SECURITIES LITIGATION AGAINST LIFE SCIENCES COMPANIES: 2024

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 2024, life sciences companies succeeded in 59% of the motions to dismiss they filed.

Five Takeaways from New Complaints Filed in 2024

1. Plaintiffs filed 44 new class actions against publicly traded life sciences companies in 2024. This marks an upward trend from 2023, with 34 new class actions against life sciences companies, and 2022, with 37 new class actions.
2. The number of new filings related to COVID-19 has tailed off since its peak in 2020–2022. In those years, we saw six or seven new filings per year, nearly all in the pre-approval (or pre-EUA) stage. By contrast, in 2023 only three new COVID-19 complaints were filed. In 2024, the number dropped to two—one against a company developing a vaccine and the other against a company with an approved vaccine facing poor sales as demand declined.
3. Geographically, the cases are concentrated in three regions, corresponding to three federal appellate circuits:
   - Fourteen new cases in the Ninth Circuit, which includes California
   - Nine new cases in the Second Circuit, which includes New York
   - Eight new cases in the First Circuit, which includes Massachusetts

   There were far fewer filings in the Third Circuit than in previous years—only three new cases.
4. Nineteen of the new cases (43%) were filed against companies with mature products. This is a slight decline from 53% in 2023, but higher than in earlier years. Companies with mature products have historically had less success in winning dismissal than companies with pre-approval products—although as noted below, that trend too has reversed this year.
5. The majority of new filings against companies with mature products arise from setbacks not unique to life sciences companies, principally sales performance. 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.

Six Takeaways from New Decisions Issued in 2024

THE NUMBERS: TWO TAKEAWAYS

1. **Success rate of 59% in the district courts, consistent with past trends**

   District courts issued 41 new decisions on motions to dismiss or motions for summary judgment filed by life sciences companies. Defendants were successful in over half—24 of 41, or 59%. That is consistent with the success rate in previous years, which has fluctuated in the 50–60% range.

   Companies won affirmance of dismissal in all eight of the cases in which appellate courts issued rulings. But none of the appellate decisions breaks new ground, and five of the eight were unpublished.

2. **Companies with mature products fared as well as those seeking FDA approval**

   In most years, companies fare better in the pre-approval cases than in mature products cases. The 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 trials and the FDA approval process. This year, however, marked a departure from that trend. Companies prevailed in 57% of the pre-approval cases (13 out of 23) and 61% of the mature product cases (11 out of 18).

THE SUBSTANCE: FOUR TAKEAWAYS

1. **Decisions on interim FDA communications after submission of an NDA provide pointers on recurring disclosure issues**

   In five cases, companies received negative feedback while an NDA or BLA was pending. The guidance that emerges from the decisions is that once this has occurred, companies are on safer ground when they stick to discussing clinical trial results, the strength of the application, and approval prospects generally. Companies are in more dangerous territory when they directly characterize the FDA's position, and in particular when they say that the FDA is aligned with their own views of outstanding issues. If at all possible, companies should avoid direct characterization of the FDA's position or communications.

2. **Decisions arising from issuance of Forms 483 provide additional disclosure guidance**

   In six decisions, companies received Forms 483, either before or after products had been approved. The decisions are largely unified in holding that companies have no standalone duty to disclose a Form 483. But the decisions also strongly suggest that a company faces peril if it does not review and revise its risk disclosures and other statements it routinely makes about contingent events after receiving a Form 483.

3. **Decisions in product launch cases yield mixed results**

   Three decisions address setbacks at the product launch stage, principally related to coverage hurdles. The results in the launch cases were mixed. The companies prevailed in two cases; the courts there closely read the challenged statements and analyzed them in the context of reasonable investors' expectations. But in the third case, Biogen suffered an eleventh-hour reversal of fortune in litigation arising from the launch of its controversial Alzheimer's disease drug, Aduhelm.

4. **Several 2024 decisions display courts' appropriately nuanced view of scienter**

   In three decisions, courts concluded that plaintiffs had adequately alleged falsity but dismissed on scienter grounds. In all three cases, plaintiffs had also established that defendants were aware of facts purportedly inconsistent with the challenged statements. All three courts held that this was not enough. Scienter requires an intent to defraud, and that is more than simply knowledge of purportedly contrary facts. To plead scienter, plaintiffs must establish what defendants believed and intended. Defendants may be aware of problems with a product but still believe that their optimistic statements about it are true—because they have confidence the problems can be addressed, even if others at the company believe otherwise.

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