Securities Litigation Against Life Sciences Companies: 2019

Securities class actions against life sciences companies are typically 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 stock 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 2019, life sciences companies succeeded in winning dismissal in approximately 60% of the cases in which they filed motions to dismiss.

Five Takeaways From New Complaints Filed in 2019

1. Securities plaintiffs filed 44 new federal class actions against publicly traded life sciences companies in 2019. This is a slight decrease from the number of new actions filed between 2016 and 2018, which ranged from 48 to 54 per year.
2. Geographically, the cases are concentrated in three regions, corresponding to three federal appellate circuits:
   - 14 new cases in the Second Circuit, which includes New York
   - 7 new cases in the Third Circuit, which includes New Jersey
   - 9 new cases in the Ninth Circuit, which includes California
3. Substantively, the cases are weighted slightly toward issues involving drugs and devices at the pre-approval stage. There are 24 new cases at the pre-approval stage, consisting of:
   - 13 new cases with product candidates in clinical trials (or at the pre-clinical stage)
   - 11 new cases with product candidates for which NDAs or other applications have been submitted but not approved
4. 20 new cases were filed against companies with approved products.
5. In 2018, the Supreme Court held in *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund,* 138 S. Ct. 1061, that state courts have jurisdiction over securities class actions arising from challenged statements in public stock offering documents. This has led to a sharp increase in the number of securities class actions filed in state court. State court is widely regarded as a more hospitable forum for securities plaintiffs than federal court; among other reasons, several of the pro-defendant procedural protections required by the Private Securities Litigation Reform Act are not automatically applied in state court. Across all industries, plaintiffs in 2019 filed 49 state court class actions challenging statements in IPO or other public offering documents. In the life sciences sector, however, the rise of state court litigation has been modest, with only five new complaints in 2019. The explanation may be that by the time a life sciences company faces the kinds of events that draw securities litigation, the company's IPO is many years in the past. Nevertheless, life sciences companies, no less than companies in other industries, have faced one of the collateral consequences of *Cyan* and the increased activity in state courts—rising costs of D&O insurance.

Seven Takeaways From New Decisions Issued In 2019

THE NUMBERS: FOUR TAKEAWAYS

1. **Success rate in the district courts is approximately 60%.** In 2019, district courts issued 38 new decisions on motions to dismiss filed by life sciences companies. Defendants were successful in 23 of the cases. This 60% success rate falls between a 65% success rate in 2018 and a 50% success rate in 2017, which was a five-year low.
2. **Companies with pre-approval products have done better in the district courts than companies with post-approval products.** Companies prevailed on motions to dismiss in 77% of the pre-approval cases but in only 52% of the post-approval cases.
3. **Poor success rate in generic drug pricing cases.** In 2016 and 2017, the plaintiffs' bar began filing securities fraud actions against generic drug manufacturers, following federal and state law enforcement activity in which certain companies were accused of conspiring to fix generic drug prices. As these cases have moved through the courts, companies have fared poorly at the motion to dismiss stage. Of the six decisions issued in 2019, defendants won dismissal in only one.
4. **A quiet year on the appellate front.** The appellate courts in 2019 issued only three decisions in securities litigation against life sciences companies. All three were victories for defendants, but only one of the three is a published opinion.

THE SUBSTANCE: THREE TAKEAWAYS

1. **Pro-defendant law continues to develop around challenged opinion statements.** Courts are continuing to apply and refine the analysis of opinion statements following the Supreme Court's 2015 decision in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175. The 2019 decisions illustrate the broad reach of *Omnicare* to a variety of statements incorporating interpretation or judgment. Defendants were largely successful in 2019 in showing both that particular statements should be treated as opinions and that plaintiffs had not met *Omnicare*'s demanding standards as to those statements.
2. **Claims based on disputes over science continue to fail.** The courts in 2019 have continued to reject claims where defendants were able to characterize plaintiffs' attack on their statements as disputes over science. In a recurring fact pattern in the 2019 cases, plaintiffs have sought to account for the difference between a successful Phase 2 trial and an unsuccessful Phase 3 trial by arguing that some aspect of the Phase 2 trial was aberrant, with the result that the Phase 2 trial results looked better than they were and could not be repeated in Phase 3. The courts have rejected such claims as impermissible attacks on trial design.
3. **Mixed results in post-approval cases based on regulatory or other litigation activity.** Historically, courts have recognized that even high-stakes government investigations do not automatically map onto securities fraud claims. Courts in some of the 2019 decisions have continued to carefully separate securities litigation from the first-order problems that led to stock price declines—for example, by holding that securities litigation is premature while the first-order activity remains unresolved, or that securities litigation is unwarranted where a government investigation does not result in adverse action against the company. In other cases, however—most notably the generic drug pricing cases—the line appears to have blurred, with the risk that securities litigation may become the vehicle for adjudicating issues more appropriately resolved in other fora.

Click here to download the full Securities Class Actions in the Life Sciences Sector 2019 Annual Survey.

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