

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

Benefit from an exceptional faculty of industry dealmakers including:

Allergan	Juvenile Diabetes Research Foundation
Amgen	Lexicon Pharmaceuticals
Baxter Healthcare	Lundbeck Research USA
CoDa Therapeutics	Merck & Co.
Cubist Pharmaceuticals	Medtronic
Cytokinetics	PATH
Dillon Capital Strategies	Poniard Pharmaceuticals
Elan BioNeurology	Pfizer
Exelixis	Takeda Pharmaceuticals International
Genentech	University of California San Francisco
Gilead Sciences	University of Louisville
GlaxoSmithKline Pharmaceuticals	Vivorte
Hydra Biosciences	VLST Corp
Idera Pharmaceuticals	And many more...
Jazz Pharmaceuticals	

Distinguished Co-Chairs:

Louisa M. Daniels VP & Asst. General Counsel Pfizer Inc (South San Francisco, CA)	Emily Leonard Partner Covington & Burling LLP (Silicon Valley, CA)
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At the key forum where the dealmakers who can launch your company to the next level convene, leading in-house counsel, licensing and business development executives, and IP counsel will share their insights and experiences on how to:

- **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.

Media Partners:



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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

Global Sponsorship Opportunities

With more than 500 conferences in the United States, Europe, Asia Pacific, and Latin America, **American Conference Institute (ACI)** provides a diverse portfolio devoted to providing business intelligence to senior decision makers who need to respond to challenges spanning various industries in the US and around the world.

As a member of our sponsorship faculty, your organization will be deemed as a partner. We will work closely with your organization to create the perfect business development solution catered exclusively to the needs of your practice group, business line or corporation.


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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
VLST Corp (Seattle, WA)

Cheni 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 biotech 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 decisions 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

12:30 Networking Lunch

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)

- Evaluating different options for the transaction
 - Two-step vs. one-step acquisitions
 - Multi-step staged acquisitions
 - Milestone-based M&A
 - Spin-offs
 - Reverse spin-outs
- Comparing different option structures and timelines
- Drafting adaptable agreements
- Incorporating deal protection
- Including effective representations and warranty provisions
 - Addressing legacy rights and obligations under prior licensing agreements
 - 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
 - Evaluating whether the companies can work together effectively
 - Devising a strategy for leveraging your partner's local strengths
 - 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 (JDRC) (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. Wagman
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
 - Reversion rights
 - Related compensation considerations
 - Ownership of IP rights – who retains them in the event of termination?
 - Partial termination issues
 - 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

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

Rekha Hemrajani

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

Thomas E. Duley

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:
 - Assigning parties' roles to ensure a clear decision making process
 - Implementing a dispute resolution mechanism
 - Determining when it makes sense to have joint control
 - Assessing risks and benefits of giving control to one party
- Creating terms to help ensure your product is developed and makes it to market
 - Effective terms for incentivizing the other party
 - Setting benchmarks and the methods for resolving changing circumstances
 - Identifying the right people to move the deal forward
 - 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. Zanewicz

Director, Office of Technology Transfer
University of Louisville (Louisville, KY)

Thomas F. Magnani

Director, Co-Chair, Intellectual Property & Competition Practice Group, Howard Rice Nemerovsky 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
 - 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
 - *Stanford v. Roche*
 - Bayh-Dole Act – can a university assign patents?
 - NIH Guidelines – the impact of federal funding
 - foundation grant mandates

- Effectively negotiating contested issues with academic institutions:
 - Ownership of IP
 - Responsibility for patent costs covering joint inventions
 - Rights to improvements
 - Exclusive commercialization rights
 - Sublicensing provisions
 - Pricing issues
 - Indirect costs for sponsored research
 - 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
 - For early-stage v. late-stage compounds
 - Distinguishing between buyer and seller valuation
 - Using comparables as a basis for value
 - Establishing what to do if there are no comparables
- Understanding the different components that contribute to valuation and ensuring that there are no disconnects
 - 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
 - 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:
 - Areas of risk – FCPA/anti-corruption, anti-kickback laws, labeling/promotion, and more
 - 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
 - Determining level of exposure
- What to do if issues are uncovered
 - Taking remedial actions and putting a plan in place
 - Knowing when to walk away (and being prepared to do so)
- Protecting yourself in the definitive agreements
 - Reps and warranties
 - 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

- What will the commercial impact of biosimilars be?
 - o Getting a clear idea of what exclusive rights are being granted to manufacturers
 - o Forecasting potential costs that will be incurred
- Overview of key BPCIA provisions that will affect existing and yet-to-be developed biologic products
 - o What must be submitted and shown to the FDA prior to receiving approval
 - o Classification of ‘interchangeability’ for certain products
 - o Testing to prove similarity to existing product
 - o Requirements for clinical trials and safety and efficacy data

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.

8:30 **Spotting Red Flags that Impact the Value and Success of a Life Sciences Transaction**

Steven J. Ritter, Ph.D., J.D.

Vice President – IP and Contracts

Idera Pharmaceuticals, Inc. (Cambridge, MA)

Experienced members of IP due diligence teams see certain issues arise time and again to significantly derail a potential partnership or acquisition. In this session they will share their “top ten lists” of issues unearthed in the course of conducting effective investigations that led to significant consequences, including specific instances of uncovering:

- Overstatement of IP rights held by the target or partner company
- Previous out-licensing activity
- Pending litigation risks
- Use restrictions that would impact on the business reasons for the partnership

9:30 **Morning Coffee Break**

9:45 **Factoring Recent Relevant IP Developments Into Your Due Diligence Analysis: Biosimilars, Myriad, Prometheus, and More**

Bradford J. Duft

President and CEO

CoDa Therapeutics, Inc. (San Diego, CA)

Peter D. Weinstein, Ph.D.

Corporate Counsel, IP

Baxter Healthcare Corporation
(Westlake Village, California)

Kevin Bastian

Partner

Kilpatrick Townsend & Stockton LLP
(San Francisco, CA)

Donald Zubn

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 has created a new regulatory structure applicable to 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 statutory subject matter
 - o *Classen, 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

11:00 **Properly Aligning the Business Objective of the Deal and the IP Diligence Assessment: An Interactive Checklist**

Christine Bellon

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

12:00 **Networking Lunch**

1:15 **Evaluating the Scope, Breadth, Validity and Enforceability of the Target’s Patents under Evolving Patent Standards and Regulatory Protocols**

Stephen Albainy Jenei

Partner
Frost Brown Todd

Ned Israelsen

Managing Partner
Knobbe Martens Olson & Bear LLP (San Diego, CA)

- Assessing and predicting the strength of the target company’s IP
 - Ensuring that granted patents or pending applications are non-obvious
 - Determining the likelihood that a valuable patent position on the end product will be established from the early stage data
 - Impact of uncertainty on risk assessment and valuation

Patent Considerations

- Predicting the strength of a pending patent especially considering evolving standards and case law
- Including an analysis of competition in the patent review
- Determining the scope of the patent portfolio
- Analyzing the validity of the patent and knowing what grounds exist for finding invalidity
- Examining the enforceability of the target’s patent

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

2:15 **Afternoon Networking Break**

2:30 **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

3:15 **Ensuring that the Purchaser/Licensee 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

4:00 **Conference Ends**

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PLUS, don't miss the in-depth and interactive Master Class that will give you the superior deal-making position:

Life Sciences IP Due Diligence Boot Camp: Conducting Effective & Strategic Due Diligence for Life Sciences Partnering and M&A

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APPROVING MANAGER _____ POSITION _____

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Please quote the name of the attendee(s) and the event code 754L11 as a reference.
For US registrants:
Bank Name: HSBC USA
Address: 800 6th Avenue, New York, NY 10001
Account Name: American Conference Institute
UPIC Routing and Transit Number: 021-05205-3
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Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches and refreshments.

Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

Cancellation and Refund Policy

You must notify us by email at least 48 hrs in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorization. If you are unable to find a substitute, please notify **American Conference Institute (ACI)** in writing up to 10 days prior to the conference date and a credit voucher valid for 1 year will be issued to you for the full amount paid, redeemable against any other ACI conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. ACI reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by ACI for changes in program date, content, speakers, or venue.

Hotel Information

American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "ACI: PHARMA/BIOTECH COLLABORATIONS" conference to receive this rate:

Venue: Sheraton Fisherman's Wharf
Address: 2500 Mason Street, San Francisco, CA 94133
Reservations: (888)–627–7024 or (415)–362–5500

Incorrect Mailing Information

If you would like us to change any of your details please fax the label on this brochure to our Database Administrator at 1–877–927–1563, or email data@AmericanConference.com.

5 Easy Ways to Register

- MAIL** **American Conference Institute**
45 West 25th Street, 11th Floor
New York, NY 10010
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