# Securities Litigation Against Life Sciences Companies: 2018

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 — 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 scrutinize the motions carefully and hold plaintiffs to the demanding statutory pleading requirements. In 2018, life sciences companies succeeded in winning dismissal in 65% of the cases in which they filed motions to dismiss.

## Five Takeaways From New Complaints Filed in 2018

1. Securities plaintiffs filed 48 new class actions against publicly traded life sciences companies in 2018. This was slightly down from new filings in 2016 and 2017 but consistent with an overall upward trend over the past five years, as several plaintiffs' firms continue to cast a very broad net.
2. Geographically, the cases are concentrated in three regions, corresponding to three federal appellate circuits:
    - 12 new cases in the Second Circuit, which includes New York
    - 10 new cases in the Third Circuit, which includes New Jersey
    - 14 new cases in the Ninth Circuit, which includes California
3. Cases against companies with drugs or devices at the pre-approval stage are sharply down this year. Only 16 such cases were filed in 2018, as opposed to 34 in 2017. Of those 16, 12 cases involved drugs or devices going through clinical trials; the other four involved drugs or devices for which NDAs or other applications had been submitted but not approved.
4. By contrast, filings against companies with approved products rose from 20 in 2017 to 28 in 2018.
5. Cases in which plaintiffs allege financial statement errors or internal control weaknesses are on the rise. Seven such cases were filed in 2018.

# Eight Takeaways From New Decisions Issued in 2018

## The Numbers: Four Takeaways

1. **Success rate in the district courts is back up**. District courts issued 48 new decisions on motions to dismiss (or summary judgment motions) filed by life sciences companies. Defendants were successful in 31 of the cases. After a notably poor 2017 (in which defendants prevailed in only 50% of the cases), this 65% success rate reflects a return to the rates we have seen over the past several years.
2. **The improvement in success rate is largely attributable to post-approval cases.** In 2017, the gap between success in the pre-approval and post-approval settings was large: Companies prevailed in more than 60% of the pre-approval cases but only 30% of the post-approval cases. In 2018, the gap has closed significantly: Companies prevailed in 73% of the pre-approval cases and 58% of the post-approval cases.
3. **Success rate may relate to volume of filings.** This improvement in success rate may be related to a less selective approach by certain plaintiffs' firms in filing cases. The number of post-approval decisions more than doubled in 2018, as the large volume of cases filed in 2016 and 2017 moved through the courts. The 2018 results suggest that the rise in new filings in 2016 and 2017 swept in many weaker cases.
4. **Success rate in the appellate courts is mixed.** Companies prevailed in four of the seven cases in the appellate courts. Substantively, however, the defeats were more significant than the victories.

## The Substance: Four Takeaways

1. **Setbacks in the appellate courts.** The Ninth Circuit's 2018 *Orexigen* decision appears to have effected a pro-plaintiff reset on important procedural questions concerning courts' ability to consider materials outside the complaint on a motion to dismiss. In *Esperion*, the Sixth Circuit adopted a harsh approach to a company's account of interim agency communications where that account was undercut by later regulatory developments. And in *Singer*, the Fourth Circuit appeared to blur the line between alleged regulatory misconduct and securities fraud by adopting an omission theory that encompassed the challenged conduct.
2. **Statements made in the course of ongoing trials present special risks.** A common pattern in cases in which companies did not prevail involves commentary on preliminary or interim results in the context of ongoing trials. This is a high-risk area. Companies may be faulted for not sufficiently advising investors that preliminary results are less than reliable. Companies that report interim results may also inadvertently take on a duty to update when they learn of subsequent, less positive results — even if those negative results are also preliminary. Adopting a consistent disclosure plan before trial results become available may alleviate some of this risk.
3. **Positive results for companies in cases involving disputes over science.** Companies prevailed in multiple cases in which they were able to characterize plaintiffs' claims as attacks on trial design or scientific analysis. The 2018 decisions uniformly reflect the rule that courts will not intervene in such disputes.
4. **Regulatory violations do not equate to securities fraud — but the line between the two areas can blur.** Courts generally recognize that even high-stakes government investigations do not necessarily equate to securities fraud. An investor asserting a securities fraud claim must identify a materially false or misleading statement. But the line between regulatory wrongdoing and securities fraud has blurred in certain decisions in which courts have held that plaintiffs state a claim where a company "puts at issue" the reasons for its success but does not disclose the challenged conduct as one such reason.

Click here to download the full Securities Class Actions in the Life Sciences Sector 2018 Annual Survey.

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