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Message from Our Managing Partner

In this issue, we turn to business and financial matters.

First, Rebecca Monson and I offer a comprehensive overview of how the new Health Information Technology for Economic and Clinical Health (HITECH) Act, signed into law last year as part of the American Recovery and Reinvestment Act of 2009 (ARRA), has made many changes to the privacy and security of health information, including establishing a federal standard for breach notifications in the health care industry.

We also report on a landmark case Pepper argued (and prevailed in) before the International Trade Commission, helping our client assert, then sell, its patent rights.

And Roger Lane and Courtney Worcester provide their top five risk management tips for venture capitalists—valuable reading in this still-fragile economy.

Online, Pepper has partnered with The Deal on a podcast series and our first edition explores midmarket pharma and health care deals, and we note the latest offerings among Pepper's Indian Series, Canadian Series, health care and life sciences webinars.

We always welcome your comments, questions and suggestions.

Sharon R. Klein, Partner

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HHS and FTC Dive Deeper Into the Breach: Update on Breach Notification Under the HITECH Act

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The Federal Trade Commission (FTC) and the U.S. Department of Health and Human Services (DHHS) each recently issued final breach notification regulations governing entities covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) along with vendors of personal health records (PHR) and related entities that are not subject to the HIPAA requirements. These final regulations are required under the Health Information Technology for Economic and Clinical Health (HITECH) Act signed into law on February 17, 2009, as Title XIII of the American Recovery and Reinvestment Act of 2009 (ARRA).

As has been widely discussed in recent months, ARRA made many changes to the privacy and security of health information including establishing a federal standard for breach notifications in the health care industry. While HIPAA addressed privacy and security of protected health information (PHI), HIPAA did not include requirements for HIPAA-covered entities to notify individuals in the event of breaches of their PHI. With the publication of these

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This publication may contain attorney advertising.

in this issue...

1 HHS and FTC Dive Deeper Into the Breach: Update on Breach Notification Under the HITECH Act
4 Patent Owners Find Protection in Landmark Case Argued Before ITC by Pepper Hamilton
5 Top Five Risk Management Tips for Venture Capitalists
6 Defense Research Institute (DRI)'s 26th Annual Drug and Medical Device Seminar
7 The Deal and Pepper Hamilton's Legal Roadmap to Success - Midmarket Pharma, Health Care Deals
8 Upcoming Webinars

latest regulations the FTC and DHHS have finalized the breach notification requirements mandated by the HITECH Act and have responded to many comments received on the proposed rules issued back in April 2009.

DHHS Interim Final Rule

Section 13402 of the HITECH Act includes the breach notification obligations for HIPAA-covered entities and their business associates for breaches of "unsecured" PHI (including methods of notification, timeliness, content of the notice, etc.). The DHHS issued an interim final rule implementing these requirements on August 19, 2009.[1] As required by the HITECH Act, these regulations were issued as interim final regulations, however, the DHHS is providing the public with a 60-day comment period. While these rules apply to breaches that occur on or after September 23, 2009, DHHS has provided for a six-month delay in enforcement and has noted that it will use its enforcement discretion to not impose sanctions for failure to provide required notifications for breaches that are discovered before February 22, 2010.

What Is, and Is Not, a Breach

In order to determine whether a HIPAA-covered entity or business associate is required to make a notification, it is necessary to determine whether there has been a "breach" of "unsecured PHI." The interim final rule defines a "breach" as the acquisition, access, use, or disclosure of PHI in a manner not permitted under the HIPAA Privacy Rule and that compromises the security or privacy of the PHI. In the event of an asserted breach of information, covered entities will need to affirmatively answer several questions before addressing the notification requirements under the new rules: (1) was PHI involved, (2) was the PHI "unsecured," and (3) was there a "breach" that passed the harm threshold as described later in this article?

The DHHS interim final rule's definition of "breach" only applies to PHI. Individually identifiable health information excluded from the HIPAA definition of PHI, such as employment records held by a HIPAA-covered entity in its role as an employer and certain student records, are not PHI and therefore are not subject to the new requirements. While the DHHS breach notification rule may not apply to such identifiable information, the covered entity will need to consider whether other notification laws do apply. Additionally, individually identifiable health information that has been de-identified in accordance with the HIPAA Privacy Rule requirements are not PHI and therefore not subject to the DHHS breach notification requirements.

> As noted in our prior article on this topic, health care entities, especially business associates, should carefully analyze their need for data to be personally identified and look for ways to properly de-identify PHI so that such data streams are outside regulatory purview.

By definition a breach requires the acquisition, access, use or disclosure of PHI in a manner not permitted under the HIPAA Privacy Rule. A violation of the HIPAA Security Rule will not itself constitute a potential breach; however, that same violation may lead to a use or disclosure of PHI not protected under the Privacy Rule, which in turn may be a potential breach. Moreover, not all violations of the HIPAA Privacy Rule will be breaches under these new requirements. Even if PHI has been acquired, accessed, used or disclosed in violation of the HIPAA Privacy Rule, in order for that violation to result in a breach the violation must pose harm to the individual. The second part of the "breach" definition includes this harm threshold; to be a breach the violation must be one "which compromises the security or privacy of the PHI," which means it "poses a significant risk of financial, reputational, or other harm to the individual." Covered entities will need to perform a risk assessment to determine if there has been significant risk of harm to individuals as a result of the impermissible use or disclosure of PHI. The DHHS provides some guidance in the preamble to the interim final rule on possible factors to consider:

- who impermissibly used, or to whom the information was impermissibly disclosed — if the recipient of the information is obligated to protect the privacy and security of the information
- if the effect of the impermissible disclosure can be mitigated so that the risk of harm to the individual is less than a "significant" risk
- if the impermissibly disclosed information was returned prior to being accessed for an improper purpose — an example provided in the preamble is if a lost or stolen laptop is returned and forensics investigation reveals no improper use
- covered entities and business associates should consider the type and amount of PHI involved in the impermissible use or disclosure. Particular attention should be paid to information that may be considered sensitive for reputational harm and employment discrimination (such as substance treatment, oncology services, mental health, etc.).
- the DHHS comments also refer readers to the OMB Memorandum M-07-16 for examples of other factors to consider.

Covered entities and business associates have the burden of demonstrating that no breach has occurred. It is critical that the risk assessment be documented so that, if necessary, a covered entity or business association can demonstrate that no breach notification was required following an impermissible use or disclosure of PHI.

With respect to limited data sets, defined in the HIPAA Privacy Rule as PHI that excludes 16 direct identifiers but is not fully de-identified, the DHHS concluded that due to the risk of re-identifying such information, impermissible uses or disclosures of limited data sets can be a breach and thus need to be evaluated to determine the risk of harm to an individual. Such a risk assessment should take into consideration the risk of re-identification of the PHI contained in the limited data set. The interim final rule also includes a narrow explicit exception for PHI that is a limited data set and also excludes birth date and zip code information — impermissible use or disclosure of such information will be deemed to not compromise the security or privacy of PHI. The DHHS concluded that if such information has a low level of risk, however, they are soliciting comments on this narrow exception. Uses of limited data set information that include birth date and zip code information continue to be permitted; however, in the event there is an alleged breach of such information it would not qualify for the narrow exception and would instead be subject to the risk analysis to determine the risk of harm.

There are three exceptions to the definition of "breach" included in the interim final rule, each of which are closely based upon the statutory exceptions to "breach" included in the HITECH Act:

- any unintentional acquisition, access, or use of PHI by a workforce member or person acting under the authority of a covered entity or a business associate, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under the HIPAA Privacy Rule
- any inadvertent disclosure by a person who is authorized to access PHI at a covered entity or business associate to another person authorized to access PHI at the same covered entity or business associate, or organized health care arrangement in which the covered entity participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the HIPAA Privacy Rule
- a disclosure of PHI where a covered entity or business associate has a good-faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

In determining whether a breach has occurred, covered entities and business associates will need to (1) determine whether there has been an impermissible use or disclosure of PHI under the HIPAA Privacy Rule, (2) determine and document, through a risk assessment process, whether the impermissible use or disclosure compromises the security and privacy of the PHI, and (3) determine whether the incident qualifies for any of the regulatory exceptions to the definition of "breach."

The full text of the article is available online at http://www.pepperlaw.com/publications_update.aspx?ArticleKey=1681.

Patent Owners Find Protection in Landmark Case Argued Before ITC by Pepper Hamilton

Legal Victory Accelerated the Sale of Saxon Innovations LLC

Pepper Hamilton LLP has prevailed in a cast that led to a recent ruling by the International Trade Commission (ITC) that will have major implications for companies that license their patent portfolios to U.S. businesses.

"This is an important ruling that significantly impacts technology companies who license their patent portfolios, as well as venture capital and private equity firms with portfolio companies that hold valuable patents," said William D. Belanger, a partner in Pepper's Boston office. "The ruling gives patent owners greater flexibility to enforce their intellectual property and may result in more case filings at the ITC."

The ITC has become an important venue for patent disputes because of its power to issue orders barring the importation of goods that infringe on U.S. patents. A 2006 Supreme Court ruling made it much more difficult to obtain broad injunctions against infringing goods in federal court, so increasingly patent holders are turning to the ITC for relief. However, very few practitioners are experienced in the rules and requirements of litigation before the ITC. Pepper is one of those few firms.

To win a patent dispute before the ITC, the plaintiff must establish a domestic industry related to the patent at issue. The ruling in *Certain Electronic Devices Including Handheld Communications Devices*, (Inv. 337-TA-673 and 337-TA-674), which caused ripples in the intellectual property field, held that patent owners can fulfill the domestic industry requirement based exclusively on the activities of their domestic licensees.

Pepper attorneys, representing Saxon Innovations LLC, filed a complaint for patent infringement against prominent international technology companies, including Samsung, Nokia, HTC, Palm and Sharp.

"One key issue in this case centered on establishing a domestic industry related to the patent. Typically, parties satisfy the domestic industry requirement by pointing to an existing factory or R&D facility that employs the patented technology," said Aaron Levangie, an associate in Pepper's Boston office. "In Saxon's case, we focused on domestic companies who licensed the asserted patents, and those licensee's activities exploiting the patented technology in the United States." The ITC ultimately ruled in favor of Saxon, creating an opportunity for patent owners who have licensed their portfolios to domestic companies.

"Pepper Hamilton helped manage this opportunity for us from the initial acquisition through the sale of the asset. This was a complex IP monetization program, and required a truly sophisticated partner, which they proved to be," said Bill Marino, CEO of Saxon Innovations. "Pepper's ITC expertise, combined with their industry knowledge and ability to manage this program on an alternate fee basis, was critical to our company's success."

"Our success at the ITC ratified the value of Saxon's patent assets and Pepper's work in obtaining this ruling and at trial was key in driving the sale," said Marino. "For such a major transaction, this deal was finalized in a remarkably short timeframe. The value of the patent sale was increased by Pepper's seamless representation on litigation and transaction matters, as well as the ITC's willingness to protect Saxon's domestic licenses."

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Top Five Risk Management Tips for Venture Capitalists

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The article was originally published in the January 2010 edition of *Reuters Venture Capital Journal*. It is reprinted here with permission.

The modern U.S. venture capital industry had its first flowering in the 1970s, in fields that lay fallow after a stiff recession. Since that time, by many accounts, the U.S. economy has been in nine more recessions, of varying magnitude and duration, including the one that we're told we're presently recovering from.

As corporate litigation and risk management lawyers, it's not our place to assess the most recent recession relative to others, except to note the obvious: It has been severe, and asset values have been materially reduced across the board. Signs of a recovery are emerging, but any recovery is still expected to be gradual and halting.

Our job in this context is to look ahead and identify practical protective steps that venture capital firms can take to reduce litigation risk, and to better position themselves for the favorable disposition of any disputes that may nonetheless arise from corporate finance and other transactions undertaken in this environment. The simple fact is that deals done in downturns are far more likely to result in stockholder disputes and lawsuits down the road—after asset values have recovered and hindsight and second-guessing have set in. How do VC firms best protect their interests?

Here are our top five suggestions for reducing that risk:

1. Migrate ... to Delaware

All of a firm's portfolio companies should be Delaware corporations. In our view, there is no advantage to incorporating elsewhere that withstands thorough analysis. This is an exceedingly simple point, but it is of key importance from a risk management perspective.

There are four basic reasons that support this statement: Delaware corporate law is far better developed than that of any other state; the judiciary is of consistently high quality; legal outcomes, while never guaranteed, are consequently more predictable and more certain; and, the personal assets of individual directors and stockholders are better protected.

So, if the firm has portfolio companies that are not Delaware-incorporated, and a significant transaction is anticipated, such as a debt or equity financing, recapitalization or restructuring, consider also conducting a migratory merger to Delaware. For experienced counsel, a migratory merger is a relatively simple exercise, particularly if the firm can fairly anticipate a favorable stockholder vote. In addition, in the context of a significant transaction, the incremental effort is relatively modest. The benefits, however, can be substantial.

One detail, all too often overlooked, is that from a risk management perspective, an effective migratory merger consists of more than the adoption of a Delaware corporate charter; in addition, the various stockholder agreements also need to be amended in parallel-to call out Delaware as the governing law, and its Court of Chancery as the forum for resolving disputes. Otherwise, there is risk of having pointless "sideshows" about what law actually governs a particular dispute, what court has authority to resolve that dispute, and so forth.

2. Invite Everybody to the Party

The basic rules of childhood once again prove their durability. If a portfolio company is undergoing a down-market financing or recapitalization, consideration should be given to inviting all accredited investors to participate on the same terms—regardless of whether they have express contractual rights of participation.

Offering such participation protects venture firms and corporate directors in two ways. If a stockholder cannot confirm accredited investor status, it is difficult to blame anyone when the law does not permit that stockholder to play. In addition, it is far more difficult for disgruntled stockholders to claim unfair dilution if they were invited to participate on the same terms as others and, for whatever reason, they elected not to do so. In most instances, the marginal dilutive effect on the professional investors who are providing the bulk of the new money will be immaterial.

3. Upgrade Company Infrastructure

"Infrastructure reinvestment" is one of the hallmarks of the current administration's plan for the nation's economic recovery. The

Defense Research Institute (DRI)'s 26th Annual Drug and Medical Device Seminar

Friday, May 21, 2010

Pepper partner Nina M. Gussack will be speaking at DRI's 26th Annual Drug and Medical Device Seminar being held in San Francisco, California. Ms. Gussack's topic will be "Private Attorneys General: Defending Consumer Protection Claims Against a Plaintiffs' Bar/AG Alliance."

For more information and to register, please visit www.dri.org.

concept applies to portfolio companies, as well. There is no better time to inspect and upgrade infrastructure than right now.

Two elements of portfolio company infrastructure stand out as having the most meaningful impact on risk management: an adequate finance and accounting function, and a properly composed board of directors.

The entire process of seeking portfolio company liquidity—be it an IPO or, more likely, an M&A transaction—will be significantly enhanced if the company has consistently maintained an accounting and finance function adequate to meet its needs throughout its development.

The term "enhanced" does not simply mean that the process will go more smoothly. It also means a significant reduction in the risk of uncovering errors, omissions and irregularities that can negatively impact valuation, derail negotiations altogether, or cause the company to miss a market window.

Literally months can be consumed in "diligencing" accounting issues after the fact and preparing fresh financial statements. Inquire into the adequacy of these functions at your more mature, revenue-generating portfolio companies, where the issue is most likely to have a material impact: Does the company have personnel with the requisite knowledge and experience for the tasks at hand? Is the accounting and finance function adequately staffed? What do the auditors say?

Similarly, review the composition of the boards of directors of the firm's more mature portfolio companies. Does each board have at least two independent, outside directors? Are the boards of the companies that are closest to a liquidity event composed of a majority of independent outside directors? If not, are candidates available, or can they be found?

Why the preoccupation with board composition? Because corporate transactions and events undertaken in a recession—down-round financings, recapitalizations, executive terminations and the like—are often driven by, or at least perceived to be driven by, existing investors holding one or more board seats, who are then invariably claimed to have acted out of self-interest.

Risk management in this context, where corporate and stockholder interests may diverge and conflict, is about vesting the corporation's authority and decision in the hands of competent and disinterested fiduciaries. Two or more disinterested outside directors can comprise an independent board committee, or a majority of disinterested directors can act for the board, provided that each is truly independent and has no material personal interest in the challenged decision.

4. Swim in the Mainstream

Terms of VC financings, like any commercial terms, evolve through economic cycles. In the most recent recession, there has been renewed or expanded use of multiple liquidation preferences, participating preferred, and preferred stock redemption terms; an increased reluctance to waive anti-dilution rights; and an increased use of "pay-to-play" provisions. Venture firms and their advisors will have differing views on the positive and negative aspects of such provisions, the details of their terms, and counter-balancing pro-company and pro-management terms.

However, all of these lie within the mainstream of the current deal-making dialogue. In this context, firms should be cautious if they wish to step substantially beyond existing market terms,

at least absent a company-specific business or finance rationale. Terms that are substantially beyond market norms are more likely to draw complaints in the first instance, as "outliers," and may prove more difficult to defend for the same reason.

5. Don't Blow Your Cover(age)

Last but not least, the liability protection provided to a venture capital firm and its personnel via indemnification provisions and insurance coverage should be reviewed at both the portfolio company and fund level. Each portfolio company should, as a matter of course, provide its directors with indemnification. Given the present litigation environment, we believe that each company should also maintain a directors' and officers' liability policy to back up those indemnification obligations. In addition, those D&O policies should be reviewed by competent personnel to ensure their adequacy, because fundamental errors can be made in such policies.

Further, if you have not done so, consider whether your firm should have its own professional liability insurance policy. Coverage for venture capital firms is not cheap, but it has proven worthwhile for firms with large portfolios and mature portfolio holdings. Finally, consider whether to seek fund indemnification. Your firm's money has been invested in its portfolio companies, and it is not unreasonable to request that a part of those funds be available for indemnification if claims later arise. VC liability policies often come with substantial retentions (i.e., deductibles), and fund indemnification is one means of financing that retention.

The Deal and Pepper Hamilton's Legal Roadmap to Success - Midmarket Pharma, Health Care Deals

There are a number of hot-button legal topics interesting to dealmakers at the moment. What key legal issues should you be thinking about in the coming months? Hear thoughtful perspectives in this series of incisive podcasts from The Deal and Pepper Hamilton LLP.

The Deal

Episode 1: Pepper Hamilton on Midmarket Pharma, Health Care Deals

Pharma and health care deals seem to have remained recession-proof. As the economic environment improves, Pepper Hamilton partners Christopher S. Miller and John W. Jones, Jr. believe dealmaking in the sector is likely to pick up. In this podcast sponsored by Pepper Hamilton, the two discuss the larger issues facing the industry and how they will affect dealmaking.

Listen today by visiting
www.thedeal.com/knowledge/podcasts/pepper-hamilton-on-midmarket-pharma-healthcare-deals.php.

Upcoming Webinars

Indian Webinar Series: Hidden Employment Law Risks In Doing Business in the United States
Wednesday, March 24, 2010
11:00 A.M. - 12:00 P.M. Eastern

Dumping Pharma
Health Care Legal Issues for 2010 and Beyond Webinar Series
Thursday, March 25, 2010
12:00 - 1:00 P.M. Eastern

Critical Considerations in Distressed M&A Transactions: *Exploring Risks and Opportunities*
Wednesday, April 7, 2010
12:00 - 1:00 P.M. Eastern

Health Care Privacy and Security After HITECH
Health Care Legal Issues for 2010 and Beyond Webinar Series
Thursday, April 22, 2010
12:00 - 1:00 P.M. Eastern

Canada-U.S. Trade Update Luncheon
Canadian Webinar Series
Thursday, April 29, 2010
12:00 - 1:00 P.M. Eastern

Solar Power for End Users - Where to Store?
Thursday, May 6, 2010
12:00 - 1:00 P.M. Eastern

Lease Considerations for Green Building
Wednesday, May 19, 2010
12:00 - 1:00 P.M. Eastern

Green Building for Owners and Developers
Wednesday, June 9, 2010
12:00 - 1:00 P.M. Eastern

To register or for more information about these webinars, please visit the webinar section of www.pepperlaw.com or contact Brian Dolan at dolanb@pepperlaw.com or at 215.981.4568.