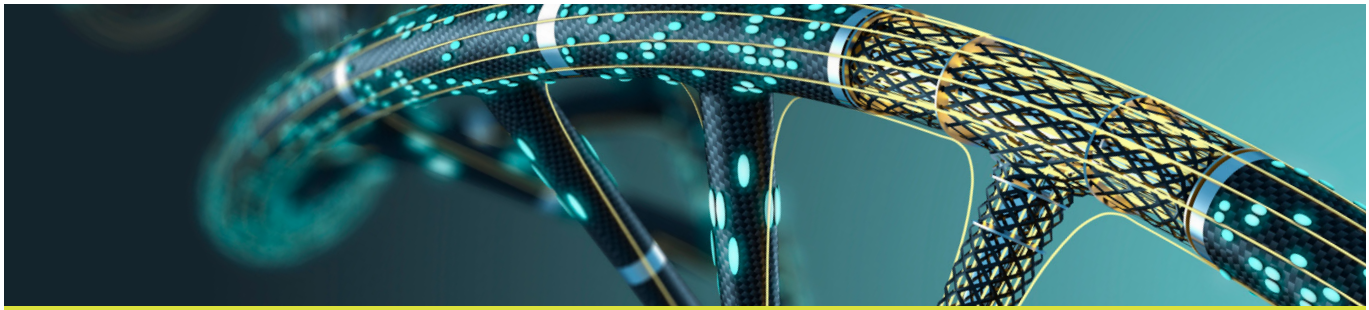

Securities Litigation Against Life Sciences Companies: 2020

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 consider the motions carefully and hold plaintiffs to the demanding statutory pleading requirements. In 2020, life sciences companies prevailed on 57% of the motions to dismiss they filed.

Five Takeaways From New Complaints Filed in 2020

1. Securities plaintiffs filed 45 new class actions against publicly traded life sciences companies in 2020, almost exactly the same number filed in 2019 (44).

2. The most significant trend in the new filings relates to the COVID-19 pandemic. Seven new cases involve COVID-19-related products, including both tests and vaccines. These products have 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:

    - 11 new cases in the Second Circuit, which includes New York
    - 8 new cases in the Third Circuit, which includes New Jersey
    - 19 new cases in the Ninth Circuit, which includes California

    In 2019, by contrast, 21 new cases were filed in the Second and Third Circuits combined, as opposed to only nine in the Ninth Circuit. The 2020 filings reflect a shift from East to West.

4. Roughly two-thirds of the new cases (29) involve pre-approval drugs or devices.

5. Of the new cases involving post-approval products, nearly half turn on alleged regulatory issues.

Seven Takeaways From New Decisions Issued In 2020

THE NUMBERS: THREE TAKEAWAYS

1. Success rate in the district courts has decreased, but only slightly. District courts issued 35 new decisions on motions to dismiss filed by life sciences companies. Defendants were successful in 20 of the cases. This 57 percent success rate is down slightly from the rate in 2018 and 2019 (65 percent and 62 percent respectively), but up from the recent low of 50 percent in 2017.

2. The success rate is higher in pre-approval cases. Consistent with past years, companies prevailed more often in pre-approval cases (67 percent) than in post-approval cases (43 percent). The relatively greater ability to anticipate and disclose risks in the pre-approval space may account for some of this disparity. The reluctance of courts to engage in disputes over science and medicine may also play a role.

3. Success in the appellate courts is up. Companies prevailed in seven of the eight cases in the appellate courts. This includes significant victories in the Second and Ninth Circuits, as well as one notable setback in the Second Circuit.

THE SUBSTANCE: FOUR TAKEAWAYS

4. **Two approaches to financial motivation as companies approach approval.** Courts have taken two distinct approaches in assessing scienter and motivation as companies approach approval. In Endologix, from the Ninth Circuit, and in a number of district court decisions, courts have reasoned that it makes little sense to posit that a company would expend resources on a trial it believes will fail, or on an NDA that it knows will not be approved. By the same token, companies are unlikely to artificially inflate stock prices when the discovery of the truth — through, for example, the denial of an NDA — is inevitable. On the other side of the ledger, several district courts have adopted plaintiffs' theory that a cash-strapped company may "gamble" on approval when it has few other options, particularly if the company or its executives may realize short-term gains from doing so.

5. **Setback in the Second Circuit on opinion statements and disputes over science.** In past years, the Second Circuit has issued leading pro-defendant decisions on opinion statements (in Tongue v. Sanofi) and on disputes over trial design and other scientific matters (in Kleinman). In its 2020 decision in NewLink Genetics, however, the Second Circuit delivered a setback on both issues. The court held that the distinction between statements of opinion and statements of fact is unimportant in determining whether plaintiffs have sufficiently pled falsity. The court also waded into a dispute over what prior studies had shown about cancer survival rates, and concluded that plaintiffs had sufficiently pled falsity by collecting studies that supported their views.

6. **Risks and disclosures around Forms 483.** In five decisions, courts considered companies' disclosure obligations when they receive Forms 483. Three decisions favored defendants; two favored plaintiffs. When a company chooses to disclose receipt of a Form 483, this will go a long way toward dispelling any inference that the company sought to deceive investors about manufacturing issues. When a company is silent about a Form 483 it has received, more nuanced questions arise about materiality and the duty to disclose. Plaintiffs will often target a company's statements about compliance with Current Good Manufacturing Practices and the risk of regulatory actions related to manufacturing, arguing that these statements are false or misleading in light of a Form 483. A company that has received a Form 483 would do well to review and, where appropriate, to revise such statements in periodic filings.

7. **Further development of substantive scienter doctrines in post-approval cases.** In the post-approval context, courts in 2020 often turned to theories on which plaintiffs rely where they have a very limited factual basis — or no factual basis at all — for asserting that executives who made the challenged statements knew that those statements were false or misleading. Two such plaintiff-friendly theories are corporate scienter (in which the knowledge of a non-speaking employee is imputed to the company) and the core operations doctrine (in which knowledge of certain key information is assumed). Companies won victories on the corporate scienter theory in 2020, including a significant victory in the Second Circuit, Jackson v. Abernathy. Results on the core operations doctrine were mixed.

Click here to download the full Securities Class Actions in the Life Sciences Sector 2020 Annual Survey.

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