21-801-cv
In re: Alkermes Pub. Ltd. Co. Sec. Litig.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 7th day of December, two thousand twenty-one.

Present:

DEBRA ANN LIVINGSTON,
Chief Judge,
JOHN M. WALKER, JR.,
RICHARD C. WESLEY,
Circuit Judges.

MIDWEST OPERATING ENGINEERS PENSION TRUST FUND,

Lead Plaintiff-Appellant,

v. 21-801-cv

ALKERMES PUBLIC LIMITED COMPANY, RICHARD F. POPS, JAMES M. FRATES, ELLIOT EHRICH, BLAIR JACKSON,

Defendants-Appellees.

For Lead Plaintiff-Appellant: S. DOUGLAS BUNCH (Carol V. Gilden, Jessica (Ji Eun) Kim, and Steven J. Toll, *on the brief*), Cohen Milstein Sellers & Toll PLLC, Washington, D.C.

For Defendants-Appellees: WILLIAM M. JAY (Deborah S. Birnbach, Tucker DeVoe, and William Evans, *on the brief*), Goodwin Procter LLP, Washington, D.C.

Appeal from a judgment of the United States District Court for the Eastern District of New York (Hall, *J.*).

UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the judgment of the district court is **AFFIRMED**.

Midwest Operating Engineers Pension Trust Fund ("Midwest Operating"), on behalf of itself and other similarly situated individuals, appeals from the district court's February 26, 2021 judgment dismissing its Section 10(b) and 20(a) Securities Exchange Act of 1934 claims against Alkermes Public Limited Company ("Alkermes"), its Chief Executive Officer Richard F. Pops ("Pops"), Chief Financial Officer James M. Frates, Chief Medical Officer and Executive Vice President of Research and Development Elliot Ehrich, and Senior Vice President of Corporate Planning Blair Jackson (together, with Alkermes, the "Defendants").[1] *See In re Alkermes Pub. Ltd. Co. Sec. Litig.*, 523 F. Supp. 3d 283, 294–95 (E.D.N.Y. 2021); *see also* Fed. R. Civ. P. 12(b)(6). Midwest Operating alleges that the Defendants defrauded investors by misrepresenting the Food and Drug Administration's ("FDA") feedback on Alkermes's new drug, ALKS 5461, and its clinical trial protocols, and that absent such misrepresentations, investors would not have been surprised when the FDA publicly disclosed its concerns, or when the FDA Advisory

[1] For the purposes of this order, all facts are drawn from the complaint and the documents incorporated by reference therein.

Committee voted against approving the drug.[2] The district court dismissed Midwest Operating's Section 10(b) claim for failing to plead scienter and dismissed its Section 20(a) claim for failing to plead a requisite underlying violation of the Securities Exchange Act.[3] *In re Alkermes*, 523 F. Supp. 3d at 294–95.

We review *de novo* the district court's Rule 12(b)(6) dismissal of Midwest Operating's claims. *See CBF Industria de Gusa S/A v. AMCI Holdings, Inc.*, 850 F.3d 58, 77 (2d Cir. 2017). In doing so, we "accept all well-pleaded factual allegations in the complaint as true" and "construe all reasonable inferences" in the "light most favorable to the plaintiff." *Lynch v. City of New York*, 952 F.3d 67, 74–75 (2d Cir. 2020) (internal quotation marks and citations omitted). For the reasons set forth herein, we affirm the district court's judgment. We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal.

1. Midwest Operating's Section 10(b) Claim

To state a claim on which relief can be granted under Section 10(b) and Rule 10b-5, "a plaintiff must plead, *inter alia*, that in connection with the purchase or sale of securities, the defendant made a false representation as to a material fact, or omitted material information, and acted with scienter." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 108 (2d Cir. 2009) (citations omitted). The Supreme Court has defined "scienter" as "a mental state embracing intent to deceive, manipulate, or defraud." *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*,

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[2] ALKS 5461 is an "opioid combination product," which Alkermes initially envisioned as a "non-addictive therapy" for treatment of both cocaine dependence and major depressive disorder ("MDD"). J.A. 30–31. If approved, ALKS 5461 would have been the first drug in a new class to treat MDD, as no other opioids have yet been formally evaluated to treat depression. J.A. 30–31.

[3] The district court did not grant Midwest Operating leave to amend its amended complaint. *See In re Alkermes*, 523 F. Supp. 3d at 295.

551 U.S. 308, 319 (2007)). A complaint alleging securities fraud must satisfy the heightened pleading requirements of the Private Securities Litigation Reform Act ("PSLRA") and Federal Rule of Civil Procedure 9(b) by "stating with particularity the circumstances constituting fraud." *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009) (citations omitted). We agree with the district court that Midwest Operating failed to plead scienter, and so affirm its dismissal of the Section 10(b) claim.

Under Section 21D(b)(2) of the PSLRA:

> in any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, *the complaint shall*, with respect to each act or omission alleged to violate this chapter, *state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind*.

15 U.S.C. § 78u-4(b)(2)(A) (emphases added). To meet the PSLRA's "strong inference" standard to show scienter, it is insufficient to "set out 'facts from which, if true, a reasonable person *could* infer that the defendant acted with the required intent,' for that gauge 'does not capture the stricter demand Congress sought to convey in § 21D(b)(2).'" *S. Cherry St.*, 573 F.3d at 110–11 (quoting *Tellabs*, 551 U.S. at 314). Rather, "[t]o qualify as 'strong' within the intendment of § 21D(b)(2), . . . an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 111 (emphases omitted) (quoting *Tellabs*, 551 U.S. at 314); *see also id.* ("[A] plaintiff alleging fraud in a § 10(b) action . . . must plead facts rendering an inference of scienter *at least as likely as* any plausible opposing inference." (citation omitted)). "This Court has [] long held that the scienter element can be satisfied by a *strong* showing of reckless disregard for the truth," *id.* at 109 (emphasis added), meaning "conscious recklessness—*i.e.*, a state of mind *approximating actual intent,* and *not merely a heightened form of negligence*," *id.*

(quoting *Novak v. Kasaks*, 216 F.3d 300, 312 (2d Cir. 2000)).[4] In determining whether this standard has been met, we "must consider whether '*all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *Id.* at 111 (quoting *Tellabs*, 551 U.S. at 323).

Midwest Operating has not adequately pleaded facts sufficient to meet this standard. Midwest Operating first argues that the Defendants' public disclosures (and lack thereof) mischaracterized the FDA's rejection of Alkermes's Sequential Parallel Comparison Design ("SPCD")—a novel approach to providing evidence of efficacy for a new drug—in its Phase 3 clinical trial design, giving rise to the strong inference of recklessness.[5] J.A. 36, 277–78. But in 2011, at the beginning of Alkermes's correspondence with the FDA on its new drug application, the FDA "strongly encouraged the Applicant to provide a detailed statistical analysis plan (SAP) and seek feedback prior to initiating the trial if they intended to use the [SPCD] to support an efficacy claim." J.A. 45, 282. In 2013, the FDA told Alkermes that the "proposed SPCD appears to be reasonable," while noting that the SPCD was still subject to review. J.A. 45, 282. And in 2015, the FDA again conveyed to Alkermes that it was considering the use of the SPCD to prove efficacy. J.A. 46, 283. Moreover, as the amended complaint alleges, the Defendants *did* disclose that the SPCD was novel and that there was a risk of FDA inflexibility in accepting the

[4] Scienter may alternatively be satisfied by "show[ing] that defendants had both motive and opportunity to commit fraud," *Rombach v. Chang*, 355 F.3d 164, 176 (2d Cir. 2004) (internal quotation marks and citation omitted), but Midwest Operating does not argue that it has pleaded facts sufficient to allege motive and opportunity here.

[5] An "SPCD" is "used for trials with high placebo response." J.A. 18. In the "first stage of SPCD[,] subjects are randomized between placebo and active treatment." J.A. 18. Then, in the second stage, "placebo non-responders are rerandomized between placebo and active treatment." J.A. 18. "Data from the population of 'all comers' and the subpopulations of placebo non-responders are then combined to yield a single p-value for treatment comparison." J.A. 18.

design. *See* J.A. 63, 88.

These correspondences and disclosures, far from raising a strong inference of scienter, instead support the primary nonfraudulent inference that the Defendants were optimistic about the FDA's review and were encouraged that the FDA was seriously considering the novel design. *See Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994) (holding that "misguided optimism is not a cause of action, and does not support an inference of fraud" in considering whether a complaint adequately pled scienter by giving rise to the inference of recklessness); *see also Rothman v. Gregor*, 220 F.3d 81, 90 (2d Cir. 2000) ("The fact that management's optimism about a prosperous future turned out to be unwarranted is not circumstantial evidence of conscious fraudulent behavior or recklessness," as management is "not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage." (citation omitted)). This is not an instance of the Defendants hiding from investors that the FDA considered the utilization of the SPCD an absolute barrier to ALKS 5461's approval. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 529 (S.D.N.Y. 2015) ("If the management knows that certain facts will *necessarily prevent* the regulatory approval . . . and conceals these facts from the investing public, then there is scienter." (emphasis added)), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *see also Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435, 443 (6th Cir. 2014) (rejecting a recklessness claim where the FDA never declared that the "presence or absence of statistically significant results in an analysis of the [treatment] population was the FDA's *absolute requirement*" (emphasis added)). Rather, when viewed in its proper context, the dialogue regarding SPCD reflects the iterative process between a company and the FDA, particularly when the agency must evaluate a novel study methodology.

Nor do the claims regarding the Defendants' alleged mischaracterization of the FDA's disapproval of Alkermes's use of MADRS-6 (instead of MADRS-10) data alter this analysis.[6] Although the FDA was initially willing to consider Alkermes's MADRS-6 approach, *see* J.A. 47, 284, it ultimately concluded (and conveyed to Alkermes) that MADRS-6 was inadequate and that "any analyses of MADRS-6 scores would be considered exploratory," J.A. 41, 285. After receiving this feedback, the Defendants publicly disclosed the FDA's conclusion:

> [W]e now know that FDA intends to focus on MADRS-10 as the primary efficacy measure, which was the efficacy measure that was collected across all of our efficacy studies. For studies that evaluated MADRS-6, they will – indicated they will review the MADRS-6 DATA, but their primary analysis will be on MADRS-10.

J.A. 88. Importantly, in the same conference call, the Defendants also disclosed that Alkermes "collected MADRS-10 in all the studies as well, so that's fine," and that they would submit that data to the FDA for review. J.A. 88. The FDA's Briefing Document shows that Alkermes in fact provided the FDA data on MADRS-6 *and* MADRS-10 for the clinical trials in question.[7] *See, e.g.*, J.A. 289, 291. Thus, although the FDA ultimately disapproved of Alkermes's reliance

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[6] MADRS-10, of the Montgomery-Åsberg Depression Rating Scale, is a "10-item diagnostic questionnaire used to measure the severity of depressive episodes in patients with mood disorders," J.A. 278, and includes the following metrics: sadness, apparent sadness, inner tension, reduced sleep, reduced appetite, concentration difficulties, lassitude, inability to feel, pessimistic thoughts, and suicidal thoughts, J.A. 289. For its Phase 3 clinical trials, in addition to using MADRS-10 data, Alkermes wished to prove efficacy by showing patients' change in MADRS-6—a variation of MADRS-10, omitting the metrics reduced sleep, reduced appetite, concentration difficulties, and suicidal thoughts—over the course of treatment with ALKS 5461. J.A. 285, 289.

[7] Where a complaint incorporates documents by reference, as Midwest Operating's amended complaint does here with regard to the FDA's Briefing Document, this Court considers such documents. *See Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 100 (2d Cir. 2015). For incorporated documents, moreover, "the documents control and this Court need not accept as true the allegations in the amended complaint" as to their content. *Tongue*, 816 F.3d at 206 n.6 (citation omitted).

on MADRS-6 data, the Defendants both disclosed that fact *and* remedied the FDA's concern by providing the MADRS-10 data. Taking a holistic analysis, the district court correctly concluded that the complaint's allegations regarding the Defendants' behavior fails to support an inference of fraudulent intent that is "cogent and at least as compelling as any opposing inference," *S. Cherry St.*, 573 F.3d at 111 (emphasis omitted) (quoting *Tellabs*, 551 U.S. at 314).[8]

Midwest Operating also suggests that the Defendants' omission that the FDA "did not agree" with the use of averaging, viewed holistically with the other allegations, gives rise to a strong inference of recklessness.[9] Again, we disagree. True, the FDA eventually conveyed to Alkermes that it disagreed with the company's averaging approach to proving ALKS 5461's efficacy. J.A. 284. *But see* J.A. 278 (the FDA noted in its Briefing Document that "[a]lthough the [FDA] did not prospectively agree with [Alkermes] on [its averaging] approach, it seems worthy of consideration"). Midwest Operating mischaracterizes Alkermes's response to this feedback by asserting that the Defendants behaved recklessly. When asked if the FDA had given insight on Alkermes's approach to averaging, Pops disclosed that Alkermes believed averaging to be "a more accurate way of capturing drug effect over time and it's central to our efficacy

[8] Midwest Operating also points to several of Alkermes's SEC filings, in which the company announced positive results using MADRS-6 data without disclosing that the FDA was considering MADRS-6's appropriateness. *See, e.g.*, J.A. 39, 67–68. But such disclosures, read collectively with the other allegations in the amended complaint, do not give rise to a strong inference of recklessness. The Defendants publicly disclosed that Alkermes was using MADRS-6 data in announcing the positive results. Moreover, at the time of such disclosures, the FDA had not yet concluded that MADRS-6 was insufficient to show efficacy.

[9] According to the FDA, "[t]ypically, studies for antidepressant therapies assess an efficacy endpoint at a specific time point following several weeks (6 to 12) of treatment, in part because the treatment effect may require several weeks to be manifested, and in part to provide evidence of durability of the treatment effect." J.A. 278. Alkermes, however, desired to show efficacy, in part, by "using [the] average of changes" in MADRS scores from the baseline of treatment to Week 3 through the end of the treatment period. J.A. 132, 284.

analysis," but emphasized that Alkermes would give the FDA "all the data available for . . . review," so the FDA could "analyze the data however they choose . . . ." J.A. 88. The FDA's Briefing Document shows that Alkermes submitted data showing averages *and* the unaveraged end-of-treatment change, as requested by the FDA. *See, e.g.*, J.A. 289, 291.

Finally, Midwest Operating argues that the Defendants mischaracterized the FDA's objection to Alkermes's use of *post hoc* data to show efficacy, giving rise to a strong inference of recklessness.[10] But importantly, in publicly announcing clinical trial results, Alkermes disclosed that it failed to meet prespecified primary efficacy endpoints measuring change in MADRS score from the beginning to the end of treatment.[11] *See* J.A. 61 (disclosing that "[n]either of the two studies met the prespecified primary efficacy endpoint, which compared ALKS 5461 to placebo on the change from baseline on the [MADRS]"). In the same disclosure, Alkermes also stated that "*post hoc* analyses achieved statistical significance for the entire 2mg/2mg dose group on the MADRS endpoint," and that "[b]ased on these analyses," it believed that its Phase 3 trial "provides supportive evidence of the efficacy of ALKS 5461 in the treatment of [MDD]." J.A. 61. As we have said before, when "it is clear that a *post-hoc* analysis is being used, it is understood that those results are less significant and should therefore have less impact on investors." *Kleinman v. Elan*

[10] In 2017, for instance, the FDA denied Alkermes's request for Breakthrough Therapy Designation—a "process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint," J.A. 40—in part because "any statistical significance in the Phase 3 study results depended on *post hoc* analyses," J.A. 40, 285; *see* J.A. 40 (pleading that the FDA explained to Alkermes that "*post hoc* analyses by themselves cannot establish effectiveness").

[11] The "prespecified primary efficacy endpoint" is the "outcome, based on a drug's expected effects, that establishes the effectiveness, and/or safety features, of the drug in order to support regulatory action." J.A. 37. According to Midwest Operating, failure to meet the prespecified endpoint "indicated that both studies failed to demonstrate the drug's efficacy." J.A. 37.

Corp., plc, 706 F.3d 145, 154 (2d Cir. 2013). This is because the FDA has publicly declared *post hoc* analysis to be "exploratory" and has "cautioned that '[a]ny conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses is unlikely to be accepted.'" *Id.* at 155 n.11 (quoting FDA Center for Drug Evaluation and Research, *E9 Statistical Principles for Clinical Trials*, 63 Fed. Reg. 49583, 49595 (Sept. 16, 1998)). Such *disclosed* use does not give rise to a strong inference of recklessness. Rather, the strongest inference is that Alkermes nonfraudulently used such data in an honest attempt to show ALKS 5461's efficacy.

Viewed collectively, the allegations in the amended complaint do not give rise to a strong inference of recklessness, and the amended complaint thus fails to plead scienter. *See S. Cherry St.*, 573 F.3d at 111. The amended complaint's "strongest inferences" are nonfraudulent—that the Defendants viewed ALKS 5461's chances of FDA approval with optimism, yet still made honest attempts to disclose the FDA's feedback where relevant and to caution the market as to the risks inherent in proposing new study designs. The district court's dismissal of Midwest Operating's Section 10(b) claim was thus appropriate.

2. Section 20(a) Claim

Midwest Operating next argues that the district court erred in dismissing its Section 20(a) claim. But having appropriately dismissed Midwest Operating's Section 10(b) claim (the only other Securities Exchange Act claim pled within the amended complaint), the district court correctly dismissed the Section 20(a) claim. *See Jackson Nat'l Life Ins. Co. v. Merrill Lynch & Co.*, 32 F.3d 697, 703 (2d Cir. 1994) (noting that "to state a claim under § 20A, a plaintiff must plead a predicate violation of the [Securities Exchange] Act or its rules and regulations").

3. Leave to Amend

Last, Midwest Operating argues that the district court erred in refusing to grant its request for leave to amend after dismissing its amended complaint with prejudice. We again disagree. We review the denial of leave to amend for abuse of discretion "unless the denial was based on an interpretation of law, such as futility," in which case it is reviewed *de novo*. *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012). Moreover, "[a] plaintiff need not be given leave to amend if it fails to specify either to the district court or to the court of appeals how amendment would cure the pleading deficiencies in its complaint." *Attestor Value Master Fund v. Republic of Argentina*, 940 F.3d 825, 833 (2d Cir. 2019) (quoting *TechnoMarine SA v. Giftports, Inc.*, 758 F.3d 493, 505 (2d Cir. 2014)) (affirming district court's denial of leave to amend where plaintiffs "have not offered specific changes they could make to their Amended Complaint to cure its deficiencies").

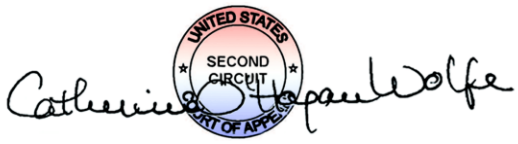
The district court did not err in refusing to grant Midwest Operating leave to amend its amended complaint. Midwest Operating first requested leave to amend in a footnote attached to the last line of its memorandum in opposition to the Defendants' motion to dismiss. J.A. 1422 n.49. It did not suggest any tangible amendments that would remedy the district court's concerns. Similarly, on appeal, Midwest Operating has not provided this Court with specific changes it would make to cure the various pleading deficiencies within its amended complaint. It generally suggests, for the first time in its Reply Brief, that it would amend by "providing new allegations to support scienter." Reply Br. at 29. But without further clarification, and given the context of this particular case, that explanation is inadequate. Midwest Operating was permitted to file an amended complaint over seven months after initiating this litigation in December 2018. In that amendment, it added over seventy pages of pleadings, incorporating the FDA's Briefing

Document and numerous public disclosures made by the Defendants. Without identifying specific changes, it is unclear what additional non-conclusory allegations Midwest Operating could plead to show scienter. Dismissal with prejudice, without leave to amend, was thus appropriate here.

* * *

We have considered Lead Plaintiff-Appellant Midwest Operating's remaining arguments and find them to be without merit. Accordingly, we **AFFIRM** the judgment of the district court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk of Court



United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007

DEBRA ANN LIVINGSTON
CHIEF JUDGE

CATHERINE O'HAGAN WOLFE
CLERK OF COURT

Date: December 07, 2021
Docket #: 21-801cv
Short Title: Karimian v. Alkermes Public Limited Compan

DC Docket #: 18-cv-7410
DC Court: EDNY (BROOKLYN)
DC Judge: Levy
DC Judge: DeArcy Hall

BILL OF COSTS INSTRUCTIONS

The requirements for filing a bill of costs are set forth in FRAP 39. A form for filing a bill of costs is on the Court's website.

The bill of costs must:
* be filed within 14 days after the entry of judgment;
* be verified;
* be served on all adversaries;
* not include charges for postage, delivery, service, overtime and the filers edits;
* identify the number of copies which comprise the printer's unit;
* include the printer's bills, which must state the minimum charge per printer's unit for a page, a cover, foot lines by the line, and an index and table of cases by the page;
* state only the number of necessary copies inserted in enclosed form;
* state actual costs at rates not higher than those generally charged for printing services in New York, New York; excessive charges are subject to reduction;
* be filed via CM/ECF or if counsel is exempted with the original and two copies.

United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
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VERIFIED ITEMIZED BILL OF COSTS

Counsel for

_____

respectfully submits, pursuant to FRAP 39 (c) the within bill of costs and requests the Clerk to prepare an itemized statement of costs taxed against the

_____

and in favor of

_____

for insertion in the mandate.

Docketing Fee _____

Costs of printing appendix (necessary copies _____) _____

Costs of printing brief (necessary copies _____ ____) _____

Costs of printing reply brief (necessary copies _____) _____

(VERIFICATION HERE)

_____
Signature