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

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Publicly-Traded Life Sciences Companies of All Sizes Remain Prime Targets of Securities Fraud Class Action Lawsuits

This past year was again noteworthy with respect to securities fraud class action lawsuits pursued against publicly-traded pharmaceutical, biotechnology and medical device companies. To begin with, 29 different life sciences companies, along with a number of those companies' directors, officers and key personnel, were sued for alleged securities fraud in 2010; these 29 lawsuits represent a marked increase from 19 such complaints in 2009 and 23 in 2008. Also of interest is the fact that the life sciences companies with larger market capitalizations were sued for securities fraud at an increased rate compared to years past. Additionally, in a continuation of a trend that we have observed for the past several years with the prolonged impact of the "Great Recession," the 2010 securities fraud lawsuits focused more on a company's finances than on industry-specific issues (e.g., likelihood of FDA approval or product safety/efficacy). Finally, with respect to the securities fraud lawsuits filed against life sciences companies over the past several years, while the companies are continuing to have some success in defeating those lawsuits at the dismissal stage, those cases that are not dismissed continue to result in multimillion dollar settlements with the company's shareholders.

In this survey, we first highlight the trends from the securities fraud lawsuits filed against life sciences companies in 2010, including a discussion of some of the notable allegations made in those suits. We then analyze the status of the securities fraud lawsuits brought in 2007, 2008 and 2009 (which we first presented in our prior surveys). We next 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, especially in light of the U.S. Supreme Court's recent decision in *Matrixx Initiatives, Inc. v. Siracusano*, which will impact the disclosure decisions of every publicly-traded life sciences company. Finally, we provide guidance that may help minimize or eliminate the risk of securities fraud class action lawsuits.

Findings

There were 29 securities fraud class action lawsuits brought against life sciences companies in 2010 out of the 176 securities fraud class action lawsuits brought against all companies during the same time period.[1,2] These 29 lawsuits represent a gross increase over the 19 such lawsuits filed in 2009 and the 23 filed in 2008; on a relative basis they represent 16% of the total securities fraud class actions brought against life sciences companies last year, which is at the top of the range we have observed over the past five years (10% in 2009, 10% in 2008, 14% in 2007, 13% in 2006 and 16% in 2005).

The year 2010 also saw a shift in the relative market capitalizations of life sciences companies targeted for securities fraud lawsuits: companies with larger market capitalizations were sued for securities fraud at a higher rate than in years past (*see* Figure 1).[3] Whereas in 2009, 63% of the life sciences companies sued for securities fraud had a market capitalization of less than $250 million, in 2010 only 31% of the securities fraud class action lawsuits were initiated against companies with market capitalizations of less than $250 million. Instead, lawsuits filed against life sciences companies with market capitalizations of between $250 million and $500 million rose to 24%, up from 10% in 2009. More significantly, 28% of the past year's lawsuits were brought against life sciences companies with the greatest market capitalizations—more than $10 billion—in marked contrast to 5% in 2009.

The Nature of the Claims

As we first reported in our prior surveys, the allegations in the securities fraud complaints against life sciences companies in recent years generally have focused more on the company's alleged financial improprieties than on alleged public misstatements regarding industry-specific issues such as product safety or efficacy, or the prospects of receiving FDA approval. This trend largely continued in 2010, as more than half of the complaints filed this past year included allegations of financial improprieties by the company.

Allegations of misstated or misleading financial results and forecasts were particularly prevalent. For instance, in August 2010, shareholders filed suit against Intuitive Surgical, Inc., in the Northern District of California, alleging that the company and certain of its officers and directors, including its chief financial officer and vice president of business development/strategic planning, inflated the market demand and financial prospects of the company's key product, the da Vinci robot, a robotic surgical device used in prostate operations. Plaintiffs claim that defendants made false and misleading statements regarding demand for the da Vinci robot despite knowing that the company's past aggressive growth could not be sustained during the economic decline. When the company released lowered sales numbers, the stock price fell and the plaintiffs sued.

[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] Although securities fraud actions filed against life sciences companies in the context of a merger or acquisition are not included in this survey, we note that consistent with the reported spike in M&A-related litigation, *see, e.g.*, Kevin LaCroix, *A Closer Look at the 2010 Securities Lawsuit Filings*, The D&O Diary (Jan. 3, 2011), *available at* http://www.dandodiary.com/2011/01/articles/securities-litigation/a-closer-look-at-the-2010-securities-lawsuit-filings (last visited February 11, 2011), we are aware of at least seven life sciences companies that were targeted by such lawsuits in 2010.

[3] Figure 1 includes 28 of the 29 life sciences companies sued for securities fraud in 2010; it omits NBTY, Inc., which was taken private in 2010.

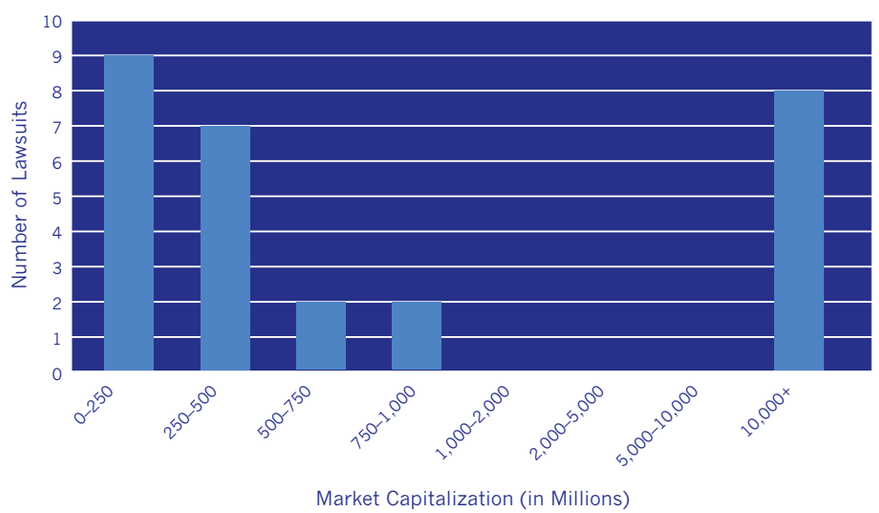

Figure 1.

Allegations in 2010 Securities Fraud Lawsuits	Number of Lawsuits
Alleged misrepresentations and/or non-disclosures regarding accounting improprieties	15
Alleged misrepresentations and/or non-disclosures regarding the prospects/timing of FDA approval	9
Alleged misrepresentations and/or non-disclosures regarding product efficacy	8
Alleged misrepresentations and/or non-disclosures regarding product safety	7
Alleged misrepresentations and/or non-disclosures regarding insider trading	5
Alleged misrepresentations and/or non-disclosures regarding marketing practices	4
Alleged misrepresentations and/or non-disclosures regarding manufacturing processes	2

Figure 2.

Similarly, in December 2010, shareholders sued Genoptix, Inc., a diagnostic laboratory services provider, in the Southern District of California, contending that the company and certain of its officers, including its chief financial officer and chief operating officer, made false and misleading statements about its market advantage over competitors and projected large future increases in market share, when in reality the company's business model was not working and the company was actually losing market share. After defendants disclosed unexpectedly low first quarter results, and the company's stock price dropped 23%, the plaintiffs sued.

Along the same lines, a number of complaints focused on alleged accounting mistakes or mismanagement. For example, in March 2010, St. Jude Medical, Inc., a manufacturer and distributor of neurostimulation devices, along with certain of its officers, was sued in the District of Minnesota on the theory that the company failed to disclose its true product sales and consumer demand during the economic recession and improperly recognized bulk sales revenues in order to meet sales projections in violation of GAAP and SEC rules.

Of course, many life sciences companies that were sued for securities fraud in 2010 still faced industry-specific allegations, such as alleged misrepresentations regarding product safety and/or efficacy (*see* Figure 2). For example, in March 2010, shareholders filed suit against AMAG Pharmaceuticals, Inc. and certain of its directors and officers in the District of Massachusetts, contending the company failed to reveal any serious adverse events (SAEs), anaphylactic reactions or fatalities experienced by patients administered its drug Feraheme, an intravenous iron-replacement drug indicated for the treatment of iron deficiency anemia associated with chronic kidney disease. When an analyst disclosed that there were a number of SAEs, several instances of anaphylactoid reactions and a possible fatality related to the drug, the company's stock declined more than 15%.

Other complaints focused on the company's alleged misrepresentations regarding the prospects of receiving FDA approval. In September 2010, shareholders brought suit in the Northern District of Illinois against Acura Pharmaceuticals, Inc. and certain of its officers and directors, including its chief scientific officer, alleging the company made false and misleading statements concerning the projected success of its drug Acurox, an opioid pain reliever designed to produce aversive side effects when consumed in excess in order to deter drug abuse. According to the complaint, defendants misled investors with positive statements about Acurox's purported aversive effects, which were not only easily overcome by abusers, but were twice as likely to affect non-abusers taking the drug. When FDA rejection of the drug became public, Acura stock value dropped nearly 50%. Similarly, in September 2010, shareholders sued AspenBio Pharma, Inc. and, among others, its Chief Medical Officer, in the Southern District of New York, alleging that defendants misled investors by touting the novelty, high sensitivity rate and projected commercial success of its product AppyScore, a diagnostic test for appendicitis. Plaintiffs claim that, in reality, AppyScore used a well-studied and commercially available protein that was hardly novel, was not an effective or efficient diagnostic tool for appendicitis and was incapable of practical application in the emergency room setting, as defendants claimed. When defendants revealed that clinical studies showed lower specificity than projected, the company stock price fell.

The Status of Cases Filed in 2007, 2008 and 2009

An important data point for publicly-traded life sciences companies to keep in mind is the relative success (or failure) of the securities fraud class actions filed against life sciences companies. For this reason, we have reviewed the status of all of the securities fraud class action lawsuits filed against life sciences companies in 2007, 2008 and 2009. *See* Figure 3 (next page) for a report on the status of those cases.

As we have noted in our previous surveys, courts will not accept a plaintiff's vague or conclusory allegations against a life sciences company or its officers/directors in lieu of the detailed pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"). The court opinions issued in 2010 in connection with motions to dismiss earlier-filed securities fraud cases reinforce the importance of pleading with particularity scienter and materially false or misleading statements or omissions. For instance,

Status (As of 2/23/11)	2010 Cases	2009 Cases	2008 Cases	2007 Cases	Total
Dismissed via motion to dismiss	0	3	6	11	20[4]
Dismissed via voluntary dismissal, stipulation to dismiss or failure to serve	3	1	2	2	8
Motion to dismiss pending	7	8	1	1	17
Summary judgment motion pending	0	0	1	1	2
Discovery/ongoing	19	3	7	3	32
Settled	0	4	6	7	17
Overall	29	19	23	25	96

Figure 3.

in November 2010, a magistrate judge in the District Court for the Southern District of Texas recommended that the complaint against Repros Therapeutics, Inc. and certain of its high-ranking officers could not proceed because plaintiffs failed to adequately plead that defendants' statements regarding the success of a clinical trial were misleading or were made with the requisite scienter. This recommendation was adopted by the District Court in January 2011. Similarly, in September 2010, a judge in the Southern District of New York dismissed a case that had been brought against Savient Pharmaceuticals, Inc. and certain of its officers, including its chief medical officer, because of a failure to adequately plead scienter, materiality or the existence of a false or misleading statement with regard to the drug at issue. This case is currently being appealed.[5]

Expectations for the Future

In our 2009 survey, we warned that in light of the Department of Justice announcement that life sciences companies would be facing enhanced scrutiny for any activities that could be found to violate the Foreign Corrupt Practices Act ("FCPA"), a publicly announced FCPA investigation could spur a follow-on securities fraud class action. Over the past year, the SEC and the Department of Justice have indeed targeted a number of life sciences companies for investigation of possible FCPA violations,[6] and a securities fraud lawsuit resulted from at least one such investigation. In August 2010, shareholders sued SciClone Pharmaceuticals, Inc. in the Northern District of California alleging that the company made false and misleading statements regarding its expansion into China and its systems of controls and procedures, which caused the company to become the focus of an FCPA investigation by the SEC. When the investigation was revealed, the company's stock price fell by approximately 40%. Although this case was voluntarily dismissed without prejudice, the lawsuit does underscore that even an announced FCPA inquiry can quickly morph into a securities fraud class action.

Additionally, on March 22, 2011, the Supreme Court issued a decision in *Matrixx Initiatives, Inc. v. Siracusano* (No. 09-1156), in which it resolved a split among the Courts of Appeal regarding whether a publicly-traded life sciences company can be liable for securities fraud for failing to disclose "adverse event reports" regarding any of its products.[7,8] The Supreme Court's opinion in *Matrixx* did away with the bright-line "statistical significance" standard for assessing the materiality of facts alleged to have been omitted or misstated by pharmaceutical and medical device companies in securities fraud claims under Section 10(b) of the 1934 Securities Exchange Act and Rule 10b-5. The Court also declined to hold that, in the absence of such statistically significant adverse event reports, a plaintiff could not meet its burden of alleging facts amounting to the strong inference of scienter required in federal securities fraud actions.

In *Matrixx*, a putative class consisting of the company's shareholders, alleged that Matrixx violated Section 10(b) of the 1934 Securities Exchange Act and Rule 10b-5 promulgated thereunder when it failed to disclose that one of its products, Zicam Cold Remedy, causes a loss of smell ("anosmia"). According to plaintiffs, despite evidence that Zicam caused loss of smell in its users, including adverse event reports filed about the product beginning in 1999, Matrixx continued to assert that Zicam was safe until

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4 Four of these dismissals are currently on appeal.

5 *See Koncelik v. Savient Pharms., Inc.*, No. 08-civ-10262 (GBD) (Oct. 28, 2010).

6 *See, e.g.*, Ashby Jones, *Feds Introducing Big Pharma to FCPA*, *The Wall Street Journal* (Oct. 5, 2010), available at http://blogs.wsj.com/law/2010/10/05/feds-introducing-bigpharma-to-fcpa/ (last visited February 11, 2011).

7 An adverse event is "any undesirable experienced associated with use of a medical product in a patient." *See* "What Is a Serious Adverse Event?" *available at* http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm (last visited February 17, 2011).

8 Dechert LLP represented the Advanced Medical Technology Association in the *Matrixx* case and filed an *amicus curiae* brief in support of Matrixx.

2004, when it stated in a press release that there was "insufficient scientific evidence" regarding the issue.[9]

In its decision, the Supreme Court recognized that the question of materiality is governed by the controlling standard of *Basic v. Levinson*, 485 U.S. 224 (1988), under which a plaintiff must show that "there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."[10] *Id.* at 231-32. Relying on *Basic*, the Court first rejected Matrixx's argument that "adverse event reports that do not reveal a statistically significant increased risk of adverse events from product use are not material information."[11] The Court reasoned that Matrixx's argument rested on the "flawed" premise that "statistical significance is the only reliable indication of causation,"[12] and that the FDA may take regulatory action based on a mere "suspicion of causation," as it did in sending Matrixx a warning letter regarding Zicam despite the absence of statistically significant data showing a link between the product and the loss of smell.[13]

Given its recognition that medical professionals and regulators may take action based on data that is not statistically significant, the Court further reasoned that "in certain cases reasonable investors would as well."[14] The Court thus concluded that statistical significance (or the lack thereof) is a relevant factor in the materiality inquiry, although the Court also noted that "it is not dispositive of every case."[15]

The Court also declined to endorse Matrixx's "proposed bright-line rule requiring an allegation of statistical significance to establish a strong inference of scienter."[16] The scienter element of a securities fraud action requires plaintiffs to plead with particularity sufficient facts to raise a strong inference that an omission was made with the intent to deceive or defraud investors.[17] Assuming, without deciding, that the scienter requirement may be satisfied by a showing of deliberate recklessness (the standard applied by the Ninth Circuit), the Court concluded that the plaintiffs had sufficiently pleaded scienter based on other allegations, such as Matrixx's issuance of a press release touting studies that purportedly confirmed that Zicam did not cause the loss of smell when, in fact, no such studies had been conducted. This allegation, taken together with numerous others in the complaint, gave rise to a "cogent and compelling" inference that "Matrixx elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market."[18]

By rejecting statistical significance as setting a minimal threshold for disclosure, *Matrixx* will require life sciences companies to assess its disclosures and investor impact more holistically, and on a case-by-case basis. At first glance, it might appear that the Court's decision would require the disclosure of every adverse event report as potentially material information. In an attempt to address such concerns, the Court explicitly stated that its decision does *not* mandate such extensive disclosure. Rather, it explained that while statistical significance alone is not determinative in the materiality analysis, the "mere existence" of such adverse event reports is also not a determining factor.[19] Instead, "[s]omething more is needed," and this "something more . . . can come from the source, context, and context of the [adverse event] reports" rather than from their existence alone.[20] Furthermore, the Court reiterated that, under the Securities Exchange Act, companies are not required to "disclose any and all material information," but are required to make disclosures only when they are "necessary to make statements made, in light of the circumstances under which they were made, not misleading."[21] Thus, "[e]ven with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market."[22]

Despite these reassurances, however, life sciences companies are now faced with heavily fact-specific questions of where to draw the disclosure line in the absence of a bright-line standard. The *Matrixx* decision, and its application by the lower courts, will need to be closely monitored by life sciences companies as they consider their disclosure obligations.

Minimizing the Risk of Securities Fraud Class Actions

There are a number of 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

9 *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1174 (9th Cir. 2009).

10 *Basic*, 485 U.S. at 231-32.

11 Slip. Op. at 9.

12 *Id.* at 11.

13 *Id.* at 14.

14 *Id.* at 15.

15 *Id.* at 15.

16 *Id.* at 20.

17 *Id.*

18 *Id.* at 21.

19 *Id.* at 16.

20 *Id.*

21 *Id.* (citation and quotation marks omitted).

22 *Id.*

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 or the loss of a key commercial partner.
2. In light of the *Matrixx* decision, review internal processes relating to communications and disclosure about products, including those that are not yet on the market.
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 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.

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. For the second consecutive year, Dechert received the "Award for Excellence" in Product Liability from *Chambers USA*. In addition, we were 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:

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