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World War Z: Why Life Sciences Companies May be in the Path of the "New" Securities Enforcement & Litigation Onslaught, & How to Avoid Trouble

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2013 is witnessing the continued rise of the life sciences sector. Life sciences companies are accessing the capital markets at a brisk clip, with over a dozen IPO's in the first few months of the year, and the best IPO month in 13 years just concluded.[2] The highest growth vectors and rates are in this sector. Life sciences is one area where U.S. companies appear to have a distinct advantage, due to a confluence of factors around intellectual property, product pipelines, marketing and markets. In sum, the U.S. economy has arguably matured through the post-industrial, service economy phase, and entered a new "life sciences economy" era, especially with the difficulties faced by green energy as a new pillar of the economy.

Like a perfect storm, and just in time, the SEC and plaintiffs lawyers are already shuffling toward this sector as a new target. The number of life sciences companies sued over securities and governance issues has multiplied rapidly over the past year.[3] It can only be expected to increase; general counsels of these companies without exception -- literally 100 percent -- report government regulation and litigation as their top concern.[4] Why?

The SEC is being revamped with new leadership and new priorities. Initiatives from new leadership are renewing the SEC's focus on financial accounting and reporting, putting the Madoff-era focus on large, outright financial frauds, and meltdown-era focus on insider trading and excessive risk-taking, partly behind the agency.[5] Likewise, private plaintiffs have gorged on financial meltdown cases, many are now subsisting on M&A, proxy and derivative cases, but starting the renew efforts at stock drop class actions.[6] This and the SEC's new focus - a whistleblower program that is finally yielding public payouts - could combine to create a new wave of stock drop, restatement, and derivative shareholder suits.

In the direct path of this possible onslaught are life sciences companies, by the nature of the industry, regulatory environment, products, life cycle, and growing share of the national economy and growth. Life science companies' unique exposure to many different regulatory regimes, combined with watershed moments in product development and approval, and the new SEC enforcement focus on financial accounting creates an attractive target for enforcement, and by extension, private plaintiffs and their counsel.

This article briefly traces the post-financial meltdown changes at the SEC and in shareholder litigation activity, discusses why the current climate puts life sciences companies at risk to the "new" focus of the SEC and plaintiffs, and offers as a takeaway the top five things boards and company management can do to avoid becoming a target.

Very Recent SEC Activity Portends a New Focus

In the past 10 years, the number of financial accounting and issuer disclosure actions brought by the SEC has steadily declined from 199 such cases in 2003 to merely 79 cases in 2012, with most of the decline occurring post-2008.[7] Although this may be partly due to the success of the Sarbanes-Oxley Act of 2002, many believe that there was a shift in SEC priorities after the financial meltdown and the failings of the SEC in the Madoff case.[8] In 2010, for example, the SEC created five specialised units to take up cases in asset management, market abuse, structured and new products, foreign corrupt practices, and municipal securities and public pensions.[9] Interestingly, financial accounting and reporting was not included in any of these five specialised units.

But after a decade of trending away from SEC enforcement of these cases, there is evidence that the SEC is poised to renew its focus on financial accounting and reporting under the leadership of Chairman Mary Jo White. For example, the SEC is beginning to create and use tools to detect accounting fraud such as the "Accounting Quality Model", [10] and reports indicate that Chairman White's new co-heads of enforcement, George Canellos and Andrew Ceresney, will announce a reallocation of enforcement resources with a focus on financial accounting fraud. [11]

Even the federal judiciary is beginning to signal that the SEC should move on from beating the tired drum that the banks' excessive risk taking sank the economy. In the recent case SEC v. Goldman Sachs & Co. et al, U.S. District Judge Katherine Forrest prevented the SEC from delving into the root causes of the financial crisis in its case against an ex-Goldman Sachs trader in its forthcoming trial of him for allegedly lying to customers. [12]

Recent Shareholder Litigation Activity

As the SEC's enforcement triage is beginning to change, the types of securities class actions brought by private plaintiffs have also begun to change since the financial meltdown in 2008. Recent reports indicate that cases related to the credit crises have dropped from 103 in 2008 to only four cases in 2012.[13] M&A and proxy cases have filled in much of the gap such that the total number of cases brought by private plaintiffs has dropped only slightly from 2008 to 2012.[14] This data suggests that now that suits from the credit crisis have dried up, plaintiffs and their lawyers are looking for other means of bringing securities class actions against companies.

Why Life Sciences in the Crosshairs?

Life sciences companies are likely to become targets of both SEC investigations and private plaintiff class actions. The many laws and regulations that life sciences companies must follow puts plaintiffs' counsel in a position to argue there were certain revelations under any one of various regulatory regimes that affected the company's stock price.

For example, life science companies have exposure under the False Claims Act (FCA) to allegations of kickbacks in their dealings with regulatory bodies or allegations of fraudulent government reimbursements.[15] Indeed, FCA claims are some of the largest pharmaceutical company settlements in history.[16] Life science companies also have Foreign Corrupt Practices Act (FCPA) exposure because they are often in the business of importing, licensing, and selling a regulated product into foreign markets.[17]

Finally, these companies are regulated by the Food and Drug Administration (FDA) in such a way that there are watershed moments in a life science company's product development and approval. For example, FDA approval of a drug or medical device is the type of single event that can have a dramatic effect on a life science company's stock price.[18] The resulting volatility of revenue creates many opportunities for plaintiffs' counsel to ask: "who knew what, and when did they know it?"

Derivative suits challenging the directors' managing of the risks associated with each of these regulatory regimes creates an additional layer of risk, even if stock prices do not measurably decline.

A public company is also, of course, under the auspices of the SEC, and life science companies are particularly prone to whistleblowers under

Dodd-Frank because of the volatile nature of their regulatory approvals, heavily regulated marketing, and the revenue recognition issues around startup medical devices and products.

To be sure, other sectors than life sciences have some of these risk factors. Energy, infrastructure, banking, and retail, for example, each face some level of regulation. But life science companies run the full gamut of problems, having more risk factors stemming from regulation than comparable industries.

Top Five Ways Management and the Board Can Reduce Risk

Anticipating this trend, what can managements and boards do to prepare their defenses to the regulatory and private litigation wave? The following are just a few takeaways to orient these efforts:

1. Have a complete legal, compliance and governance review structure in place. Do this out of the gate; do not wait for product approval, going public, or otherwise. The cleanup and litigation costs are always more than just laying the right foundation.
2. Train the Board, whether through a "directors' college," law firm education opportunities or free presentations. Do it early and often.
3. Enter foreign markets with great care. Even in the exploratory phase, have the right compliance structure.
4. Hire the right, experienced counsel at the first sign of trouble. Again, cost savings up front can be dwarfed by the cost of cleanup later.
5. Constantly review, update, and ensure compliance with stock plans, board resolutions, bylaws, and the charter. Train stock administrators, as this is often forgotten until going public.

These steps, implemented early in a life sciences company's history, can help minimise or mitigate risk.

Conclusion

As the financial meltdown recedes into history, the SEC is poised to adjust its focus from insider trading and financial fraud to financial accounting and reporting. Private plaintiffs and their counsel are similarly looking for opportunities as the financial meltdown claims have begun to dry up.

Life sciences companies are an attractive target because of their unique exposure to a broad range of regulatory regimes, the watershed moments in a company's lifecycle, and the resulting volatile revenue that is characteristic of the industry. To mitigate the risk of becoming a target, the management and board should take certain steps to educate themselves and lay the right foundation before any problems arise. It is always cheaper to ensure compliance up front than it is to deal with the cleanup and litigation costs later.

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