



Venable Vitae

A PUBLICATION OF VENABLE'S LIFE SCIENCES GROUP

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One of the nation's leading law firms, Venable provides comprehensive legal services in representing fast-growing and emerging life science companies—including advice on corporate affairs, protection of intellectual property, help in dealing with the government and strategies for resolving disputes.

Our Life Sciences attorneys, including many with advanced degrees in scientific fields, offer a combination of technical expertise and business and transactional experience that get projects done quickly to meet the demands of today's competitive environment.

Venable lawyers practice in all relevant legal specialties:

- Corporate Formation and Finance
- IP Patents and Trademarks
- Technology Transactions
- Regulatory
- Government Contracting
- Government Relations
- Tax Issues
- Real Estate
- Labor and Employment
- International Trade
- Product Liability
- Patent Litigation

For more information about Venable's Life Sciences team, visit www.venable.com/life-sciences.

Venable Vitae provides a convenient compilation of articles and listing of events relevant to Life Sciences companies - whether just starting up or established, nonprofit or for profit. This industry faces an increasingly complex set of challenges ranging from technology and science to business, policy and legal matters. We hope this publication helps shed some light on these topics.

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Hot Topic

A "V" Shaped Recovery for Life Sciences Companies?

It was reassuring to see reports at the Mid-Atlantic Bio conference held in DC in November that financing for the life sciences industry bounced sharply upward in March 2009 after a long, hard drop. Also, Steve Burrill's tally in Genetic Engineering News (11/1/2009) shows that biotech partnering deals more than doubled through Q3 2009 over the same period in 2008, from about \$10B to about \$22B, and financing also rose to about \$13B from about \$8B. These are difficult times for life sciences companies, and no one can accurately predict the effects of health care reform, intellectual property reform, international competition, and overall economic strains. But research, development, collaboration, and commercialization of new products and services continues in the face of these challenges, and anecdotes and data suggest that there are many green shoots -- life in life sciences - that can contribute to a prolonged recovery.

Survey

We would appreciate your input about legal seminars for life sciences companies that we are developing for 2010. Please take a moment to complete this one page survey. Click here to access the survey.

Articles

Your Websites Terms and Conditions Are Probably Unenforceable

Most websites have Terms and Conditions which govern a user's or visitor's rights in regard to the content of the website and/or the dealings between the parties. However, the fact that they are posted does not mean that they will be enforceable.

Hope for Biotech Claims in View of In re Bilski?

Since the Federal Circuit issued its *In re Bilski* decision in October of 2008, there has been significant trepidation in the biotechnology community concerning its impact. Recent decisions from the Federal Circuit and guidelines from the PTO have begun to shed light on this subject and, while conflicting, offer a ray of hope for biotech claims.

What Your Business Needs to Do About the New HIPAA Rules

Whether you are an employer that provides health insurance for your employees, a business in the growing health care industry, or a hospital or other medical provider, you need to know about some key changes to the privacy and security rules under the Health Insurance Portability and

Accountability Act of 1996 ("HIPAA"), which have been substantially broadened under the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act").

Intellectual Property Rights and Innovation

The United States recently announced a national innovation strategy, joining a growing group of countries seeking to harness innovation to serve their national interest. An effective system for protecting patents, copyrights, and other intellectual property promotes innovation by balancing exclusive rights with accessibility.

The Who, What, When of Invention

Increasingly, inventions derive from collaboration between researchers at two or more organizations, and researchers are moving from one employer to another. Recent decisions highlight the importance of careful inventorship determinations when a patent application is first prepared and during its prosecution.

Calculating Collateral Patent Damages: Lucent v. Gateway and the Entire Market Value Rule

When a patent owner proves infringement, U.S. patent law permits recovery of a reasonable royalty or an amount equal to the profits the patent owner would have made if the infringer had not infringed. Sometimes an infringer sells infringing and non-infringing components or products together. In these cases the Entire Market Value Rule can greatly increase the amount of a lost profits or reasonable royalty award.

China's Disclosure of Origin Law to Enter Into Force on October 1, 2009

As of October 1, 2009, China's Patent Law will require disclosure of the origin of any genetic resources used in an invention for which patent protection is sought in China. With the entry into force of these changes to its Patent Law, China joins a growing number of countries that impose similar requirements on patent applicants.

Covenant Not to Sue May Invoke Patent Exhaustion Doctrine

Patent exhaustion is prompted by a first authorized and unrestricted sale of a patented product, and operates to terminate all patent rights to a protected product. The 2009 Federal Circuit case *TransCore LP v. Electronic Transaction Consultants Corp.* expands the patent exhaustion doctrine, holding that a covenant not to sue may trigger the patent exhaustion doctrine and preclude a patent holder from suing a subsequent third party purchaser for infringement.

Events

How to Avoid Overtime Classification Mistakes in Light of Increased Wage and Hour Litigation

Business & Legal Report's four-part virtual boot camp series on December 14, 16, 17, and 21, 2009. Misclassified employees expose employers across the country to substantial risk. In 2009, more class action lawsuits were filed against employers on wage and hour issues than any other employment issue - with more on the way for 2010. Federal regulators have announced plans to hire more field investigators and increase payroll audits next year to uncover these payroll violations. Deciding which employees meet Fair Labor Standards Act (FLSA) guidelines for exemptions can be a great challenge, and an honest mistake can subject you to several years' worth of back pay (plus additional damages and attorney's fees). With the risk of wage and hour litigation on the rise, now is the time for Boot Camp.

December 14, 2009 Webinar Series

European Pharmaceutical Regulatory Law Boot Camp

Attend this conference and learn to navigate the European regulatory maze that plays such an essential part in the successful commercialization of pharmaceutical and biological products. The European Pharmaceutical Regulatory Law Boot Camp was developed to give FDA lawyers and U.S. regulatory affairs professionals – as well as other professionals who need to understand the regulatory backdrop of the pharmaceutical industry – a critical working knowledge of core regulatory competencies necessary for working within the established protocols of the EMEA and other European regulatory bodies responsible for the regulation of pharmaceutical products.

January 25, 2010 and January 26, 2010 The Carlton on Madison New York, NY

Spotlight

Patent Prosecution

Led by a team of experienced patent attorney-scientists and engineers from a broad variety of technical disciplines, Venable attorneys have prepared and prosecuted tens of thousands of patents worldwide for U.S. and international clients.

In 2008, when the patent allowance rate was one of the lowest on record, our patent allowance rate was 64% —20% higher than the overall rate at the USPTO.

Venable attorneys advise clients ranging from emerging technology companies, to universities, to large multinational organizations with complex patent portfolios that span the globe. In audits of their IP assets, we help our clients find hidden value, evaluate new technology, survey the competition for possible infringements and assess the patents of potential acquisition targets.

We explore how our clients can use patents to build their competitive advantages by asking questions like:

- What are other companies doing to compete with your products and how can we block them?
- Does your company have any technology that can be licensed, or dropped?
- What are the options for accessing valuable technologies of other companies?

To discuss these questions and learn how Venable's Patent Prosecution Group can help you meet your business goals, go to http://www.venable.com/patent-prosecution-practices/.

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