# Dechert Survey of Securities Fraud Class Actions Brought Against Life Sciences Companies

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April 2009

# Life Sciences Companies of All Sizes Remain Firmly in the Crosshairs of the Plaintiffs' Securities Bar

In 2008, 23 different pharmaceutical and biotech companies, along with numerous of those companies' directors, officers, and key medical and research personnel, were sued for alleged securities fraud. While the number of securities fraud lawsuits against life sciences companies in 2008 remained fairly constant as compared to 2007, the nature of the claims differed dramatically. In 2008, the majority of the securities fraud lawsuits focused not on public statements regarding the prospects for FDA approval, product efficacy, or product safety as they did in 2007 (though those claims were still often present), but rather on the company's financial information—particularly allegations of accounting mistakes, improperly prepared financial statements, and misleading information regarding a company's financial health. Also noteworthy given last year's trend of having the biggest life sciences companies sued for securities fraud, in 2008, securities fraud plaintiffs targeted companies with smaller market capitalizations over 50% of the time.

In this survey, we first highlight the trends we observed in the securities fraud lawsuits filed against life sciences companies in 2008, including a discussion of some of the notable allegations made in those suits. We then analyze the status and results of the securities fraud lawsuits brought in 2007, including an assessment of whether these cases have fared any differently than other securities fraud cases. We next look at significant recent developments and offer our observations as to what the future may hold for life sciences companies in the securities fraud arena. Finally, we provide some useful practices for life sciences companies to consider for minimizing the risk of, or adverse impact from, securities fraud class action lawsuits.

## Findings

**(1) While the number of securities fraud class actions brought against life sciences companies in 2008 remained about the same as in 2007, the percentage compared to all other securities fraud class actions dipped due to an increase in the number of securities fraud complaints brought in other sectors.**

Life sciences companies were the target of 23 securities fraud class actions in 2008. While this number is only two less than in 2007, it represents only 10% of the 225 total securities fraud class actions filed in total in 2008, compared to 14% in 2007, 13% in 2006, and 16% in 2005. This drop in percentage is attributable to the fact that securities fraud class actions in the financial services sector skyrocketed in 2008.[1]

**(2) Life sciences companies with smaller market capitalizations were primarily targeted in 2008.**

Similar to years past, more than half of the life sciences companies that were sued for securities fraud had a market capitalization of less than $250 million (see Figure 1). While life sciences companies with the greatest market capitalization—more than $10 billion—were sued at nearly that same rate in 2007, that trend did not continue in 2008; only 17% of total actions were brought against the largest life sciences companies.

[1] The total number of securities fraud class actions is based on information reported by the Securities Class Action Clearinghouse in cooperation with Cornerstone Research. *See* http://securities.stanford.edu. A useful and corroborating source for much of this information can be found at *The D&O Diary* blog, www.dandodiary.com/2009/02/articles/securities-litigation/a-closer-look-at-the-2008-life-sciences-securities-lawsuits/.

**(3) The substantive allegations against life sciences companies were primarily focused on issues related to accounting improprieties and inflated revenues.**

While the claims concerning drug efficacy and safety, marketing, manufacturing, and FDA approval that predominated in prior years also appeared in 2008, they were far fewer in number than in 2007. As discussed in more detail in the next section, and in a departure from the 2007 results, the majority of claims in 2008 hinged on allegations of faulty accounting and inflated revenues, rather than on industry-specific issues related to the safety, efficacy, or marketing of a particular product.

**(4) Research personnel at life sciences companies continue to be named as individual defendants in securities fraud lawsuits.**

In 2007, we reported on a trend that we expected would continue: plaintiffs' lawyers would employ the theory that because certain key research personnel had a high-level position within the company and access to internal information, they both knew and failed to disclose the alleged adverse non-public information. This trend did continue in 2008, where key research personnel were named as individual defendants in five separate cases.

## The Nature of the Claims

**Alleged misrepresentation/non-disclosure regarding accounting improprieties**

Of all the allegations in the securities fraud complaints against life sciences companies in 2008, the most common allegations pertained to accounting improprieties and/or misstated or misleading financial results and forecasts. Altogether, nearly

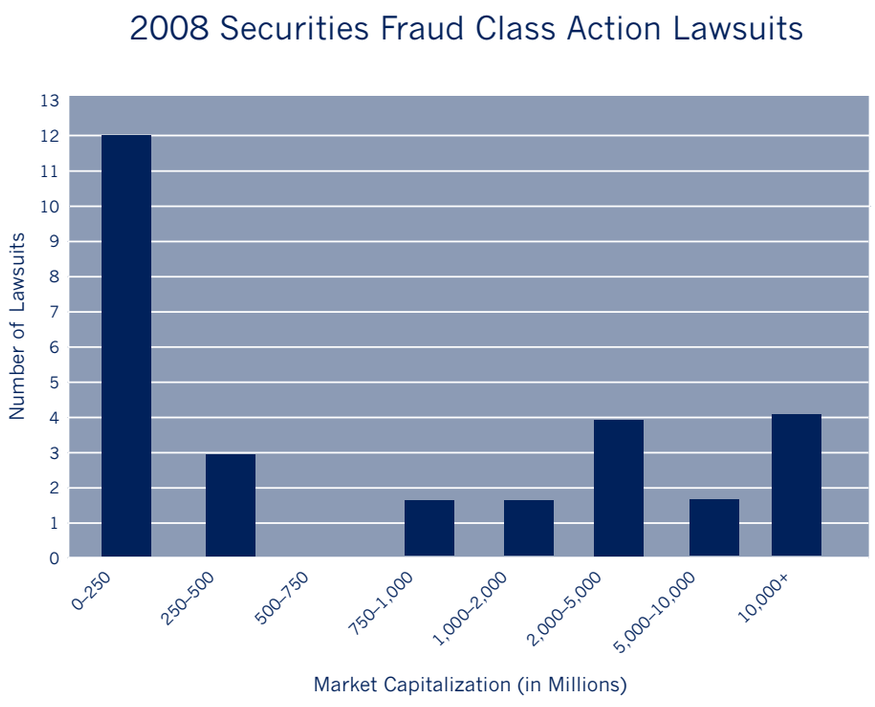


**Figure 1.**

| Allegations in 2008 Lawsuits | Number of Lawsuits |
|---|---|
| Alleged misrepresentations and/or non-disclosures regarding accounting improprieties | 10 |
| Alleged misrepresentations and/or non-disclosures regarding product safety | 6 |
| Alleged misrepresentations and/or non-disclosures regarding marketing practices | 6 |
| Alleged misrepresentations and/or non-disclosures regarding product efficacy | 5 |
| Alleged misrepresentations and/or non-disclosures regarding manufacturing processes | 3 |
| Alleged misrepresentations and/or non-disclosures regarding likelihood of FDA approval | 2 |
| Alleged misrepresentations and/or non-disclosures regarding the status of pending patent infringement litigation | 1 |

**Figure 2: Lawsuit allegations span the drug product life cycle.**

half of the 2008 complaints made such allegations, and eight of the complaints rested solely on such allegations. For example, a putative class of shareholders filed suit in the Southern District of Florida against Arthrocare, alleging that the company overstated its financial results and engaged in improper accounting practices primarily by improperly recognizing various non-revenue generating transactions as revenue. The complaint alleged that when the company's fraudulent accounting practices were revealed through a series of news stories and partial disclosures, its stock price fell over 50%.

Other complaints focused on alleged accounting mistakes or mismanagement. For example, a putative class of shareholders filed suit in the Southern District of New York against China Shenghuo Pharmaceutical Holdings, Inc., after the company issued a press release acknowledging that its prior financial statements could not be relied upon and needed to be restated due to accounting errors. According to the complaint, the announcement caused the company's stock to lose nearly 19% of its value.

### Alleged misrepresentation/non-disclosure regarding the commercialization or marketing of a product

In approximately 25% of the 2008 securities fraud complaints against life sciences companies, shareholders brought suit alleging that the defendants either improperly marketed their product for off-label purposes, illegally promoted their product to physicians by way of kickbacks, or made positive statements about the ability to market products that they knew were commercially not viable. For example, shareholders brought suit against Spectranetics Corp. in the District of Colorado alleging, among other things, that defendants failed to disclose that they were illegally and extensively marketing lasers and catheters for uses that had not been approved by the FDA. When it became public that Spectranetics was the subject of an unannounced visit by federal officials who were seeking information relevant to this practice, among others, Spectranetics' shares fell 47% before NASDAQ halted trading.

### Alleged misrepresentation/non-disclosure regarding product safety

Another 25% of the 2008 securities fraud complaints alleged that defendants made false and misleading statements about the safety of their products, or more typically, that defendants withheld the negative safety results of clinical trials. For example, shareholders brought suit against Savient Pharmaceuticals, Inc., in the Southern District of New York, alleging that defendants failed to disclose five serious adverse events (SAEs) experienced by patients in two clinical trials of the drug pegloticase. According to the complaint, once defendants finally disclosed the SAEs, Savient's stock price declined significantly.

### Alleged misrepresentation/non-disclosure regarding product efficacy

Allegations of misrepresentation or non-disclosure regarding product efficacy appeared in securities fraud complaints in 2008 in a straightforward form, typically alleging failure to disclose that clinical trials indicated a product lacked efficacy. For example, the shareholder complaint filed in the District of New Jersey against Schering-Plough Corporation alleged that defendants knew but failed to timely reveal that the drug Vytorin, a combination of Zetia and Zocor, performed no better than did the cheaper generic form of Zocor. According to the complaint, the defendants misled investors with positive statements about Vytorin that were not only unsupported, but were undercut by the ENHANCE study; the shareholders further alleged that the defendants knew that once these results were made public, the medical community would turn away from Vytorin to less expensive generics. Hence, according to the complaint, once the study results were released, it became clear to the market that Schering-Plough's earnings forecasts were artificially inflated, and its stock price began to decline.

## The Status of the 2007 Cases

As of the time this survey goes to print, of the 25 securities fraud class actions filed against life sciences companies in 2007, eleven

have been dismissed and two have settled.[2] The two settlements were for $1 million and $5 million respectively, which is within the standard range of settlements according to the collected data on settlements in securities fraud litigation in general.[3] Of the eleven dismissals, eight are final and three are on appeal. This dismissal rate mirrors that of shareholder class actions in general.[4]

The court opinions issued in connection with the motions to dismiss underscore that the scienter element of a securities fraud claim against a life sciences company has teeth. In all of the opinions generated by the 2007 dismissals, the courts held that plaintiffs failed to adequately plead scienter. The opinions make clear that though plaintiffs may be given multiple opportunities to amend their complaints, they will not be able to survive a motion to dismiss with general, conclusory, or generic allegations of knowing misconduct. Defense counsel familiar with the detailed pleading requirements of the Private Securities Litigation Reform Act will not be surprised by this result, and will continue to use the scienter requirement as a sword to attack vague complaints, demanding either detailed and coherent facts or dismissal at the pleading stage.

| Status of 2007 Cases (as of 3/31/09) | Number of Cases |
|---|---|
| Motion to Dismiss Pending | 8 |
| Dismissed | 11 |
| Discovery/Ongoing | 4 |
| Settled | 2 |

## Expectations for the Future

### Life sciences companies' inherent vulnerability may increase when the boom of securities class actions in the financial sector busts

As we noted in our previous surveys, life sciences companies are particularly vulnerable to securities lawsuits because of their inherently volatile stock prices, often driven by a drug or device product life cycle fraught with potential for adverse and unpredictable events. That vulnerability may increase in the coming months and years when the boom of securities class actions in the financial sector busts. Specifically, in 2008, while the number of securities fraud class actions against life sciences companies remained relatively steady, even dropping by two complaints from 2007, the total number of securities class actions skyrocketed in 2008 as compared to prior years, with the bulk of complaints clustered in the financial sector. The current economic crisis has made the financial sector a particularly inviting target for plaintiffs' lawyers, and may have distracted them to some extent from pursuing life sciences companies. Of course, such trends are cyclical, and last only as long as the targets exist. Once plaintiffs' targets in the financial sector dry up, other sectors, including life sciences, may see an increase in lawsuits aimed their way.

### Off-label marketing guidelines are in flux

Early in 2009, in the final days of the Bush administration, the FDA issued new guidelines making it easier for drug manufacturers to communicate off-label drug usage information to doctors. Specifically, the FDA eliminated the requirement that drug manufacturers submit academic articles on the benefit of a particular off-label use to the FDA for verification before such article could be given to a doctor. While it is unclear whether the Obama administration will change this policy, it highlights the degree to which issues relating to off-label marketing and promotion continue to be in flux, and consequently can provide fodder for the class action plaintiffs' bar. Life sciences companies involved in the off-label promotion of a product must stay abreast of the changes in, and nuances of, the FDA's guidelines in this regard to ensure protection from securities fraud lawsuits that could well increase, if and when administrative guidelines in this area become more restrictive.

## Minimizing the Risk of Securities Fraud Class Actions

There are several steps that life sciences companies can take to reduce the risk of, or impact from, securities fraud class actions. Aside from the obvious strategy of ensuring that the companies' statements and public filings are truthful and accurate, the following should be considered:

1. Be alert to events that may negatively impact the drug product life cycle. Some potentially troubling issues are obvious, e.g., clinical trial failures and FDA rejection. Others, however, are not so obvious, such as manufacturing problems, the loss of a key commercial partner, or an increased percentage of revenues coming from off-label uses. As discussed in this survey, these events often trigger securities fraud class actions.

2. Explain to managers how issues in their specific areas of responsibility could become the basis of a securities fraud class action. For example, R&D managers and marketing executives need to understand that how they conduct clinical trials and tests may not only affect the drug development process, but also expose the company to the risk of a securities fraud class action.

3. Ensure that public statements and filings contain appropriate "cautionary language" or "risk factors" that are specific and meaningful, and cover the gamut of risks throughout the entire drug product life cycle—from development to production to commercialization.

4. Ensure that the sometimes fine line between puffery and statements of fact is not crossed in public statements

[2] This dismissal rate includes one voluntary dismissal, and does not distinguish between dismissals with or without prejudice.

[3] *See*, e.g., Stephanie Plancich, et al., *2008 Trends: Subprime and Auction-Rate Cases Continue to Drive Filings, and Large Settlements Keep Averages High* at 16 (July, 2008), available at www.nera.com/image/BRO_Recent_Trends_8.5x11_0808.pdf.

[4] *Id*. at 10.

or filings, or even in extemporaneous statements during analyst calls and media commentary. While soft puffery conveys a positive message and image about a company that is not misleading under the securities laws, it is upon hard statements of fact that class action lawyers—with the benefit of 20/20 hindsight—will concoct a lawsuit.

5. Develop and publish an insider trading policy to minimize the risk of inside trades during periods that might help class action lawyers later develop a theory. Class action lawyers aggressively monitor trades by insiders to develop allegations that a company's executives knew "the truth" and unloaded their shares before it was disclosed to the public and the stock plummeted.

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## Dechert's Life Sciences Practice

Dechert LLP represents life sciences companies, multinational corporations, financial institutions, investment companies, and private funds in litigation, transactional, corporate, tax, and regulatory matters. Dechert was again recognized as one of the top three product liability practices in the country by *The American Lawyer*, while *The National Law Journal* once again named Dechert to its top ten "Defense Hot List." Our trial team has played a major role in landmark class actions in the United States, and our lawyers have earned a reputation for aggressively, creatively, and effectively representing clients in high-risk litigation.

In addition to publishing the *Dechert Survey of Securities Fraud Class Actions Brought Against Life Sciences Companies*, our group regularly publishes other materials of interest to life sciences practitioners. If you would like to receive these materials, please contact:

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## About Dechert LLP

With 18 offices in the United States, Europe, and Asia, Dechert LLP is an international law firm focused on corporate and securities, business reorganization and restructuring, complex litigation and international arbitration, financial services and asset management, finance and real estate, intellectual property, labor and employment, and tax law.

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