

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

March 2015

Publicly Traded Life Sciences Companies in the United States Are an Increasingly Popular Target of Securities Fraud Class Action Lawsuits

The past year was particularly noteworthy with respect to the relative number of securities fraud class action lawsuits brought against publicly traded pharmaceutical, biotechnology and medical companies. In 2014, 38 different life sciences companies (along with their directors, officers and key personnel) were sued for alleged securities fraud in 39 different complaints — representing a remarkable increase from the 19 such lawsuits filed in 2013. In terms of substance, the 2014 securities fraud lawsuits continued the trend that we have observed in previous years of focusing on industry-specific issues (e.g., alleged misrepresentations regarding product efficacy) as compared to generalized claims of financial improprieties. Notwithstanding the significant number of new lawsuits, however, in 2014 life sciences companies continued to enjoy relative success in obtaining dismissals of the securities fraud lawsuits brought in prior years.

In this survey, we first highlight trends from the securities fraud lawsuits filed against life sciences companies in 2014, including a discussion of some of the notable allegations made in those suits. We then summarize and analyze the status of securities fraud lawsuits filed in the preceding five years. We next discuss how the U.S. Supreme Court's 2011 decision in *Matrixx Initiatives, Inc. v. Siracusano* has affected the litigation landscape, concerning the standard for asserting a claim for securities fraud against a pharmaceutical company that has failed to disclose adverse events associated with a product. We also provide an update on the impact of *Amgen Inc. v. Connecticut Retirement Plans & Trust Funds*, which lowered the bar for plaintiffs seeking class certification in all Rule 10b-5 cases, including those against life sciences companies. Finally, we provide guidance that may help minimize or eliminate the risk of securities fraud class action lawsuits.

Findings

The Numbers

There were 39 securities fraud class action lawsuits brought against life sciences companies in 2014, out of the total of 170 securities fraud class action lawsuits brought against all companies in the same time period.¹ Hence, approximately 23% of the 2014 cases were brought against life sciences companies. This represents a sharp increase in the percentage of cases brought against life sciences companies from prior years. For example, in 2013, only 11% of the 167 total securities fraud lawsuits were brought against life sciences companies. Looking back further, the 23% figure for 2014 securities class action suits brought against life sciences companies is well above the figures for 2012 (18%), 2011 (9%) and 2010 (16%).

The securities fraud complaints filed in 2014 have followed previous years' trends of focusing more on life sciences companies with relatively smaller market capitalizations (see **Figure 1**). In 2014, 57% of the life sciences companies sued for class action securities fraud had market capitalizations of less than \$500 million. This is in line with previous years — 61% in 2011, 50% in 2012 and 63% in 2013. However, the plaintiffs' bar is not completely neglecting the larger life sciences companies, as life sciences companies that have at least \$2 billion in market capitalization were named as defendants in approximately 21% of the lawsuits filed in 2014. Also, in 2014 a complaint was filed against Teva Pharmaceutical Industries, which has a market capitalization of over \$49 billion, and in 2013, complaints were

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*.

filed against AbbVie, Inc. and Sanofi, which have market capitalizations of over \$90 billion and \$121 billion, respectively.²

2014 Securities Fraud Class Action Lawsuits

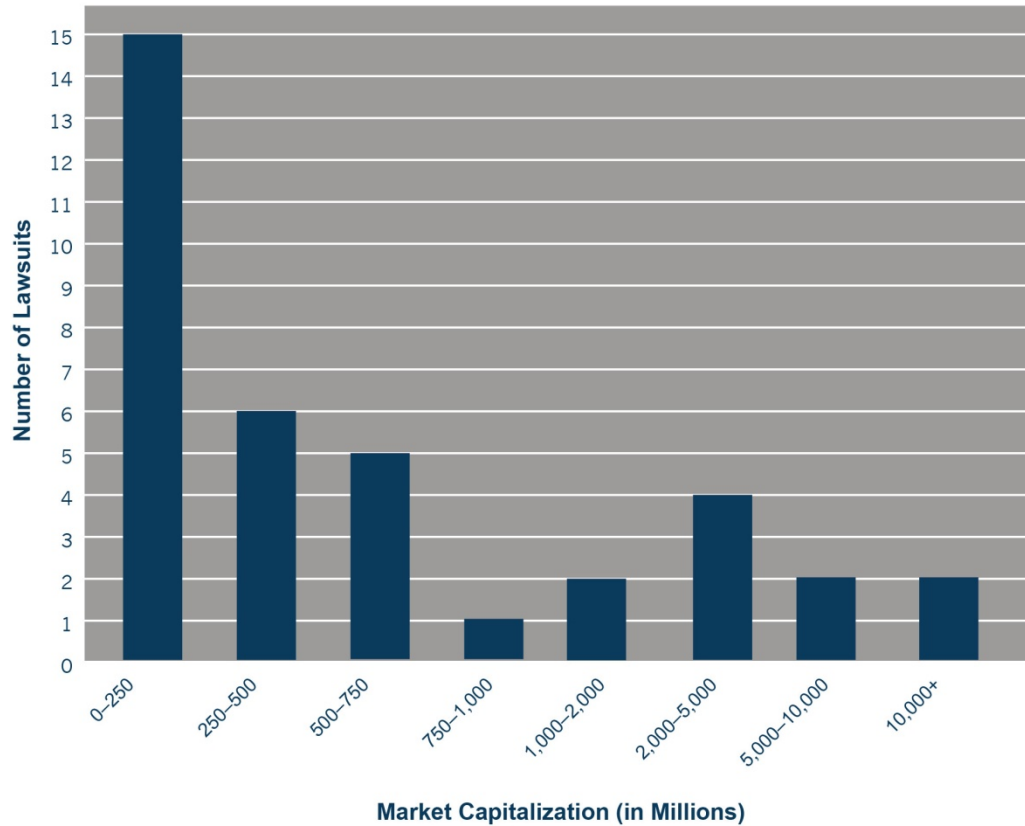


Figure 1.

The Nature of the Claims

The trend that began in 2011 of a return to more industry-specific allegations — such as alleged misrepresentations or omissions regarding marketing practices, prospects/timing of FDA approval, product efficacy, product safety, manufacturing and other healthcare-related allegations — continued in full force in 2014 (see **Figure 2**). Indeed, approximately 56% of 2014 claims alleged misrepresentations or non-disclosures regarding product efficacy or prospects/timing of FDA approval. Claims of inaccurate financial reports/accounting improprieties held relatively steady at 44% in 2014. It should be noted that it was not uncommon in 2014 to see both industry-specific and generalized financial allegations contained in the same lawsuit.

² Market capitalization figures current as of February 5, 2015.

Allegations in 2014 Securities Fraud Lawsuits Against Life Sciences Companies	Number of Lawsuits
Alleged misrepresentations and/or non disclosures regarding product efficacy	5
Alleged misrepresentations and/or non disclosures regarding financial reports/accounting improprieties	8
Alleged misrepresentations and/or non disclosures regarding product safety	8
Alleged misrepresentations and/or non disclosures regarding marketing practices	4
Alleged misrepresentations and/or non disclosures regarding prospects/timing of FDA approval	5
Alleged misrepresentations and/or non disclosures regarding insider trading	3
Other alleged misrepresentations and/or non disclosures, including misrepresentations regarding CMO's continued employment with company and timing of completion of clinical trial	7
Alleged misrepresentations and/or non disclosures regarding manufacturing process	3

Figure 2.

Complaints against life sciences companies in 2014 evidenced a wide range of potential disclosure pitfalls. For example, in October 2014, plaintiffs sued iBio in the District of Delaware, alleging that the company misled investors that a license and collaboration agreement it entered into with Caliber Biotherapeutics meant that iBio would now have a role in the production of ZMapp, an experimental Ebola virus drug. Caliber was one of several companies being considered to help manufacture additional supply of ZMapp with government assistance. As an historic Ebola crisis raged, iBio's CEO made statements to the *Washington Post*, and the company issued a press release, implying that iBio would play a role in the emergency response to the Ebola virus outbreak. After an article on the website *SeekingAlpha.com* allegedly debunked any connection between iBio and ZMapp production, its stock price fell 32%. In another 2014 case involving allegedly puffed-up promotion by the defendant, plaintiffs sued Galena Biopharma, after an article on *TheStreet.com* represented that the company paid an investor-relations firm to publish articles under aliases promoting the company's stock, without disclosing who paid for the articles. Galena's stock price fell 14% after the company acknowledged having retained the named investor-relations firm.

Another trend observed in 2014 were claims filed after the defendant had received a warning letter from the FDA. There were four such cases in 2014, including suits filed against Impax Laboratories in both 2013 and 2014. In March 2013, plaintiffs sued Impax after the FDA issued a warning letter regarding the cGMP compliance of its manufacturing facility, which was followed by an FDA inspection of the facility and a Form 483 from the agency detailing manufacturing deficiencies. In August 2014, Impax again faced a securities fraud class action, this time arising out of quality control issues raised by the FDA about a Taiwanese manufacturing facility to which the company had planned to transfer its production activity.

A number of complaints claiming financial improprieties and insider trading were also filed in 2014. In August 2014, plaintiffs sued Lannett Company for financial improprieties regarding its drug digoxin, which accounted for approximately 23% of Lannett's net sales. Plaintiffs alleged that the company failed to disclose that it was fixing, maintaining and controlling prices of digoxin in violation of Connecticut antitrust laws, as well as allocating and dividing customers and territories with competitors relating to the sale of digoxin, in violation of Connecticut antitrust laws. Further, the company allegedly failed to disclose that it faced possible investigation by the Connecticut Attorney General. Upon the company's disclosure that it had received a subpoena from the Connecticut Attorney General's office, the company's share price fell over 17%. The complaint named Lannett's CEO, CFO and Director of Financial Reporting/Principle Accounting Officer as defendants.

The Status of Cases Filed Since 2011

The relative success (or failure) of securities fraud class actions filed against life sciences companies is an important data point for consideration. Accordingly, we have reviewed the status of all securities fraud class action lawsuits filed against life sciences companies since 2011. See **Figure 3**.

Status (as of 1/5/15)	2014 Cases	2013 Cases	2012 Cases	2011 Cases	Total
Dismissed (via motion or otherwise)	4	6	13	0	23
Motion to dismiss pending	7	6	1	5	19
Summary judgment pending	0	1	0	0	1
Discovery/ongoing	28	3	11	12	54
Settled	0	3	6	0	9
Overall	39	19	31	17	106

Figure 3.

In 2014, life sciences companies targeted by securities fraud lawsuits consistently sought to have the complaints dismissed at the pleadings stage. As we have noted in previous surveys, courts will not accept a plaintiff's vague or conclusory allegations of securities fraud against a life science company in lieu of the detailed pleading requirements of the Private Securities Litigation Reform Act (PSLRA). For example, in January 2015, the Southern District of New York granted a motion to dismiss a securities fraud class action complaint against Sanofi, finding that statements predicting on-time FDA approval of Lemtrada (a multiple sclerosis drug) were statements of opinion protected under the PSLRA safe harbor, and were genuinely believed when they were made. Further, the court found that statements regarding results of ongoing clinical trials, and Lemtrada's adverse effects on patients, were not misleading as to material facts, and that plaintiffs had failed to plead scienter as to claims arising out of these statements.

However, it is equally worth noting that securities fraud lawsuits still carry a substantial risk of exposure, and even when settled can result in very large payments. In January 2015, Pfizer reached a \$400 million settlement less than a month before a jury trial in a securities fraud class action against the company was set to begin. Plaintiffs claimed Pfizer misled investors about the company's marketing of four drugs, and that it concealed it was giving kickbacks to physicians to promote sales of the drugs.

Expectations for the Future

Lessons from *Matrixx Initiatives, Inc. v. Siracusano*

On March 22, 2011, the U.S. Supreme Court handed down its decision in *Matrixx Initiatives, Inc. v. Siracusano*, resolving a circuit split over whether a plaintiff can state a claim for securities fraud where a pharmaceutical company fails to disclose adverse events associated with a product even though the reports were not alleged by the plaintiffs to have been statistically significant.³ In so doing, the *Matrixx* Court upheld the "basic mix" reasoning set out years

³ *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011).

before in *Basic, Inc. v. Levinson*,⁴ finding that information is “material” when it is “substantially likely that a reasonable investor would have viewed this information as having significantly altered the ‘total mix’ of information made available.”

In the several years since *Matrixx*, however, the Supreme Court’s directive has been subject to varying interpretations. While it is evident that Rule 10b-5 does not create an affirmative duty on companies to disclose any and all information to the public, courts have held that incomplete statements regarding adverse event data can support a Rule 10b-5 claim.

For instance, in *Bartelt v. Affymax, Inc.*, the District Court for Northern District of California denied defendants’ motion to dismiss where plaintiff investors alleged that the company failed to disclose multiple instances of life-threatening and other adverse reactions to the company’s drug.⁵ Plaintiffs claimed the company withheld the full extent of the increasing number of serious allergic reactions caused by the company’s drug, including death, and that the company had requested label changes from the FDA to warn doctors of adverse reactions that could occur but did not inform investors of the possible change. Here, the district court adhered to the *Matrixx* court’s recognition that a “contextual inquiry may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link.”⁶

In contrast, in *In re Rigel Pharm., Inc., Sec. Litig.*, the first Ninth Circuit case to address the implications of *Matrixx*, the court affirmed the district court’s order granting defendants’ motion to dismiss. The *Rigel* court specifically held that: (1) a case should not proceed past the initial pleading stage where allegations are made that a company should use different or allegedly better statistical methodology when evaluating clinical trial results; and (2) disclosure of initial top-line data followed later by more detailed information does not render such disclosures false or misleading.⁷ The Ninth Circuit’s decision suggests that *Matrixx* did not create an affirmative duty for a company, in the absence of other statements, to disclose potential issues with its products, even if those issues are material. Disclosure is only required under the Ninth Circuit’s reasoning when necessary to make other statements the company made, in light of the circumstances under which they were made, not misleading.

Finally, in *In re Viropharma, Inc., Sec. Litig.*, the District Court for the Eastern District of Pennsylvania denied a motion to dismiss where plaintiffs claimed that the company misrepresented that a drug would qualify for three additional years of marketing exclusivity based on pending approval from the FDA for several new conditions of use.⁸ The court, in agreeing with the *Matrixx* court that “there is no bright-line rule for determining materiality,” held that while defendants are not obligated to disclose all conversations regarding ongoing discussions with the FDA, the court could not rule out that reasonable investors would not consider certain information significant where the FDA’s conclusions regarding deficiencies in drug studies were essential to any discussion of exclusivity.⁹ Thus, the court held that defendants had a corresponding duty to reveal that information plaintiffs’ had adequately alleged material misrepresentations.

⁴ *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988).

⁵ 2014 WL 231551, at *11-12 (N.D.Cal. Jan. 21, 2014).

⁶ *Matrixx*, 131 S. Ct. at 1321.

⁷ 697 F.3d 869 (9th Cir. 2012).

⁸ 21 F.Supp.3d 458 (E.D. Pa. 2014).

⁹ See *id.* at 471-72.

Update on the Bar for Plaintiffs Seeking Class Certification in All Rule 10b-5 Cases, Including Life Sciences Companies

Companies faced with securities fraud class action suits were dealt a blow from several recent decisions by the U.S. Supreme Court. First, in *Amgen Inc. v. Connecticut Retirement Plans & Trust Funds*, ruling that at the class certification stage (a critical stage in the life of any securities fraud class action) plaintiffs need only plausibly allege, not prove, materiality. Next, in *Halliburton Co. v. Erica P. John Fund, Inc. (Halliburton II)*,¹⁰ the Supreme Court refused to overturn the fraud-on-the-market presumption (first announced in *Basic Inc. v. Levinson*), but recognized that defendants can rebut that presumption at the class certification stage by showing a lack of “price impact.”¹¹ Although these issues have not yet been directly addressed in life sciences class action suits, *Amgen* and *Halliburton II* could significantly protect life sciences companies in defending against securities fraud class action suits.

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 being derived from off-label uses.
2. Review internal processes relating to communications and disclosure about products, including those that are not yet on the market.
3. Develop and publish employee guidelines tailored to specific areas of business operations. Communications by the R&D and marketing departments become subject to particular scrutiny in securities fraud lawsuits filed against life sciences companies.
4. Ensure that the 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.
5. 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 securities laws, it is upon hard statements of fact that class action lawyers — with the benefit of 20/20 hindsight — will concoct a lawsuit.
6. 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

¹⁰ 134 S. Ct. 2398 (2014).

¹¹ *Id.* at 2417.

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.

7. Be aware that while incomplete statements do not create liability, such omissions must not make the actual statements misleading.

Dechert's Life Sciences Practice

Dechert represents life sciences companies, multinational corporations, financial institutions, investment companies and private funds in litigation, transactional, corporate, tax and regulatory matters. We have twice received the "Award for Excellence" in Product Liability from *Chambers USA*, and we have been ranked in the top tier for product liability by both *The Legal 500* and *Benchmark Litigation*. 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:



David A. Kotler
Partner
+1 609 955 3226
david.kotler@dechert.com
dechert.com/david_kotler

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