6th National Conference On

PHARMA/BIOTECH

IP DUE DILIGENCE

Innovative strategies to successfully conduct due diligence in M&A’s, licensing agreements, and other transactions

January 28-29, 2009 | Marriott East Side, New York, NY

Distinguished Co-Chairs:

Mary Ann Dillahunty
Vice President, Intellectual Property
Oncolytics Biotech, Inc.
(Calgary, AB)

William R. Majarian
Vice President
Corporate Intellectual Property
GlaxoSmithKline (King of Prussia, PA)

Nowhere else will you find a faculty of this caliber who will share insights on:

• Defining the company’s business goals before you begin the due diligence review
• Navigating the dynamic labyrinth of cases that can impact the company’s IP rights
• Ensuring a data trail that tracks the disclosure of appropriate information
• Gauging the effect of the patents in question on the company’s freedom to operate
• Cultivating a sufficient search strategy to enhance your knowledge base of the IP’s strengths, weaknesses, and potential
• Evaluating the benefits, disadvantages, and consequences of protecting the asset under a patent instead of a trade secret
• Analyzing the company’s options when discovering negative information in a late stage of the due diligence review
• Uncovering the vulnerable spots for ‘in licensing’ deals
• Crafting an effective due diligence checklist

Network with and gain practical insight from key industry experts responsible for the diligence review from:

AstraZeneca Pharmaceuticals
Avalon Pharmaceuticals
BioMarin Pharmaceutical
Columbia University
Elan Drug Technologies
EDF Ventures
Eli Lilly
GlaxoSmithKline
GTx
H. Lundbeck A/S
The History Factory
Hydra Biosciences
Javelin Pharmaceuticals
Johns Hopkins University
MIT Technology Licensing
Novo Nordisk
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Pfizer
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Thomas, McNerney & Partners
Trubion Pharmaceuticals
VGX Pharmaceuticals
Wyeth Pharmaceuticals
ZymoGenetics
and many others

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Without proper IP due diligence, a pharmaceutical or biotech company’s attorneys can get blindsided. And a potentially lucrative deal can vanish.

Because IP due diligence is a mission critical phase of the deal, even the most seasoned veteran must continually sharpen the arrows in the quiver of due diligence strategies. Failure to do so can trigger a terrific avalanche of consequences ending in disaster.

The time is now to benchmark IP due diligence strategies against industry leaders from pharmaceutical and biotech companies, leading universities, and venture capitalists.

The time is now to learn how to navigate the dynamic labyrinth of IP due diligence to achieve a thorough, successful, and advantageous due diligence review.

The time is now to teach the arrows in the quiver of due diligence strategies.

Because IP due diligence is a mission critical phase of the deal, even the most seasoned veteran must continually sharpen the arrows in the quiver of due diligence strategies. Failure to do so can trigger a terrific avalanche of consequences ending in disaster.

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The time is now to benchmark IP due diligence strategies against industry leaders from pharmaceutical and biotech companies, leading universities, and venture capitalists.

The time is now to learn how to navigate the dynamic labyrinth of IP due diligence to achieve a thorough, successful, and advantageous due diligence review.

The time is now for ACI’s 6th National Conference on Pharma/Biotech IP Due Diligence.

With a faculty including 33 in-house counsel from the leading pharmaceutical and biotech companies and an outstanding roster of outside counsel, this conference will show you how to add power to your due diligence review by successfully penetrating the complexities uncovered during this crucial, complex, and potentially costly stage of the deal making process.

• Understanding the company’s financial limitations, deal rationale, and deadlines to prevent surprises during the due diligence process
• Classifying the patents in question to identify issues that will affect the company’s freedom to operate
• Organizing a complete history of the IP in question to minimize the danger of missing information that will potentially affect the deal
• Assessing the validity, value and consequent risk of the IP at issue
• Presenting the uncovered risks to management in a way that management can fully understand, evaluate, and act accordingly
• Defining the changes in the law, marketplace, and technology that may negatively impact the patent’s value

Drill deeper into the issues by taking advantage of our Master Class: Drafting a Comprehensive Due Diligence Report – One Size Does Not Fit All. Focusing on a step-by-step breakdown, this in-depth workshop peels back the layers of proven strategies for implementing the due diligence checklist, preserving the integrity of the due diligence report, and identifying points of exposure should the intellectual property be the subject of litigation.

Don’t delay your registration for this invaluable educational and networking opportunity. Meet the industry leaders and learn how they tackle the massive challenges inherent in intellectual property due diligence for the pharmaceutical and biotech sectors.

REGISTER NOW by calling 888-224-2480, faxing your registration form to 877-927-1563, or registering online at www.americanconference.com/diligence.

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For more information about this program or our global portfolio of events, please contact:

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Group Leader & Business Development Executive
American Conference Institute
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Who You Will Meet

From pharmaceutical, biotech, and other life sciences companies
• Patent and IP counsel
• General/Corporate Counsel
• IP, Licensing, and Business Development
• Executives, financial analysts, and investment bankers for life sciences companies
DISTINGUISHED FACULTY

Co-Chairs:

Mary Ann Dillahunt
Vice President, Intellectual Property
OncoLogics Biotech, Inc.
(Calgary, AB)

William R. Majarian
Vice President, Corporate Intellectual Property
GlaxoSmithKline
(King of Prussia, PA)

Speakers:

Thomas M. Argenti, Ph.D.
Senior Director, Licensing, Global Business Development
Wyeth Pharmaceuticals
(Collegeville, PA)

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Partner
Brinks Hofer Gilson & Lione P.C.
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The Bittenbender Firm
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Executive Director of Johns Hopkins Technology Transfer
Johns Hopkins University
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(Princeton, NJ)

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Patent Counsel
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(Cambridge, MA)

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(Dallas, TX)

Mary Lincoln Campbell
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EDF Ventures (Ann Arbor, MI)

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(Seattle, WA)

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(Memphis, TN)

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(Seattle, WA)

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(Boston, MA)

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Director of Business Critical Research
The History Factory
(Chantilly, VA)

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The Procter & Gamble Company
(Cincinnati, OH)

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(Duluth, GA)

Alex Zisson
Partner
Thomas, McNerney & Partners, LLC
(Stamford, CT)

Register now: 888-224-2480 • fax: 877-927-1563 • AmericanConference.com/diligence
7:30  Registration and Continental Breakfast

8:15  Co-Chairs’ Opening Remarks

8:30  Defining the Company's Goals before You Begin the Due Diligence Review and Crafting an Accordant Checklist

Thomas M. Argentieri, Ph.D.
Senior Director
Licensing, Global Business Development
Wyeth Pharmaceuticals (Collegeville, PA)

Theresa A. Devlin
Senior Patent Attorney
AstraZeneca Pharmaceuticals LP (Boston, MA)

Mary Catherine DiNunzio (Moderator)
Head of Global Patent Alliances
H. Lundbeck A/S (Copenhagen, Denmark)

Mark S. Cohen
Senior Partner and Chair of Life Science Group
Pearl Cohen Zedek Latzer LLP (New York, NY)

Henry P. Doggrell
Vice President and General Counsel
GTx, Inc. (Memphis, TN)

Thomas S. Kim
Senior Director of Intellectual Property
VGX Pharmaceuticals, Inc. (Blue Bell, PA)

Christine McCormack
Senior Patent Attorney
AstraZeneca Pharmaceuticals LP (Boston, MA)

• Defining the business goals of the transaction
  - Why is the IP important to this particular transaction?
  - Does the IP accomplish the company's goals?
• Identifying, measuring, and quantifying the competitive landscape
• Understanding the company's financial limitations, deal rationale,
  and deadlines to prevent surprises during the due diligence process
  - Clarifying the due diligence assignment for the transaction
  - Allocating the company's budget to fulfill the due diligence review
  - What should or should not be in writing in the due diligence process?
• Measuring the depth of your due diligence based on the company's proposed transaction, goals, and past experience
  - Partnership
  - Collaboration
  - Joint Venture
  - License
  - Acquisition
  - Merger of equals
• Matching the due diligence required with the subject of the transaction
  - Product line
  - New product
  - Company in whole
• Setting realistic expectations for the company and creating an effective game plan
  - How far will the company continue with due diligence if you uncover factors negatively impacting the IP’s value?
• Cultivating a communication process to update the business decision makers with the progress of the due diligence in an ongoing manner

10:00  Coffee Break

10:15  Navigating the Dynamic Labyrinth of Recent Cases, Rules, and Regulations Affecting the Company’s Due Diligence Analysis

Mary Ann Dillahunty
Vice President, Intellectual Property
Oncolytics Biotech, Inc. (Calgary, AB)

Eric J. Marandett
Partner and Chair, Intellectual Property Litigation Group
Choate Hall & Stewart LLP (Boston, MA)

Mark Rachlin
Senior Patent Counsel, Litigation
GlaxoSmithKline (King of Prussia, PA)

The complexities of cases in the pharmaceutical and biotech arenas add new layers of responsibility for the due diligence team. The greatest challenge is forecasting the cases’ impact on the IP. Additionally, due diligence attorneys must incorporate PTO rules and regulations into a due diligence review to fully gauge the consequences on the IP. This session will provide insight, clarity, and expertise on this volatile area.

• Metabolite (patentable subject matter)
• Aventis, Nilssen, McKesson (inequitable conduct)
• Quanta (patent exhaustion)
• In Re Seagate (patent validity, privileges)
• KSR (obviousness)
• Medimmune (patent validity)
• Roche (second-tier patents)
• EBay (compulsory licenses)
• Enzo (authority of Board of Patent Appeals)

11:15  Setting up an Electronic Data Room to Protect the Company’s Vital Interests

Richard J. Berman (Moderator)
Partner
Arent Fox LLP (Washington, DC)

Steven A. Bossone
Patent Counsel
Shire HGT, Inc. (Cambridge, MA)

Thomas David
Senior Vice President, Operations
Avalon Pharmaceuticals, Inc. (Germantown, MD)

• Ensuring that the business decision makers mirror your communications and update you frequently on changes in exit strategies, renegotiation points, and deal value assessment
• Predicting fires that you may have to put out during the due diligence research
• Tailoring a flexible due diligence checklist to the type of transaction, the company’s goals, and the case law
• Editing the checklist to eliminate irrelevant actions
• Selecting, managing, and monitoring outside counsel for the company’s transactions
• Picking the company’s internal due diligence team members according to the specific transaction

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- Creating a mechanism that allows the expansion of access as needed
- Deciding the physical location of the electronic data room
- Encrypting the information if data is accessible on an Internet site
- Monitoring the copies of documents that leave the room
- Protecting against a breach of confidence through the duplication of documents

12:15 Networking Luncheon

1:30 Sweet Land of Liberty…Let Freedom to Operate Ring!

Michelle L. Lewis
Senior Patent Attorney
ZymoGenetics, Inc. (Seattle, WA)

David S. Resnick
Partner and Leader, Biotechnology/Chemistry Team
Nixon Peabody LLP (Boston, MA)

Brian J. Walsh
Assistant General Counsel
ZymoGenetics, Inc. (Seattle, WA)

• Classifying the patents in question to identify issues that will affect the company's freedom to operate
  - Gauging the weak spots that will lessen the company's ability to commercialize the patent at issue
  - Defining the changes in the law, marketplace, and technology that may negatively impact the patent's value
  - Predicting the scope of the patent in a volatile, uncertain, and challenging patent landscape
  - Factoring the patents’ exposure to risk of litigation
  - Identifying potential patent term extensions of competitors and the target company
  - Examining the dangers of potential blocking IP
  - Looking beyond the target company's affirmations to ensure the necessary information that protects attorney-client privilege

3:35 Refreshment Break

4:05 I've Got A Trade Secret: Incorporating the Target Company’s Soft IP Assets in Your Due Diligence Analysis

Carl C. Butzer
Partner
Jackson Walker LLP (Dallas, TX)

Beth G. Maser
Director of Business Critical Research
The History Factory (Chantilly, VA)

Andrew A. Paul
Senior Counsel
Procter & Gamble Company (Cincinnati, OH)

• Determining the pharma or biotech company's trade secrets and their strength
  - Why did the company decide to protect under trade secret law and not patent law?
  - How strong is the trade secret protection under current case law?
• Examining the impact of protecting the asset under a patent instead of a trade secret
• Establishing the extent of people privy to the company’s IP trade secrets
• Examining the value of the target company’s good will according to Generally Accepted Accounting Principles
• Creating a timeline of the company's history, use, and marketing of its trademarks
  - How has the target company monetized its trademarks?
  - Conducting an independent trademark search to uncover potential gaps in the chain-of-title that can affect the trademark value
  - Identifying potential competitors, infringers, and counterfeiters with similar trademarks

5:15 Conference Adjourns To Day Two

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7:30    Continental Breakfast
8:30    Co-Chairs’ Opening Remarks
8:40    Using Due Diligence to Reveal, Analyze, and Measure the Specific Risks for the Pharmaceutical or Biotech Target or Licensor

Kate Deeley
Senior Vice President & General Counsel
Trubion Pharmaceuticals (Seattle, WA)

Seth H. Jacobs
Senior Patent Counsel
Pfizer, Inc. (New York, NY)

George C. Jen, Ph.D.
Senior Director, Legal Global Partnership
Roche Palo Alto LLC (Palo Alto, CA)

Thomas G. Plant
Assistant General Patent Counsel
Eli Lilly and Company (Indianapolis, IN)

Ira A. Schreger (Moderator)
Partner
Loeb & Loeb LLP (New York, NY)

- Organizing a complete history of the IP in question to minimize the danger of missing information that will affect the due diligence review and potentially the deal
  - Assignments
  - Source documents
  - Chain-of-title
  - Exclusive vs. Non-Exclusive licenses
  - Confidentiality Agreements
  - Marketing strategies
- Ensuring that the target company has rights to the IP it is selling or licensing
- Crafting a method of disclosing relevant information that allows the tracking of persons with access to the information
- Assessing the validity, value and consequent risk of the IP at issue
  - Identifying, measuring, and countering potential challenges to the patent
  - Expanding the scope of the due diligence to encompass other patents in the patent family
  - Confirming the revenue generated and projected by the patent
- Guarding against the loss of institutional knowledge triggered by the departure of long-term employees
- What are the company's obligations to disclose testing results, methods, and theories?
- Uncovering common pitfalls in the licensor's patent portfolio
- Developing a productive working relationship with the licensor
- Compiling a discrete package of information that demonstrates everything the target disclosed to the potential buyer, licensee, or collaborator
- Protecting against future fraud claims

10:00    Coffee Break
10:10    Dissecting the Due Diligence Challenges for a Pharma/Biotech Acquirer, Licensee, or Collaborator

Allen R. Baum (Moderator)
Partner
Brinks Hofer Gilson & Lione P.C. (Raleigh, NC)

Luisa Bigornia
Vice President, Intellectual Property
BioMarin Pharmaceutical, Inc. (Novato, CA)

William R. Majarian
Vice President, Corporate Intellectual Property
GlaxoSmithKline (King of Prussia, PA)

Bruce A. Pokras
Senior Corporate Counsel
Pfizer, Inc. (New York, NY)

- Ensuring that you have all relevant information about transactions, agreements, and communications from the seller, licensor, or collaborator
  - Obtaining access to the inventors’ notebooks, records, and memoranda along with internal legal communications
  - What documents may exist that you don’t already have?
  - Getting information about an agreement that’s redacted
- Evaluating the target company's Orange Book listings
  - Dissecting the ramifications of overlisting and underlisting
- Gauging the strength, validity, and value of the IP protection independently
- Adjusting the due diligence strategy to consider the impact of the courts’ view of actions that lead to inequitable conduct
  - How do the courts analyze materiality and intent?
- Presenting the uncovered risks to management in a way that management can fully understand, evaluate, and act accordingly
- Creating due diligence request lists
  - Supplying a draft of the technical agreement
  - “Road testing” the target’s IP to determine whether it can withstand litigation
- Analyzing the validity of the target company's patents
  - Looking at the target company's patents with a litigator’s perspective and applying a KSR analysis to determine their strength in potential litigation
- Adjusting your strategy to obtain as complete a picture as possible of the target’s IP

11:30    Balancing between the Company’s Attorney-Client Privilege and the Need to Disclose Information

Thomas E. Duley (Moderator)
Of Counsel
Morgan Lewis & Bockius LLP
(San Francisco, CA)

Kelly L. McDow
Associate General Counsel, Associate Director
The Procter & Gamble Company (Cincinnati, OH)

Richard B. Murphy
Vice President, Intellectual Property
sanofi pasteur (Swiftwater, PA)

- Drafting a joint representation agreement that will serve both sides during due diligence
  - Clarifying what will be disclosed during due diligence
  - Warranting that the company’s information will be protected if the transaction is not completed
- What is the appropriate level of disclosure for the target company’s R&D plans involving the IP at issue?
- When do you allow access to the company’s patent opinions?

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Adjusting Your Due Diligence Approach in Transactions with Universities

Wesley D. Blakeslee
Executive Director of Johns Hopkins Technology Transfer
Johns Hopkins University (Baltimore, MD)

Tena Herlihy
Counsel
MIT Technology Licensing Office (Cambridge, MA)

Cynthia L. Kanik, Ph.D. (Moderator)
Of Counsel
Lahive & Cockfield, LLP (Boston, MA)

Jeffrey M. Sears, Ph.D.
Associate General Counsel
Columbia University (New York, NY)

• Determining the level of profit sharing for university researchers in the pharmaceutical and biotech fields
• Identifying the university researchers and their potential legal claims
  - To what extent will university researchers battle for inclusion on patents, profits, or notoriety?
• Setting the company's expectations on the university's promises of a patent portfolio against the financial, time, and personnel resources of the university
• Understanding the university's motivations to fully evaluate their IP decisions
• Negotiating the return of rights if the licensee fails to commercialize the IP
• How can the university's choices of patent prosecutors influence future handling of the patents at issue?
• Managing expectations of timelines that can be delayed given bureaucratic academic processes and a seemingly lesser need for profit than the private sector
• Incorporating the laws unique to universities in your due diligence review
• Countering the potential negative impact of researchers publishing key data prior to obtaining patent protection?
  - Desire to exploit vs. Desire to publish

Analyzing the Needs of a Venture Capitalist in the Company's Due Diligence Research

Barbara A. Ruskin, Ph.D. (Moderator)
Partner, Ropes & Gray LLC (New York, NY)

Mary Lincoln Campbell
Managing Director
EDF Ventures, (Ann Arbor, MI)

Thomas D. Weldon
Chairman and Managing Director
Accuitive Medical Ventures (Duluth, GA)

Alex Zisson
Partner, Thomas, McNerney & Partners, LLC (Stamford, CT)

• Ensuring the VC knows the limitations on information uncovered during due diligence
• Guiding the VC’s outside counsel successfully through the labyrinth of due diligence by reducing focus on minutiae that does not impact the deal value
• Fostering a collaborative relationship with the VC’s outside counsel to form the basis of a smooth due diligence process and potential future deals

Assessing the Findings of the Due Diligence Review upon Its Completion

James M. Gould
Legal Director – Global Patent Litigation
Schering-Plough Corporation (Kenilworth, NJ)

David P. Frazier, Ph.D.
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner LLP (Washington, D.C.)

• Evaluating the company’s options when discovering negative information in a late stage of the transaction
• When should an acquirer abdicate the deal, change the price, or prompt corrective action?
• What is the level of risk that the acquirer is willing to assume in light of competitors with different risk levels?
• Deciding whether to expand the scope of the due diligence review
• Crafting a strategy to effectively confront the target company with information that could impact the deal

Networking Luncheon
Sponsored by Ropes & Gray

12:30 Networking Luncheon

Refreshment Break
3:45

Assessing the Findings of the Due Diligence Review upon Its Completion

3:55

M A S T E R C L A S S
FRIDAY JANUARY 30, 2009 - 9:00 – 12:00

Drafting a Comprehensive Due Diligence Report - One Size Does Not Fit All

Christine P. Bellon
Vice President, Intellectual Property and Legal Affairs
Hydra Biosciences, Inc. (Cambridge, MA)

Adda C. Gogoris
Partner
Darby & Darby P.C. (New York, NY)

Mercedes K. Meyer, Ph.D.
Partner
Drinker Biddle & Reath LLP (Washington, D.C.)

Because each deal has its own idiosyncrasies, complexities, and pressures, due diligence attorneys need an effective report drafting strategy. Further, the due diligence team must be able to act quickly, deftly, and precisely when structuring its report specifically for the transaction at issue. In this intensive, interactive, and hands-on Master Class, our faculty will penetrate the complexities of drafting an effective due diligence report, including:

• Creating an executive summary to clarify the major points of the due diligence report
• Clarifying the analysis used to assess the company's risk in moving forward with the transaction
• Preserving the integrity, value, and confidentiality of the due diligence report
• Factoring the search results, patent validity, and case law in the due diligence report
• Analyzing the costs associated with strengthening the protection of the IP
• Looking beyond the business transaction to potential litigation involving the IP post-closing
• Identifying points of exposure should the IP be the subject of future litigation
• Presenting a complete picture of other agreements, promises, and obligations involving the IP

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Exceptional intellectual property attorneys in the pharmaceutical and biotech industries will show you how to conduct a thorough, successful, and efficient due diligence review. Learn from the experts at:

6th National Conference On

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