Position your company in light of emerging trends in deal structuring and increasing M&A activity

Optimize business development strategies by incorporating the key takeaways from recent life sciences deals

Structure option deals including multiple staged acquisitions and hybrid deals to meet both parties’ objectives

Negotiate milestone payments and other essential critical terms to maximize profitability

Raise capital by cultivating lucrative relationships with key industry players including universities, research institutions, non profits and government organizations

Strengthen bargaining position through an effective due diligence analysis

Protect assets and minimize risk by including critical termination provisions

Forge strategic alliances to facilitate continued growth and sustainability in emerging markets

Maintain effective alliance management to ensure mutually beneficial influx of capital and resources

Additionally, gain hands-on and in-depth guidance into conducting a thorough IP due diligence analysis to assess true asset and portfolio value before a deal at the Life Sciences IP Due Diligence Boot Camp.

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Life sciences companies’ future successes hinge upon successful partnerships — gain the advanced strategies your company needs to maximize profit and revenue by forging mutually beneficial collaborative agreements.

The flurry of big-dollar deals and the upswing in mergers and acquisitions in 2011 points to a clear trend: successful collaborative agreements are integral to a company’s ability to bring products to the market and to develop the next generation of therapeutic blockbusters in light of the impending patent cliff. At ACI’s Fifteenth Advanced Forum on Structuring, Negotiating, and Managing Life Sciences Collaborative Agreements and Acquisitions, learn proven effective techniques to structure alliances and negotiate the best terms to meet your company’s critical needs.

Meet the key dealmakers who will give you the contacts and intelligence you need to launch your company and product portfolio to the next level.

A frontline faculty of senior industry insiders — including senior executives and corporate counsel from Merck, Amgen, Genentech, Gilead, Pfizer, Medtronic, GlaxoSmithKline, Exelixis and many more — will share best practices to enable your company to advance its key business development strategies, including:

- Expanding product lines through new technology and entrance into strategic emerging markets
- Structuring options and payments to meet specific financial needs and account for cost and risk sharing
- Negotiating partnerships and obtaining funding to translate early stage research into commercial products
- Positioning your IP portfolio to enhance competitive position
- Building flexible provisions for potential future M&A into your agreement

Replenish pipelines, reduce development costs and risks, and leverage existing assets

While there are many challenges for life science companies in the current economy, including the looming loss of patent protection on many blockbuster drugs and skyrocketing research and development costs, there is also an enormous potential for growth through strategic partnerships. This conference will arm you with the tools and connections to maximize the value of any deal and protect your assets.

Be confident that there are no impediments to commercializing the IP

Protect potentially lucrative business opportunities and spot the red flags that can cause a good deal to go bad at our full-day post-conference Master Class: Life Sciences IP Due Diligence Boot Camp. Whether you are on the acquiring side or the targeted side, you cannot afford to miss the opportunity to learn proven-effective tactics from leading in-house IP counsel to determine the value of the true commercial value of the property.

Join your colleagues and get the most current and comprehensive information and advice on structuring and managing collaborative agreements, in an environment that will provide valuable networking opportunities with the players driving the year’s top deals.

Register now by calling 888-224-2480, faxing your registration form to 877-927-1563 or registering online at www.AmericanInstitute.com/CollabSF.

Who You Will Meet

- Biotech, Pharmaceutical and Device Professionals
  - Business Development
  - Licensing and IP Executives
  - Alliance Managers
  - General / Corporate Counsel
- Attorneys practicing in the areas of:
  - Life science transactions
  - Intellectual property
  - Licensing

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Day One: Wednesday, July 20, 2011

7:30 Registration and Continental Breakfast

8:15 Co-Chairs’ Opening Remarks

Louisa M. Daniels
VP & Asst. General Counsel
Pfizer Inc (South San Francisco, CA)

Emily Leonard
Partner
Covington & Burling LLP (Silicon Valley, CA)

8:30 Market Watch: Understanding the Driving Forces and Changing Dynamics Impacting the Current Deal-Making Landscape

Philip J. Honerkamp
Vice President, Deputy General Counsel
Jazz Pharmaceuticals, Inc. (San Francisco, CA)

Ron Myers
Vice President, Corporate Development and Legal Affairs
VLSI Corp (Seattle, WA)

Cheri Kwok PhD, CLP
Senior Vice President, Corporate Development
Poniard Pharmaceuticals (San Francisco, CA)

Francis J. Aquila
Partner
Sullivan & Cromwell LLP (New York, NY)

Judith A. Hasko
Partner
Latham & Watkins (Menlo Park, CA)

• Assessing recent trends in deal structuring
  - Where does the pendulum stand between biotechs and pharma?
  - Exploring the FIBCO (fully integrated biotech pharmaceutical company) model
  - Relative negotiating strength evidenced in the terms of recent transactions
  - How have the year’s mergers and acquisitions impacted negotiating agreements?

• Reviewing drivers behind evolving types of alliances
  - How deal strategies are being adjusted to account for recent regulatory developments and shifts in intellectual property law
  - Heightened partnering activity by generic manufacturers
  - Impact of the growing use of royalty monetization by life science companies as a method for securing financing

• Correct takeaways from the year’s top deals
  - What rights were granted and underlying development strategies
  - Recognizing how certain other rights may have been retained
  - Examining how the parties came together and arrived at mutually beneficial terms
  - Analyzing current market information on financial deal terms
  - Dissecting recent upfront and milestone payments
  - What royalties are being negotiated for different drug candidates

9:45 Integrating Increasing M&A Activity into Your Business Development Strategy

Jennifer B. Johnson, CPA
Manager, Transactions, Worldwide Business Development
GlaxoSmithKline (King of Prussia, PA)

Scott Joachim
Partner
Perkins Coie (Palo Alto, CA)

Ruth Voor
CEO
Vivorte LLC (Louisville, KY)

• Looking at the M&A market and what types of deals are currently on the horizon
  - Why dealmakers are expecting things to heat up in 2012
  - Assessing valuation trends and any disparities between the perceived value of companies and the prices being paid
  - Evaluating whether your potential partners may be looking to be acquired
  - Investigating their respective goals
  - Determining who the decision makers are
  - Performing a proactive audit in advance of various types of negotiations
  - Identifying different financial terms for a collaboration that may serve to facilitate or hinder a later acquisition
  - Selecting appropriate terms for the possibility that a partnership will lead to a full M&A
  - Rights to the co-developed intellectual property
  - Terminating the arrangement
  - Right of first refusal
  - Right of first offer
  - Right to participate in any future financing activity
  - Protecting the company should a change of control take place
  - Including for drafting change-of-control provisions in the initial agreement

11:00 Morning Coffee Meet-and-Greet

11:15 Best Practices for Selecting the Deal Structure and Negotiating Your Most Beneficial Collaborative Agreement Yet

Michael Flaschen
Corporate Counsel
Amgen (Thousand Oaks, CA)

Catherine A. Sazdanoff
Vice-President, Corporate Development
Takeda Pharmaceuticals International (Chicago, IL)

Jeff Wade
Executive Vice-President of Corporate Development and Chief Financial Officer
Lexicon Pharmaceuticals (The Woodlands, TX)

Daniel Boeglin
Partner
Baker and Daniels (Indianapolis, IN)

Marya A. Postner, Ph.D.
Partner
Cooley LLP (Palo Alto, CA)

• Weighing alternatives and what will best meet your company’s needs when negotiating provisions for:
  - Straight licensing
  - Co-promotion
  - Co-commercialization
  - Co-development
  - Cross-licensing
  - Profit-sharing and co-funding
  - Out-licensing

• Ensuring that your business models are incorporated into the deal
• Protecting rights on future developments
• Drafting terms for mutually beneficial co-promotions and incorporating provisions for monitoring/audits of performance
• Matching the best compensation structure for the needs of the parties
• Upfront and milestone payments
• Structuring royalty payments
• Cost/profit sharing
• Co-development and co-promotion allocation
• Equity/loans
• Novel structures that work
• Ensuring proper timings for payments are structured into the agreement to prevent economic losses
1:45 Negotiating Options, Staged Acquisitions, Hybrid Transactions and Straight-Forward M&As

Brian P. McVeigh, CPA, CMA, CLP MBA
Vice President, Worldwide Business Development Transactions
GlaxoSmithKline Pharmaceuticals (King of Prussia, PA)

Jason Okazaki
Senior Director, Corporate Legal
Gilead Sciences, Inc. (Foster City, CA)

Adam Golden
Partner
Kaye Scholer LLP (New York, NY)

Gilead Sciences, Inc. (Foster City, CA)

Stephen Johnson
Partner
Kirkland & Ellis LLP (San Francisco, CA)

Allergan Inc. (Irvine, CA)

Henry Ma
Contracts Counsel
Merck & Co., Inc. (Whitehouse Station, NJ)

Adam Golden
Partner
Kaye Scholer LLP (New York, NY)

• Evaluating different options for the transaction
  o Two-step vs. one-step acquisitions
  o Multi-step staged acquisitions
  o Milestone-based M&A
  o Spin-offs
  o Reverse spin-outs
• Comparing different option structures and timelines
• Drafting adaptable agreements
• Incorporating deal protection
• Including effective representations and warranty provisions
  o Addressing legacy rights and obligations under prior licensing agreements
  o Indemnification/insurance provisions

3:00 Afternoon Coffee Meet-and-Greet

3:15 Streamlining Entry into Lucrative Emerging Markets via Strategic Partnering

Sundeep Lal, Ph.D., MBA
Executive Director and Head,
Emerging Markets Business Development
Global Human Health Business Development
Merck & Co., Inc. (Whitehouse Station, NJ)

Henry Ma
Contracts Counsel
Allergan Inc. (Irvine, CA)

Stephen Johnson
Partner
Kirkland & Ellis LLP (San Francisco, CA)

• Evaluating which emerging areas to look to for international deals
• Pros and cons of current hot spots for partnerships outside of the U.S.
• Predicting future economic conditions in different emerging markets
• Key players and recent business development deals
• Contrasting the deal structuring frameworks of Russia, Brazil, India and emerging Asian markets
• Uncovering and contrasting the legal and regulatory deal structuring framework and cultures of Asia and the European Union
• Macro drivers moving the emerging growth market
• Exploring the pharma gold rush into emerging markets
• Assessing the potential for negotiating a successful joint venture with a foreign entity
  o Evaluating whether the companies can work together effectively
  o Devising a strategy for leveraging your partner’s local strengths
  o Anticipating what obstacles will have to be faced and the potential deal-breakers
• Setting terms for profitable co-promotions and negotiating provisions for sharing local sales
• Avoiding common pitfalls associated with global agreements and steering clear of contract terms that violate the legal requirements of foreign jurisdictions and may risk invalidation
• Employing a practical local IP strategy within the agreement
• Ensuring that foreign patent laws are considered before marketing your products in new markets

4:15 Beyond the Shadow of the Valley: Alternative Pathways and Partnerships to Facilitate Funding Drug Discovery and Development

Louisa M. Daniels
VP & Asst. General Counsel
Pfizer Inc (South San Francisco, CA)

Karin Hehenberger, M.D., Ph.D.
Senior Vice President, Strategic Alliances
Juvenile Diabetes Research Foundation (JDRF) (New York, NY)

Shannon Shanahan
Associate General Counsel
Program for Appropriate Technology in Health (PATH) (Seattle, WA)

• Analyzing the potential for non-profit organizations to collaborate with for-profit companies with potential product lines aligning with their charitable purposes or missions
• Identifying foundations and therapeutic areas with compatible goals and ideals to maximize funding partnership possibilities
• How “big pharma” and smaller companies can strategically align with non-profit to meet competing objectives and mutually benefit from strategic alliances with non-profit foundations
• Attracting investors with funding abilities and regulatory connections
• Determining the appropriate level of input and oversight for this evolving business model
• Translating research and development discoveries into actual drugs, diagnostics, and vaccines
• Strategies for overcoming potential limitations on market size or profitability

5:15 Conference Adjourns to Day 2

Day 2: Thursday, July 21, 2011

7:30 Registration and Continental Breakfast

8:15 Co-Chairs’ Opening Remarks

8:30 Preparing for the Exit: Proactively Drafting Critical Termination Provisions to Protect Company Assets

Laura Berner
Senior Corporate Counsel, Transactional Law Group
Genentech (South San Francisco, CA)

Suzan V. Levin
Senior Attorney, Research Unit Counsel
Pfizer Inc (Cambridge, MA)

Marjorie C. Wagner
Associate General Counsel
Cytokinetics, Inc. (South San Francisco, CA)

Emily Leonard
Partner
Covington & Burling LLP (Silicon Valley, CA)

• Understanding what safeguards must be included in the agreement in regards to the current economic environment
• Ensuring both parties retain some value to the product at the end of the day
• Clearly defining the circumstances that warrant termination
• Drafting unwind provisions to ensure a smooth transition
  o Reversion rights
  o Related compensation considerations
  o Ownership of IP rights – who retains them in the event of termination?
  o Partial termination issues
  o Obligations to transfer programs
• Determining the effects of termination on existing sublicenses
• Strategies for enforcing cooperation in the event of termination
• Looking at how the right termination provisions impacted real deals

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9:45  Protecting Current and Future Collaborations: The Dos and Don'ts of Partnering / Negotiations

Rrekha Hemrajani
Vice President, Business Development
Exelixis (South San Francisco, CA)

Thomas E. Daily
Of Counsel
DLA Piper (San Francisco, CA)

- Dissecting failed agreements that ultimately led to litigation between the parties
- Repartnering a returned compound and overcoming stigma
- Assessing terms in distribution agreements that can be a problem down the road
- Drilling down to what the respective parties are being permitted to do in terms of product development and marketing and anticipating where things can go wrong
- Helping to ensure that the parties can get along by:
  o Assigning parties' roles to ensure a clear decision making process
  o Implementing a dispute resolution mechanism
  o Determining when it makes sense to have joint control
  o Assessing risks and benefits of giving control to one party
- Creating terms to help ensure your product is developed and makes it to market
  o Effective terms for incentivizing the other party
  o Setting benchmarks and the methods for resolving changing circumstances
  o Identifying the right people to move the deal forward
  o Overcoming regulatory hurdles including compliance with recordkeeping and reporting requirements
- Using best practices for establishing clear milestones and deliverables
- Providing for how the parties will defend against lawsuits and patient complaints

10:45  Networking Coffee Break

11:00  Aligning Divergent Interests to Negotiate Mutually Beneficial Collaborative Research Agreements with Academic Institutions

Joel B. Kirschbaum, Ph.D.
Director, Office of Technology Management
University of California San Francisco (San Francisco, CA)

Michael G. McCully
Head of Business Development and Licensing
Elan BioNeurology (South San Francisco, CA)

James R. Zaniewicz
Director, Office of Technology Transfer
University of Louisville (Louisville, KY)

Thomas F. Magnani
Director, Co-Chair, Intellectual Property & Competition Practice Group, Howard Rice Nemerovsk Canady Falk and Rabkin PC (San Francisco, CA)

- Current synergies, cultural differences and common objectives between industry and academia
- Crafting agreements with individual scientists or academic departments
  o Defining the three main types of agreements with universities: material transfer agreements, licensing, and research collaborations
- Balancing interests in confidentiality v. publication rights
- Demystifying the legal, regulatory and tax restrictions unique to academia that impact the contract terms
  o Stanford v. Roche
  o Bayh-Dole Act – can a university assign patents?
  o NIH Guidelines – the impact of federal funding
  o foundation grant mandates
- Effectively negotiating contested issues with academic institutions:
  o Ownership of IP
  o Responsibility for patent costs covering joint inventions
  o Rights to improvements
  o Exclusive commercialization rights
  o Sublicensing provisions
  o Pricing issues
  o Indirect costs for sponsored research
  o Allocation of risk
- Setting royalty terms and establishing valuation with nascent technology

12:15  Networking Lunch

1:30  Utilizing Applicable Valuation Models to Set Realistic Expectations for a Deal

Gary Brewster
Senior Vice President, Healthcare Practice
Houlihan Lokey Howard & Zukin (San Francisco, CA)

Joe Dillon
President
Dillon Capital Strategies (West Chester, PA)

Jeffrey C. Selman
Partner
Nixon Peabody LLP (Palo Alto, CA)

Annika Reinemann, CFA, ASA
Partner
Cogent Valuation (San Francisco, CA)

- Devising appropriate and useful models for establishing valuation
  o For early-stage v. late-stage compounds
  o Distinguishing between buyer and seller valuation
  o Using comparables as a basis for value
  o Establishing what to do if there are no comparables
- Understanding the different components that contribute to valuation and ensuring that there are no disconnects
  o Providing for sufficient consideration of product patents, regulatory approvals, manufacturing rights and know-how and other ancillary IP
- Factoring anticipated market forces and trends into an analysis of product valuation
  o Potential royalties and upfront payments on drugs
- Understanding how companies can position assets for maximum valuation

2:45  Mitigating Legal Risks in the Life Sciences M&A Setting: A Six-Step Approach

Derek Devgun
Principal Legal Counsel, Mergers and Acquisitions
Medtronic (Minneapolis, MN)

- Conducting a baseline legal risk assessment:
  o Areas of risk – FCPA/anti-corruption, anti-kickback laws, labeling/promotion, and more
  o Identifying wants, needs, must-haves and must-not-haves
- Building your diligence team internally and externally
- Tips for the actual process of doing your diligence
  o Determining level of exposure
- What to do if issues are uncovered
  o Taking remedial actions and putting a plan in place
  o Knowing when to walk away (and being prepared to do so)
- Protecting yourself in the definitive agreements
  o Reps and warranties
  o Indemnification
- Planning for the ultimate integration

3:45  Networking Coffee Break
4:00 Licensing Strategies for Biosimilars: Regulatory, Commercial and IP Considerations for the New Frontier

Ralph A. Loren
Partner
Edwards Angell Palmer & Dodge, LLP (Boston, MA)
- Structuring deals and terms that incorporate rights granted under the new pathway
  o Factoring the right safeguards into the agreement
  o Including appropriate terms for addressing exclusivity
  o Analyzing emerging follow-on strategies and players
- What does the current biologic market look like?
  o Identifying potential blockbusters
  o Exploring the potential for new alliances

5:00 Conference Concludes

POST-CONFERENCE MASTER CLASS
July 22, 2011 • 8:30 a.m.—4 p.m. (Registration at 8 a.m.)

Conducting Effective & Strategic Due Diligence for Life Sciences Partnering and M&A

Whether negotiating a merger, collaboration or licensing agreement, the diligence review team must be confident that there will be no impediments to commercializing the IP that is being gained as part of the deal. This in-depth Master Class will help ensure that you make informed decisions regarding how the IP at issue will increase the company’s overall value, whether by expanding a product line or opening the door to emergence in a new market.

Kevin Bastian
Partner
Kilpatrick Townsend & Stockton LLP
(San Francisco, CA)
Donald Zuhn
Partner
McDonnell Boehnen Hulbert & Berghoff LLP
(Chicago, IL)

This session will provide you with insights into how recent court decisions and legislative activity relating to patent law and follow on biologics will affect analyses undertaken during IP due diligence, particularly within pharmaceutical, biotechnology and medical device companies. As patent and IP case law continues to evolve and Congress continues to address key issues relating to patent law and follow on biologics, now is an important time to take inventory of your company’s current diligence review process to ensure that you are up-to-speed on what the current status of the law is on these important issues.

Points of discussion during this session will include:
- Gene patents after Myriad
- The continuing lineage of Medimmune (standing to sue) and Quanta (patent exhaustion)
- Bilski (patentable subject matter) and the USPTO’s interim guidelines on examining patentable subject matter
- Clasen, Prometheus and other Bilski progeny
- Seagate (willfulness and opinions of counsel)
- McKesson/Larson/Exergen (inequitable conduct issues relating to the reporting of art and their potential impact on patent portfolios)
- Unique issues relating to the regulation of and patent exclusivity allowed for follow-on biologics
- Patent reform – an overview of the key provisions

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Properly Aligning the Business Objective of the Deal and the IP Diligence Assessment: An Interactive Checklist

Christine Bellow
Vice President of Intellectual Property & Legal Affairs
Hydra Biosciences (Cambridge, MA)

Nicholas M. Boivin
Director, Intellectual Property Counsel
Cubist Pharmaceuticals, Inc. (Lexington, MA)
Kate H. Murashige
Senior Partner
Morrison Foerster (San Diego, CA)

- Ensuring that the driving force behind the deal and the objectives of the diligence review are properly factored together
  - Knowing what the deal makers are looking for and what “IP due diligence” means to the parties
  - Avoiding runaway patent diligence disconnected from the strategy of the deal
- Determining the appropriate scope and depth of IP due diligence necessary for:
  - Internal IP assessment
  - Auctions
  - Venture based financing/start up investment
  - Strict licensing deals
  - Strategic alliances – collaboration/in-license/co-development/co-promotion
  - Divestiture/spin outs
  - Mergers and acquisitions
  - Subsequent private placement
  - Public offering
- Updating the checklist based on the type of the transaction
- Deciding what not to include in the checklist
- Knowing when to go outside of the checklist when appropriate during due diligence review
- Examples of different types of checklists
- Choosing the right counsel for the deal
- Assigning roles for senior management and involving the supporting players
- Discussing new and evolving methods for conducting the review process while also mitigating your risk and exposure

Regulatory Considerations
- Understanding how Orange Book listings affect your diligence analysis
- Accounting for the impact an abbreviated approval pathway for biologics will have on your diligence assessment
- Medical device clearance – reviewing the status of 510(k) submissions for patented products

Afternoon Networking Break

Who Invented What When? Reducing and Resolving Inventorship Disputes

Warren D. Woessner, J.D., Ph.D.
Founding Shareholder
Schwegman Lundberg & Woessner (Minneapolis, MN)

- Legal standards of inventorship
  - Inventorship vs. co-authorship
  - Identifying inventors early in the process
  - Changing named inventors – the how’s and when’s
  - Resolving inventorship disputes – some case studies including *Stanford v. Roche*

- Have the Bayh-Dole requirements been met?
- Determining whether or not the target owns or has adequate rights in the patent estate and proprietary technology
  - Who is the owner of record?
  - Doing a title search – are there any existing liens on the target’s IP?
  - Making certain that the target company can convey clear title
- Uncovering whether the target’s patents have been properly maintained in compliance with statutory requirements
- Employing techniques for effectively documenting who owns what and what entities are involved
  - Clearly establishing exclusive and non-exclusive rights
- Options for dividing up control of IP based on field of use

Ensuring that the Purchaser/Licensor Has the Right to Commercialize the IP at Issue

Margaret “Peg” M. Buck
Head of Section, U.S. Legal Affairs and Patents
Lundbeck Research USA (Paramus, New Jersey)

- Requesting the necessary materials and information from the target
- If FTO analysis was previously performed, critically reviewing the target’s FTO opinion
- Has there been an appropriate FTO analysis relating to the source and production of underlying tangible materials?
- Has IP been encumbered through material transfers with third parties?
- Designing an appropriate search
- Assessing infringement risks
- Identifying and analyzing potential blocking patents
- Addressing other FTO concerns
  - Critically reviewing asserted Orphan Drug status
  - Analyzing current case law that can affect the FTO analysis
  - Evaluating whether “Safe Harbor” (or EU Bolar) provisions have kicked in

Conference Ends
Registration Form

Life Sciences Collaborative Agreements and Acquisitions
Maximizing Opportunities and Rewards in Your Licensing, Strategic Alliances and Partnering Deals

July 20–21, 2011 • Sheraton Fisherman’s Wharf • San Francisco, CA

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