# Securities Litigation Against Life Sciences Companies: 2021

Securities class actions against life sciences companies are almost always 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 will 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 will 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 a company makes the challenged statement 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 2021, life sciences companies succeeded in 58% of the motions to dismiss they filed.

## Five Takeaways From New Complaints Filed in 2021

1. Securities plaintiffs filed 49 new class actions against publicly traded life sciences companies in 2021, up slightly from class action filings in 2019 (44) and 2020 (45).
2. The most significant trend in the new filings relates to the COVID-19 pandemic. Six of the new cases arose from setbacks in the development of COVID-19-related products. Such products proceeded through a distinct procedural pathway at the FDA, the Emergency Use Authorization.
3. Geographically, the cases are concentrated in three regions, corresponding to three federal appellate circuits:
   - 13 new cases in the Second Circuit, which includes New York
   - 7 new cases in the Third Circuit, which includes New Jersey
   - 19 new cases in the Ninth Circuit, which includes California
4. Roughly 80% of the new cases (39) involve pre-approval drugs or devices.
5. Of the pre-approval cases, nearly half (18) arise from setbacks at the final stages of the approval process, after a company has submitted an NDA, BLA, or premarket clearance application.

## Six Takeaways From New Decisions Issued in 2021

### The Numbers: Two Takeaways

1. **Success rate in the district courts was consistent with the success rate in 2020.** District courts issued 33 new decisions on motions to dismiss or motions for summary judgment filed by life sciences companies. Defendants were successful in 19 of the cases. This 58% success rate was in line with a 57% success rate in 2020, but down from the five-year high of 65% in 2018.
2. **The success rate in post-approval cases was the same as that in pre-approval cases.** Companies in 2021 prevailed as often in the post-approval as in the pre-approval cases. This is in marked contrast with the normal trend, in which success rates in the pre-approval cases can be as much as 40% higher than in the post-approval cases. The diminished success rate in the pre-approval context may be the result of stronger-than-usual confidential witness allegations in the cases decided in 2021. The increased success rate in the post-approval context appears to reflect the weakness of a series of complaints filed against companies with quarterly misses unrelated to any regulatory setback or issue.

### The Substance: Four Takeaways

1. **Mixed results the first round of COVID-19-related cases.** Courts ruled on motions to dismiss in four cases involving COVID-19-related products in 2021, granting dismissal in two and denying dismissal in two. Companies won dismissal in cases involving development of a rapid antigen test and a monoclonal antibody treatment. In both cases, the courts placed the companies' highly optimistic statements in the context of the early months of the pandemic, when reasonable investors knew that many steps remained before the FDA could grant approval. Courts denied motions to dismiss in two cases involving the development of vaccines, concluding that plaintiffs had adequately alleged that statements about manufacturing partnerships were deliberately misleading in light of undisclosed obstacles facing the manufacturers.
2. **The progeny and significance of *Endologix*.** In its 2020 decision in *Nguyen v. Endologix*, the Ninth Circuit introduced a key insight: Most alleged frauds in the pre-approval context are inherently unsustainable. Eventually, a product will fail to gain approval, which means that defendants can only delay the inevitable. Given that reality, many theories of scienter in pre-approval cases are simply implausible. The notable exception comes in cases in which plaintiffs are able to allege that defendants obtained a financial benefit from the purported fraud by selling stock during a period of temporary inflation. In 2021, district courts have begun to apply the *Endologix* analysis, which in principle should apply to all stages of product development up to approval. Application of *Endologix* in 2021 led to dismissal.
3. **The securities law overhang of post-approval regulatory issues.** Nearly all of the 2021 decisions denying motions to dismiss in the post-approval cases involved securities claims piggybacked onto adverse regulatory scrutiny of or action related to sales, market, or billing practices. The courts in these cases often embraced the proposition that when a company puts its sources of revenue "at issue," it must also disclose that its performance was driven by (purportedly) improper conduct. Stated at this level of generality, the proposition appears dangerously open-ended: Companies cannot help but put the sources of their revenue at issue. In practice, however, the proposition may be checked by the more defendant-friendly principle that companies need not disclose uncharged wrongdoing, or by arguments that plaintiffs have failed to adequately plead scienter. Careful tailoring of risk disclosures in this area may ward off securities liability.
4. **Mixed approaches and results related to "core operations."** In both the pre-approval and the post-approval setting, plaintiffs who are unable to plead particularized facts supporting a strong inference of scienter may fall back on the generalized theory that a court can infer scienter when the alleged fraud occurred in an area at the "core" of a company's business. District courts in the Second and Third Circuits rejected such allegations in 2021, while district courts in the Ninth Circuit in two cases accepted the allegations. In both of the unfavorable decisions, however, many factors were in play beyond the importance of a product to the company's business.

Click here to download the full Securities Class Actions in the Life Sciences Sector 2021 Annual Survey.