revenue but also found that the company disclosed the trend in the registration statement upon which investors brought suit. *See Arfa*, 504 F. App'x at 16. Thus, the Second Circuit in *Arfa* found that plaintiffs did not plead an Item 303 omission – because there was no omission. *Arfa* at [3-4.]. In the case below, the First Circuit found that "the allegations in the Complaint, when read in context, plausibly plead Item 303 and 503 omissions in connection with the 23 SAEs." App. 18. The First Circuit also found that "[c]ommon sense" dictated that if Petitioners had disclosed the information, an investor would have been "less likely" to invest in the Company (which is a statement of materiality). *See* App. 19.

B. The Eighth Circuit Did Not Employ the Test with Which Petitioners Claim the First Circuit Conflicted

Petitioners cite *Romine* from the Eighth Circuit as another example of what they think is a required two-part test – first for Item 303 and then for *Basic*. *See* Pet. at 26-27, quoting *Romine v. Axciom Corp.*, 296 F.3d 701, 707-08 (8th Cir. 2002). But Petitioners fail to adduce that in *Romine* the Eighth Circuit performed two separate analyses related to a customer contract for two very different purposes. For Item 303, the Eighth Circuit found that the single contract did not establish a trend. *See Romine*, 296 F.3d at 708. For this reason, there could be no Section 11 liability premised on Item 303. The Eighth Circuit then moved on to a different point: potential Section 11 liability outside of Item 303 for omitting to state a material fact required to make other statements not

misleading. That is not an Item 303 analysis (*i.e.*, it is not the second part of what Petitioners describe as a required two-part test). For this general inquiry distinct from Item 303, the Eighth Circuit concluded that the company "made no affirmative representations concerning this contract," and that disclosure was not otherwise required under *Basic*. *See Romine*, 296 F.3d at 708-09. The upshot is that *Romine* does not show that the Eighth Circuit requires a separate *Basic* analysis for Section 11 claims based on Item 303 – and thus *Romine* shows no conflict between the First and Eighth Circuits on this point.

C. The Eleventh Circuit Did Not Employ the Test with Which Petitioners Claim the First Circuit Conflicted

Petitioners cite *Oxford* from the Eleventh Circuit as another example of what they somehow see as a required two-part test. *See* Pet. at 27, citing *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1189-92 (11th Cir. 2002). But Petitioners make the same mistake with *Oxford* as they did with *Romine*. The duty to disclose may come from Item 303 ***or*** may come from the requirement to state a material fact required to make other statements not misleading. In *Oxford*, the Eleventh Circuit found that the omitted sales data was not a "trend" under Item 303. *See Oxford*, 297 F.3d at 1191-92. After completing the Item 303 analysis (and finding that the investors failed to show a duty under Item 303), the Eleventh Circuit proceeded to a different analysis entirely untethered from Item 303: whether the company triggered a different duty to disclose (apart from the duty under Item 303) by omitting sales data that was needed to make the company's statements about market acceptance not misleading. *Oxford* does not

show that the Eleventh Circuit requires a separate *Basic* analysis for Section 11 claims based on Item 303 – but that imaginary requirement is the point of law on which Petitioners mistakenly claim there is a conflict.

D. The Third and Fifth Circuits Did Not Employ the Test with Which Petitioners Claim the First Circuit Conflicted

Petitioners cite from the Third Circuit a Section 11 case that is not premised on Item 303. *See* Pet. at 27, citing *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 274 (3d Cir. 2005). Then jumping to the Fifth Circuit, Petitioners cite a Section 11 case that is premised on Item 303, but where the Court found that there was no Item 303 "trend." *See* Pet. at 27, citing *Kapps v. Torch Offshore, Inc.*, 379 F.3d 207, 215 (5th Cir. 2004). Not surprisingly given that Item 303 either was not at issue (*In re Merck*) or did not trigger a duty to disclose because there was no trend (*Kapps*), these cases neither announce nor employ any form of the "two-part" formulaic test for Section 11 claims premised on Item 303 that Petitioners advocate as a rule for the case below.

III. AN ANSWER FROM THIS COURT TO THE QUESTION PRESENTED WOULD NOT CHANGE THE OUTCOME BELOW

Petitioners argue that "the First Circuit refused to conduct a materiality analysis" under what Petitioners call the "*Basic*/*Matrixx* standard." *See* Pet. at 21, 28. As shown above, the First Circuit evaluated materiality in detail considering both quantitative and qualitative matters, including whether the omitted information was available

otherwise to investors and whether the 23 SAEs would be important to investors – *albeit* reaching fact-based conclusions with which Petitioners disagree and selecting language and structure with which Petitioners quibble. Hoping for a different outcome from the same devastating facts, Petitioners want the Court to review this case to analyze the materiality of the 23 SAEs consistent with *Basic* and *Matrixx*. That factbound analysis and drawing of fact-based inferences has already been performed by the First Circuit even if the Court did not rely upon or cite to *Basic* and *Matrixx*. Any assertion that the First Circuit's findings were erroneous – *which they were not* – would not provide a compelling reason to grant review. *See* Sup. Ct. R. 10. The only way for the Court to change the outcome below would be to revisit and overturn the factual findings and fact-based inferences made by the First Circuit on the question of the materiality to investors of the omitted information.

In seeking to revisit the First Circuit's fact determinations, Petitioners claim that the 23 SAEs were consistent with prior disclosures from the clinical trials, and thus were not material because they would not change the "total mix" of information available to investors under *Basic*. *See* Pet. at 23. The First Circuit devoted considerable attention to the question of prior disclosure, and concluded that the 23 SAEs were neither quantitatively nor qualitatively consistent with prior disclosures. *See* App. 20-25. In the same analysis, the First Circuit concluded that the allegations of the Complaint "more than suffice" to plead that the 23 SAEs were omissions under Items 303 and 503. App. 20. Following its reasoning but not citing *Basic* or quoting "total mix," the First Circuit determined that investors would have found the 23 SAEs to be important enough to have

changed their investing decisions. "AMAG knew that the riskier Feraheme appeared, the less attractive the drug would be as a method of treatment, and ***the less likely an investor would be to invest in AMAG***, whose profits entirely depended on Feraheme's commercial success." App. 19 (emphasis added). In short, there is nothing more to do or find under *Basic*.

In order to further their quest to have the First Circuit's fact determinations concerning materiality revisited, Petitioners contend that the application of what they call the materiality standards in *Matrixx* "would result in dismissal of the SAC because the mere existence of the 23 SAE reports would be insufficient to sustain a materiality finding." *See* Pet. at 34. There is no doubt that the First Circuit did not rely upon *Matrixx* to assess the SAEs. But there also can be no serious doubt that the First Circuit applied reasoning consistent with *Matrixx* to assess the SAEs. The fact that the First Circuit did not rely upon *Matrixx* does not mean that it found the "mere existence" of the SAEs to be dispositive on the issue of materiality. In a Section 10(b) case, this Court held in *Matrixx* that for SAEs to be material, their "mere existence … in and of itself" is not enough. *Matrixx Initiatives, Inc.*, 131 S. Ct at 1321. "Something more is needed, but that something more is not limited to statistical significance and can come from the source, content, and context of the reports." *Id.* (internal quotation omitted). "This contextual inquiry may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link" *Id.* In *Matrixx*, this Court instructed that SAEs are neither *per se* material nor *per se* immaterial.

The First Circuit acted in line with *Matrixx*. The First Circuit did not rely upon the "mere existence" of the SAEs, and did not find the SAEs to be *per se* material. Instead, the First Circuit considered the source, content and context of the SAEs. The source of the SAEs was "the medical community AMAG needed to win over to remain as a going concern." App. 25. The content of the SAEs was a "death, two life-threatening reactions, and fourteen hospitalizations." App. 19. The death was that of a "70–year–old patient [who] died following one 510 mg injection of Feraheme" and "the drug had been identified by the treating physician as the 'Primary Suspect' for the fatality." App. 9. The two life-threatening events were "anaphylactic reactions in two female patients with a 'life-threatening' outcome requiring hospitalization." App. 9.

The First Circuit also evaluated the context of the SAEs throughout the Opinion. Feraheme was a "make-or-break drug for AMAG's future." App. 3. "AMAG's efforts to secure FDA approval for Feraheme initially failed … due, in part, to a single occurrence of anaphylaxis among 1,726 patients exposed to the drug." App. 7. From the Complaint: "Feraheme was sold in a market dominated by well-known alternatives with proven safety and efficacy records," "AMAG's profitability entirely depended on Feraheme's commercial success," "the FDA twice declined to approve Feraheme due to safety concerns." App. 18. "If the FDA initially declined to approve Feraheme due to a single case of anaphylaxis during clinical trials, a death, two life-threatening anaphylactic reactions, and fourteen hospitalizations undoubtedly could have raised ***red flags*** with the agency." App. 19 (emphasis added). "Moreover, because the FDA investigators had found no drug-related deaths as of the time of Feraheme's approval,

we can reasonably infer that the FDA could have sprung into action due to a Feraheme-related death." *Id.* "FDA intervention due to the 23 SAEs would have meant trouble for AMAG." App. 19-20.

The First Circuit did not rely upon *Matrixx* to evaluate the SAEs; nonetheless, the First Circuit analyzed the source, content and context of the reports in reaching its conclusion that the reports were material. In short, as with *Basic*, there is nothing more to do or find under *Matrixx*.

IV. THE FIRST CIRCUIT DREW ONLY PERMISSIBLE INFERENCES; THEREFORE, THE BAD OUTCOMES THAT PETITIONERS SPECULATE MAY FLOW FROM IMPERMISSIBLE INFERENCES ARE NOT OF NATIONAL IMPORTANCE

Petitioners contend that "the First Circuit improperly afforded Respondents an inference that the 23 SAEs were all caused by *Feraheme*," and that *Matrixx* barred that inference. *See* Pet. at 31. Petitioners misunderstand *Matrixx*. In *Matrixx*, this Court rejected an automatic inference of materiality in a Section 10(b) case based on adverse event reports, but permitted (and found) an inference of materiality even where the adverse event reports might not be statistically significant for medical causation. "[A]ssessing the materiality of adverse event reports is a 'fact-specific' inquiry … that requires consideration of the source, content, and context of the reports." *Matrixx* at 1321-22, quoting *Basic* at 236. "This is not to say that statistical significance (or the lack thereof) is irrelevant—only that it is not dispositive of

every case." *Id.* "This contextual inquiry may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link." *Id.*

Even if Petitioners were correct that *Matrixx* barred an inference of scientific or medical causation (which it did not) instead of barring an automatic inference of materiality in a Section 10(b) case (which it did), Petitioners are incorrect that the First Circuit inferred causation. The First Circuit did not go that far. Instead, the First Circuit held that even if there was no statistical significance to the SAE events (*i.e.*, they were in line with prior rates), the Court was more concerned with the allegation that "when the Offering took place, the news that Feraheme had possibly caused a death, as well as other serious side effects reported in the 23 SAEs, was already circulating within the medical community AMAG needed to win over to remain as a going concern." That allegation, along with others discussed by the Court in its Opinion demonstrating the materiality of the 23 SAEs, prevented the First Circuit from concluding that Respondents failed to state plausible Section 11 claims for "omissions of Item 303 uncertainties and Item 503 risks." *See* App. 25.

The First Circuit evaluated the SAEs and their materiality consistent with how this Court proceeded in *Matrixx*. Petitioners' speculate about a long list of bad outcomes that they think might befall pharmaceutical companies and "sick people" if all SAEs (with our without causation) were automatically deemed to be material. *See*

Pet. at 31-34. But the First Circuit did not automatically deem the SAEs to be material. As such, with or without review, the pharmaceutical industry will not as a result of the Opinion, as Petitioners speculate, have to "refrain from seeking capital in the public markets" and "sick people" will not be deterred from "buying and using drugs necessary to maintain or improve their health." *See* Pet. at 31, 33. The First Circuit properly weighed the materiality of the SAE reports to investors, found that the reports under the circumstances present were material to investing decisions, and found Section 11 claims were sufficiently alleged for Petitioners' failure to disclose the reports as they were required to have done by Items 303 and 503. The Opinion does no disservice to pharmaceutical companies or the consumers who use their products, and it protects investors by ensuring that illegal non-disclosure such as that by Petitioners is a wrong that is made right. That outcome promotes confidence in the public capital markets. Employing Section 11 as Congress intended for enforcing fair disclosure and compliance with SEC regulations is a desirable outcome, and it is the outcome that will flow from the Opinion.

CONCLUSION

Petitioners have not established any compelling reasons for this Court to grant the Petition. Therefore, Respondents respectfully request that the Petition be denied.

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Respectfully submitted,

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