Neil Aronson
is the Chairman of the Business & Finance Department of Mintz Levin Cohn Ferris Glovsky and Popeo, PC, which has its headquarters in Boston, Massachusetts. Neil is a member of the American Bar Association Business Section on Corporate Governance and a member of the National Association of Corporate Directors.

Life after Enron and ImClone: Special concerns for the biotechnology company

Neil H. Aronson
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Abstract
The recent enactment of federal legislation and the ongoing adoption of comprehensive regulations by the Securities and Exchange Commission (SEC) and stock exchanges create a new era for corporate governance. For public biotechnology companies, these new laws and regulations create specific concerns and significant criminal and civil sanctions. Private companies considering a public offering should also consider the implications of these statutes and regulations. In the future, investors are expected to reward both public and private companies that enact strong corporate governance practices.

Biotechnology companies will need to carefully review and modify document retention, disclosure, compensation and stock trading policies to comply with the following new requirements:

- Document retention policies will need to address complex recordkeeping requirements imposed both by the Sarbanes–Oxley Act of 2002 (SOA) as well as a myriad of regulations imposed by the Food and Drug Administration and the Environmental Protection Agency.

- Severe penalties for improper certification by senior officers of SEC reports places added pressure on public biotechnology companies. Officers will need to establish systems to regularly review the accuracy of disclosures involving all intellectual property, regulatory and healthcare reimbursement disclosures in these periodic reports

- Compensation plans for officers and directors must prevent future loans (and modifications to existing loans) and address corporate governance concerns now raised by institutional investors and the media.

- New reporting requirements for insider sales require that corporations develop systems to accurately track insider sales and to establish systems to prevent insiders and their family members from trading during critical periods preceding Food and Drug Administration and other regulatory actions.

***Keywords:** corporate governance, Sarbanes–Oxley Act of 2002, document retention policies, insider trading, compensation*

INTRODUCTION

Since the enactment of the Securities Act of 1933 following the Great Depression, changes to securities laws, and regulations promulgated by the Securities and Exchange Commission (SEC), have focused on improving disclosure and preventing insider trading and fraudulent activities. However, sound corporate governance practices have been left primarily to the discretion of the individual corporation and, in some instances, state corporate law. Prior to the corporate scandals that surfaced in late 2001, stock exchange listing requirements included only limited corporate governance reforms.

In retrospect, the dot.com meltdown starting in 2000 was inevitable and investors, while certainly disappointed in

Neil H. Aronson
Chairman, Mintz Levin,
Business and Finance Department,
One Financial Center,
Boston, MA 0211, USA

Tel: +1 617 542 6000
Fax: +1 617 617 542 2241
E-mail: nharonson@mintz.com

Major scandals have led to reform at all levels

Public companies and those with business before the FDA face new stiff criminal penalties for unlawful destruction of documents

Document retention policies must be content neutral

poor results from these new ventures, were not surprised. However, when seemingly more 'stable' major corporations such as Enron, WorldCom, Adelphia and Tyco were beset by claims of improper accounting, questionable business transactions between corporation seemingly designed for the sole purpose of inflating revenues, misuse of corporate funds and destruction of documents, major stress fractures in the US capital markets appeared. Document destruction by one accounting firm and highly questionable practices by some well-known research analysts helped to add to this frenzy of distrust among investors in the US stock markets. Adding to this mixture were media stories of highly questionable stock sales by several major executives at companies such as ImClone and questionable practices of a number of investment banks in connection with allocating initial public offering (IPO) shares to select chief executive officers (CEOs) and other preferred clients. And where was the SEC? During the great bull market of the 1990s, the very limited resources of the SEC were focused on dealing with an epidemic of internet fraud while tackling complex revenue recognition and accounting issues.

Legislation introduced in any election year is always politicised and Congress's desire to try to reform the US capital markets in an important election year resulted in the swift passage in July of last year of the Sarbanes–Oxley Act of 2002 (SOA). President Bush immediately signed the SOA into law. At about the same time, actions by the New York Stock Exchange (NYSE), NASDAQ, the SEC and others added additional rules and regulations applicable to public companies. Under SOA, the SEC is required to adopt even more rules and a number of new rules and regulations have recently been promulgated with more to follow under current SEC plans. For biotechnology companies, the SOA and resulting new regulations create special areas of concern. And private companies may be surprised to learn that some of the provisions of the SOA also apply to them.

DOCUMENT RETENTION POLICIES

In the wake of the obstruction of justice verdict against Arthur Andersen, every company should now undertake an enterprise risk evaluation to review its business practices and to minimise business and legal risks. Under the SOA, any company or individual who alters or destroys a record or document with the intent to impair the object's integrity or availability for use in an official proceeding is subject to fine or may be imprisoned for up to 20 years. Although passed with the Andersen case in mind, the law applies to an attempt to impede the investigation by any 'official proceeding' and could be invoked by the Food and Drug Administration (FDA), Environmental Protection Agency (EPA) or others. Among the business practices that are the focus of regulators and trial lawyers are corporate practices and policies on document retention. Prudent companies must take a fresh look at their document management policies to make sure they are reasonable, comply with all laws and regulations, and are implemented and followed throughout their organisations.

There is no cookie-cutter approach to creating an effective document retention policy. Every biotechnology company should ask itself the following questions about its document retention policy.

Does the policy meet certain legitimate business needs?

Arthur Andersen found itself in trouble in part because of the language in its document retention policy, and testimony of certain of its employees, that this policy encouraged the destruction of documents that could be used against it in litigation or otherwise put the accounting firm in a bad light. Andersen was also convicted in part because it allowed documents to be destroyed when it was reasonable to assume that the documents would be

Document retention policies must have an effective 'stop' function to end document destruction

relevant to ongoing investigations or litigation. A proper document retention policy is neutral in determining which types of documents to destroy, creates an effective 'stop' function to prevent destruction of relevant documents when an investigation or litigation is pending or likely to ensue, establishes reasonable time periods for retention of documents, and, as discussed below, takes into consideration special state and federal law requirements.

Document retention policies must comply with FDA requirements

Does the policy meet specific legal requirements?

State and federal laws impose certain specific requirements regarding the retention of relevant documents. These include federal laws relating to the retention of documents concerning marketing approvals for drugs and compliance with good manufacturing and good laboratory practice data retention requirements, complaints involving the safety of medical devices, personnel records and new provisions of the SOA that relate to the retention of financial accounting records for public companies. An appropriate document retention policy will incorporate all relevant federal and state recordkeeping requirements.

Officer certification requirements apply to more than just financial statements

Is the policy implemented effectively?

Simply having a document retention policy is not enough. Most companies' problems stem not from the policy adopted but from failing to implement and monitor compliance with these policies on a consistent basis. All employees should be reminded of the policy on a regular basis, and businesses should periodically audit their compliance with the policy. A reasonable programme of regular document retention and destruction without regard to specific content may help to rebut an otherwise adverse inference in litigation arising from the destruction of relevant documents.

Does the policy contain an effective 'stop' function?

Once litigation or an investigation is anticipated or reasonably should be anticipated, a company must be able to suspend the destruction of documents, even if called for as part of a document management policy. Failure to cease document destruction when necessary can result in criminal charges and in a variety of severe sanctions in civil matters, even when there is no evidence of bad faith or intentional misconduct by the destroying party.

OFFICER CERTIFICATIONS AND ADDITIONAL DISCLOSURES REQUIRED IN SEC REPORTS

Under the SOA and the SEC rules adopted pursuant to the SOA, the chief executive and chief financial officers (CEO and CFO) of a public company are required to certify periodic reports, including quarterly and annual reports. The SOA requires certification of the *entire* report, not just the financial statements. Specifically, the officer is required to certify that, to his or her knowledge, the report 'does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading.'[1] The principal financial and executive officers are responsible for establishing and maintaining 'disclosure controls and procedures' that will ensure that material information is made known to them, and are also responsible for evaluating the effectiveness of these procedures on a quarterly basis. An officer making a knowingly false certification is subject to severe criminal penalties as well as civil liability under federal securities laws.

The phrase 'disclosure controls and procedures' is a new concept under the SEC's disclosure rules, and is defined as:

Controls and other procedures of an

issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the [Exchange] Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms . . . [and] is accumulated and communicated to the issuer's management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.[2]

The new certification requirements make clear that (i) all issuers must now take greater care in the preparation and implementation of their controls and procedures, and (ii) each issuer's CFO and CEO must personally ensure, prior to the submission of each annual and quarterly report, that the disclosure controls and procedures, as designed, are adequate. For many companies, this results in unprecedented personal involvement by the CEO and CFO in the process of preparation of SEC disclosure documents. At the very least, any officer required to make such certification will want to have written documentation supporting his or her certification in the event the disclosure or non-disclosure is challenged.

FDA and reimbursement status must also be certified

Biotechnology companies need to place special emphasis on the certification as it relates to intellectual property, FDA and other regulatory matters. Reporting companies are required to describe several aspects of their intellectual property portfolios in their annual reports to the SEC and may be required to include such information in their quarterly reports where there has been a material change in their intellectual property position. Detailed disclosure regarding a company's patents, trade marks, copyrights and trade secrets is required in the *Business* section of an annual report.[3] Other areas of an annual report in which intellectual property disclosure appears are the *Risk Factors* section, if there are important elements of risk relating to the use and protection of the company's intellectual property assets, and the *Legal Matters* section, if the company is engaged in any material litigation with respect to its intellectual property portfolio. In addition, each of these areas may need to be updated in a company's quarterly reports to the SEC if material developments or changes have occurred in the required disclosure since the filing of the annual report. It is customary for a company to report in both its quarterly and annual reports (a) that the company protects its intellectual property rights, (b) the number of its patents, trade marks and/or copyrights (and/or the existence of company trade secrets) and the importance of all intellectual property assets to the company's business, and (c) any third party intellectual property barriers to the company's ability to conduct its business.

Officer certification requirements also apply to intellectual property matters

Similar discussion of the status of FDA approvals of products, compliance with FDA regulatory requirements, the status of the reimbursability to consumers of prescription costs by governmental and private insurers, and other regulatory investigations and actions are also required disclosure in a company's quarterly and annual reports.[4] Finally, biotechnology companies also need to disclose material amounts spent on customer-sponsored research and development activities, as well as the risk of loss or rights to renegotiation of material private and government contracts.[5]

Companies need to establish appropriate review procedures

As a result of the new certification requirements of Sections 302 and 906 of the Act, each company filing reports with the SEC, in order for its CEO and CFO to be able to make the required certifications, must implement procedures to ensure that all necessary disclosure regarding its intellectual property assets, FDA and other regulatory matters is gathered, processed and updated in a timely manner. Further, these procedures have to be adequate so that the certifying officers can satisfy themselves that all of the disclosure regarding these matters is

Directors selected by a corporate partner may not qualify as 'independent'

complete and accurate.[6] Following the SEC's suggestion, many public companies are establishing disclosure committees comprising the controller, legal counsel, the principal risk management officer and representatives of the company's different business units who report to the CEO and CFO. Officers should also regularly meet with internal and external legal and other advisors to ensure proper disclosure regarding these matters in SEC reports.

The SEC has also issued new rules that require companies (other than small business issuers) to provide an overview of their aggregate contractual obligations and an overview of their contingent liabilities and commitments. The SEC is concerned that companies have not adequately disclosed short- and long-term liquidity and capital resource requirements. These regulations require aggregation of these contractual obligations by the type of obligation, quantified by the dates when payments are due. Companies are also required to disclose the expected amount (or range of amounts) of contingent liabilities or commitments and when these contingent liabilities will expire.[7] For the biotechnology venture, special consideration should be paid to disclosure requirements for collaborative research and development agreements where the financial sponsor may retain certain financial or intellectual property rights or retain future royalty or other financial rights following the commercial introduction of a new drug.

New rules require additional disclosure about funding under collaborative research and development agreements

Audit committees must include a 'financial expert'

Composition of Board of Directors and Board Committees

Both the NYSE and NASDAQ have proposed rules requiring the Board of Directors of a public company to be composed of a majority of 'independent' directors by 2004.[8] In the past, independence requirements related solely to the audit committee. As a result, biotechnology companies will need to determine the extent to which their directors will be able to meet the independence requirement. In particular, former employees, consultants and employees of joint venture and collaborative partners serving as directors may not meet the independence test.

Currently, the NYSE and NASDAQ employ different standards in determining whether an individual qualifies as an 'independent' director. For NYSE-listed companies, a director is independent if, among other things, he or she 'has no material relationship' to the company. The NYSE guidelines also provide that a director is independent only if the company has not employed him or her during the past five years. Also, a director is not deemed to be 'independent' if he or she is, or in the past five years has been, part of an interlocking directorate in which an executive officer of the listed company has served on the compensation committee of another company that concurrently employs the director. NASDAQ's requirements are slightly less rigid, requiring that a director may not have received more than US$60,000 in non-director fees from the company and may not have been employed by the company during the prior three years, among other things.[9]

Even more stringent rules apply to the audit committee. Under the SOA, all members of the audit committee must be 'independent'. Many companies will also now have to add to the audit committee a board member who meets the SEC's requirements for a 'financial expert'. The SOA requires that members of a public company's audit committee will be considered independent only if the members of the audit committee receive solely directors' fees as compensation for their services and are not otherwise considered an affiliate of the company. Thus, any individual receiving *any* consulting fees or other non-director-based remuneration from the company, even though qualifying as independent for determining eligibility to serve on the board of directors, is precluded from serving on the audit committee. Both the NYSE and NASDAQ have proposed tightened independence standards in addition to those required by SOA. For example, a venture capitalist or employee of a corporate partner that owns 20 per cent or more of the company's stock is also precluded from serving on the audit committee in most circumstances. The SEC has proposed a limit of 10 per cent stock ownership, and, as of this date, the difference in opinion between the SEC and the exchanges has not been resolved.

Financial restatements could result in disgorgement of officer bonuses and other compensation

Approval by stockholders of equity plans

Proposed NYSE and NASDAQ standards will require that all stock option plans receive stockholder approval. Under these new regulations, increasing the number of shares under an existing plan, and any material modification to an equity plan (including repricing of existing options), will require stockholder approval. Excluded from this approval requirement are the conversion of equity plans acquired in a merger or acquisition, so-called inducement plans for new employees, and certain tax-qualified non-discriminatory employee benefit plans, including 401(a) and employee stock purchase plans meeting the requirements of Section 423 of the Internal Revenue Code.

Obtaining stockholder approval of option and other compensation plans will be more difficult

Obtaining stockholder approval of these plans will also now be more difficult. Previously, brokerage firms were allowed to vote customers' proxies on proposals relating to certain equity and compensation plans, even when the beneficial owner of the shares had not provided voting instructions. The new NYSE proposals forbid brokerage firms from voting customers' shares on stock plan proposals unless the brokerage firm has received instructions from the beneficial owner of the shares. While NASDAQ has not adopted this rule, the NYSE has indicated that its rules apply to any brokerage firm that is an NYSE member. As a result, biotechnology companies, which rely heavily on the use of stock options to recruit and retain research and development personnel, will need to carefully address the need for additional shares in any proxy materials and issue these materials well in advance of any stockholder meeting to ensure that a majority of the holders of the company's securities agree to any increase in the company's stock option pool.

Impact on officer compensation

The SOA holds CEOs and CFOs directly and personally accountable for their company's non-compliance with SEC financial reporting requirements in certain situations. If the company is required to restate its financial statements as a result of misconduct that causes material non-compliance with any financial reporting requirements under the securities laws, Section 304 of the SOA provides that the CEO and CFO must reimburse the company for:

- any bonus or other incentive-based or equity-based compensation received by the individual during the 12 months following the first public issuance or filing with the SEC of the financial reporting document, and

- any profits realised from the sale of securities of the issuer by such individual during the same 12-month period.

The definition of what constitutes misconduct remains to be answered. Under the SOA, it appears that the misconduct need not be directly tied to the CEO or CFO but that the provisions may apply when a subordinate engages in misconduct unknown by the CEO or CFO. Also, the SOA implies that multiple 12-month periods will be implicated when a restatement covers several prior years and SEC filings.

New loans (and modifying existing loans) are prohibited

Concerned by the excesses at Tyco and Adelphia, Section 402 of the SOA also prohibits personal loans to executive officers and directors. These include any loans made after 30th July, 2002, as well as any modifications to loans existing on that date, such as extensions or reductions

Companies considering going public should not grant loans to officers

in interest payable under the loan. Private companies considering a public offering should note that the SEC has taken the position that it will retroactively apply the prohibition to private companies as well, even if not public at the time a post-30th July, 2002, loan was made, but which subsequently effect a public offering. This new law will hit biotechnology companies particularly hard. Many biotechnology companies, located in areas where residential housing costs are quite high, in addition to providing relocation expenses, have often provided low-cost mortgages or other favourable loans to assist a transferred employee in purchasing a new home. As a result, companies may need to increase compensation to these relocated employees for the additional costs incurred in obtaining mortgages through traditional lenders. Similarly, company loans to allow officers and directors to purchase the company's stock or exercise stock options are also now prohibited, making it more difficult for public companies and those considering going public to help finance employee equity purchases.

Officers and directors cannot borrow money from the company to exercise options

Trading during blackout periods and new trading disclosure requirements

Companies will now need to monitor insider stock sales during blackout periods more carefully. Many public biotechnology companies often impose blackout periods for at least senior officers during the period preceding the announcement by the FDA or an advisory panel on approval of a new drug or immediately prior to a major news announcement, such as a new collaborative arrangement or news relating to patent matters. Section 306(a) of the SOA prohibits any director or executive officer of an issuer from, directly or indirectly, purchasing, selling or otherwise acquiring or transferring any equity security of the issuer during a pension plan blackout period that prevents plan participants and beneficiaries from engaging in transactions involving the company's equity securities held in their plan accounts. These prohibitions apply only if the securities acquired or disposed of by the director or executive officer were acquired in connection with his or her service or employment as a director or executive officer. Section 306(a) also requires an issuer to notify its directors and executive officers, as well as the SEC, of an impending blackout period on a timely basis. The new regulation will exempt from the statutory trading prohibition several categories of transactions that occur automatically, are made pursuant to an advance election, such as under a 10b5-(1) trading plan, or are otherwise outside the control of the director or executive officer.

New blackout rules may make it more difficult for officers and directors to sell stock

The Section 306(a) trading prohibition is triggered only if a pension plan blackout period lasts more than three consecutive business days and temporarily suspends the ability of at least 50 per cent of the participants or beneficiaries under all individual account plans maintained by the issuer to purchase, sell or otherwise acquire or transfer an interest in issuer equity securities held in an account plan. In the case of a foreign private issuer, the Section 306(a) trading prohibition is triggered only if the 50 per cent test is satisfied and the number of US plan participants subject to the temporary trading suspension is either (1) greater than 15 per cent of the issuer's worldwide workforce, or (2) greater than 50,000 in number.

A violation of the Section 306(a) trading prohibition by a director or executive officer is a violation of the Exchange Act, subject to possible SEC enforcement action. In addition, Section 306(a) provides that an issuer, or a security holder on its behalf, may bring an action to recover the profits realised by a director or executive officer from a prohibited transaction during a blackout period. The SEC has stated that the amount recoverable in a private action is generally the difference between the amount paid or received for the equity security on the date of the transaction during the blackout period and the amount that would have been paid or received for the equity security if the transaction had taken place outside the blackout period.

Under new SEC rules, changes to SEC reports disclosing insider purchases and sales now require accelerated disclosure of such trades within two business days of the trade. As a result, companies should consider the advisability of instituting securities trading mandatory pre-clearance procedures, if such procedures are not already in place. A pre-clearance procedure will typically provide that directors and executive officers of the company and any other person designated by the company as being subject to the company's pre-clearance procedures, together with their immediate family members, may not engage in any purchase or sale transaction involving the company's securities without first obtaining pre-clearance of the transaction from the company's compliance officer. Companies may also want to consider the use of a 'captive' broker who understands the company's policies to help ensure compliance with pre-clearance procedures and can help to prevent deliberate or inadvertent violations of federal securities laws. One need only look at the harm caused to ImClone by Samuel Waksal's insider trading activities to understand the need for absolute compliance.

Establish pre-sale clearance procedures to minimise the risk of insider trading

To ensure compliance, consider using 'captive' brokers and apply insider trading rules to family members

CONCLUSION

Public companies are now subject to significantly greater scrutiny by both the SEC and the exchanges listing their securities. As a result of Enron and other scandals, the SOA now imposes very harsh criminal and civil penalties for violation of the SOA and potential delisting if a company fails to abide by its stock exchange's listing requirements. Biotechnology companies that are already public, and those private companies considering going public, will need to carefully monitor existing and proposed laws and regulations by the SEC and the stock exchanges.

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References and notes

1. For more information about these rules generally, please see our Client Advisory entitled 'Update on the Sarbanes-Oxley Act (Fourth in a Series): SEC Finalizes Certification Rules for Quarterly and Annual Reports' (URL: http://www.mintz.com/newspubs/Bus-Fin&Sec/SECAdvisory91202.pdf).
2. New Exchange Act Rules 13a–14(c) and 15d–14(c).
3. This assumes that at least one intellectual property right is an 'important' asset to the company. See Item 101(c)(x) of Regulation S-K.
4. See Item 101(c)(xii) of Regulation S-K.
5. See Item 101(c)(ix) and (xi) of Regulation S-K.
6. Moreover, having in place well-documented procedures and policies with respect to the status and handling of intellectual property and trade secret information serves the additional purpose of bolstering protection of the company's intellectual property rights against third parties, especially when the company seeks to enforce its intellectual property and trade secret rights under contract or common law, and is required to demonstrate that it has taken all necessary and appropriate steps to a Court or an arbitrator.
7. See SEC Release No. 33-8182, 'Disclosure in Management's Discussion and Analysis About Off-Balance Sheet Arrangements, Contractual Obligations and Contingent Liabilities and Commitments,' as directed by new Section 13(j) of the Securities Exchange Act of 1934, added by Section 401(a) of the SOA.
8. Accordingly, many private companies considering an initial public offering may want to consider recruiting 'independent' directors in advance of any public offering.
9. The NYSE's proposed standards may be found at URL: http://www.nyse.com/pdfs/corp_gov_pro_b.pdp. The NASDAQ's proposed listing standards may be found at URL: http://www.nasdaq.com/about/ProposedRuleChange.stm#Recent.