

Nixon Peabody

Private Equity Newsletter

Editor's note

We are pleased to introduce the inaugural issue of the Nixon Peabody *Private Equity Newsletter*. We will provide a one-stop shop of cutting-edge private equity coverage that addresses a variety of private equity matters. Each issue will start with articles from our three practice groups that comprise the Private Equity Team at Nixon Peabody: Leveraged Buyouts, Investment Funds, and Venture Capital and Emerging Companies. In addition, each issue will feature an industry focus which, in our view, represents a subject matter in an industry that private equity firms are currently examining. Finally not to be too formulaic in our approach, we will periodically bring you special features that we feel our readers will view as timely and interesting.

In this issue

Today we bring you articles on recent actions against club deal participants (p.1), key differences between the limited partnership laws of Delaware and the Cayman Islands (p.3), and VC directors' fiduciary obligations to boards of venture backed companies (p.5). Finally, our "industry focus" looks at the need for heightened regulatory due diligence when buying or investing in life science companies (p.8). Our feature article offers some suggestions for hedge funds investing in the debt of distressed companies (p.10).



NIXON PEABODY LLP
ATTORNEYS AT LAW

Leveraged Buyouts

Club deals and DOJ investigation considerations for private equity investors

The DOJ investigation

In 2006, the “Club Deal” (a transaction in which a consortium of private investment funds collaborates to offer a joint bid for a target company) became a staple of the leveraged buyout universe. With the recent explosion of mega-buyouts and the rise of clubs, many large-cap public companies are no longer viewed as “untouchable” by private investment funds. Recent buyout speculation has centered on companies with household names, such as Home Depot, Dell, and Sprint-Nextel. With the ever-expanding size of private equity funds, the migration of hedge funds and their vast pools of capital into the leveraged buyout space, and the increasing collaboration between private equity funds and hedge funds, the size of buyouts has continued its upward trajectory. Industry insiders predict that a \$100-billion buyout is now a possibility. However, the proliferation of club deals is not without controversy. In the last few months, questions have arisen challenging the validity of the bidding techniques used by private equity funds and other club participants during the auction process.

It has been reported that, in October 2006, the U.S. Department of Justice (“DOJ”) antitrust division sent informal letters to Kohlberg Kravis Roberts & Company, Silver Lake Partners, the Carlyle Group, Clayton Dubilier & Rice, and Merrill Lynch & Co., requesting information about their business practices and participation in recent high-profile auctions. In these letters, the DOJ expressed heightened concerns that investment funds may be “conspiring” or “colluding” as part of a club to artificially reduce the purchase prices of the companies that are the targets of buyouts. These charges appear to be focused on two actual or perceived industry practices: first, private equity firms “sharing the market” by declining to participate in certain auctions, with the understanding that other private equity firms will reciprocate by declining to participate in other

auctions (thereby reducing the number of bidders in each auction), and, correspondingly, depressing the prices to be realized by the seller; second, private equity firms teaming up with one another to avoid protracted and costly bidding wars, once again depressing the prices to be realized by the selling stockholders.

Given the preliminary nature of the DOJ inquiries, it is much too early to predict with any sense of certainty the possible outcomes of the investigation. However, there is considerable speculation within the private equity community that the DOJ’s inquiry is simply much ado about nothing. The viewpoint of the U.K. Financial Services Authority (“FSA”), for example, is generally considered at odds with that of the DOJ. A November 6, 2006, FSA “discussion paper” regarding the current state of the private equity industry made no mention of club deals being anti-competitive. The FSA reportedly arrived at its position based on the fact that target company stockholders are not obligated to accept bids submitted by would-be acquirors and because of the pro-competitive justifications for club deals, such as facilitating larger transactions and diversifying individual firm risk. Nonetheless, given what is at stake and the likely ripple effect within the private equity community if the DOJ is successful in bringing charges against such funds, the investigation should not be summarily dismissed as frivolous or baseless.

In the event of a successful action by the DOJ against private equity and hedge funds, it is likely that the limited partners in such funds will face the lion’s share of any penalties and fines levied by the DOJ, given the financial benefits the limited partners have realized as a result of their participation in such funds. It will be interesting to see whether the general partners and controlling persons of such investment funds are asked to step forward to bear a portion of the penalties or fines themselves, perhaps in the form of a haircut on management fees or a clawback against their carried interest allocations. It will also be interesting to see if those limited partners in private equity funds who are penalized for collusive practices consider removing (or attempting to remove) the general partners of such funds, either for cause or, where available, without cause, which typically requires a supermajority vote of the limited partners.

Protective considerations

Regardless of the outcome of the DOJ investigation, there is always the looming presence of the plaintiff's bar to contend with.

Despite the long odds – and displaying a certain degree of opportunism, as of the date of this publication – at least one lawsuit has already been filed in the Southern District of New York against several well-known private investment funds . . .

that have been active participants in club deals over the course of the last several years.¹ Given the deep pools of capital available within private equity and hedge funds, we would expect that class action lawyers will continue to pursue these types of claims if there is even a slight chance for a lucrative payday.

Therefore, regardless of whether the DOJ decides to pursue criminal or civil charges against private equity funds and other club participants, all investment funds contemplating any collaborative activity in this area would be well-served to consider adopting procedures designed to preempt potential antitrust concerns or anticompetitive charges in future auctions. Such procedures might include one or more of the following:

- The club participants should be able to demonstrate a legitimate business purpose for such participation, other than merely reducing the competitiveness of the auction process (e.g., reducing the size of the investment in relation to the size of the fund or the ability to compete in auctions that would otherwise be beyond their fund's capacity, etc.).
- An investment fund should adopt internal controls and procedures to limit or prohibit the sharing of information with other funds or companies that are not part of their club and that may also be participating in the auction.
- If an investment fund has lost an auction, it should give careful consideration before switching teams to the winning club. Similarly, the auction winner should hesitate

to invite any member of a losing auction team to join its winning team, as these practices may give the appearance that the bidding was “rigged” from the outset.

- If, going into an auction process, an investment fund knows that it will be unable to win the bid without teaming up with other funds, it should consider reaching out to such funds and forming the club during or before completion of the auction process. While this approach may still reduce the number of auction participants, it is less likely to taint the losing bidders with the stigma of having put in sham bids.
- Where possible, an investment fund might seek alternative means of raising capital that would not require teaming up with the “competition,” perhaps looking to its own limited partners to co-invest alongside the investment fund to achieve greater scale.

The measures suggested above could provide an extra layer of protection against a lawsuit or DOJ charge that a participant conspired or otherwise colluded with the “competition” to fix the ultimate winning bid. Of course, at this early stage of the DOJ investigation, it is premature to suggest a fool-proof safe-harbor approach for club participants to adopt in the auction process.

It is not yet clear how the markets generally, or the private equity community in particular, will react to the DOJ investigation. Just recently, several private equity and hedge funds have joined together to form the Private Equity Council, a trade group formed to lobby on the industry's behalf (which may be viewed as an industry-wide reaction to the DOJ investigation). To date, it does not appear that the investigation or the threat of criminal or civil charges has deterred the formation of clubs.

Since word of the DOJ inquiry first surfaced, several private equity funds and hedge funds have continued to team up to acquire companies such as Reader's Digest, Clear Channel Communications, Biomet, Inc., and Harrah's in multi-billion-dollar, go-private transactions announced in November and December 2006. It remains to be seen whether this trend will continue if the DOJ decides to pursue

¹ *Murphy v. Kohlberg Kravis Roberts & Co.*, No. 06-13210 (S.D.N.Y. filed Nov. 15, 2006). Merrill Lynch & Co., Kohlberg Kravis Roberts & Company, the Carlyle Group, Silver Lake Partners, the Blackstone Group, Thomas H. Lee Partners, Apollo Management, Warburg Pincus, Clayton, Dubilier & Rice, Bain Capital, Texas Pacific Group, Madison Dearborn Partners, and Providence Equity Partners, Inc. have all been named in the lawsuit.

criminal or civil charges against any of the private equity funds or club participants that are the subject of the current inquiry.

Bradley C. Vaiana, Partner

Peter Nurnberg, Associate

Investment funds

Differences between Cayman Islands and Delaware Limited Partnerships

United States private equity funds have long considered Delaware the “gold standard” jurisdiction for formation of domestic pooled investment vehicles. Delaware entities provide ease of formation and amendment, superior quality of jurisprudence with respect to matters of business, and clarity and ease of interpretation of law for practitioners. As the world market shrinks, private equity funds increasingly invest in portfolio companies outside of the United States. To maintain tax efficiency for limited partners, many funds invest in non-U.S. companies through entities formed in tax “flow-through” jurisdictions. The Cayman Islands jurisdiction has long been favored due to the well-established legal, banking, and government business services there.

Although both Cayman Islands and Delaware partnership laws trace their roots to the British Partnership Act of 1890, which was fundamentally premised on the right of contract between parties, they differ significantly in some respects. For example, the Delaware Limited Partnership Law (DRULPA) often thoroughly enumerates the rights and remedies associated with its provisions, while the Cayman Islands Exempted Limited Partnership Law (EPL) presumes that, where the statute is silent, the agreement will control. This article seeks to highlight differences in some of the more important provisions of DRULPA and the EPL that may create unanticipated results for the investor.

Side letters and ancillary agreements

Delaware and Cayman Islands common law both recognize the integration of ancillary agreements to a partnership

agreement. Many limited partners in Delaware partnerships enter into side letter agreements to address regulatory, policy, tax, and other matters. Side letter provisions may affect the economic relationship between an individual investor and the partnership by, for example, reducing the management fee, extending enhanced information rights, or granting the limited partner an advisory committee seat in exchange for its commitment. Cayman Islands common law, however, does not permit ancillary agreements to change the material terms of an agreement without the consent of all partners. Accordingly,

an ancillary agreement (such as a side letter) may not change the “material” terms of a Cayman Islands limited partnership agreement.

To combat this restriction in the EPL, one option we’ve increasingly seen in the marketplace is the use of New York- or Delaware-governed side letter agreements by partners in Cayman Islands limited partnerships that would allow limited partners to obtain material changes from the partnership agreement.

Freedom of Information Act

Subject to a limited partner’s reasonable demand for any purpose reasonably related to it as a limited partner, DRULPA has historically provided for a limited partner’s right to receive information concerning the partnership. In recent years, however, media and other organizations have used public entity limited partners to obtain information about private equity funds through state Freedom of Information acts (FOIAs). Public disclosure of information about the portfolio companies of such funds can be damaging to the funds and their portfolio investments.

The fund sponsors’ response was to dramatically limit the breadth and scope of information disclosed to limited partners. Delaware legislators subsequently codified the enforceability of such provisions under DRULPA; however Cayman Islands legislators did not react similarly. DRULPA now gives general partners the right to keep trade secrets, disclosures not in the best interest of the partnership, and disclosures required by law or contract confidential from limited partners. Limited partners in Delaware limited part-

nerships frequently use side letters to provide for enhanced information rights. To avoid discomfort as to the enforceability of a side letter governed by Cayman Islands law as discussed above, limited partners in Cayman Islands limited partnerships may wish to negotiate specific terms enabling them to receive the information they require in the partnership agreement itself (with details of how the information may be provided in a side letter) or enter into side letter agreements governed by New York or Delaware law, as mentioned above.

Derivative actions

DRULPA allows a limited partner to bring a cause of action on behalf of the limited partnership when the general partner refuses to do so, or if an effort to force the general partner to do so is *unlikely to succeed*. The limited partner must show why the general partner wrongfully refused to bring the action or why demanding that the general partner bring the action would be futile. Conversely, for a limited partner in a Cayman Islands limited partnership to bring a derivative action, it is necessary to demonstrate that the general partner failed to bring such action *without good cause*, a more difficult standard to establish than “unlikely to succeed.” This distinction is important where it is possible that the general partner has not pursued a remedy on behalf of the partnership because of collusion, self-dealing, or other issues not reflecting the best interests of the partnership. Given the higher EPL burden of proof, limited partners of EPL-governed entities may wish to negotiate for a lower threshold voting requirement to remove the general partner, so that the obstructing general partner may be replaced with a person who will pursue appropriate remedies on behalf of the partnership.

Assignment of limited partner interests

DRULPA allows a limited partner to assign its interest in a limited partnership without any reference to the authority of the general partner. Thus, restrictions contained in Delaware partnership agreements are frequently modified through side letters, establishing in advance the right to transfer to affiliates or others. Conversely, the EPL dictates that any assignment of partnership interests requires the consent of the general partner in its sole discretion, and

consents to transfer may not be waived by the partnership agreement. Because, under Cayman Islands common law, ancillary agreements cannot change the material terms of partnership agreements, the consent requirement cannot be changed through side letters.

Default provisions

DRULPA permits a partnership agreement to provide for virtually any specified penalty or consequence (including forfeiture of the limited partner’s interest) in the event of a limited partner’s default (e.g., failure to make a capital call), despite any punitive characteristics. In contrast, under the Cayman Islands common laws of equity and public policy, default provisions must reflect a reasonable pre-estimate of damages, rather than a penalty or amount not tied to such analysis. As such, penalties not tied to making the injured party whole may be found unenforceable in the Cayman Islands.

Indemnification

Under DRULPA, parties have complete and ultimate authority to define the terms of indemnification provisions (other than with respect to a breach of the implied covenant of good faith and fair dealing) in the limited partnership agreement. The EPL, however, is silent with respect to indemnification. Because indemnification rights are not addressed . . .

under the EPL, a limited partnership may not be able to indemnify a partner absent an express provision in the partnership agreement.

Moreover, litigation of indemnification provisions contained in the limited partnership agreement in the Cayman Islands may be more narrowly construed than the same provision might be construed in Delaware. Thus, we would recommend that potential investors in partnerships governed by the EPL negotiate and draft indemnification provisions with care and specificity.

Third-party beneficiaries

Although DRULPA explicitly recognizes the rights of third-party beneficiaries, the EPL does not recognize the rights of a person not a party to the limited partnership agreement. Rights of third-party beneficiaries may affect the return to the partnership of excess distributions of carried interest made to the general partner, indemnification, confidentiality provisions, and the indemnification of representatives serving on an advisory committee. The general partner (through a “clawback” provision in the partnership agreement) generally has an obligation to return to the partnership distributions made to it in excess of the carried interest to which it is entitled. Because the general partner is typically an entity with no assets of its own, the fund must look to the principals to return such excess distributions. As a result, the partnership is often a third-party beneficiary of the principals of the general partner to return any over-distribution. In contrast, in the event that the principals have not executed a guarantee or otherwise established a contractual basis for their obligation to return distributions to the partnership, the limited partners of an entity formed under the EPL may have no recourse if the general partner becomes insolvent. Under the EPL, it is not clear that persons not a party to the limited partnership agreement are covered by the indemnification provisions therein, no matter how carefully the indemnification provisions are drafted. This issue is also relevant for individuals representing investors on a partnership’s limited partner’s advisory committee. Such individuals may wish to enter into an indemnity to ensure proper coverage by the fund.

In conclusion, both Delaware and the Cayman Islands provide an excellent legal framework for the formation of a pooled investment vehicle. Nonetheless, it is important to be aware of the sometimes-subtle differences between the laws of the two jurisdictions. With this knowledge, wise negotiating positions can be taken early on, before litigation leads to unexpected results for the parties.

Andrea R. Cohen, Counsel

Venture capital and emerging companies

Venture capital partners and corporate governance: 10 current challenges faced by directors on portfolio company boards

Venture capital (“VC”) firms provide much-needed capital to privately held companies, and they typically monitor their investments by taking seats on the company’s board. Sitting on a portfolio company board is a challenging proposition in today’s landscape, however, carrying with it potentially greater liability than in the past when the VC director does not satisfy his or her fiduciary duties to the company and its shareholders. A VC director’s fiduciary duties may collide with the interest of the VC director’s fund or may involve situations where the fund is unfairly benefited to the detriment of other shareholders. Coupling this with the obligations owed by the VC partner serving on the company’s board to the fund’s limited partners, many VC directors find themselves between the proverbial rock and a hard place. Although a fund could consider whether board observer rights coupled with preferred stock protective provisions would adequately accomplish its monitoring goals, more often than not, it is important for the fund to contribute its expertise to the portfolio company by appointing one or more directors to the board. VC directors must address these challenges proactively to help mitigate the risk of their personal liability and the correlative damaging effects to the portfolio company.

The landscape

The Sarbanes-Oxley Act of 2002 (SOX), Health Insurance Portability and Accountability Act, and the Graham-Leach-Bliley Act, and other statutes in the post-Enron era have ushered in new challenges for directors and management, even of private companies. These challenges have grown strong in the public company arena, feeding on a diet of corporate malfeasance, scandals, legal prosecutions, reactionary rule-making, an increased societal focus on corporate

accountability, and increased shareholder activism in the wake of these concerns. In the day and age where shareholder activism is at an all-time high, shareholders of private companies are demanding transparency and are increasingly taking their cues from the public arena.

Fiduciary duties

Recent cases such as Disney, WorldCom, and Enron (and their recent settlements) provide insights into the evolving standards faced by VC directors. Generally, there are two primary fiduciary duties owed by directors to the portfolio company and its shareholders. Directors first and foremost owe a duty of care that an ordinarily prudent person would exercise in a similar position. Further, a director owes a duty of loyalty to provide an elevated priority to the company's interest over his or her own interests in making business decisions. These fiduciary duties mandate that a director must reasonably believe his or her actions to be in the best interests of the corporation and its shareholders. The case law surrounding directors' fiduciary duties is developing at a breakneck pace. The Delaware Supreme Court handed down an opinion in *Stone v. Ritter*, in November 2006, that underscored the fact that the duty to act in good faith is a critical element of the duty of loyalty, and held, for the first time in Delaware, that a director could violate the duty of loyalty even absent a financial interest in the underlying transaction. However, early interpretations of *Stone v. Ritter* are positive in respect of director oversight liability, and the consensus appears to be that directors are not liable unless they failed (i) to implement reporting or information systems or controls or (ii) consciously failed to monitor them once implemented. VC directors must actively ensure these controls are in place and participate in their oversight to minimize their potential liability.

Executive compensation

Executive compensation is a bellwether legal issue today and a catalyst for potential director liability. As the recent resignation of Bob Nardelli as CEO of Home Depot has highlighted, rich compensation and termination packages for senior executives should be carefully evaluated. A director who does not actively participate in this process could be open to potential liability. A VC director should seek advice

from outside independent experts to gauge the reasonableness of proposed executive compensation plans.

Require safeguards at your fund.

Fund managers must be very cognizant that a portfolio company's non-public information is confidential and must be safeguarded with appropriate diligence. A VC firm should have a written insider trading policy that is reviewed and provided to all the employees of the fund. It is also a good idea to have at least annual legal training sessions regarding the laws surrounding confidentiality and securities issues. Complications arise when VC directors sit on multiple portfolio company boards, which may create conflicts of interests, particularly as portfolio companies broaden their missions and overlap in competing markets. General partners of VC funds should periodically review their information-sharing procedures to ensure that proper safeguards are in place, mitigating these situations in particular. In addition,

if a fund's portfolio companies are doing business with each other, special care should be taken to ensure that self-dealing is avoided.

A fund's investments in portfolio companies in competition with each other may also raise antitrust issues.

Personal liability and pressure points

Individual, personal liability of directors is a reality with financial consequences. VC directors should not assume that insurance or indemnification provisions or agreements of their portfolio companies will be a panacea for their decision-making or monitoring activities. The "business judgment rule" presumes that courts will not second-guess informed and diligent decision-making by independent/disinterested directors. However, deliberate indifference and inaction by a director is arguably a breach of his or her fiduciary duties.

Certain transactions require special care

Certain financing and change-of-control transactions require a VC director to apply special care in the exercise of his or her fiduciary duties. The advice from outside experts, such as investment bankers, financial and legal experts and

others, can be useful in proving that the decision-making process was thorough as well as validating the fairness of the transaction terms. Exploring and/or seeking alternative offers and requesting fairness opinions are additional recommended avenues that boards should pursue. These activities will help the board demonstrate that it fully explored all alternatives and made a fully informed decision in the best interests of the company and all of its shareholders.

Conflicts of interest change the dynamic

When determined to be “interested,” directors lose the presumption of the business judgment rule and are faced with the heightened burden of establishing that their decision was substantively and entirely fair. Funds should review their portfolio companies’ informational procedures and resolve conflicts as early as possible. In addition, if the portfolio company is teetering on insolvency, certain fiduciary duties are owed to creditors of the portfolio company and cannot be ignored in the decision-making process. Recusal of one-self from the decision-making process is advisable when conflicts of interest arise, although continued and frequent recusals may violate a director’s duty of care.

The portfolio company’s insurance and governing documents

A director must diligently review the governing documents, indemnification agreements, and insurance policies that the company has in place. Protections can run the gamut from true specialty venture capital asset protection coverage to limited D&O coverage. A director must take the time to fully understand the coverage and, most importantly, the limitations/exclusions. Yearly insurance audits from a qualified insurance broker or consultant, and the consideration of new products and best practices in the marketplace, are essential.

The need for continued regulatory compliance programs

A good company compliance framework includes mechanisms for augmenting internal controls, documentation procedures, and broadening the organizational structure to help ensure ongoing compliance in the future. VC directors

should mandate that their portfolio companies invest in training, software and processes, and related technology to improve the documentation process and continue self-assessment to ensure accountability. VC boards must ensure that “compliance complacency” does not set in.

The need for process and corporate formalities

The *Stone v. Ritter* case underscored that directors will be assessed on their decision-making processes and oversight of the information systems and controls put into place by the portfolio company. Active attendance at board meetings, detailed minute-keeping, seeking full board and shareholder approval for applicable decisions, and recusal of interested directors where needed and appropriate are a must. The company’s records should clearly record its decision-making processes, including steps the board takes in analyzing alternatives, engaging experts and third parties, evaluating strategic alternatives, making efforts to understand the effect of dilution on all shareholders (if applicable), taking steps to neutralize self-dealing, etc. The appointment of a compliance officer who regularly reports to the board and assists in developing and monitoring these efforts is advisable.

VC directors of portfolio companies are in a unique position to help catalyze growth, but must continue to focus on discharging their fiduciary duties and ensuring that compliance and confidentiality practices are in place to advance the best interests of the company and all of its shareholders.

H. Bryan Brewer, Partner

Recent news

We are pleased to announce that Dan Offner and Dave Anderson have joined our firm as partners in the Venture Capital and Emerging Companies Group, based in our Los Angeles office.

Industry spotlight

The importance of regulatory due diligence in life science transactions

Traditionally, due diligence audits for significant transactions of companies doing business in the life science industry have focused on financial, intellectual property, and other key business considerations. Sophisticated financial sponsors and investors know that a critical component of due diligence audits is the regulatory portion. In today's market, buyers and investors must identify, understand, and manage the regulatory risks inherent in dealing with manufacturers and distributors of pharmaceutical, biotech, and medical device manufacturers, as well as other life science companies.

The value of regulatory due diligence audits in the highly regulated life science industry

The life science industry, already a heavily regulated industry, is likely to confront further regulation from the federal government, state governments, and international governmental authorities in the near future. The existing regulations include laws, regulations, guidances, and other issuances of the Food and Drug Administration ("FDA"), Centers for Medicare and Medicaid Services, Federal Trade Commission, Drug Enforcement Agency, United States Department of Agriculture, Department of Transportation, Department of Environmental Protection, and each of their state equivalents.

The life science industry has also experienced a dramatic increase in government investigations and enforcement actions targeted at the industry over the past decade, which are likely to continue as regulators gain in sophistication in and understanding of the industry, and as settlements from these investigations, continue to generate substantial revenue for the government. The government has successfully pursued investigations and won civil and criminal enforcement actions and monetary penalties, against both life science companies and investors – including companies acquiring or investing in the target company after the questionable activities had ceased.

Against this background, the need for and value of regulatory due diligence in an acquisition or investment becomes readily apparent. The results of such due diligence will generate information that can then be translated into fact-specific representations and warranties, which can then be used to allocate risk among the parties.

Critical components of regulatory due diligence audits

While the scope of the regulatory due diligence audits will vary case by case, the following is a description of the general components of both federal and state regulatory audits.

Clinical research

A due diligence audit of clinical research sponsored by a target company focuses not only on the research agreements themselves and the parties to them, but also on matters such as Good Clinical Practices and Good Laboratory Practices, approvals by and oversight of the research by institutional review boards (both commercial and institution affiliated), privacy and confidentiality of subject-related health information, documentation and compliance with human-subject protection requirements (including the informed consent process), restrictions on the promotion of investigational products, compliance with investigation-related submissions (e.g., new drug submissions and device exemptions, including underlying supporting data), adverse event reporting, and compliance with record-keeping requirements.

Moreover, federal grant recipients must comply with additional laws and regulations, such as time and expense reporting requirements, conflicts of interest, and additional human-subject protection requirements. These requirements may also apply to certain sites used for research by the sponsor manufacturing company. Thus, a thorough due diligence review should include an examination of such sites as well as determining, for example, if a federal-wide assurance is in place that makes these requirements apply to all research conducted at that site.

Products

The products of a company and the way in which the company does business should always be examined. One should also analyze whether the target has rights of access to other data and FDA records, and the strengths of those access rights. An . . .

examination of each product and its class should reveal whether any particular product or class is inherently risky; for example, because of off-label uses.

We also recommend reviewing the status of any remaining marketing exclusivity periods on a product-by-product basis, as well as adverse events associated with both the product and its class. Packaging, labeling, promotional practices, advertising (whether directed to health-care professionals or consumers), and disease state awareness or reminder ads must be reviewed as well. The audit should also look at similar products in the market, from both the branded and generic perspective.

Governmental investigations

A critical part of any regulatory compliance review necessarily entails a detailed examination of all government contacts, correspondence, investigations, enforcement actions, inspections, warning letters and untitled letters, and enforcement actions. In addition, an analysis should be undertaken of the target's compliance with any current corporate integrity agreements, required reports, post-marketing requirements, establishment listings, and Good Manufacturing Practices.

Reimbursement and pricing issues

Regulatory due diligence can also provide a valuable understanding of how, or whether, products will be covered and paid for by third-party payors after market launch. Such information can be useful in determining the adequacy of existing reimbursement rates from Medicare/Medicaid, and whether new rates should be sought. This reimbursement and pricing review should also look at whether there are 340B drug pricing issues and other pricing issues involving government contracts. In addition, a buyer or investor should determine whether current reimbursement rates are

likely to rise or fall, and whether the products are part of ongoing government cost containment efforts, such as competitive bidding programs for reimbursement of certain orthotic, orthopedic, and DME products. For medical devices, the due diligence review should include an analysis of coding advice disseminated by the company to its customers and whether the codes are "crowded," which could have a potentially adverse impact on reimbursement. Such information would bear heavily on the issue of whether a new code or reimbursement rate should be sought, which, in turn, has a direct bearing on deal price.

Operational review

Various operational aspects of the sales force, both internal and outsourced, should be examined, with a particular emphasis on compensation methodology, training, monitoring, promotional materials, expense accounts, and relationships with medical liaisons and other non-sales-related divisions of the target. Likewise, the target's relationship with providers, key opinion leaders, institutions, hospitals, and other potential referrers and customers should be reviewed, with an eye toward evaluating issues such as compensation arrangements, a fair market value assessment, and the selection process for advisory boards, consultants, research grants, speakers' bureaus, and other relationships that may give rise to actions for false claims, fraud and abuse, anti-kickback violations, and other regulatory violations. Standard Operating Procedures relating to grant-making procedures, sales force promotional activities, discounts, gifts to providers, and conflicts of interests are also of particular concern. The target's human resource division should be consulted to determine if any employees or ex-employees could be potential whistleblowers for false claims actions. A thorough review should include interviews with other key employees as well.

The target's agreements and arrangements with distributors and customers should be reviewed to identify discounts, rebates, free goods, and other benefits or payments, to determine if such arrangements, and the companies in general, are compliant with Best Pricing, rebate, and other pricing requirements.

Conclusion

In light of the highly regulated industry in which life science companies operate, regulatory due diligence audits now play an important role in helping buyers and investors identify, understand, and manage the regulatory risks inherent in their deals. Like other complex due diligence audits, a regulatory due diligence audit is only as good as the due diligence team that conducts the review. Based on the complexity of the transaction and the products and companies involved, the regulatory due diligence team should likely include not only FDA regulatory attorneys but also consultants with experience in the specific class of the target's products or technology. The time, effort, and resources invested in such a regulatory due diligence audit will likely produce far-reaching dividends for a buyer or investor in the life science sector.

Jill Alvarez, Partner

Special feature

Lessons for hedge funds investing in distressed debt

Hedge funds are active traders and are showing up more often in the market for distressed investments. They participate in a variety of ways: as members of bank syndicates holding first-and second-lien debt; as buyers of distressed unsecured debt; as debtor-in-possession (DIP) lenders; as purchasers of claims or equity, and as sponsors of a plan of reorganization. Not constrained to make only a single type of investment, a hedge fund can adapt its strategy to the particularities of the debtor and its creditor constituencies.

When a loan goes into default, hedge funds are naturally becoming more significant players in the bankruptcy arena and are coming under significant scrutiny as other creditors vie for a piece of a pie not big enough to feed everyone at the debtor's table. The hedge fund, therefore, is likely to find itself an increasingly common target of a debtor-in-possession trying to reorganize its business using the special tools available in a bankruptcy case, or an organized creditor

constituency looking to enhance its recovery. These cases can be learning experiences for other hedge funds looking to avoid making themselves easy targets.

One such situation came in a decision handed down on November 16, 2006, in the Chapter 11 cases of Radnor Holdings Corp. in Delaware.² When Radnor began to have financial problems, hedge fund Tennenbaum Capital Partners, along with two of its affiliates, got involved. They made a \$25-million preferred stock investment in Radnor, loaned Radnor \$95 million to refinance existing secured debt, and provided Radnor with an additional secured loan of \$23.5 million. Tennenbaum also designated one of the four members of Radnor's board of directors, pursuant to its Investor's Rights Agreement, and retained the rights to increase that representation if certain levels of EBITDA were not met and to veto certain employment agreements and transactions with affiliates. Tennenbaum obtained these protections even though, at all times, it held less than 20 percent of the equity of Radnor.

In its complaint, the Creditors' Committee (appointed to represent the interests of Radnor's general unsecured creditors) accused Tennenbaum of having entered into the loans with no expectation of Radnor's being able to repay them, but rather as a means to acquire Radnor – a so-called “loan to own” strategy. In the Creditors' Committee's view, Tennenbaum insisted on terms for the secured loan that it knew Radnor could not meet and that would ultimately cause the loan to go into default. In its lawsuit, the Creditors' Committee sought to: (i) recharacterize Tennenbaum's secured loans to Radnor as equity, or, as an alternative, to equitably subordinate Tennenbaum's secured claims to the claims of the general unsecured creditors; (ii) prohibit Tennenbaum from using its \$128 million in secured claims to make a credit bid on the sale of Radnor's assets; and (iii) recover as preferences monies Radnor had paid to Tennenbaum more than 90 days but less than one year before Radnor's bankruptcy filing, on the basis that Tennenbaum was an “insider” of Radnor.

Fortunately for Tennenbaum, at the end of the lengthy trial, Judge Walsh found that the Creditors' Committee had not proven its case or that existing statutes or case law precluded

² *Official Comm. of Unsecured Creditors of Radnor Holdings Corp. v. Tennenbaum Capital Partners, LLC* (In re Radnor Holdings Corp.), Adversary Proceeding No. 06-50909, Chapter 11 Case No. 06-10894 (Bankr. Del. filed Nov. 16, 2006).

it from succeeding. The Bankruptcy Court held against the Creditors' Committee and in favor of Tennenbaum on all counts, a result that is likely to continue to cause secured creditors and boards of directors to look kindly on Delaware as a venue of choice for bankruptcy cases. There are a number of important lessons for hedge fund investors in the Bankruptcy Court's decision, including:

1. Tennenbaum's ability to designate a board member and the fact that it designated a board member did not make it an "insider" for purposes of the Bankruptcy Code.
2. The financial covenants and other such provisions in Tennenbaum's credit agreement did not, by themselves, make Tennenbaum an "insider" of Radnor. Day-to-day control is necessary for "insider" status and the opportunity to exercise control.
3. Tennenbaum's designated director's abstention from voting on matters that involved Tennenbaum was a significant factor in protecting him from a finding that he breached his duty of loyalty to Radnor.
4. All allegations that Tennenbaum's designated director breached his duty of care to Radnor failed because Radnor had a Certificate of Incorporation that contained a standard exculpation clause permitted by Delaware corporate laws. Such a provision being part of the certificate of incorporation should be on the checklist of any prospective director of a Delaware corporation considering taking such a position.
5. Tennenbaum having obtained solvency certificates from Radnor officers at the time of its loans to, and investments in, Radnor helped avoid an "aiding and abetting breach of fiduciary duty" claim.
6. The parties' . . .

intent at the time of the transaction is the critical element in determining whether a recharacterization should take place.

If the parties intend a loan, then the court will not recharacterize the loan debt as equity. To determine the parties' intent, the court may look at various factors. For

the Tennenbaum Court, the following factors were relevant in determining that debt was in fact intended:

- the transaction documents referred to the obligations as debt;
- the parties consistently referred to the obligations as "loans" or "indebtedness" (a word to the wise . . . don't refer to a loan as an "investment");
- the debt instruments contained a fixed maturity date;
- the hedge fund lender was given the right to enforce the payment of principal and interest;
- the transaction documents did not contain voting rights;
- the loans were treated as priority debt instruments and proceeds were used for either working capital or to replace/pay down existing debt; and
- the transaction documents provided the lender with a security interest with priority in a liquidation or insolvency.

Ultimately, that the borrowers were experiencing a liquidity crisis at the time of the loan was simply not enough of a basis to warrant recharacterizing the loan.

Clearly, hedge funds will continue to provide funds to willing businesses in a variety of forms. As the law of averages implies, a certain percentage of those companies will stumble and wind up in (or near) bankruptcy. And just as night follows day, hedge funds will be targeted by debtors and creditors for attack as they try to enhance their own positions in bankruptcy cases. Being forewarned is being forearmed, and the lessons outlined above should help hedge funds structure such investments in a manner that protects their investments.

Mark Berman, Partner

Upcoming events

January 2007

Dennis Drebsky of our Financial Restructuring Practice will be a featured panelist at the 2007 Distressed Investing Conference, co-produced by the Turnaround Management Association and *The Deal*, being held in Las Vegas from January 17–19.

The panel, entitled “Horses of Different Colors or Different Animals? A Las Vegas Bout: *Private Equity v. Hedge Funds*,” will be held from 2:00 to 3:00 p.m. on January 18, and will discuss and debate how private equity firms and hedge funds differ in terms of investment and exit strategies, risk tolerance levels, and liquidity issues, and where the two industries result in culture clashes.

For more information about, or to register for, this conference, please visit www.turnaround.org.

April 2007

Charley Jacobs of our Investment Funds Group will appear on a panel entitled “Funds of Funds Weigh In on Terms, Investor Relations” at the 19th Annual Buyouts Symposium East, April 17-18 in New York City.

More information about this symposium is available at <http://events.tfn.com/bs2007e/>.

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