SECURITIES LITIGATION AGAINST LIFE SCIENCES COMPANIES: 2022

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. Where the challenged statement is 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.

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 2022, life sciences companies succeeded in 52% of the motions to dismiss they filed.

FIVE TAKEAWAYS FROM NEW COMPLAINTS FILED IN 2022

1. Plaintiffs filed 37 new class actions against publicly traded life sciences companies in 2022, down significantly from such class action filings in 2020 (45) and 2021 (49).
2. The most significant trend in the new filings relates to the COVID-19 pandemic. Six of the new pre-approval cases arose from setbacks in the development of COVID-19-related products, which proceed through a distinct procedural pathway at the FDA, the Emergency Use Authorization. This is consistent with the COVID-19-related filings in 2020 (seven) and 2021 (six). As a likely indicator of things to come, we also saw the first new filings against companies with approved COVID-19 products. There were two such filings; together with the six pre-approval filings, the COVID-19 cases account for more than 20% of the year's total filings.
3. Geographically, the cases are concentrated in three regions, corresponding to three federal appellate circuits:
   - 11 new cases in the Second Circuit, which includes New York
   - 5 new cases in the Third Circuit, which includes New Jersey
   - 10 new cases in the Ninth Circuit, which includes California

   This reflects continuing concentration in these three regions. In all other regions of the country combined, only eleven new securities class actions were filed against life sciences companies.
4. Roughly 60% of the new cases (23) involve pre-approval drugs or devices.
5. Of the pre-approval cases, nearly 40% (9 out of 23) arise from setbacks at the final stages of the approval process, after a company has submitted a New Drug Application (NDA), Biologics License Application (BLA), or premarket clearance application.

SIX TAKEAWAYS FROM NEW DECISIONS ISSUED IN 2022

The Numbers: Two Takeaways

1. Success rate in the district courts was down slightly from 2021; success rate in the appellate courts was 100%. District courts issued 29 new decisions on motions to dismiss or motions for summary judgment filed by life sciences companies. Defendants were successful in just over half—15 of the 29, or 52%. That is down from success rates of 58% in 2021 and 57% in 2020. In the appellate courts, companies prevailed in all six cases.
2. The success rate in pre-approval cases was higher than that in post-approval cases. In a return to the normal trend, companies prevailed in roughly 60% of the pre-approval cases but only 40% of the post-approval cases. In 2021, the success rate was equal in the two settings; that appears to have been an aberration. The normal trend appears to reflect plaintiffs' challenges in establishing falsity and scienter in cases where the challenged statements concern inherently unknowable events—the outcome of clinical trials and the FDA approval process.

The Substance: Four Takeaways

1. Largely favorable results for companies in the second round of COVID-19-related cases. Courts ruled on motions to dismiss in five cases involving companies developing COVID-19 tests or vaccines. Companies prevailed on motions to dismiss in three and lost in one. In the fifth, the court dismissed claims against the company but allowed plaintiffs to proceed with Section 11 claims against underwriters, holding that plaintiffs had adequately alleged falsity. Courts were generally receptive to arguments that optimistic statements about the prospects for approval in the early days of the pandemic were forward-looking or non-actionable puffery. In the one case in which the company, Novavax, did not prevail on the motion to dismiss, the court concluded that plaintiffs had adequately alleged that the company's favorable statements about FDA approval were misleading, given undisclosed information about contamination at contract manufacturing facilities.
2. Appellate victories for companies developing oncology drugs. Life sciences companies prevailed in all five of the 2022 appeals in pre-approval issues. Three cases involving oncology drugs—*Nektar Therapeutics, Bristol-Myers Squibb,* and *Karyopharm Therapeutics*—bring into focus the appellate courts' sophisticated understanding of challenges in designing and conducting clinical trials in general and oncology or immuno-oncology trials in particular.
3. Divergent approaches to the analysis of economic motivation in pre-approval cases. Companies have historically succeeded in defeating scienter allegations when they point out that if they did not believe a drug or device would be approved, they would not expend time and resources on development and FDA review. In several recent decisions, courts have been receptive to an argument by plaintiffs that while a company may not know that its drug or device will not be approved, it can mislead investors by underselling risk. We discuss several difficulties with this approach, and ways in which companies can seek to reframe unfavorable judicial analyses of risk.
4. The enduring challenge of securities litigation arising from ongoing regulatory activity. When companies with approved products report regulatory scrutiny of sales, marketing, pricing or billing practices, plaintiffs' attorneys often piggyback onto the underlying regulatory activity with a securities action. Courts continue to struggle, at times to companies' detriment, with timing issues. Courts agree that companies need not accuse themselves of uncharged or unadjudicated wrongdoing, but often agree with plaintiffs that by discussing the reasons for their economic performance, companies may put the underlying conduct "at issue," and thereby assume a duty to disclose questionable practices. Robust cautionary statements may help alleviate risk in this area.

Click here to download the full Securities Class Actions in the Life Sciences Sector 2022 Annual Survey.

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