SECURITIES LITIGATION AGAINST LIFE SCIENCES COMPANIES: 2023

SIDLEY

Securities class actions against life sciences companies are mostly second-order problems. The first-order problem is a business or regulatory setback that, when disclosed by the company or a third party, triggers a stock price decline. Following the decline, plaintiffs' class-action attorneys search the company's previous public statements and seek to identify inconsistencies between past positive comments and the current negative development. In most cases, plaintiffs' attorneys then seek to show that any arguable inconsistency amounts to fraud — that is, they will claim that the earlier statement was knowingly or recklessly false or misleading. When the challenged statement appears in a public offering document (that is, a registration statement or prospectus), plaintiffs need only show that the statement was materially false or misleading, not that it was made with scienter or caused their losses.

Under the Private Securities Litigation Reform Act of 1995, securities fraud plaintiffs must meet heightened pleading standards to survive a motion to dismiss, and they are not entitled to discovery while the motion is pending. As a result, securities defendants file motions to dismiss in virtually every case. These motions are generally lengthy and complex. For the most part, federal courts consider the motions carefully and hold plaintiffs to the demanding statutory pleading requirements. In 2023, life sciences companies succeeded in 56% of the motions to dismiss they filed.

5 Takeaways from New Complaints Filed in 2023

1. Plaintiffs filed 34 new class actions against publicly traded life sciences companies in 2023. This continues a downward trend that began last year. We saw 49 new class actions against life sciences companies in 2021, but only 37 in 2022, and only 34 in 2023.

2. The number of new filings related to COVID-19 products has unsurprisingly tailed off. In 2020 through 2022, we saw six or seven new filings per year, nearly all in the pre-approval (or pre-EUA) stage. In 2023, there were three new COVID-19 filings, one against a company developing a treatment for the disease and two against companies whose sales suffered as the demand for their COVID-19-related products dropped off.

3. Geographically, the cases are concentrated in four regions, corresponding to four federal appellate circuits:

   - 11 new cases in the Second Circuit, which includes New York
   - 9 new cases in the Ninth Circuit, which includes California
   - 5 new cases in the First Circuit, which includes Massachusetts
   - 5 new cases in the Third Circuit, which includes New Jersey

   This reflects continuing concentration in these regions. New filings in other circuits were negligible.

4. More than 50% of the new cases (18) involve mature products. That is a departure from earlier years, and notable because companies with mature products have historically had less success in winning dismissal than companies with pre-approval products.

5. The majority of new filings against companies with mature products arise from setbacks not unique to life sciences companies, principally sales performance and financial reporting issues. In previous years, we have seen a greater concentration of cases arising from regulatory issues, particularly alleged improprieties in regulated areas of marketing and billing.

6 Takeaways from New Decisions Issued in 2023

THE NUMBERS: 2 TAKEAWAYS

1. **Success rate of 56% in the district courts, consistent with past trends.** District courts issued 25 new decisions on motions to dismiss or motions for summary judgment filed by life sciences companies. Defendants were successful in over half — 14 of 25, or 56%. That is consistent with the success rate in previous years, which has fluctuated within the 50%–60% range.

2. **The success rate in pre-approval cases was higher than that in post-approval cases.** As in most years, companies fared better in the pre-approval cases, winning dismissal 80% of the time. The success rate in post-approval cases was only 50%. This trend appears to reflect plaintiffs' challenges in establishing falsity and scienter in cases where the statements they attack concern inherently unknowable events — the outcome of clinical trials and the FDA approval process.

THE SUBSTANCE: 4 TAKEAWAYS

1. **High-profile setbacks in COVID-19 manufacturing and Alzheimer's disease drug development lead to challenging litigation.** Two unfavorable decisions in 2023 arose from high-profile setbacks. Emergent BioSolutions, a prominent manufacturer of COVID-19 vaccines, experienced various problems with contamination. This became the subject of a congressional investigation, which ultimately determined that the company had destroyed 400 million vaccine doses. The District of Maryland denied the company's bid for dismissal, holding that while plaintiffs failed to allege that the company's statements were false, they adequately pled that the statements were misleading in light of undisclosed manufacturing problems. A second litigation defeat was handed down by the First Circuit, which reversed in part a trial court dismissal of claims against Biogen in connection with its controversial Alzheimer's disease drug. The company couched its statements about a post hoc analysis of trial results as opinions, but the First Circuit held that even the favorable framework for analyzing opinions could not protect the statement that all data showed that the drug was effective at sufficiently high doses.

2. **Plaintiffs gain traction with claims that companies understated the risk that the FDA would not approve their products.** Companies have historically argued that fraud claims arising from drug development are nonsensical: A company would not devote years of clinical trials and hundreds of millions of dollars to drug candidates it knew were doomed. In 2023, as in the past several years, plaintiffs have defeated that argument with the claim that a company may not have known that its product would not succeed, but knew of significant risks of failure that it concealed from investors. These decisions can pose challenging disclosure problems. Companies surely cannot be expected to quantify risk, but the decisions suggest that companies may need to disclose more granular information about interim FDA feedback than the case law has historically required — or refrain from characterizing interim FDA developments altogether.

3. **Closing in on the end of the generic drug price-fixing saga.** 2023 marked the end, or close to the end, of an antitrust story we have been covering for the past seven years. In 2016, a consortium of state attorneys general alleged a broad price-fixing conspiracy in the generic drug industry. Dozens of manufacturers were eventually swept in, and the public companies inevitably became the targets of Section 10(b) litigation. Defendants fared poorly at the pleading stage, and litigation proceeded against at least a half-dozen companies. Several settled, some for hundreds of millions of dollars. Mylan and Perrigo stayed the course through summary judgment and were largely rewarded for doing so. The claims against Mylan were dismissed and the claims against Perrigo were dismissed in part, with only a very narrow channel left for plaintiffs to prevail.

4. **Courts continue to grapple with "claims within claims."** As the generic drug cases show, the securities plaintiffs' bar routinely seeks to piggyback on underlying regulatory activity when companies report scrutiny of sales, marketing, pricing, or billing practices. These cases can present difficult problems for courts. Should they require the securities plaintiffs to prove the underlying violations? Should they defer if the matter is being adjudicated elsewhere? The 2023 decisions reflect a range of approaches. The most helpful decision, Mylan, lays out a rigorous two-part structure for litigating "claims within claims." The plaintiffs essentially had the burden of prevailing in an antitrust action before they could assert a securities claim — and then additionally had to prove the elements of falsity, scienter, and causation. The Mylan plaintiffs could not carry that burden. In other cases, where courts took at face value plaintiffs' allegations of regulatory violations, plaintiffs fared better.

VIEW THE
2023 ANNUAL SURVEY