The SEC's enforcement programme on biotechnology's communications with the investment community

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Abstract

The proliferation of biotechnology start-up companies has led to increased scrutiny by the regulators of the securities markets. The author, a former head of a field office of the United States Securities and Exchange Commission, examines the growing cooperation among regulatory agencies in the U.S. and the basic structure of the disclosure and anti-fraud provisions of the U.S. securities laws. The author articulates the approaches that the SEC division of enforcement has taken to investigating and prosecuting violations of the securities laws by biotechnology companies and provides useful guidance for dealing with news that may impact the securities markets.

INTRODUCTION

The biotechnology industry, and medical instrument and pharmaceutical companies in particular, are in the unenviable position of serving at least two sets of constituents who expect and deserve a high level of respect and commitment. The public consumers of biotechnology products – patients – expect that firms will treat them as if the consumers' health concerns were their own. Scrupulous attention to medical safety and honest disclosure of medical risk are essential elements of biotech firms' DNA. No less scrupulous attention is required to financial safety. Honest disclosure of financial risk is the *sine qua non* of financial success for biotech firms, and it is no accident that when financial incentives erode fairness to the patient constituency, the financial constituency will ultimately punish the firm.

The investing public and the professional investment community are hungry for information about biotechnology firms, and the markets are particularly sensitive to product development and regulatory approval – arguably more so than to financial disclosures.[1] This environment presents tempting opportunities for management to satisfy investors' appetites, opportunities that come with potential pitfalls. It may seem like a good idea to stimulate investor interest and pick up a flagging stock price with announcements of regulatory and product development milestones. But such announcements are not one time events; they can live on and impose unintended disclosure obligations down the road when the news may not be as positive. The stakes can escalate in such circumstances, as spin overpowers facts.

Biotechnology firms are no different from most other public companies with respect to most US Securities and Exchange Commission (SEC) enforcement issues; false and misleading public statements regarding financial results and financial prospects may be the subject of enforcement action regardless of industry sector. The biotech field may

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differ from many others, however, in the degree to which the market reacts to news about the product development and regulatory approval. The subtleties of Food and Drug Administration (FDA) communications and processes and FDA concerns about the confidentiality of drug sponsor's filings can complicate any evaluation of biotech firms' public disclosures. The FDA and the SEC have improved their communications so that the securities regulators have more sophisticated understanding of FDA processes and terminology. This renewed commitment to cooperation between the agencies may portend renewed emphasis on drug development disclosures among SEC enforcement staff.

DISCLOSURE-BASED CHARGES

Overview of SEC disclosure regime

The SEC's disclosure regime

Companies with public securities trading in US markets are subject to the SEC's disclosure regime, which includes annual and quarterly public reports of financial and other information as well as event-driven updates. These filings must include the information specified in the rules, and, at least as to annual filings, are regularly reviewed by the staff of the Commission's division of corporation finance. Regulation FD[2] prohibits selective disclosure of information to market professionals, essentially requiring broad public dissemination of material information in order to minimise information imbalances in the market. As a corollary, insider trading law prohibits trading by insiders and others in possession of material non-public information.

In addition, SEC filings and other publicly disseminated statements must comply with the 'antifraud' provisions of the US securities laws, particularly as they apply to fraud in the offer and sale of securities (typically, but not always, associated with initial or follow on offerings of securities) and in connection with the purchase and sale of securities.[3]

The securities laws in the USA provide opportunities for both private citizens and the SEC to bring actions arising from alleged violations of certain of the antifraud provisions. Much of the law interpreting the antifraud provisions in pharmaceutical and biotechnology cases was developed in private, rather than SEC-initiated, cases. The growing importance of biotechnology and pharmaceuticals as in investment sector and the relatively complex technology and regulatory overlay has prompted renewed SEC attention to the area.

Enhanced cooperation between the SEC and the FDA may facilitate increased SEC enforcement scrutiny of firms' disclosures of drug and product development status and communications with the FDA. In February 2004, the SEC and the FDA announced an effort at enhanced cooperation and information sharing between the two agencies. In addition to identifying key points of contact for communication, the agreement reiterated the FDA's commitment to provide technical support to the SEC, which will aid the Commission's staff in correctly interpreting communications between the FDA and the applicants who seek its approval for drugs and products. In addition, dealing with the thorny issue of confidentiality of FDA filing information, the agencies' agreement underscores the FDA's commitment to providing the SEC staff with *non-public* information in aid of its enforcement activities.[4]

Misleading disclosure cases – Section 17(a) of the Securities Act and Section 10(b) of the Exchange Act

As a general rule, the antifraud provisions of the federal securities laws prohibit the use of manipulative or deceptive devices in the offer and sale, or in connection with the purchase and sale, of any security. The most common form of securities fraud is that based on the misrepresentation or omission of a material fact. Section 17(a) of the

Securities Act prohibits fraud in the offer or sale of a security. Specifically, Sections 17(a)(1) and (3) of the Securities Act make it unlawful to employ any device, scheme or artifice to defraud, or to engage in any transaction, practice or course of business that operates or would operate as a fraud or deceit upon the purchaser, respectively. Section 17(a)(2) of the Securities Act makes it unlawful 'to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.' Section 10(b) of the Exchange Act and Rule 10b-5 thereunder prohibit essentially the same conduct, if committed in connection with the purchase or sale of securities.

To prove violations of Section 17(a)(1) of the Securities Act and Section 10(b) of the Exchange Act and Rule 10b-5, the Commission must establish that the defendants acted with scienter, 'a mental state embracing intent to deceive, manipulate, or defraud.'[5] In most jurisdictions, scienter may be proved by a showing of recklessness.[6] Scienter is not required to establish violations of Sections 17(a)(2) or (3) of the Securities Act, which may be based on negligence.[7] Negligence consists of the failure to conform to the standard of care of a reasonably prudent person.[8] Only the SEC, and not the private bar, may bring suits under section 17(a).[9] Misrepresentations and omissions must be material in order to give rise to violations of the antifraud provisions. A statement or omission is material if 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]

Materiality of financial information

Materiality – significant alteration in the total mix

Materiality is a key issue in securities fraud cases. It is a sometimes an elusive quality; the formula is easy to recite, but it can be difficult to apply rigorously. Ostensibly, the materiality test is objective – what information would significantly alter the total mix of information in the mind of a 'reasonable investor'?

Materiality and financial reporting

The Financial Accounting Standards Board, a private body in the USA that promulgates financial accounting and reporting standards, has adopted the following articulation:

> The omission or misstatement of an item in a financial report is material if, in light of surrounding circumstances, the magnitude of the item is such that it is probable that the judgment of a reasonable person relying upon the report would have been changed or influenced by the inclusion or correction of the item.[11]

Materiality of financial information has been the subject of many actions under the federal securities laws, and the issues presented in the context of the pharmaceutical or biotech industry are often no different than in any other context. Thus, for example, in *SEC v Bristol Myers Squibb*, which Bristol Myers settled for US$150m, the Commission alleged that Bristol Myers inflated its financial results primarily by stuffing its distribution channels with excess inventory near the end of every quarter, making pharmaceutical sales to its wholesalers ahead of demand and thereby improperly recognising US$1.5bn in revenue; creating 'cookie jar reserves' to cover earnings shortfalls when products were returned, and understating contingent liabilities associated with customers' rights to return product that had been 'stuffed' into the distribution channel. These accounting practices were similar to accounting abuses that appeared in companies in various industries as they struggled to satisfy Wall Street earnings expectations.

The distortion of financial results that

attended these types of cases was of a magnitude that made it relatively easy to determine that the mis-statements were material. Although the accounting industry typically judges materiality under arbitrary numerical tests (for example, 5–10 per cent of a company's net income),[12] litmus tests of this type should be used extremely carefully.[13] SEC enforcement staff also look to the market's response to false statements or corrective disclosures for an indication of materiality. Materiality must be viewed in context, and can have a qualitative aspect as well as a quantitative aspect.[14]

Materiality and non-financial disclosure – product development and regulatory approval status

Difficult to assess materiality outside the accounting and financial results context

It can be more difficult to assess materiality outside the accounting and financial results context. Because biotechnology companies are heavily dependent on patient safety and regulatory approval of their products, those issues can be key disclosure points. Assessing their materiality requires particular care. Quantitative benchmarks such as statistical significance and FDA approval milestones are attractive because they have the appearance of acceptance and relative certainty. Several courts have held that side effect information, for example, is not material unless the incidence of the side effects is statistically significant.[15]

Even results that are not statistically significant may be material, however, given the markets' dramatic reaction to patient health and safety information and to information about each step of the approval process. Patient safety has become such a concern that companies appear willing to remove drugs from the market even in the absence of statistically significant results. For example, in February, 2005, shares of Elan Corp. fell from US$26.99 to $8.05 overnight when the company announced it was pulling Tysabri from the market because *two* patients had died from a brain infection after taking the drug. The market may have reacted to Elan's loss of the revenue stream from Tysabri, rather than to the fact that two patients died while taking it. Nonetheless, Elan's experience suggests that even statistically insignificant events – events that could be the result of nothing more than chance – may be material because of the way the market reacts to patient safety concerns.

Another area of significant concern to investors, but not necessarily possible to quantify, is disclosure of a drug sponsor's communications with the FDA. Even interim communications, short of absolute approval or disapproval, can be material. Obviously misrepresentation of a product's approval status is a material fact; without required approval the product cannot legally be marketed. A company that falsely represents a product as approved when it is not has almost inevitably misrepresented a material fact. In 2004, the SEC suspended trading in the shares of Vaso Active Pharmaceuticals because of questions regarding the accuracy of the company's claims to FDA approval of its products. Vaso Active ultimately filed a settled federal court injunctive action based on allegations that the company had falsely represented that the FDA had approved its products.[16]

The interpretation of regulatory communication short of approval, however, can present closer questions. For example, the SEC brought charges against a company and its executives who had received a communication from the FDA that the company's new drug application was 'not approvable' because the drug had not shown effectiveness used in isolation. The company, in making its public disclosures, did not indicate that it had received a 'not approvable' letter, but rather that it anticipated that further clinical testing would probably include use of the drug in combination with other drug therapies. The Commission determined that the company's press releases glossed over the strong negative implications of the FDA's 'not approvable' letter, a fact deemed material

to full understanding of the company's press releases.[17]

Very recently the SEC brought fraud charges against Biopure, alleging that the company that fraudulently put a positive spin on negative developments in its dealings with the FDA. According to the SEC complaint, the company failed to disclose that safety and data integrity concerns had caused the FDA to put the company's Investigative New Drug Application on hold, and falsely stated that the FDA was continuing its review of the company's Biologic License Application when in fact the FDA had issued a complete response letter. The complaint notes the market's reactions to the alleged false statements and to the subsequent disclosures of the FDA's actions.[18]

When to disclose – initial disclosure and the duty to update

When to disclose?

Disclosure cases in the biotechnology field, especially those relating to drug and product approval status, often prompt the question, would the company have been better off saying nothing at all? In general, an obligation to disclose a fact arises only if an SEC rule or regulation requires the disclosure, if insiders are trading in the company's stock, or if the information in the marketplace would become materially false and misleading if the facts were not disclosed. Excluding the first two categories – a specific regulatory mandate or insider trading – in order for omission to be actionable under the antifraud provisions, the company must have made some statements to the public that are misleading because the material facts were not disclosed.[19] In other words whether or not an obligation to disclose arises when material developments occur depends in large part on what has already been disclosed.

Some events are so clearly significant to the life of a company that the obligation to disclose them requires little or no analysis. For example, a merger is an event that substantially alters the life of a company; when a potential merger moves from exploration and negotiation to an agreement in principle, it must be disclosed.[20] Events in the life of a biotechnology company, however, will run the gamut from a fundamental event such as a merger to the minutiae of correspondence from the FDA or the results of a particular experiment or clinical trial. The issue of whether, or when, facts along the spectrum must be disclosed depends to a large extent on what the company has already stated publicly. In one sense, the more you have said, the more you may have to say.

Once a biotech company decides whether to fulfil a regulatory requirement or to stimulate interest in the company, to introduce information about product development approval into the market, it is likely that subsequent events related to that subject, for good or for ill, will have to be disclosed, and disclosed promptly. For example, in *In the matter of Zila, Inc., and Joseph Hines*,[21] the FDA advised Zila that it would give priority review to its new drug application (NDA) and consider it on a fixed date. Zila issued a press release giving the date of the FDA's review, and predicted that the FDA committee would recommend approval of the drug. There was no regulatory requirement that Zila issue that release. Having done so, however, it was in a difficult position when the FDA provided Zila with a draft of its report on the NDA indicating that it was 'incomplete, seriously flawed, of questionable quality, and [that] definitive conclusions regarding the efficacy of [the drug] cannot be drawn.'

The company made no disclosure relating to the FDA's draft report, and its public relations officer, ignorant of the draft report, continued to make positive statements to the press in the days leading up to the FDA review. The FDA review meeting was public and by the time it ended and the committee had rejected the NDA, Zila's stock had lost 45 per cent of its value. The SEC determined that the company's failure to disclose the

unfavourable draft report was materially misleading in the context of its earlier optimistic statements about FDA approval.[22]

The Commission charged ICN Pharmaceuticals with fraud under similar circumstances. ICN filed an NDA for a drug to treat hepatitis C. The company announced that the FDA was giving the application priority review. Shortly thereafter, the FDA advised ICN in writing that NDA was not approvable for the drug as a stand-alone therapy. The company, however, issued a press release advising only that it intended to amend its application to include a request for approval in combination with other drug therapies. The Commission alleged that the omission of the fact that the FDA had advised that the application was 'not approvable' constituted securities fraud, as the company's optimistic press release was misleading without disclosure of the FDA's position.[23]

The importance of making full disclosures as new events cast doubt on prior disclosures

Zila and *ICN* demonstrate the importance of making full disclosures as new events cast doubt on prior disclosures. Firms do not need to set out to deceive to find themselves with a tangled web of facts that will become misleading if not updated. *Zila* also illustrates the danger of disclosing anything more than the simple facts as they evolve. Arguably if Zila had done nothing more than disclose that the FDA was giving priority consideration to the NDA and reviewing it on a certain date, it would not have been obliged to disclose the negative draft report. Instead, management decided to use the positive development as an opportunity to gain favourable coverage. Having injected the issue into the public domain, however, it could not legally suppress the negative news that followed.

NON-FRAUD CHARGES

The SEC's action against British Biotech, plc, is an example of how the SEC may address misleading disclosures without bringing charges under the anti-fraud provisions. British Biotech publicly announced the filing of its initial new drug application for an anti-cancer medicine, and made periodic press releases and SEC filings regarding the positive results of clinical trials. It failed to disclose, however, that its trials were designed to test the presence of cancer antigens as a surrogate marker for tumour progression, and that the FDA had specifically advised that the surrogate markers could not be used as evidence of efficacy in obtaining FDA approval. The SEC instituted a settled administrative cease and desist proceeding against British Biotech and several of its executives based on the company's omission of the FDA's position on its use of surrogate markers in its clinical trials, without which its optimistic press releases were misleading.[24] The Commission based its action on section 13(a) of the Securities Exchange Act, 15 USC §78m(a), a reporting provision that may be violated without fraudulent conduct.

Under appropriate circumstances the Commission can also take more drastic action. For example, if it determines it to be in the public interest, the Commission has the authority to temporarily suspend trading of a company's shares, and may even do so without notice to the company.[25] At least two biotechnology companies, Vaso Active Pharmaceuticals, noted above, and BioCurex, have been the subject of trading suspensions in recent years, both suspensions attributable to serious doubts about the accuracy of disclosures regarding FDA approval of their products and the results of studies regarding those products.[26] Although trading suspensions are ordinarily of short duration, they can have a devastating impact on the subject companies, and the Commission exercises its discretion in this area carefully.

INSIDER TRADING

The biotechnology field is not unique in its susceptibility to insider trading, but few insider trading cases have achieved as much publicity as the case of Imclone CEO Sam Waksal. The case might have remained obscure if not for Waksal's

alleged tip to Martha Stewart, a well-known television and publishing personality and, notably, former stockbroker.[27]

Insider trading cases may be based on two theories. The classic theory applies to corporate insiders – executives, employees, directors and others who may become insiders temporarily by virtue of services they perform for the company. Insiders, possessed of material non-public information about the company that employs them, commit fraud when they trade in their company's stock on the basis of such information. The short form description of this theory is 'disclose or abstain' – the insider must disclose the non-public information, or refrain from trading. The second theory, referred to as the misappropriation theory, posits that those who obtain material non-public information about a company through violation of a duty of trust and confidence owed to the source of the information commit fraud when they trade on the basis of that information.

The SEC has prosecuted numerous actions against insiders and others for trading in the shares of biotechnology companies on the basis of material non-public information, many of them brought against directors and officers of biotech companies who have traded in advance of positive or (with unfortunate frequency) negative news.[28]

Biotechnology firms are subject to other, more insidious, forms of insider trading resulting from the frequent participation of academic and medical researchers and consultants in research and development efforts. In August 2005 news sources reported allegations that hedge fund and other professional investors paid medical researchers to provide confidential information about drug development projects on which they are working.[29] The *Seattle Times* had reported finding at least 26 cases in which medical researchers, some paid as much as US$500 per hour, had leaked confidential and critical details of their research to investment firms, enabling them to profit from stock price moves after drug trial results became public.[30] Such allegations, if true, could fit into either the 'classical' or 'misappropriation' theory of insider trading, depending on the status of the researcher as a corporate insider, and whether the researcher was otherwise subject to a duty of trust and confidence with respect to the information.

REGULATION FD

Regulation FD

Another important limitation on public companies' communications of material information to the public is found in Regulation FD.[31] The biotech industry is not uniquely subject to Regulation FD, but the often intense coverage of biotech stocks and the sensitivity of biotech share prices to news make this an important issue. Moreover, one of the seminal cases under Regulation FD involved a biotech company, Schering-Plough.[32]

Regulation FD provides, in substance, that public companies may not selectively disclose material non-public information to investment professionals or holders of the company's shares where it is foreseeable that the holder will purchase or sell shares on the basis of the information. If the disclosure is intentional, it must be accompanied by a simultaneous public disclosure of the same information; if inadvertent, public disclosure must follow 'promptly'.[33] The SEC adopted Regulation FD out of a concern that issuers were 'disclosing important non-public information, such as advance warnings of earnings results, to securities analysts or selected institutional investors, or both, before making full disclosure of the same information to the general public.'[34]

In *Schering-Plough*, the Commission found that company representatives had private meetings with the advisers to four major mutual funds in which they put a darker gloss on more equivocal statements that had been made publicly. The company had earlier disclosed uncertainties over patent litigation and the possibility of ensuing difficulties that could be mitigated if the company

prevailed in the litigation. Subsequent internal forecasts indicated that the company's results were likely to fall well short of Wall Street expectations. Armed with these internal forecasts, Schering-Plough's CEO Richard Kogan and the company's investor relations manager met with analysts and portfolio managers of four large institutional investors, and painted a darker picture for the company. Immediately thereafter the institutional investors downgraded their recommendations on Schering-Plough and sold substantial numbers of shares, dragging the price of the stock down sharply.

Schering-Plough agreed to a cease and desist order, and to a settled district court action in which, although neither admitting nor denying the Commission's allegations, it paid a civil penalty of US$1m. In its Order instituting the cease and desist proceedings, the Commission opined that although Kogan may not have intended to suggest that the institutional investors sell their shares, his:

> . . . statements, demeanor and general expressions of concern for Schering's prospects during private meetings amounted to selective disclosure and prompted a significant sell-off in Schering stock. These communications to selective groups of industry professionals are precisely the kind of selective disclosures that Regulation FD was designed to prevent. . . .[T]he investing public was placed at a disadvantage relative to [the] institutional investors privy to the disclosures.[35]

Biotechnology companies should be vigilant about selective disclosure of emerging facts to industry professionals

The Commission has applied its traditional analysis of what constitutes material non-public information for Regulation FD purposes. For example, in *In the Matter of Flowserve Corporation et al.,*[36] the Commission based its charges in a settled cease and desist proceeding on the company's selective disclosure to four brokerage firms, midway through a fiscal quarter that the company's earnings guidance was unchanged. The Commission found that the information was material; that is, a disclosure that the company was on track to meet its earlier earnings guidance was a material fact for purposes of Regulation FD.

The difficulty of assessing materiality is evident from the facts that the courts do not always agree with the SEC's view. In the first litigated case under Regulation FD, *SEC v Siebel Systems, Inc.,* the court found that the SEC had been overly zealous in its characterisation of the company's private statements, relating to the timing and sources of projected revenues, as materially different from its earlier public statements.[37]

As these cases demonstrate, materiality is a fact-intensive concept over which regulators, companies and courts may be expected to differ. When it comes to source and timing of revenues, biotechnology companies are arguably little different in this regard from other public issuers. But in light of the market's sensitivity to product approval and development news, biotechnology companies should be particularly vigilant about selective disclosure of emerging facts to industry professionals.

CONCLUSION

The SEC's approach to enforcement of the securities laws in the biotechnology field is in many respects no different from its approach in other areas. The market's sensitivity to product development and regulatory approval events in the field, however, and the arcane and highly specialised language that characterise it may attract heightened scrutiny from SEC enforcement staff, particularly with the renewed commitment to cooperation between the FDA and the SEC. Although biotechnology companies may wish for media attention, they should be careful how they seek it; the glare of the media spotlight can be unforgiving of flaws.

References and notes

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19. See, eg, *Schlifke v Seafirst Corp.,* 866 F.2d 935, 944 (7th Cir. 1989): '10b-5 only proscribes omissions that render affirmative statements misleading; thus, incomplete disclosures, or 'half-truths,' implicate a duty to disclose whatever additional information is necessary to rectify the misleading statements.'
20. See *Basic, Inc. v Levinson,* 485 US 224 (1988)
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23. See *In the Matter of David C. Watt,* Securities Exchange Act Release No. 46899, Admin. Proc. File No. 3–10951 (25th November, 2002). The SEC sued David Watt, the company's general counsel, in a settled administrative proceeding, and sued the company and its CEO in federal district court. The district court case was ultimately settled with the company paying a civil penalty of US$1m and the CEO paying US$500,000. See *SEC Lit. Release No. 17861*, 25th November, 2002.
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