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

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March 2010

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

The past year was another noteworthy one with respect to securities fraud class action lawsuits pursued against publicly-traded pharmaceutical, biotechnology, and medical device companies. To begin with, 19 different life sciences companies, along with a number of those companies' directors, officers, and key medical and research personnel, were sued for alleged securities fraud in 2009—this represented a slight decline from the 23 such cases filed in 2008. Continuing a trend that began with the onset of the "Great Recession" during the latter half of 2007, the majority of the securities fraud lawsuits filed against life sciences companies in 2009 tended to focus more on public statements regarding the company's finances, particularly allegations of accounting irregularities and contentions that the company misled investors about its financial health, as opposed to alleged misstatements or omissions regarding the company's products themselves (such as the likelihood of FDA approval or product safety and efficacy). Also in line with our recent observations, the majority of the life sciences companies that were sued for securities fraud in 2009 had a market capitalization of less than $250 million. Finally, and perhaps most noteworthy, is the recent success that life sciences companies have had in challenging these lawsuits, as evidenced by the fact that 13 of the 25 securities fraud complaints brought just two years ago have now been dismissed by the courts.

In this survey, we first highlight the trends we observed in the securities fraud lawsuits filed against life sciences companies in 2009, including a discussion of some of the notable allegations and theories advanced in those suits. Next, we analyze the status and results of the securities fraud lawsuits filed against life sciences companies in 2007 and 2008 (which we first presented in our prior surveys). We then look forward by assessing the potential securities fraud litigation impact of the Justice Department's recently announced FCPA focus on life sciences companies and by analyzing an important statute of limitations issues that is currently pending before the United States Supreme Court. Finally, we provide some useful guidance for life sciences companies to consider for minimizing the risk of, or adverse impact from, securities fraud class action lawsuits.

Findings

There were 19 securities fraud class action lawsuits brought against life sciences companies in 2009 out of the 178 total number of securities fraud class action lawsuits brought against all companies in 2009.[1] This means that approximately 10% of the 2009 cases were brought against life sciences companies, which remained within the range we have observed over the past four years, e.g., 10% in 2008, 14% in 2007, 13% in 2006, and 16% in 2005.

Continuing a 2008 development, the majority of the life sciences companies that were sued for securities fraud in 2009 had a market capitalization of less than $250 million (see Figure 1). Indeed, only one of the 19 securities fraud cases was brought against a life sciences company with a market capitalization of over $10 billion. These statistics conform with the size of the industry overall; life sciences companies with a market capitalization of less than $250 million comprise approximately 65% of the total industry, whereas less than 5% of life sciences companies have a market capitalization of at least $10 billion.[2]

[1] The number of securities fraud class actions brought against life sciences companies as well as 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.

[2] This data is derived from the OneSource database.

The Nature of the Claims

As we first observed last year, the "Great Recession" has impacted the types of allegations contained in the securities fraud class actions brought against life sciences companies. The lawsuits filed now focus more on the company's alleged financial improprieties than claims about public misstatements regarding industry-specific issues such as product safety or efficacy or the prospects of receiving FDA approval. This trend largely continued in 2009.

For example, in December 2009, shareholders filed suit in the Northern District of California against Accuray Inc., which sells the "CyberKnife system," a mechanism used to perform robotic surgery. Plaintiffs claim that the company overstated its financial results by giving false and misleading information about backlog from sales and servicing of the CyberKnife system, and that when the company revised its backlog calculations, the stock price fell. Similarly, in August 2009, shareholders filed suit in the Northern District of California against Align Technology, Inc., the maker of the Invisalign braces system, alleging that the company made materially misleading financial statements when it failed to disclose that its sales force was focused on reducing backlog rather than obtaining new business.

Last year also saw the continued filing of cases alleging accounting fraud by life sciences companies. For instance, in November 2009, shareholders brought suit in the Northern District of California alleging that Hansen Medical, Inc., a company that develops robotics products to aid medical professionals in their positioning, manipulation, and control of catheters and catheter-based technologies, issued materially false and misleading statements

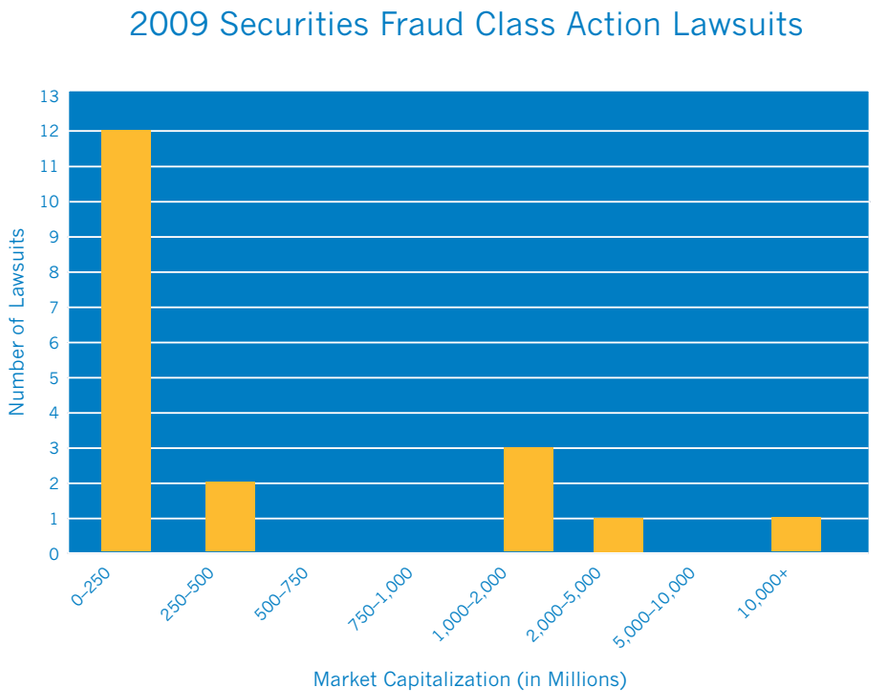

Figure 1.

Allegations in 2009 Securities Fraud Lawsuits	Number of Lawsuits
Alleged misrepresentations and/or non-disclosures regarding accounting improprieties	9
Alleged misrepresentations and/or non-disclosures regarding product safety	6
Alleged misrepresentations and/or non-disclosures regarding the prospects/timing of FDA approval	6
Alleged misrepresentations and/or non-disclosures regarding product efficacy	4
Alleged misrepresentations and/or non-disclosures regarding insider trading	3
Alleged misrepresentations and/or non-disclosures regarding manufacturing processes	2
Alleged misrepresentations and/or non-disclosures regarding antitrust violations	1
Alleged misrepresentations and/or non-disclosures regarding marketing practices	1

Figure 2.

about its financial results and compliance with generally accepted accounting principles (GAAP) when it allegedly improperly recognized revenues associated with its Sensei Robotic Catheter System. Plaintiffs claim that when the company disclosed it had made this error and restated its financial results, its stock price fell by around 9%. Along the same lines, Zynex, Inc., a company that sells medical devices for rehabilitation use, was sued for securities fraud in the District of Colorado based on the allegation that it engaged in accounting fraud which caused it to overstate its income and net accounts receivable. Plaintiffs contend that the company's stock price fell by over 50% as a result of the company's disclosure of its accounting error.

Of course, a number of the life sciences companies that were sued for securities fraud in 2009 still faced industry-specific allegations, such as that the company and its leaders had misrepresented the safety or efficacy of a product in development. For example, in July 2009, shareholders brought suit in the District of Arizona against Matrixx Initiatives, Inc., the company that makes Zicam, a homeopathic cold remedy. The plaintiffs there contend that the defendants delayed disclosing negative reports that Zicam caused a loss of smell in certain users, and that when the defendants revealed that they received a warning letter from the FDA about Zicam, the value of Matrixx stock dropped approximately 70% in one day. Shareholders likewise brought suit against Repros Therapeutics, Inc. in the Southern District of Texas, claiming that the company had made material misstatements about Proellex, a drug used to treat symptoms of uterine fibroids and endometriosis, because they allegedly did not disclose the drug's negative side effects.

Additionally, in two different instances, shareholders alleged that life sciences companies did not adequately disclose problems with the FDA's Good Manufacturing Process (GMP) standards at their facilities. Shareholders sued Genzyme Corp., a biotechnology company, in the District of Massachusetts contending that the company did not reveal that, among other problems, failure to comply with GMP standards caused a delay in approval of one of its products and shortage of another, and that contamination issues led to the halt of production of two other products. Similarly, shareholders sued Caraco Pharmaceutical Laboratories, Ltd. in the Eastern District of Michigan, alleging that while Caraco had disclosed that it received a warning letter from the FDA about its facilities, the company falsely claimed it had corrected the problems; plaintiffs further allege that a few months after its reassurances that the problems had been alleviated, Caraco issued a voluntary recall of certain drugs because of manufacturing problems, and later announced that U.S. marshals had seized products from the company's facilities because of GMP compliance problems, leading to a decline in share value.

The Status of Cases Filed in 2007 and 2008

As of the time this survey goes to print, of the 23 securities fraud class actions filed against life sciences companies in 2008, 18 are still pending, four have been dismissed[3] and one has settled for $3.85 million. Of the dismissals, three are final and one has been appealed. The fact that only one case has settled and that roughly 75-80% of the 2008 cases are still pending is in line with overall trends for securities class actions on the whole.[4]

The cases in which defendants' motions to dismiss were granted all held that plaintiffs had failed to allege a material misrepresentation or omission. For example, one court held that plaintiffs' complaint against Inverness Medical Innovations, Inc. could not proceed because the defendants only had engaged in puffery, rather than actionable misrepresentations; another court held that a claim against Biovail Corp. could not go forward because plaintiffs did not adequately plead scienter. This continues the trend we noted in our 2008 Survey that courts will not accept a plaintiff's vague or conclusory allegations as a replacement for the specific types of pleading required by the Private Securities Litigation Reform Act.

[3] This figure includes one voluntary dismissal with prejudice.

[4] *See generally* Stephanie Plancich, et al., *Recent Trends in Securities Class Action Litigation: 2009 Year-End Update* (December 2009), available at www.nera.com/image/Recent_Trends_Report_1209.pdf (last visited January 27, 2010).

Status of 2008 Cases (as of 3/26/10)	Number of Cases
Dismissed via motion to dismiss	4
Dismissed via voluntary dismissal or stipulation to dismiss	2
Motion to dismiss pending	7
Discovery/ongoing	9
Settled	1

Figure 3.

Going back one year further, of the 25 securities fraud class action lawsuits brought against life sciences companies in 2007, courts have granted motions to dismiss or for summary judgment in 13 of those cases.[5] This is an exceptionally high rate of dismissals,[6] and certainly suggests that the securities fraud complaints brought against life sciences companies (at least in 2007) were not particularly well founded. The majority of the 2007 cases that were dismissed were done so, at least in part, because plaintiffs failed to adequately plead scienter—again reinforcing the notion that the scienter element of a securities fraud claim against a life sciences company has bite.

Of the four cases brought in 2007 that have settled, one of those cases—against Bristol-Myers Squibb Co. ("BMS") for allegedly misleading statements made about BMS's attempt to settle a patent infringement case regarding its drug Plavix—settled for $125 million; this serves as an important reminder of the large exposure that life sciences companies and their leaders can face for alleged securities fraud.

Status of 2007 Cases (as of 3/26/10)	Number of Cases
Dismissed via motion to dismiss	12
Summary judgment granted for defendants	1
Motion to dismiss pending	1
Discovery/ongoing	5
Settled (including voluntary dismissals)	6

Figure 4.

Expectations for the Future

Potential Securities Fraud Litigation Impact of Department of Justice's Announced FCPA Focus on Life Sciences Companies

On several occasions throughout 2009, key members of the Department of Justice made clear that life sciences companies would be facing enhanced scrutiny for any activities that could run afoul of the Foreign Corrupt Practices Act ("FCPA").[7] In general, the FCPA prohibits the actual or attempted bribery of foreign government officials to assist in obtaining or retaining business.[8] Life sciences companies who transact business abroad either already are or certainly should be taking a close look at their compliance policies for purposes of avoiding violations of the FCPA. For purposes of the present discussion, however, these companies also will need to be attuned to the highly probable link between a publicly announced FCPA violation (even potentially an announced inquiry) and a follow-on securities fraud class action.

We previously have reported on a variety of instances in which a government enforcement action—whether by the SEC, the DOJ, or even the FDA—spurs the filing of a securities fraud lawsuit alleging that the company and its leadership made misleading statements by, among other things, failing to disclose that they were violating the law at issue in the government action. The FCPA is no exception to this trend. For example, several years ago, a class action suit was filed against blood-testing company Immunocor, Inc. alleging that the company's public statements concerning an FCPA bribery investigation understated the scope of the company's violations. After its motion to dismiss was denied, the company settled the securities litigation for $2.5 million. Given the significant exposure that a securities fraud class action lawsuit typically brings, publicly-traded life sciences companies would be wise to take appropriate preventive steps to avoid having an FCPA issue morph into a securities fraud issue.

Statute of Limitations for Securities Fraud Cases to be Clarified by the Supreme Court

The United States Supreme Court is now considering a securities fraud statute of limitations issue that has important ramifications for targets of such claims, particularly publicly-traded life sciences companies.

The statute of limitation for a Section 10(b)/Rule 10b-5 securities fraud claim requires a plaintiff to commence the action within two years "after the discovery of the facts constituting a violation" in which to sue.[9] Courts generally agree that when this limitations

5 Of these 13 dismissals, four are currently on appeal and one has a pending motion for reconsideration.

6 *See* Stephanie Plancich, et al., *2008 Trends: Subprime and Auction-Rate Cases Continue to Drive Filings, and Large Settlements Keep Averages High* (2008), available at www.nera.com/image/bro_recent_trends_8.5x11_0808.pdf (noting that the two year dismissal rate for shareholder class actions filed since July 21, 2001 is 24%) (last accessed March 2, 2010).

7 *See*, e.g., Lanny Bruer, Assistant Attorney General, Keynote Address at the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (November 12, 2009).

8 *See generally* 15 U.S.C. §§ 78DD-1, *et seq.*

9 *See* 28 U.S.C. §1658(b). The statute of repose for such claims, which sets an absolute outside time limit, is five years from the violation. *Id.*

period begins to run on the date the plaintiff is on "inquiry notice" of its securities fraud claim. [10] The question as to precisely when a plaintiff is on "inquiry notice" of a securities fraud claim against a publicly-traded life sciences company (and potentially its directors, officers, and even key research personnel), has been the subject of two recent decisions by the U.S. Court of Appeals for the Third Circuit.

In *In Re Merck & Co., Inc. Securities, Derivative & ERISA Litigation*, 543 F.3d 150, 161 (3d Cir. 2008) ("Merck"), plaintiffs brought a securities fraud lawsuit arising out of Merck's recall of Vioxx, a pain reliever, from the U.S. market in 2004. In granting Merck's motion to dismiss, the district court found that the plaintiffs' suit was barred by the statute of limitations because the inquiry notice period had expired before the plaintiffs filed suit.[11] On appeal, the Third Circuit held that a plaintiff is not on "inquiry notice" of a securities fraud claim until it has "storm warnings" that the defendant acted with scienter, and that the plaintiffs did not have such "storm warnings" until there was evidence suggesting that Merck did not believe the information it publicly stated about Vioxx's safety.[12] Despite evidence that public questions had been raised with respect to the safety of Vioxx for more than two years prior to commencement of the securities fraud action—including the filing of consumer protection and products liability lawsuits, a publicly disclosed FDA warning letter to Merck, and significant media attention regarding the issue—the Third Circuit found those circumstances to be insufficient to give plaintiffs a reason to disbelieve Merck's representations about the safety of Vioxx in a *securities* context, because, for example, the FDA "was acting as a regulator of drug advertising, rather than as a regulator of the securities markets."[13] The appellate court further reasoned that plaintiffs had no reason to suspect that Merck did not believe its statements about Vioxx until a 2003 study came to light that the court found cast doubt on the veracity of Merck's public statements regarding Vioxx's safety.[14]

In January 2009, the Third Circuit returned to the inquiry notice issue in *Alaska Electrical Pension Fund v. Pharmacia*, 554 F.3d 342, 347 (3d Cir. 2009) ("*Pharmacia*"), which arose out of plaintiffs' claims that the defendants had misrepresented a study regarding Celebrex.[15] In *Pharmacia*, the Court reiterated its holding in *Merck* and found that, at least under the circumstances of that case, "investors are not put on inquiry notice of fraud . . . when an apparently legitimate scientific dispute arises between the FDA and a pharmaceutical company." [16] Prior to the lawsuit, defendants and the FDA had a dispute over the propriety of defendants' decision to use data from only the first six months of their Celebrex study.[17] The Third Circuit found that this disagreement did not establish storm warnings of securities fraud because "the transcript of the [FDA] meeting explicitly supports a finding that the experts believed that the dispute between defendants and the FDA was a good faith, legitimate scientific dispute."[18]

In November 2009, the U.S. Supreme Court heard argument on Merck's appeal of the Third Circuit's decision; a ruling is expected by June 2010. Until the Supreme Court rules, however, publicly-traded life sciences companies (as well as their directors, officers, and key research personnel who are named as defendants in securities fraud complaints) will need to consider that courts may reject an argument that public information regarding a product's lack of efficacy, or disagreements between the company and the FDA, or even mass tort lawsuits regarding the product's alleged lack of safety, is legally sufficient to put a plaintiff on "inquiry notice" of an alleged securities fraud claim.

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 lifecycle. 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.
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

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10 *See,* e.g., *Alaska Electrical Pension Fund v. Pharmacia*, 554 F.3d 342, 347 (3d Cir. 2009) ("The statute of limitations will begin to run when the plaintiff is on inquiry notice").

11 *Merck*, 543 F.3d at 153.

12 *Id.* at 172.

13 *Id.* at 171.

14 *Id.* at 172.

15 Defendants in *Pharmacia* filed a petition for certiorari with the Supreme Court on April 22, 2009; as of the printing date of this survey, the Court has not yet ruled on the petition.

16 *Pharmacia*, 554 F.3d at 350-51.

17 *Id.* at 345.

18 *Id.* at 349.

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 contains 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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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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