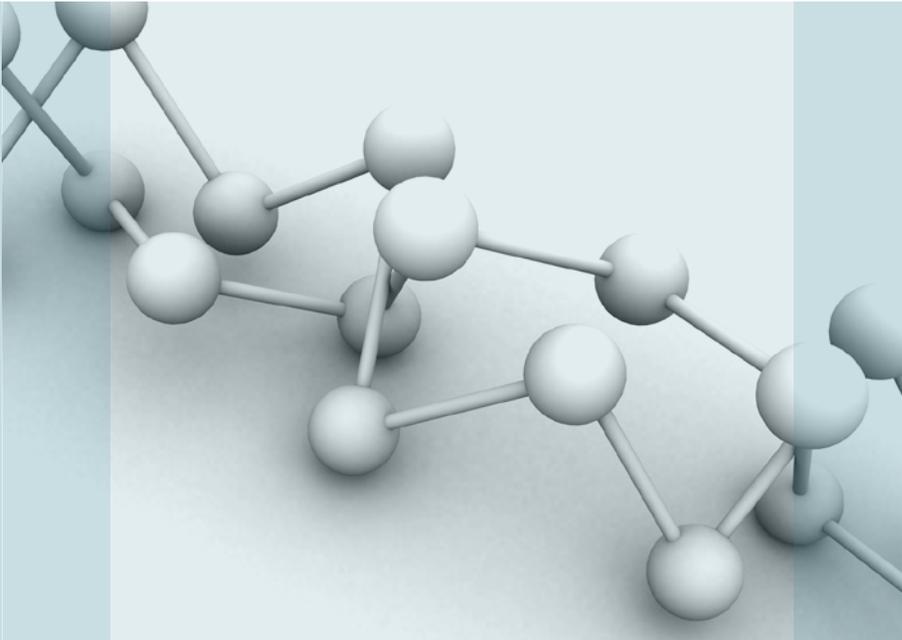


# Dechert Survey of Securities Fraud Class Actions Brought Against Life Sciences Companies



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## Life Sciences Companies Remain in the Crosshairs of Securities Fraud Class Action Lawyers

In 2004, pharmaceutical and biotechnology companies—both large and small—remained squarely in the sights of securities fraud class action lawyers. In 2004, 25 life sciences companies were sued for securities fraud, on top of the 32 that were sued in 2003.

As we observed in last year's survey, the predominant reason behind this assault on life sciences companies is the combination of the volatility of a life sciences company's stock price and an FDA approval process that is rife with potentially adverse events and developments. But unlike in the recent past, when the plaintiffs' targets were largely start-up or early stage biotech companies, in 2004 it was the largest industry players who were targets of class actions.

In this survey, we discuss this and other trends in securities fraud class actions against life sciences companies. We then offer recommendations on how life sciences companies can minimize the risk of securities fraud class action lawsuits.

## FINDINGS

### (1) The number of securities fraud class actions brought against life sciences companies remains high.

While the total number of securities fraud class actions filed across all industries in 2004 rose slightly compared to 2003, from 216 to 233, or 8%, the number of securities fraud lawsuits brought against life sciences companies—although still high—decreased in 2004, from 32 to 25, or 22%. The securities fraud class action lawsuits against life sciences companies comprised 10% of all such lawsuits filed in 2004, which is down slightly from 15% in 2003, but still up from 9% in 2002.

### (2) While companies with smaller market caps remain the most frequent targets, the largest life sciences companies also faced a growing number of suits.

As the chart below (Figure 1) illustrates, nearly half of the life sciences companies that were sued in 2004 have a market capitalization of less than \$250 million, which is similar to what we observed in 2003. However, the percentage of the largest life sciences companies (market caps greater than \$5 billion) who were sued rose from just over 15% to 20% in 2004.

### (3) The substantive allegations against life sciences companies continue to span the drug product life cycle.

As in 2003, while the traditional securities fraud claim of misrepresentations/omissions regarding the company's financial outlook remained a prevalent theory, the securities fraud lawsuits brought against life sciences companies in 2004 again focused on the entire range of the drug product life cycle. Among the different aspects of the drug development process, claims that companies had deceived investors regarding product efficacy and safety again topped the 2004 list.

Additionally, the plaintiffs also continue to challenge multiple aspects of a particular drug's development process in a given complaint.

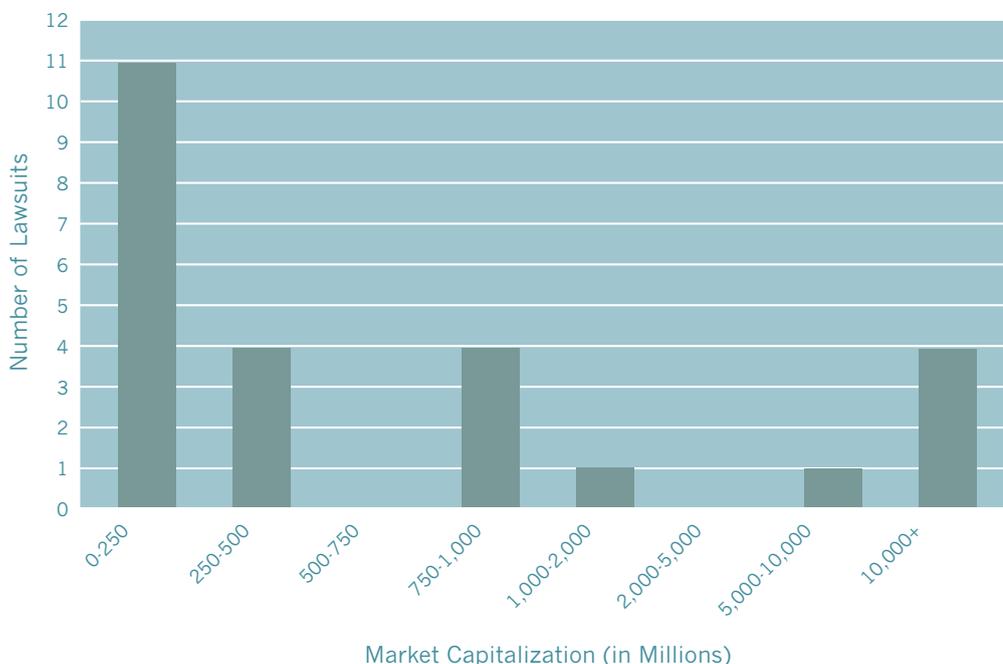
### (4) Research personnel at life sciences companies were more frequently named as individual defendants in securities fraud lawsuits.

A new development in 2004—with far-reaching implications—is that research personnel of life sciences companies, including chief medical officers, were named as defendants in seven of the 25 securities fraud cases against life sciences companies. To join these key research personnel as individual defendants, plaintiffs' lawyers simply alleged that the researchers, like CEOs and other executives, are controlling persons of the defendant companies and are therefore responsible for the acts taken by the company. The lawsuits in which these key research personnel are named as defendants run the gamut of types of allegations regarding failures throughout the drug development process.

### (5) Alleged insider trading was increasingly cited as evidence that the company purportedly acted fraudulently.

In eight of 25 cases filed against life sciences companies in 2004, plaintiffs specifically cited stock sales by company insiders during the time of the alleged fraud as evidence that not just the insider—but the company as a whole—acted with the fraudulent intent required to plead a federal securities fraud claim.

## 2004 Securities Fraud Class Action Lawsuits



**Figure 1: While nearly half of all life sciences companies sued for securities fraud in 2004 have a market capitalization of less than \$500 million, over 20% have a market capitalization of greater than \$5 billion.**

Allegations in 2004 Lawsuits	Number of Lawsuits
Alleged misrepresentations and/or non-disclosures regarding product efficacy	11
Alleged misrepresentations and/or non-disclosures regarding product safety	5
Alleged misrepresentations and/or non-disclosures regarding clinical trial results	4
Alleged misrepresentations and/or non-disclosures regarding the likelihood of FDA approval	2
Alleged misrepresentations and/or non-disclosures regarding description of a product	1
Alleged misrepresentations and/or non-disclosures regarding marketing or commercialization of a product	1
Alleged misrepresentations and/or non-disclosures regarding the quality of a manufacturing process	1
Alleged misrepresentations and/or non-disclosures regarding business strategy	1
Alleged accounting improprieties and/or inflating revenues	6

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

## THE NATURE OF THE CLAIMS

### Alleged misrepresentations/non-disclosures regarding product efficacy

As in 2004, the most common type of securities fraud claim brought against life sciences companies involved allegations that the company misrepresented the efficacy of its product. In June 2004, a putative class of shareholders in POZEN, Inc. brought suit in the Middle District of North Carolina against POZEN and three of its executives for alleged misrepresentations regarding the efficacy and safety of two of the company's leading product candidates for the treatment of migraine headaches: MT 100 and MT 300. Plaintiffs allege that POZEN repeatedly touted the efficacy of MT 100 to the investing public, including describing various clinical trials in which MT 100 provided significant benefits compared to placebo. However, the FDA issued a not-approvable letter for MT 100 in which the FDA found that MT 100 did not meet its primary endpoints for efficacy in two clinical studies. POZEN's stock price dropped 37% on the day of the FDA's announcement.

### Alleged misrepresentations/non-disclosures regarding product safety

Again in 2004, another common type of securities fraud claim brought against life sciences companies regarding the drug development process was that the company misrepresented the safety of its product. In May 2004, a putative class of shareholders in Genta, Inc. brought suit in the District of New Jersey against Genta and two of its executives, including its chief medical officer, for alleged misrepresentations regarding the efficacy and safety of the drug Genasense, which was being developed to treat skin cancer. Plaintiffs alleged that Genta represented to the investing public that Genasense was not associated with serious adverse reactions. However, a Phase III clinical trial allegedly showed increased toxicity and a higher rate of serious adverse events on the Genasense arm. The FDA found that the trial did not provide substantial evidence of effectiveness to outweigh the increased toxicity of Genasense.

After the FDA's findings were released, Genta's stock price dropped 65%.

### Alleged misrepresentations/non-disclosures regarding clinical trial results

As in 2003, a common securities fraud claim in 2004 involved allegations that the company misrepresented or failed to disclose clinical trial results. In September 2004, a putative class of shareholders sued Maxim Pharmaceuticals and its CEO and CFO for securities fraud in the Southern District of California. In January 2001, the FDA rejected Maxim's drug Ceplene as a treatment for malignant melanoma after reviewing results from a Phase III clinical trial. In September 2003, Maxim announced that enrollment had been completed for a second Phase III clinical trial for Ceplene; Maxim called this a "confirmatory" trial intended to supplement the results of the first Phase III trial, which led to the rejection of Ceplene by the FDA. In April 2004, Maxim announced that the FDA had approved Ceplene as a treatment protocol. However, in September 2004, Maxim announced that the second Phase III clinical trial failed to meet its primary endpoint. Maxim's stock price decreased by 48%. Plaintiffs alleged that the company failed to disclose that the first Phase III trial for Ceplene was fundamentally flawed, and that Maxim's statements regarding the later "confirmatory" Phase III trial were misleading because the later trial was actually intended to refute the negative results from the original Phase III trial.

### Alleged misrepresentations/non-disclosures regarding the likelihood of FDA approval

Another common type of securities fraud claim in 2004 involved allegations that the company misrepresented the likelihood of FDA approval. In May 2004, a putative class of shareholders sued Allos Therapeutics, Inc. and its CEO for securities fraud in the District of Colorado. In 2003, Allos completed a Phase III study of its drug Efaxproxiral for treatment of various metastasized brain cancers which failed to meet its endpoints. However, Allos filed a new drug application with the

FDA to develop Efavoxir as a treatment for brain metastases from breast cancer and later announced a new Phase III study for this purpose. The FDA accepted the new drug application for review, but in April 2004 rejected the drug. Allos stock fell by 45% after news of the rejection hit the market. Plaintiffs alleged that the FDA's findings contrasted with Allos's positive statements regarding the breast cancer subset in the first Phase III study.

#### **Alleged misrepresentations/non-disclosures regarding the commercialization and marketing of a product**

Securities fraud cases against life sciences companies in 2004 also involved allegations that a company misled the public about the commercialization and marketing of a product. In December 2004, a putative class of shareholders of Praecis Pharmaceuticals sued the company and three of its executives for securities fraud in the District of Massachusetts. Plaintiffs alleged that the defendants misled the public about the distribution and commercialization of its drug Plenaxis, which is used to treat advanced prostate cancer. Specifically, plaintiffs charged the company with failing to disclose that the FDA approved Plenaxis with severe marketing restrictions which reduced the potential market for the drug. In addition, plaintiffs alleged that the company failed to disclose that it was not able to establish effective messaging to educate physicians about Plenaxis and had difficulties convincing physicians to prescribe the drug because of concerns over use and reimbursement. When Praecis disclosed the marketing difficulties it faced with respect to Plenaxis, its stock fell 25%.

#### **Alleged misrepresentations/non-disclosures regarding the description of the product**

In 2004, life sciences companies were reminded that they also must be aware of the terminology they use to describe their products in public statements. In December 2004, a putative class of shareholders sued Geopharma, Inc. in the Southern District of New York. The product at issue was Mucotrol, which Geopharma was developing for the treatment of mucositis in cancer patients. Defendants referred to Mucotrol as a "drug" in a press release reporting successful clinical study results. Defendants later reported that the FDA had approved Mucotrol, but as a "device" and not as a drug. Plaintiffs contended that Mucotrol was much less marketable as a device than as a drug. Plaintiffs further alleged that defendants knew about the crucial difference in marketability between a "device" and a "drug" and failed to disclose this information in press releases and press conferences. When this difference was discovered and disclosed by financial reporters, Geopharma's stock dropped 60%.

#### **Alleged misrepresentations/non-disclosures regarding the quality of the manufacturing process**

Again in 2004, life sciences companies were sued for securities fraud based on allegations that they misled the public about the quality of their manufacturing processes. In October 2004, a putative class of shareholders of Chiron Corporation sued Chiron and its CEO for securities fraud in the Northern District of California, alleging that Chiron misled the public about potential sales in the United States of its flu vaccine,

Fluvirin. Plaintiffs specifically claimed that Chiron failed to disclose that its plant in Liverpool was not in compliance with government health and safety regulations and faced systemic quality-control issues. Plaintiffs sued after U.K. regulatory authorities suspended Chiron's license to manufacture Fluvirin before the company was able to sell any of the vaccine for the 2004-2005 flu season. When this information became public, Chiron's stock fell 29%.

#### **Alleged misrepresentations/non-disclosures regarding business strategy**

An Israeli life sciences company that is publicly traded in the U.S., Taro Pharmaceutical Industries, Ltd., and several of its officers, including its vice-chairman in charge of clinical research, were sued for securities fraud in August 2004 in the Southern District of New York, based on alleged misrepresentations and omissions regarding its business strategy. The allegations stemmed from Taro's decision to evolve from a generic drug manufacturer and seller to a vertically integrated company which developed and sold proprietary drugs as well as generics. Plaintiffs alleged that the company represented to investors that this corporate transition and the corporate strategy of expansion was not having any adverse impact on the company. Plaintiffs further alleged, among other things, that Taro failed to disclose that its generic drug division was not generating sufficient cash flow to launch and support the corporate transition, and that the company's drug pipeline was weak. After the company reported lower than expected first quarter earnings in April 2004 due to rising SG&A expenses, the company's stock price dropped 30%. The company announced that the results were due to a strategic decision to invest substantially in the company to develop profitable products. In July 2004, Taro shareholders filed suit after the company reported lower than expected second quarter earnings, and the stock dropped another 38%.

## **OTHER KEY EVENTS**

### **The largest pharmaceutical companies were targets of securities fraud suits**

In 2004, some of the largest pharmaceutical companies in the world became the targets of the plaintiffs' securities fraud lawyers. The event that precipitated several of these suits was perhaps the most significant event in the life sciences industry in 2004: Merck's withdrawal of the Cox-2 inhibitor Vioxx from the market on September 30, 2004.

Shortly after Merck withdrew Vioxx from the market, a putative class of shareholders sued the company and several of its officers in various federal courts. In February 2005, these cases were consolidated by the Judicial Panel on Multi-District Litigation in the District of New Jersey for coordinated pre-trial proceedings. Plaintiffs allege generally that Merck and several of its officers misrepresented Vioxx's safety profile as far back as 1996. The plaintiffs' lawyers even extend the class period well beyond September 30, 2004, the date of the withdrawal, in an effort to allege higher damages. Plaintiffs allege that Merck's market capitalization declined by over \$37.2 billion after both

the withdrawal of Vioxx and a November 1, 2004, *Wall Street Journal* article which alleged that Merck officials knew about problems with Vioxx for several years.

In the wake of Merck's withdrawal of Vioxx, plaintiffs' lawyers began to watch Pfizer closely because it sold and marketed the other two Cox-2 inhibitors approved by the FDA, Bextra and Celebrex. In December 2004, the plaintiffs' bar continued their assault on the largest pharmaceutical companies by bringing a securities fraud suit against Pfizer in the Southern District of New York.

As in the Vioxx suit, the plaintiffs allege generally that Pfizer misrepresented the safety profile of Bextra and Celebrex. The major difference, however, is that although Bextra sales were suspended in 2005, Pfizer had not withdrawn the drugs from the market at the time the plaintiffs brought the suit. In their complaint, the plaintiffs point to various press articles from October and November 2004 questioning Pfizer's representations concerning the safety of the drugs. The event that led the plaintiffs to bring suit was not the withdrawal of the drug but rather when the FDA required that a cardiovascular safety warning be added to the Bextra label. In comparison to the 26% stock price drop when Vioxx was withdrawn, Pfizer's stock price dropped 0.47% upon this news in December 2004.

It is telling that the plaintiffs brought suit even though Pfizer had not withdrawn either Bextra or Celebrex from the market, either voluntarily or at the direction of the FDA. Clearly, large pharmaceutical companies are being carefully targeted by the plaintiffs' bar. Indeed, in 2005, such major companies as AstraZeneca and GlaxoSmithKline have been sued for securities fraud.

#### **A significant decision on the duty to disclose adverse event reports**

A 2004 decision by the U.S. District Court for the Southern District of New York (Judge William H. Pauley) raises significant issues for all life sciences companies, and for their executives, because it tightens the relationship between adverse event reports and the duty under the federal securities laws to disclose information and update previous public statements.

In *In re: Bayer AG Securities Litigation*, 2004 WL 2190357 (S.D.N.Y. 2004), plaintiffs filed suit against Bayer after its stock price dropped by 17% following Bayer's withdrawal of the cholesterol-lowering drug Baycol from the market in August 2001. The plaintiffs alleged that Bayer and certain of its officers made material misstatements and omissions in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder.

In particular, the plaintiffs contended that Bayer's pre-withdrawal statements regarding Baycol's safety and profitability were rendered materially inaccurate by Bayer's failure to disclose adequate information about the drug's health risks that it received through numerous adverse event reports. Plaintiffs alleged that there was a meeting of Bayer's Global Drug Safety executives in August 2000, approximately one year before Baycol was withdrawn, to address growing concerns about the drug's safety. According to the plaintiffs, from this

meeting a "consensus" emerged among Bayer executives that the dangers from the adverse event reports were "putting the brand at risk."

The court denied Bayer's motion to dismiss various counts of the complaint, holding instead that Bayer had a duty to update pre-withdrawal statements about Baycol's safety and profitability.

The court began its analysis by recognizing the general rule that a duty to update under Section 10(b) exists when a statement, even if reasonable at the time it is made, becomes misleading because of a subsequent event. To determine whether adverse event reports rendered the prior statements misleading, the court applied the statistical significance test previously set forth in *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998): "drug companies need not disclose isolated reports of illnesses ... until [they] ... provide statistically significant evidence that the ill effects may be caused by—rather than randomly associated with—use of the drugs and are sufficiently serious and frequent to affect future earnings." *Bayer*, 2004 WL 2190357, at \*9. The *Bayer* court found that adverse event reports, in combination with other evidence, can put a pharmaceutical company on notice concerning a drug's safety risks, and thus give rise to a duty to disclose new information or update previous statements.

Once it reached this legal determination, the court then concluded that because the August 2000 meeting of Bayer's Global Drug Safety executives brought about a "consensus" that the damages from the adverse events reports were "putting the brand at risk," Bayer believed the adverse event reports to be sufficiently serious and frequent to affect future earnings under the statistical significance test. In Judge Pauley's words, "when the consensus emerged, Bayer crossed the Rubicon." 2004 WL 2190357, at \*10. The court therefore held that this consensus triggered a duty under the securities laws on the part of Bayer to update previous statements that Baycol was a "highly effective and safe treatment" with a "proven safety profile." By the same reasoning, the "consensus" was also found to trigger a duty on the part of Bayer to update previous forward-looking statements regarding Baycol's effect on the company's operating margin and potential for future growth. According to the court, Bayer's failure to update any of these public statements could give rise to liability under the federal securities laws. For this reason, the court denied this aspect of Bayer's motion to dismiss.

Given that the motion to dismiss stage is often the key battleground in whether a company sued for securities fraud can avoid an extracted settlement, the *Bayer* decision could have a significant impact in any case where a life sciences company is sued based on the theory that the company withheld internal and allegedly adverse information about a drug's safety or efficacy.

## MINIMIZING THE RISK OF SECURITIES FRAUD CLASS ACTIONS

There are several steps that could reduce the risk of securities fraud class actions. Aside from the obvious strategy of ensuring that the companies' statements and public filings are truthful and accurate, counsel should do the following:

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 or the loss of a key commercial partner. As described previously, these events can trigger 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 need to understand that how they conduct clinical trials and tests can 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 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 the truth was disclosed to the public and the stock plummeted.



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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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