Simpson Thacher

Securities Law Alert

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Simpson Thacher's "work is top-notch" and the Firm is "vastly experienced in complex litigation."

–*Chambers USA* (quoting a client)

First Circuit: Disclosure of FDA Concerns Undercuts Any Inference of Scienter

On April 9, 2020, the First Circuit affirmed the dismissal of a securities fraud action alleging that a biopharmaceutical company failed to disclose "material facts about [the company's] manufacturing problems and the impact those problems were likely to have on the FDA's approval" of the company's ocular pain drug. *Mehta v. Ocular Therapeutix*, 2020 WL 1808366 (1st Cir. 2020) (Stahl, C.J.). The First Circuit found it significant that defendants fully disclosed the FDA's concerns regarding certain manufacturing issues. The court held that these disclosures belied any inference of scienter.

Plaintiffs challenged statements in the company's 2016 and 2017 Forms 10-K representing that the company manufactured its ocular pain drug "using current Good Manufacturing Practices [cGMP]", as well as an executive's May 2017 statements describing the company's drug manufacturing process as "fully developed." Plaintiffs argued "that a strong inference of scienter can be drawn from those alleged misstatements because defendants made them despite having received" Forms 483 from the FDA in February 2016 and May 2017 that "apprised defendants of [the company's] manufacturing problems."

The First Circuit held that plaintiffs' "allegations do not give rise to a strong inference of scienter." The court noted that the 2016 and 2017 Forms 10-K "disclosed receipt of the February 2016 Form 483, described its relevance to [the company's] manufacturing capabilities, and warned of its implications." The 2016 and 2017 Forms 10-K also specifically warned investors that resolution of the issues identified in the February 2016 Form 483 was a prerequisite for FDA approval. The First Circuit found "[t]hese informative disclosures about the nature and consequences of the February 2016 Form 483 undercut any inference that defendants intentionally or recklessly misled investors" concerning the company's compliance with cGMP regulations. Rather than inferring scienter, the court determined that "the more reasonable inference of nonfraudulent intent is that defendants were [simply] stating their intention to comply with cGMP regulations as the governing standards for their drug product manufacturing operations."

As to the May 2017 statements concerning the "fully developed" nature of the company's manufacturing processes, the First Circuit noted that a company executive specifically disclosed the receipt of a Form 483 from the FDA one day earlier and discussed its ramifications. The First Circuit found that these disclosures "made pellucid that [the company's] manufacturing process was considered deficient by the FDA." The court also credited defendants' representation that in the FDA approval context, the phrase "fully developed" refers to a process that "has surpassed the concept or piloting stage but must still be tested and validated to determine whether the process works as intended and meets the necessary standards." The court determined that "[i]n light of that term of art and [the executive's] disclosures during the conference call that contravene[d] plaintiffs' characterization of his statements, the more reasonable and compelling inference drawn from the complaint's allegations is that [the executive] spoke with nonfraudulent intent in describing [the company's] manufacturing process as 'fully developed.'"

Eighth Circuit: Affirms the Dismissal of a Securities Fraud Action Against a Major Retailer for Failure to Allege Scienter

On April 10, 2020, the Eighth Circuit affirmed the dismissal of a securities fraud action alleging that a major retailer and several of its executives made misstatements concerning the company's ultimately unsuccessful foray into the Canadian market. *In re Target Corp. Sec. Litig.*, 2020 WL 1814268 (8th Cir. 2020) (Kobes, C.J.). The Eighth Circuit determined that "[n]othing in the complaint makes a 'compelling' case for fraud." Rather, the court found "the more compelling inference" is that the company's executives "did not understand the magnitude of the problems they faced" with the Canadian stores.

Background

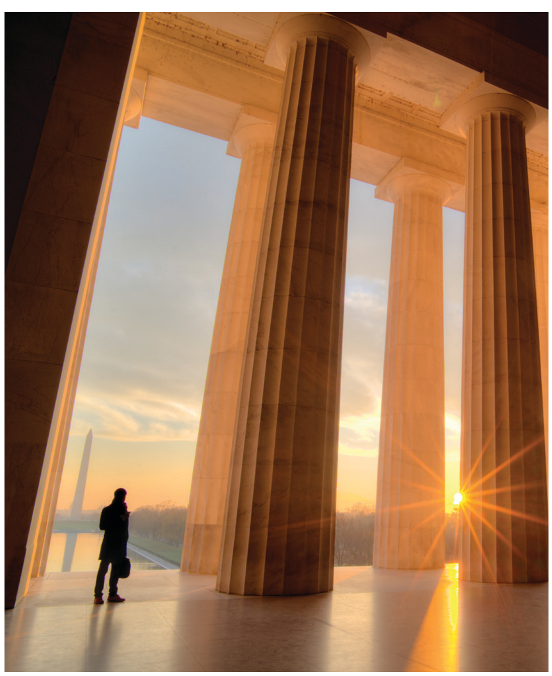
Between March and November of 2013, the company opened 124 new stores in Canada, and also "developed new supply chain and information technology infrastructure to support them." The company's "decision to develop these new systems proved disastrous," as its "new inventory forecasting software provided inaccurate demand forecasts and employees did not understand how to use it." The company's "other systems compounded these problems," leading to "some shelves sitting empty and others overflowing with inventory." In January 2015, the company "announced plans to shutter its Canadian stores." Plaintiffs subsequently brought suit alleging that defendants "misled investors by understating the seriousness of the problems with" the company's Canadian operations by "overstating their ability to correct" the problems and "making unrealistic projections about the profitability of the Canadian stores." The court granted defendants' motion to dismiss, and plaintiffs appealed.

Plaintiffs Failed to Allege that the Individual Defendants Knew the Statements Were False When Made

The Eighth Circuit found that "none" of plaintiffs' allegations satisfied the scienter requirement. For example, plaintiffs challenged a March 2013 statement by the company's CFO representing that the company had achieved "all" of its "objectives" with respect to building the technology for its Canadian operations. Plaintiffs contended that at the time the CFO made this statement, defendants knew or recklessly disregarded "systemic problems . . . in [the company's] supply chain IT systems." The Eighth Circuit noted that plaintiffs offered "no particularized explanation of how or when [the company's] executives learned this statement was false." The court emphasized that it "disregard[s] 'blanket' or 'catch-all' assertions of scienter."

Plaintiffs also challenged statements representing that the company was "tuning" its Canadian technology systems, on the grounds that defendants "actually knew more drastic action was needed." The Eighth Circuit found that the complaint did "not show" that the executives were aware that their "tuning" efforts would fail, and emphasized that the Private Securities Litigation Reform Act ("PSLRA") "does not allow pleading fraud by hindsight."

The Eighth Circuit found that "[t]he strongest, but still insufficient, allegation" concerned the company's May 2014 representation that the longer the Canadian stores had been open, the better they were performing. Plaintiffs alleged that defendants must have known that this statement was false because in August 2014, the company "revealed that same-store sales had fallen more than 11% in Canada over the previous year." The Eighth Circuit stated that "financial deterioration alone is not enough to show fraud." The court explained that "the apparent incongruity" between the May 2014 statement and the August 2014 financial results was not sufficient to "show that the May 2014 statement was necessarily false, let alone that [company] executives knew it was false."



The Individual Defendants' Stock Sales Did Not Give Rise to an Inference of Scienter

The Eighth Circuit also found defendants' stock sales insufficient to raise an inference of scienter. The court explained that while "insider stock sales can be probative of motive, they are not inherently suspicious and become so only when the level of trading is so dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." In the case before it, plaintiffs "allege[d] that the individual defendants sold 10-20% of their shares during the class period." The court noted that it has "found sales of up to 32% of an individual's stock not inherently suspicious." The court also found it significant that "[t]he bulk of the sales were made early in the class period and provide no motive for defrauding investors in the following months."

The District Court Did Not Err in Denying Leave to Amend

The Eighth Circuit found "no abuse of discretion" in the district court's denial of plaintiffs' motion for leave to amend. The Eighth Circuit noted that while "the amended complaint added color and detail to the investors' allegations, it still failed to allege that [company] executives knew that they were making false statements." The Eighth Circuit found that the new allegations in the amended complaint were "perfectly consistent with the narrative that [the company] had serious problems that none of its executives understood."

Southern District of New York: Underwriting a Tranche of Securities Does Not Subject the Underwriter to Section 11 Liability for the Entire Securitization

On March 11, 2020, the Southern District of New York held that the underwriter of one tranche of securities was not subject to liability under Section 11 of the Securities Act of 1933 ("Securities Act") with respect to a different tranche of securities from the same securitization that it did not underwrite. *Federal Deposit Ins. Corp. v. First Horizon Asset Securities*, 2020 WL 1165848 (S.D.N.Y. 2020) (Stanton, J.).[1] The court granted the underwriter's motion for summary judgment on the Section 11 claim.

The court rejected plaintiff's contention that a defendant's "liability as an underwriter is not limited to the tranche or class of subordinated certificates" that the defendant actually underwrote. The court explained that "the right to sue that Section 11 gives a purchaser of a security is to sue 'every underwriter with respect to such security,' or underwriters of the security at issue." *Id.* (quoting 15 U.S.C. § 77k(a)). The court held that this "right does not encompass suing every underwriter with respect to the entire securitization and each of its securities."

The court also found meritless plaintiff's alternative argument that even though the defendant underwriter "did not directly purchase or sell the senior certificates" at issue, the defendant was nonetheless subject to Section 11 liability "because of its 'direct or indirect participation' in the distribution of the senior certificates." *Id.* (quoting 15 U.S.C. § 77b(a)(11)). The court recognized that "[p]ersons may be liable [under Section 11] for participation [in the distribution of securities] even though they did not themselves directly sell or offer securities or purchase securities for resale." *Id.* (quoting *In re Lehman Bros. Mortg.-Backed Sec. Litig.*, 650 F.3d 167 (2d Cir. 2011)). However, the court emphasized that Section 11 does not reach "persons who provide services that facilitate a securities offering, but who do not themselves participate in the statutorily specified distribution-related activities." *Id.* (quoting *Lehman Bros.*, 650 F.3d 167).

Here, plaintiff asserted that the defendant "participated in the distribution of the [senior] certificates by performing due diligence on the loans backing the certificates in the securitization" and reviewing the prospectus supplements. Plaintiff contended that "[b]ecause many of the loans backing the senior certificates are the same as those backing the subordinated certificates" that the defendant underwrote, the defendant's "contribution to the securitizations was not limited to the subordinated certificates." The court held that while the defendant's efforts "helped facilitate the securities offerings, those activities do not involve the purchase, offer, or sale of the securities and are thus not part of their distribution."

Plaintiff also argued that the senior certificates "would never have been offered without [the defendant's] participation" because "the collateral underlying the subordinate certificates, and the credit protection they provided, was material to investors" who purchased the senior certificates. The court held that "[e]ven if those statements are true, those relationships are not part of the purchase, offer, or sale of the senior certificates."

The court concluded that "there is no genuine issue whether [the defendant] is an underwriter of the senior certificates at issue; it is not."

Southern District of New York: Plaintiffs Adequately Pled a Securities Fraud Claim Based on an Alleged Violation of Item 303 of Regulation S-K

On April 14, 2020, the Southern District of New York held that plaintiffs "alleged a plausible securities fraud claim premised on a violation of Item 303" of Regulation S-K. *Plumbers & Pipefitters Nat'l Pension Fund v. Davis*, 2020 WL 1877821 (S.D.N.Y. 2020) (Woods, J.). "Item 303 requires a public company to describe in its Forms 10-K or 10-Q 'known trends or uncertainties' that the company 'reasonably expects will have a material favorable or unfavorable impact

1. Simpson Thacher represented NatWest Markets Securities Inc. (f/k/a RBS Securities Inc.) in this matter.

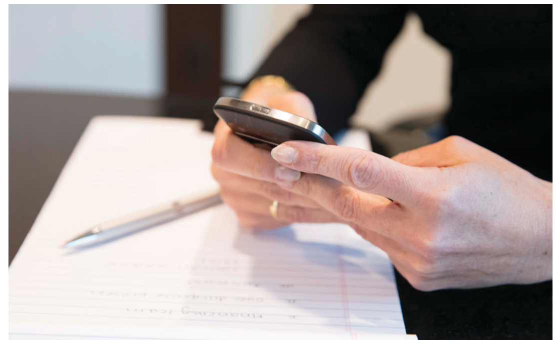
on net sales or revenues or income from continuing operations." *Id.* (quoting 17 C.F.R. § 229.303(a)(3)(ii)). The court stated that if a violation of Item 303 "is adequately alleged, it can give rise to liability under Section 10(b) because Item 303 creates a legal disclosure obligation with which a regulated company must comply."[2]

In the case before it, plaintiffs alleged that a manufacturer of sports equipment and apparel "flooded the market with discounted inventory to increase its short-run sales figures." Plaintiffs further alleged that "partially as a result of [d]efendants' sales practices, there was a marked increase in inventory of unsold [ ] goods at [the company's] retailers." Plaintiffs "argue[d] that [the company's] practice of flooding the market with inventory far in excess of demand was a trend that required disclosure" under Item 303.

The court found plaintiffs "adequately alleged that [the company's] sales practices created a trend of increasing inventory," and determined that "[i]t was both reasonably foreseeable and material to [the company's] future performance that a buildup of inventory would lead to a decline in [the company's] future sales." The court further held that plaintiffs' allegations "create[d] a plausible inference that [d]efendants had actual knowledge of this trend because they received repeated warnings that [the company's] sales tactics were cannibalizing future sales." The court concluded that plaintiffs "adequately pleaded" a securities fraud claim based on a violation of Item 303.

The court further held that plaintiffs adequately alleged misstatements regarding the sources and nature of the company's sales growth, as well as potential risks to the company. The court found that "[b]ecause [d]efendants specifically cited their strategy as a source of their success, they were obligated to tell the whole truth with respect to that strategy by disclosing that their sales growth was, at least in part, the result of short-run sales tactics that led to a buildup of inventory at [the company's] customers."

The court further found that defendants' disclosures regarding the risk of "inventory levels in excess of consumer demand" were false or misleading because defendants allegedly "had actual knowledge that [the company's] customers already had excessive levels of inventory" at the time they made those statements.



Southern District of New York: Plaintiffs Must Allege "How and Why" an Alleged Misstatement Was False and Misleading at the Time It Was Made

On April 2, 2020, the Southern District of New York dismissed a securities fraud action because plaintiffs failed to "show how and why" defendants' alleged misstatements were false and misleading at the time they were made. [*In re Adient plc Sec. Litig.*, 2020 WL 1644018 (S.D.N.Y. 2020) (Abrams, J.)]. The court underscored that "simply stating that the statements are false is not enough" to state a securities fraud claim.

Plaintiffs alleged that defendants made misstatements regarding the company's progress towards its projected margin expansion, as well as improvements in the company's metals business. The court noted that "[t]he underlying premise of the allegations regarding both sets of statements is that [d]efendants failed to disclose certain operational issues that existed within the [m]etals business." Plaintiffs suggested that the company's "projected margin expansion was not achievable" because of these issues.

The court found plaintiffs' allegations insufficient to plead actionable misstatements. The court observed that "[d]efendants

2. The court cited to *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94 (2d Cir. 2015). In *Stratte-McClure*, the Second Circuit held that "a violation of Item 303's disclosure requirements can only sustain a claim under Section 10(b) and Rule 10b-5 if the allegedly omitted information satisfies *Basic*'s test for materiality." Please click here to read our discussion of the Second Circuit's decision in *Stratte-McClure*.

repeatedly made it clear that improvements in the [m]etals business was just one component of the projected margin expansion." The court found that "even if it is true that [m]etals was not achieving certain specific improvements, such a finding does not lead to the conclusion that [the company's] overall projected margin expansion or plan to improve [m]etals in general was 'unreasonable' or 'unrealistic'—let alone false—at the time statements about it were made."

The court also found that "[p]laintiffs seem to conflate [d]efendants' statements about progress towards the projected margin expansion, on the one hand, and progress in improving the [m]etals business, on the other." The court pointed out that "[v]irtually all of the challenged statements in the [complaint] about the [c]ompany being 'on track' were made in the context of the overall projected margin expansion, and did not concern specific improvements in the [m]etals division." The court found that it was "entirely possible that, at the time these statements were made, [the company] was 'on track' to reach its projected margin expansion at some point in the future, regardless of any specific operational issues that may have existed in [m]etals at the time."

The court noted that many of the statements at issue were subjective statements of opinion regarding the company's progress towards the margin expansion. Plaintiffs' "theory of liability as to these opinion statements is that [d]efendants allegedly failed to disclose underlying facts that directly contradicted those statements." But the court found that the complaint "does not plausibly allege any specific material facts—omitted from [d]efendants' statements—that rendered the opinion statements false or misleading to a reasonable investor." The court observed that defendants in fact "publicly acknowledged that [m]etals needed 'fixing'" and "disclosed specific operational issues in the [m]etals business as they arose."

The court also found that many of the statements at issue were forward-looking within the meaning of the PSLRA, even though they included both present and future statements. The court explained that "when the present-tense portion of mixed present and future statements does not provide specific information about the current situation, but merely says that, whatever the present situation is, it makes the future projection attainable, the present tense portion of the statement is too vague to be actionable apart from the future projection." The court found "statements that the [c]ompany was 'on track' to reach the projected margin expansion and related growth" were "too vague to be actionable apart from the future projection," as they "provide no specific information as to [the company's] current circumstances."

Southern District of New York: Disclosures Concerning the Possibility That Problems Might Arise Are Insufficient If Those Problems Have Already Occurred

On March 30, 2020, the Southern District of New York held that plaintiffs adequately alleged claims under Sections 11 and 12(a)(2) of the Securities Act of 1933 based on misstatements concerning the termination of experienced employees and the integration of acquisitions. *City of Omaha Police & Fire Ret. Sys. v. Evoqua Water Techs. Corp.*, 2020 WL 1529371 (S.D.N.Y. 2020) (Nathan, J.).[3] The court found defendants warned of problems that could potentially occur, when in fact the problems had allegedly already occurred.

Plaintiffs alleged that the company had adopted "a policy or practice" of cutting costs by replacing experienced sales employees with "far less experienced (and less qualified and effective) employees." Plaintiffs contended that the company "strong-armed many employees into retirement by, for example, "setting impossible-to-meet quotas." Plaintiffs asserted that the loss of experienced employees "had a significant adverse impact on the business." Defendants responded that the company had disclosed the initiation of a "Voluntary Separation Plan" that "include[d] severance payments to employees as a result of streamlining business operations for efficiency." The company also warned

3. "Section 11 of the Securities Act imposes liability on issuers and other signatories of a registration statement that 'contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.'" *Evoqua*, 2020 WL 1529371 (quoting 15 U.S.C. § 77k(a)). "Section 12(a)(2) provides similar redress where the securities at issue were sold using prospectuses or oral communications that contain material misstatements or omissions." *Id.*

that the "failure to retain" sales personnel "could materially adversely impact [its] ability to operate or grow [its] business." The court found these disclosures inadequate because "[d]efendant's disclosures . . . were hypothetical" yet "the risks disclosed by [d]efendants had *already* materialized." The court emphasized that "[w]arning of risks that *could* occur at some *future date* does not warn investors that those risks have already come to pass."

Plaintiffs also alleged that defendants made misstatements "regarding [the company's] acquisitions and efforts at integrating those companies into its operations." Plaintiffs asserted that the company failed to disclose that it "terminated the staff members responsible for integration" and "faced serious problems in integrating one of its new acquisitions." Defendants argued that the company specifically cautioned that it "may have difficulty in operating or integrating any acquired businesses, assets, or product lines profitably." The court found this warning insufficient because plaintiffs alleged that "*at the time that statement* was made," the company "had *already* fired integration staff" and the integration of one acquisition "was *already* going poorly." The court underscored that "[a] hypothetical disclosure about potential future problems is . . . not curative" if the problems had already occurred at the time of the alleged misstatements.

Defendants also argued that certain of its statements were inactionable puffery. For example, defendants pointed to the company's statement that "[o]ur management team has also expanded our operations to new target markets and geographies and has demonstrated successful acquisition and integration capabilities." The court recognized that "a representation that something is a 'success' can be puffery." But in the statement at issue, "the word [success] modifies a particular noun—acquisition and integration capabilities." The court found that when read "in context," this statement "represents that [the company] *has* demonstrated these capabilities successfully." The court held that it could not "conclude that *no* reasonable investor would rely on this statement, and thus [the] puffery doctrine cannot defeat [p]laintiffs' claim at this stage of litigation."

Southern District of New York: The "Mere Existence" of Reports of Adverse Pharmaceutical Events Is Not Material, Standing Alone

On March 26, 2020, the Southern District of New York dismissed a securities fraud action alleging that a pharmaceutical company failed to disclose certain serious adverse events ("SAEs") experienced by patients using the company's liver disease drug. [*Liu v. Intercept Pharms.*, 2020 WL 1489831 (S.D.N.Y. 2020) (Kaplan, J.)](). The court recognized that "[a]dverse events are material when there is a scientifically reliable basis for inferring a potential causal link between the drug and the adverse event." But the court emphasized that "[t]he mere existence of reports of adverse events is not material." Rather, "[s]omething more is needed."

At issue in the case before it were reports that 27 out of 3,000 patients—or less than 1% of users—experienced one or more SAEs during the one-year long class period. The SAEs consisted of "nineteen deaths and eleven cases of serious liver injury."[4] Plaintiffs argued that they "sufficiently [had] pled 'something more'" by pointing to factors such as "the FDA's historic concern with liver injuries"; an FDA investigation into the SAEs commenced after the company announced that a patient in its Phase 2 trial had died; and "the FDA's concerns about the 'vulnerabilities'" of certain very sick patients and "the known need for these patients to receive a lower dose" of the drug.

The court found these factors insufficient to demonstrate the materiality of the SAEs. The court explained that liver damage "is a known

4. Three patients suffered liver injuries prior to their deaths.

complication of most prescribed drugs." The court also found that FDA actions taken after the disclosure of an SAE did not demonstrate the materiality of the SAEs that were not previously disclosed. The court reasoned that plaintiffs "falsely equate[d] FDA action taken *after* the statements at issue were made with whether adverse events were material under the securities laws *at the time* the statements were made." The court also found that "[t]o the extent that there were concerns about the vulnerabilities of late-stage patients," these concerns did not support a finding of materiality because "these patients ha[d] compromised livers and already were quite sick." The court emphasized that "some adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill."

The court observed that "[w]hen plaintiffs' argument is stripped of its allegations of 'something more,' they are left only with the occurrence of serious liver injury or death in fewer than 1 percent" of patients. The court found that these allegations "[fell] short" of adequately pleading that a "reasonable investor would have viewed the thirty reported SAEs as significantly altering the total mix of information available."

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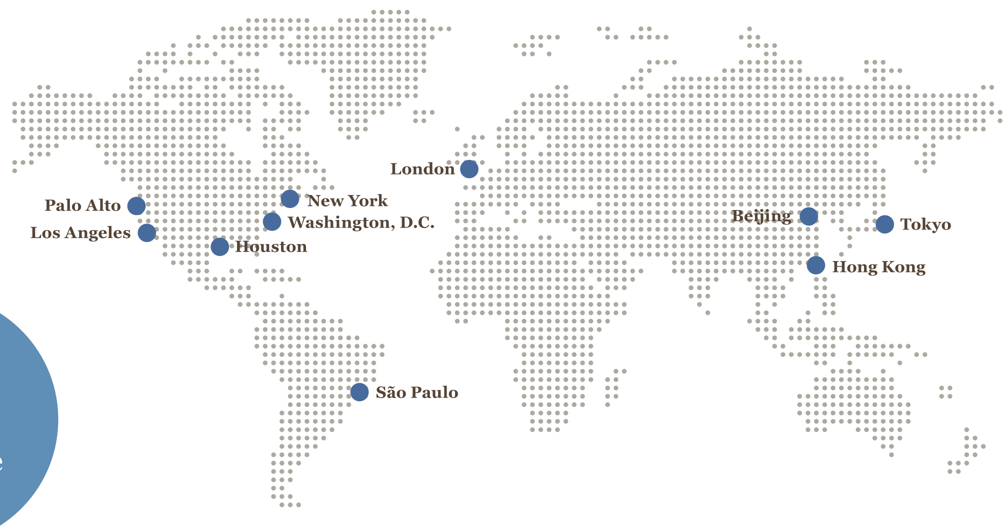

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