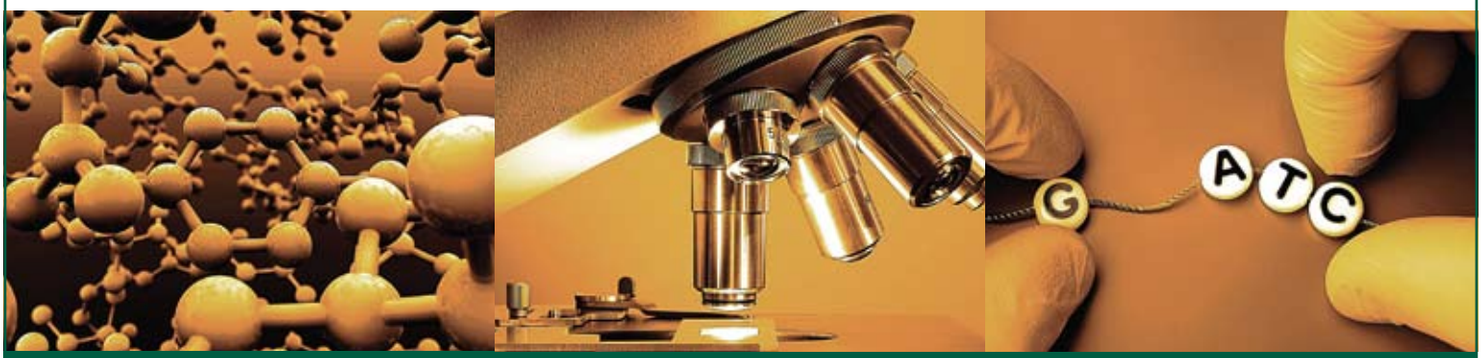
Dechert Survey of Securities Fraud Class Actions Brought Against Life Sciences Companies



Dechert
LLP

June 2008

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

In 2007, 25 different pharmaceutical and biotech companies, along with several of those companies' directors, officers, and key medical and research personnel, were sued for alleged securities fraud. These 25 securities fraud lawsuits represent a significant increase over 2006, when 16 securities fraud lawsuits were brought against the industry. Among these 25 lawsuits, securities fraud plaintiffs sued an increasing number of life sciences companies with the largest market capitalizations—and thus the largest potential exposures. That trend is likely to continue in the coming years, as structural industry factors and practices prompt plaintiffs' lawyers to develop new theories of liability.

While plaintiffs may have shifted targets, their theories of liability remain largely the same. Because life sciences companies are in the business of venturing into the unknown, their stock price is inherently volatile. Moreover, it is an unmistakable fact that only a small number of new drugs survive the FDA approval process, often leading life sciences companies to face bad news concerning adverse events, patient harm, or unexpected results. And, as we have seen time and again, when the news is bad, investors—and class action lawyers—react. To compound the problem, life sciences companies continue to face what seems to be an unsolvable dilemma: reporting good news can lead to accusations of misrepresentations if later results do not continue to be positive, but failure to report news to the markets can lead to accusations that the company is covering up the truth. Thus, the volatility of a life sciences company's stock, the various challenges that these companies face in the life cycle of a drug, and the required disclosure of information are all factors that make life sciences companies particularly vulnerable to securities fraud class actions.

In this survey, we first highlight some of the trends we observed in the securities fraud lawsuits filed against life sciences companies in 2007, including a discussion of some of the notable allegations made in those suits. We then 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 best practices for life sciences companies to consider for minimizing the risk of, or impact from, securities fraud class action lawsuits.

Findings

(1) The number of securities fraud class actions brought against life sciences companies increased substantially in 2007.

Life sciences companies were the target of 25 securities fraud class actions in 2007. While that number is not a high watermark, it is a 56% increase over the 16 securities fraud class actions filed against life sciences companies in 2006. The 25 securities fraud lawsuits brought against life sciences companies in 2007 represent approximately 14% of the 175 securities fraud class actions filed in total in 2007, compared to 13% in 2006, 16% in 2005, 10% in 2004, 15% in 2003, and 9% in 2002.[1]

(2) Life sciences companies with the largest market capital were increasingly targeted in 2007.

We noted in previous years that nearly half of the life sciences companies that were sued for securities fraud had a market capital of less than $250 million. A new trend emerged in 2007: as indicated in Figure 1, the number of life sciences companies with the greatest market capital—more than $10 billion—were sued almost at the same rate as the companies with less than $250 million in market capital.

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

As in prior years, a great many class actions against life sciences companies in 2007 were based on allegations concerning the life cycle of drug products. As explained in more detail in the next section, many of the companies were sued based on the information they communicated, or failed to communicate, to the public about a drug's efficacy, safety, and/or the results of the FDA approval process. The traditional securities fraud claims of misrepresentation/omission regarding the company's financial health also remained a common theme.

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

We previously observed that key research personnel of life sciences companies were being named as individual defendants in securities fraud actions. This trend continued in 2007—in five separate cases, plaintiffs' lawyers employed 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.

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

In eight of the cases filed against life sciences companies in 2007, 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.

The Nature of the Claims

Alleged misrepresentation/non-disclosure regarding product safety

A common theme that resonated in the securities fraud complaints filed against life sciences companies in 2007 was that the company misrepresented or failed to disclose material information regarding the safety of a product. For example, a putative class of shareholders filed a securities fraud action in the Eastern District of New York against Eli Lilly & Co., two of its officers, and

[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.

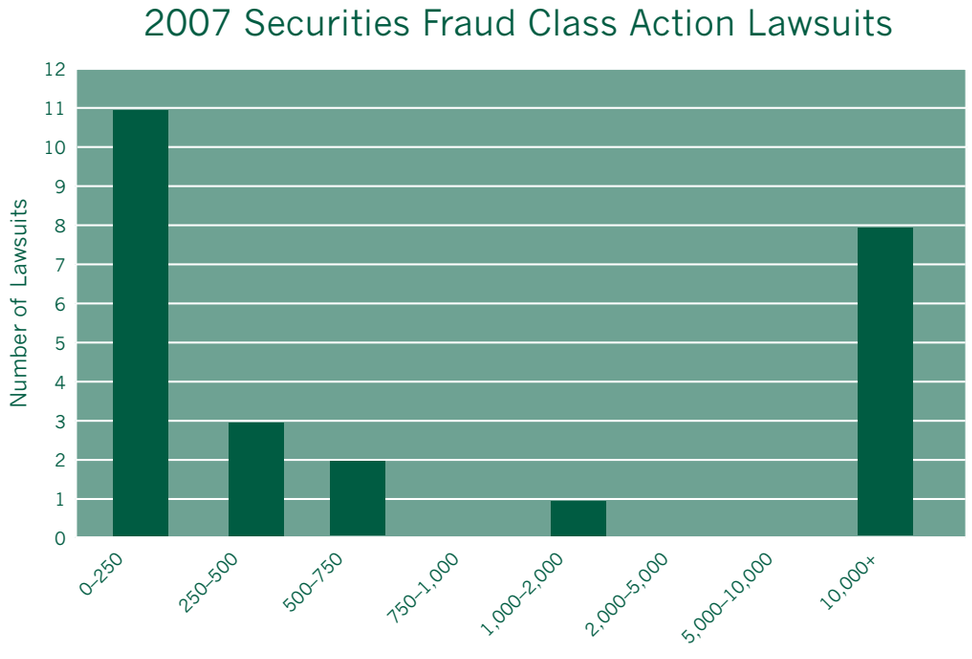


Figure 1.

Allegations in 2007 Lawsuits	Number of Lawsuits
Alleged misrepresentations and/or non-disclosures regarding product safety	13
Alleged misrepresentations and/or non-disclosures regarding product efficacy	13
Alleged misrepresentations and/or non-disclosures regarding likelihood of FDA approval	12
Alleged insider trading	9
Alleged misrepresentations and/or non-disclosures regarding marketing practices	6
Alleged misrepresentations and/or non-disclosures regarding manufacturing processes	3
Alleged accounting improprieties and/or inflated revenues	3
Alleged misrepresentation and/or non-disclosure regarding the status of pending patent infringement litigation	2

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

the company's chief medical officer. The complaint alleged that the defendants concealed known facts regarding the company's best-selling drug Zyprexa. Specifically, defendants allegedly stated numerous times that no one had produced scientific evidence that Zyprexa caused diabetes and weight gain; however, the company's pre-clinical studies allegedly revealed the opposite. The complaint also alleged that the defendants promoted the off-label prescription of Zyprexa to elderly patients with dementia, even though the defendants were aware of the drug's increased risk of death within that population. When the public learned of these allegedly hidden facts, the company's stock price fell more than 6%.

Alleged misrepresentation/non-disclosure regarding product efficacy

As with allegations concerning the safety of the product, more than half of the complaints in 2007 alleged that life sciences companies misrepresented or failed to disclose material information regarding a product's efficacy. For example, a putative class of shareholders of Dendreon Corp. filed a securities fraud suit in the Western District of Washington against the company, the company's CEO, and a member of the board of directors. The plaintiffs alleged that the defendants led investors to believe in the imminent approval of the biologic license application ("BLA") of Provenge, a drug the company was developing to treat prostate cancer. Within two days of the positive news, the company's stock price nearly tripled, and on the same day, the CEO sold more than 25% of his shares. One month later, the FDA requested additional clinical data concerning the drug's efficacy. Plaintiffs alleged that the defendants failed to disclose that the BLA would not be approved because they knew that one of the company's Phase III clinical studies was flawed inasmuch as it lacked a statistically significant number of patients with cancer. After the market learned of the FDA's request, the company's stock price dropped more than 60%.

Alleged misrepresentation/non-disclosure regarding the likelihood of FDA approval

Often intertwined with allegations concerning a product's safety and efficacy are allegations that a life sciences company misrepresented or omitted material facts regarding a product's potential for FDA approval. A putative class of shareholders of GPC Biotech AG filed a securities fraud class action in the Southern District of New York against the company and certain of its officers and directors, including its chief medical officer. The plaintiffs alleged that the defendants failed to inform them about the methodology the company was using to measure the efficacy of Satraplatin, a drug that was being developed to treat prostate cancer. According to the plaintiffs, the company embarked on a Phase III clinical trial using an endpoint with which the FDA was "unfamiliar" and had "no prior experience." In addition, the FDA had questioned whether the researchers were actually unaware of which patients received the placebo and which ones received the drug. The FDA notified the defendants about its concerns, but the defendants allegedly did not disclose that information to the market. Instead, the defendants allegedly announced that the FDA would consider approving Satraplatin and presented data claiming the drug was "extremely effective." Following the positive news, the stock closed at $32.81. Several weeks later, the FDA announced that it would not approve Satraplatin and would wait until the end of 2008 to reassess the overall survival benefit of the drug. GPC's stock price fell to $13.16 after the market learned of the FDA's decision.

Alleged misrepresentation/non-disclosure regarding clinical trials

Life sciences companies also were confronted with allegations concerning the information they disclosed or failed to disclose about a drug's clinical trials. A putative class of shareholders of Pozen, Inc., filed a securities fraud suit in the Middle District of North Carolina against the company and certain of its officers and directors. According to the complaint, in August 2005, Pozen sought regulatory approval of Trexima, a drug it was developing to treat migraine headaches. The approval was delayed in June 2006 because regulators asked for clinical information regarding the

drug's effect on the heart. In July 2006, the defendants announced they had reached an agreement with regulators that would require Pozen to produce the study data the company already had about Trexima's cardiovascular safety. But, according to the plaintiffs, the defendants failed to disclose that regulators had required additional clinical testing. The defendants also allegedly failed to disclose that the study data in their possession actually showed that the drug carried safety risks that would significantly delay, if not ultimately preclude, regulatory approval of Trexima. One year later, the company announced that regulators would once again delay approval because the defendants were now required to address a potential safety implication, which their own clinical data had shown was a problem all along. That same day, defendants also announced that the agreement they had reached with regulators in July 2006 actually required additional clinical data/testing of Trexima's effect on blood pressure. These disclosures allegedly caused the company's stock to fall by 45%.

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

Another type of securities fraud claim in 2007 concerned allegations that the defendants either marketed the product for off-label purposes or misled investors about the commercialization of the product. For example, a putative class of shareholders filed suit in the Central District of California against Amgen, Inc., and certain of its officers and directors for violating securities laws. The plaintiffs alleged that Amgen developed two blockbuster drugs, Aranesp and Epogen, which the FDA had approved for the treatment of anemia caused in cancer patients by chemotherapy. Amgen, however, allegedly marketed those products for an off-label use—to treat anemia caused by cancer itself, rather than by the chemotherapy. Amgen sold several hundred million dollars' worth of those drugs each year for allegedly off-label uses. Ultimately, the FDA mandated a "black box" warning regarding the off-label use of Aranesp and Epogen. Once the market learned of these revelations, the value of the company's stock declined significantly (although the plaintiffs did not allege by how much).

Alleged misrepresentation/non-disclosure regarding the quality of the manufacturing process

Several complaints in 2007 alleged that life sciences companies and certain directors/officers misrepresented or omitted material facts regarding the manufacturing quality of the product. One such example is the putative class action that shareholders of Medtronic, Inc., filed in the District of Minnesota against the company and certain of its officers and directors for violations of the securities laws. According to the complaint, Medtronic developed, manufactured, and marketed defibrillator leads known as "Fidelis Leads." In January 2007, Medtronic received nearly 700 reports of injuries allegedly caused by fractures in the Fidelis Leads. In response, the company sent out a letter to physicians who were treating patients with the Fidelis Leads, explaining that the failure in Fidelis Leads was due to physician error or "variables within the implant procedures." The company continued to receive reports of the failure of Fidelis Leads, yet allegedly continued to tout the market's acceptance of the product. By the end of September 2007, Medtronic had received more than 1,650 reports. In October 2007, Medtronic acknowledged that the failure of Fidelis Leads was due to a manufacturing defect, which was a "possible or likely contributing factor" in the deaths of five patients. The company later announced that it would suspend the distribution of Fidelis Leads. Upon releasing this information to the market, Medtronic's stock price fell 11%.

Alleged misrepresentation and/or non-disclosure regarding the status of pending lawsuits that could affect a product's patent

In two cases filed in 2007, plaintiffs sought to hold life sciences companies liable for securities fraud under the theory that the companies misrepresented or failed to disclose material facts regarding the status of pending litigation that could impact the patent protection for a product. In one example, a putative class action was filed against Bristol-Myers Squibb Co. and two of its executives in the Southern District of New York. The plaintiffs claimed that the defendants misled the market concerning the terms of a proposed settlement agreement with Apotex Corp., a competitor, to prevent it from introducing into the market a generic equivalent of Bristol-Myers' best-selling drug Plavix. The defendants allegedly omitted the fact that the proposed settlement agreement would limit Bristol-Myers' damages and patent enforcement rights if regulators did not approve the settlement because of possible antitrust violations. The state attorneys general rejected the settlement agreement in May 2006, but Bristol-Myers did not disclose that information to investors. Instead, Bristol-Myers entered into secret oral side agreements with Apotex, which reported that information to the FTC and the Department of Justice ("DOJ"). The DOJ immediately opened a criminal investigation into Bristol-Myers' conduct. In July 2006, the company revealed that it was under investigation, at which point its stock declined 7.5%. In August 2006, investors learned about the terms of the settlement agreement between Apotex and Bristol-Myers. That same day, the company's stock declined an additional 7%.

Other Key Events

In *In re Boston Scientific Corporation Securities Litigation*, 490 F. Supp.2d 142 (D. Mass. 2007), the U.S. District Court for the District of Massachusetts issued a decision that helped clarify the circumstances under which FDA warning letters are not material and, therefore, need not be disclosed to the investing public. Boston Scientific ("BSC") is engaged in the business of manufacturing medical devices in the area of cardiovascular and endosurgery. *Id.* at 144. According to the plaintiffs, the defendants failed to inform the market about three FDA warning letters that had been issued to the company. One letter stated the company had not taken "specific system-wide corrective actions that are necessary to bring [one of its] facilit[ies] into compliance." *Id.* at 150. Another letter stated that certain deficiencies at a different BSC facility caused its medical devices "to be adulterated." *Id.* at 151. The final letter, which concerned deficiencies of a third facility, noted that the facility faced "serious regulatory problems." *Id.*

A putative class of shareholders sued the company and its executives for securities fraud, and the defendants moved to dismiss the complaint for failure to state a claim. In granting the defendants' motion to dismiss, the court held that the FDA warning letters were not material; therefore, BSC did not have an affirmative duty

to disclose them. *Id.* at 161. While the court acknowledged that materiality is typically "a question of fact that proceeds to the jury, rather than being resolved . . . on a motion to dismiss" (*Id.*), the court offered several reasons why this case was an exception. It reasoned that BSC is a global corporation operating in a regulated industry, and so "it would be 'unduly burdensome and impractical to publicly disseminate the results of every inspection of every plant.'" *Id.* (citing *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 52 (2d Cir. 1995)). In addition, the court noted "there is nothing magical about an FDA warning letter" because the language of those letters is boilerplate. *Id.* at 162 (quoting *Anderson v. Abbott Laboratories*, 140 F.Supp.2d 894, 904 (N.D. Ill. 2001)). Finally, the court stated that "the FDA warning letters were unrelated to any product recall or enforcement report, and resulted in no adverse action against BSC." *Id.*

While the *Boston Scientific* decision does not establish an absolute rule that FDA warning letters are always immaterial, it does serve to better define the contours of whether life sciences companies will be required by the securities laws to disclose the substance of those letters.

Expectations for the Future

Life sciences companies will continue to be targets of securities fraud lawsuits

We expect that life sciences companies will remain particularly vulnerable to securities fraud lawsuits. The structural factors that lead plaintiffs' lawyers to target life sciences companies—volatile stock prices and a drug or device product life cycle fraught with potential for adverse and unpredictable events, such as a negative clinical trial result or FDA decisions—remain challenging, especially in the current stock market and regulatory environment.

Plaintiffs will continue to seek to develop new theories of liability, such as securities fraud lawsuits based on "off-label" communications or sales

The questions raised by off-label promotion of drugs and devices have become an increasingly important regulatory issue for life sciences companies. It is, therefore, increasingly likely that more securities lawsuits will be premised on off-label communications or sales. For example, if a company's revenues are partially obtained through undisclosed off-label sales, plaintiffs may claim that a stock price decline is due to a revelation that the product was not being bought for the purposes the company had represented. Or, if the company claims in its public statements that it was in full compliance with all laws and regulations, but was in fact improperly promoting off-label use, the stock price drop could be blamed on the disclosure of the unlawful off-label practices. Companies should therefore act with care when considering the proper disclosure for any known off-label uses or sales.

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, counsel should consider 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, 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 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.

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:

Michael L. Kichline
+1 215 994 2439
michael.kichline@dechert.com

David A. Kotler
+1 609 620 3226
david.kotler@dechert.com

About Dechert LLP

With more than 1,000 lawyers 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, real estate finance, financial services and asset management, intellectual property, labor and employment, and tax law.

For more information, visit www.dechert.com.

U.S.
Austin
Boston
Charlotte
Hartford
Newport Beach
New York
Philadelphia
Princeton
San Francisco
Silicon Valley
Washington, D.C.

EUROPE
Brussels
London
Luxembourg
Munich
Paris

ASIA
Hong Kong

Dechert
LLP
www.dechert.com