DECHERT SURVEY OF SECURITIES FRAUD CLASS ACTIONS BROUGHT AGAINST U.S. LIFE SCIENCES COMPANIES

Dechert LLP

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

The past year was particularly noteworthy with respect to the absolute and relative number of securities fraud class action lawsuits brought against publicly traded pharmaceutical, biotechnology and medical companies. In 2012, 27 different life sciences companies (along with their directors, officers and key personnel) were sued for alleged securities fraud in 28 different complaints[1] — representing a sharp increase from the 17 such lawsuits filed in 2011. In terms of substance, the 2012 securities fraud lawsuits continued the trend that we observed last year 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 2012 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 2012, 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 the impact of the U.S. Supreme Court's recent decision in *Amgen Inc. v. Connecticut Retirement Plans & Trust Funds*, as well as the potential ramifications from a securities fraud standpoint of the key off-label marketing decision issued by the U.S. Court of Appeals for the Second Circuit in *U.S. v. Caronia*. Finally, we provide guidance that may help minimize or eliminate the risk of securities fraud class action lawsuits.

[1] Two complaints were filed against St. Jude Medical Inc. in the U.S. District Court of Minnesota on June 14, 2012 and December 7, 2012 by different plaintiffs alleging similar but not identical claims.

Findings

The Numbers

There were 28 securities fraud class action lawsuits brought against life sciences companies in 2012, as compared to a total of 152 securities fraud class action lawsuits brought against all companies in the same time period.[2,3] Hence, approximately 18% of the 2012 cases were brought against life sciences companies. Last year, therefore, witnessed a sharp rise in securities fraud class action lawsuits against life sciences companies both from a gross perspective (17 lawsuits in 2011) and from a relative perspective (9% in 2011). While filings against life sciences companies increased in 2012, the total number of securities fraud class actions decreased markedly from the 188 that were filed in 2011. This past year's 18% proportion of securities fraud class actions brought against life sciences companies is well above the percentage of securities fraud complaints filed against life sciences companies in recent years (9% in 2011, 16% in 2010, 10% in 2009, 10% in 2008, 14% in 2007, 13% in 2006).

The securities fraud complaints filed in 2012 also followed last year's trend of focusing more on life sciences companies with relatively smaller market capitalizations (see **Figure 1**). In 2012, 50% of the life sciences companies sued for class action securities fraud had market capitalizations of less than $250 million, as compared to 58% in 2011 and 31% in 2010. However, the plaintiffs' bar is not completely neglecting the larger life sciences companies, as life sciences companies that have at least $1 billion in market capitalization were named as defendants in approximately 35% of the lawsuits filed in 2012 (10 out of 28). Also, two complaints were filed against St. Jude Medical, Inc., which has a market capitalization of over $10 billion.

The Nature of the Claims

The trend that began in 2011 of a shift back 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 2012 (see **Figure 2**). Indeed, approximately 43% (12 of the 28 complaints) alleged misrepresentations or non-disclosures regarding product efficacy. Interestingly, claims of inaccurate financial reports/

[2] 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* and the *D&O Diary* blog.

[3] As in prior years, we include lawsuits alleging claims under Section 10(b) of the Securities Exchange Act of 1934. Class action lawsuits alleging claims only under Section 11 of the Securities Act of 1933, or lawsuits arising out of mergers or other such change in control transactions are not included in this survey.

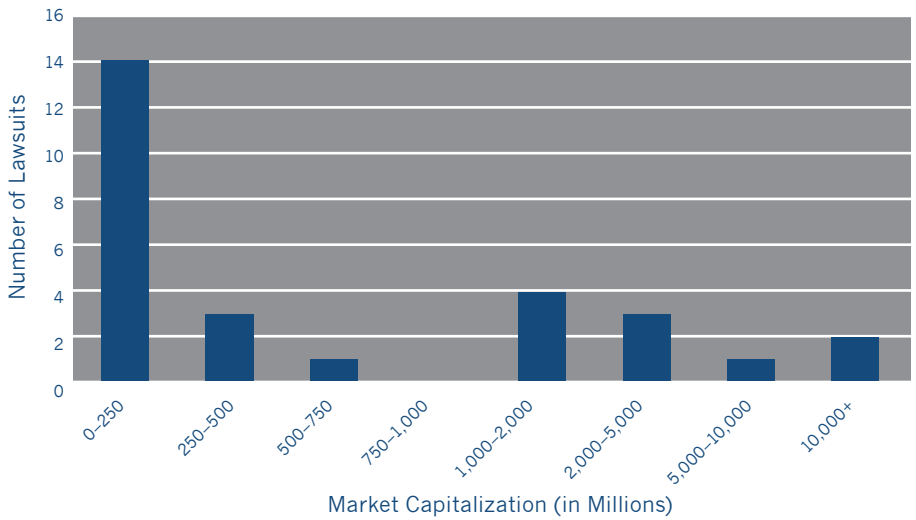

Figure 1.

Allegations in 2012 Securities Fraud Lawsuits Against Life Sciences Companies	Number of Lawsuits
Alleged misrepresentations and/or non disclosures regarding product efficacy	12
Alleged misrepresentations and/or non disclosures regarding financial reports/accounting improprieties	12
Alleged misrepresentations and/or non disclosures regarding product safety	7
Alleged misrepresentations and/or non disclosures regarding marketing practices	6
Alleged misrepresentations and/or non disclosures regarding prospects/timing of FDA approval	6
Alleged misrepresentations and/or non disclosures regarding insider trading	4
Other alleged misrepresentations and/or non disclosures including misrepresentations regarding CMO's continued employment with company and timing of completion of clinical trial	2
Alleged misrepresentations and/or non disclosures regarding manufacturing process	1

Figure 2.

accounting improprieties increased to 43% — this figure fell somewhere between the 2011 (35%) and 2010 (51%) numbers. It should be noted that in the 2012 lawsuits it was not uncommon to see both industry-specific and generalized allegations brought in the same lawsuit.

Plaintiffs did not lack for creativity with some of their allegations in 2012. For example, in the Southern District of New York (S.D.N.Y.), plaintiffs brought a lawsuit in April 2012 against NeurogesX, Inc., a biopharmaceutical company that focuses on developing and commercializing pain management therapies. Plaintiffs alleged that NeurogesX fraudulently stated that its Chief Medical Officer (CMO) would continue to be employed by the company even after the Chief Executive Officer (CEO) retired. In reality, according to plaintiffs, the CMO was actively seeking other employment and NeurogesX was allegedly aware of his efforts to do so because the CMO's knowledge can be imputed to the company. Plaintiffs allegedly invested in the company based, in part, on the assurance that the CMO would remain at the company. In September 2011, the CMO accepted a position at another company, and shortly thereafter the stock price fell.

Another case brought in the S.D.N.Y. in June 2012 against AEterna Zentaris, Inc., a company that was developing a novel anti-cancer agent known as perifosine, included the claim that defendants misled investors regarding the timing and success of AEterna's clinical trial of perifosine. Plaintiffs alleged that the defendants made false or materially misleading public statements because the company knew that the trial would be completed later than the second half of 2011.

Complaints asserting multiple industry-specific claims were also filed in 2012. For example, in February 2012, BioSante Pharmaceuticals, Inc. a pharmaceutical company that was developing LibiGel, a product designed to improve the sex drive of women suffering from female sexual dysfunction, was sued in the Northern District of Illinois. The complaint alleged that the company, along with its CEO, issued a series of materially false and misleading statements to investors about LibiGel's commercial viability, effectiveness and market potential that caused shares of the company to trade at artificially high prices. Specifically, plaintiffs claimed that the company stated that the product had a "statistically significant" effect on female patients treated with LibiGel, and that it was "the most clinically advanced pharmaceutical product in the U.S." Additionally, the complaint alleged that the company and its CEO misled investors by routinely analogizing LibiGel's market potential to the $2 billion dollar market for male erectile drugs, often comparing it to products like "Viagra, Levitra and Cialis." The company also issued numerous statements regarding its view as to the likelihood of FDA approval, such as the statement in its August 2011 10-K that "we continue to believe that LibiGel has the potential to be the first product approved by the FDA for this common and unmet medical need." On December 14, 2011, the company issued a press release disclosing for the first time that the product failed to yield positive results in large-scale efficacy tests. Following the release of this news, the company's shares declined by over 75% of their value.

Complaints claiming financial improprieties and insider trading were still prevalent in 2012. For example in November 2012, plaintiffs sued Align Technology, Inc. in the Northern District of California for allegedly issuing materially false and misleading statements regarding Align's current financial condition, quarterly and year-end revenue, and earnings forecast for 2012.

Status (as of 3/7/2013)	2012 Cases	2011 Cases	2010 Cases	2009 Cases	2008 Cases	Total
Dismissed via motion to dismiss	0	2	10	4	7	23
Dismissed via voluntary dismissal, stipulation to dismiss, default judgment, or failure to serve	4	1	3	3	2	13
Motion to dismiss pending	13	6	4	0	0	23
Summary Judgment motion pending	0	0	0	0	0	0
Discovery/ongoing	11	7	8	3	3	32
Settled	0	1	4	9	11	25
Overall	28	17	29	19	23	116

Figure 3.

As a result of these alleged misrepresentations and omissions, Align's stock allegedly traded at artificially inflated prices, and allowed Company insiders to sell more than 1.5 million shares of Align stock at such prices for illegal insider trading proceeds of more than $52 million.

The Status of Cases Filed Since 2008

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 2008. See **Figure 3** for a report on the status of those cases.

In 2012, life sciences companies targeted by securities fraud lawsuits have quickly sought to have the complaints dismissed based on inadequate pleadings, with motions to dismiss having already been filed in 46% of the cases. As we have noted in previous surveys, courts will not accept a plaintiff's vague or conclusory allegations against a life science company in lieu of the detailed pleading requirements of the Private Securities Litigation Reform Act (PSLRA). For example, in January 2013, a district court in the Middle District of Tennessee dismissed a securities fraud lawsuit against BioMimetic Therapeutics based on alleged misrepresentations regarding the safety and efficacy of its synthetic bone growth product, Augment, as well as its prospects for FDA approval.[4] The Court held that the allegations in the complaint "do not suggest a knowing and deliberate intent to deceive or defraud, let alone highly unreasonable conduct . . . ."[5] The Court further held that the company "could have characterized things differently, but what it disclosed was sufficient" because it did not withhold any information that would have been material to a reasonable investor.[6] Similarly, a district court in the Northern District of California dismissed securities fraud claims against Cooper Companies, Inc. based on alleged misrepresentations regarding the safety of one line of the company's contact lenses.[7] The Court held the plaintiffs' allegations to be "insufficient . . . to give rise to a strong inference of scienter."[8]

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 2012, the class action lawsuit against Medtronic Inc. (first discussed in our 2008 survey) settled for $85 million.[9] The 2011 class action against MannKind Corp. resulted in a settlement payment of more than $16 million.[10]

4 *Sarafin v. BioMimetic Therapeutics, Inc.*, No. 3:11-0653, 2013 U.S. Dist. LEXIS 4909 (M.D. Tenn. Jan. 10, 2013).

5 *Id.* at *37.

6 *Id.* at *38.

7 *Greenberg v. Cooper Companies, Inc.*, No. 11-cv-05697, 2013 U.S. Dist LEXIS 2944, *6-10 (N.D. Cal. Jan. 7, 2013).

8 *Id.* at *26.

9 *Minneapolis Firefights' Relief Assoc., v. Medtronic Inc.*, No. 08-6324, (D. Minn. July 20, 2012) (Stipulation and Agreement of Settlement).

10 *In re Mannkind Corp. Sec. Litig.*, No. 11-cv-00929, (C.D. Cal. Aug. 6, 2012) (Stipulation of Settlement).

Expectations for the Future

The Supreme Court Lowers the Hurdle for Plaintiffs Seeking Class Certification in All Rule 10b-5 Cases, Including Against Life Sciences Companies

On February 27, 2012, the U.S. Supreme Court handed down its decision in *Amgen Inc. v. Connecticut Retirement Plans & Trust Funds*,[11] resolving a split among the circuits as to whether in a misrepresentation case under SEC Rule 10b-5: (i) a district court must require proof of materiality of the alleged misstatements before certifying a class based on the fraud-on-the-market theory; and (ii) the district court must allow rebuttal evidence to the applicability of the fraud-on-the-market theory. One element of a Rule 10b-5 claim is that the plaintiff relied on the material misrepresentation or omission. Ordinarily it would be extremely difficult to certify a securities fraud class because establishing individual reliance on behalf of each class member would result in the predominance of individual issues over common ones; however, in *Basic Inc. v. Levinson*, the Supreme Court held that it was appropriate "to apply a [rebuttable] presumption of reliance supported by the fraud-on-the-market theory"[12] to overcome this class certification hurdle. The fraud-on-the-market theory is based on the notion that "in an open and developed securities market, the dissemination of *material* misrepresentations or withholding of material information typically affects the price of the stock, and purchasers generally rely on the price of the stock as a reflection of its value."[13]

In *Conn. Retirement Plans & Trust Funds v. Amgen Inc.*, the U.S. Court of Appeals for the Ninth Circuit held that at the class certification stage in a securities fraud class action, plaintiffs need only plausibly allege, not prove, materiality, and defendants may not rebut the fraud-on-the-market presumption.[14] In a 6-3 decision, the U.S. Supreme Court affirmed the Ninth Circuit's decision.[15] Prior to this decision, the Second and Fifth Circuits followed (and the First Circuit noted in dictum) an opposite approach — a plaintiff must prove materiality for class certification, and defendants may rebut the applicability of the fraud-on-the-market theory.[16] The Third Circuit had adopted an intermediate position that did not require proof of materiality, but did allow defendants to rebut the presumption of reliance.[17]

The Supreme Court's decision in *Amgen* is expected to have a profound impact on the critical class certification stage in securities fraud class action lawsuits filed against life sciences companies, especially in the Second, Fifth and First Circuits, where the previously required higher threshold for plaintiffs to overcome the class certification barrier now will be lessened. Following *Amgen*, many more cases may survive class certification, and life science companies therefore may be forced into larger settlements.

Truthful Off-Label Marketing May Cease Giving Rise to Securities Fraud Class Action Lawsuits

The promotion of off-label uses for drugs has proved problematic throughout the life sciences industry, and in addition to numerous products liability lawsuits, also has resulted in securities fraud lawsuits where the alleged promotion of an off-label use caused the company's stock to trade at an artificially inflated rate. For instance, in 2012, Medtronic Inc., paid over $85 million to settle a securities fraud class action lawsuit asserting such claims. Securities fraud claims based on alleged off-label marketing also were brought in a new lawsuit against Abiomed Inc. in the District Court of Massachusetts.

However, in *U.S. v. Caronia*,[18] the U.S. Court of Appeals for the Second Circuit issued an important decision when it ruled that off-label promotion, when truthful, may be protected speech under the First Amendment — and therefore presumably could not serve as the predicate for a later-filed securities fraud class action. To date, *Caronia* has altered only the FDA's criminal prosecutions, and it does not appear to have had any effect on civil claims involving off-label use. Life science companies certainly should not treat *Caronia* as providing *carte blanche* for truthful off-label marketing, but the door has

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11 133 S. Ct. 1184 (Feb. 27, 2013).

12 *Basic Inc. v. Levinson*, 485 U.S. 224, 250 (U.S. 1988).

13 *Id.* at 244 (quoting *Peil v. Speiser*, 806 F.2d 1154, 1161 (3d Cir. 1986)) (emphasis added).

14 660 F.3d 1170, 1172 (9th Cir. 2011).

15 133 S. Ct. 1184 (Feb. 27, 2013).

16 *In re Salomon Analyst Metromedia Litig.*, 544 F.3d 474, 481-86 (2d Cir. 2008); *Oscar Private Equity Invs. v. Allegiance Telecom, Inc.*, 487 F.3d 261, 265 (5th Cir. 2007); *In re PolyMedica Corp. Sec. Litig*, 432 F.3d 1, 7 n.11 (1st Cir. 2005).

17 *In re DVI, Inc. Sec. Litig.*, 639 F.3d 623, 631-32 (3d Cir. 2011).

18 703 F.3d 149 (2d Cir. 2012).

now been opened for the possibility that such speech may be constitutionally protected.

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 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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