

American Conference Institute's 12th Advanced Forum on

Structuring, Negotiating and Managing

Pharma/Biotech Collaborative Agreements

Allocating Risk, Responsibilities & Rewards in Licensing, Strategic Alliances and Partnering Deals

July 14 – 15, 2009

Sheraton Fisherman's Wharf • San Francisco, CA

THE event for your legal, business development and licensing teams.
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Morgan Lewis & Bockius LLP

James C. Snipes

Covington & Burling LLP

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University of Utah

VLST Corp.

Leading in-house counsel, licensing and business development executives and expert attorneys in the field will share their insights and experiences on how to:

- **ANTICIPATE** emerging trends in investment capital and current deal structuring
- **STRENGTHEN** market power by ensuring effective due diligence
- **NEGOTIATE** essential critical terms including built-in milestones to maximize profitability
- **DEVELOP** strategies to determine the impact of M&A activity and best position your company for an acquisition
- **MINIMIZE** risks by clearly defining critical termination terms
- **ENSURE** effective alliance management
- **PROTECT** future rights on emerging technologies such as follow-on biologics

Master Class July 16, 2009

Collaborations in Troubled Times: Structuring a Deal with a Struggling Counterparty

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Meet the key dealmakers who will launch your company to the next level and provide the well-needed infusion of capital and products

2009 has ushered in a new paradigm for Pharma/Biotech deal structuring. The current economic climate has altered both the approach and management of collaborative agreements and companies are now struggling to quickly adapt. For Pharma and Biotech companies to survive and thrive, it has become more essential than ever to not only cultivate relationships with the key industry players, but also to maximize the value of the deal and protect your assets by incorporating the evolving trends into current and future agreements.

Based on extensive research with industry professionals, ACI's **Advanced Forum on Structuring, Negotiating, and Managing Pharma/Biotech Collaborative Agreements** was designed to provide you with the most up to date strategic analysis of current deal structuring while also delivering **outstanding networking and business development** opportunities to ensure you walk away with the contacts and intelligence you need to forge successful new alliances.

An exceptional faculty of diverse speakers will show you how to develop and cultivate lucrative relationships by sharing strategies on and solutions for:

- Capitalizing on shifting trends in the venture capital investment landscape
- Drafting critical termination terms
- Forging and protecting lucrative relationships with investors
- Negotiating partnerships with start-up innovators and government programs
- Contending with increased pressure from anxious investor's seeking an immediate healthy return on their investment
- Redefining alliance management priorities
- Positioning your IP portfolio to increase your market power
- Negotiating milestones into the compensation structure
- Converting a licensing deal into an acquisition

Additionally, learn the vital strategies necessary in today's economic environment by attending the Master Class: **Collaborations in Troubled Times: Structuring a Deal with a Struggling Counterparty**

Join your colleagues and register today for this timely event by calling 888-224-2480; by faxing your registration form to 877-927-1563; or registering online at www.americanconference.com/collab2009

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Wendy Tyler
Group Leader & Business Development Executive
American Conference Institute

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DAY 1 – Tuesday, July 14, 2009

8:00 **Registration and Continental Breakfast** 

8:45 **Co-Chairs' Opening Remarks**

Thomas E. Duley
Of Counsel
Morgan Lewis & Bockius LLP

James C. Snipes
Partner
Covington & Burling LLP

9:00 **Predicting Future Trends & Developing Emerging Strategies in the Current Economic Environment**

Yael Weiss, M.D., Ph.D.
Director, Licensing and External Research
Merck and Co., Inc. (San Francisco, CA)

Jones W. Bryan, Ph.D.
Vice President Business Development and Licensing
Supernus Pharmaceuticals (Rockville, MD)

Anna Protopapas
Senior Vice President, Corporate Development and Strategy
Millennium, The Takeda Oncology Company
(Cambridge, MA)

Lesley Stolz, Ph.D.
Vice President Corporate & Business Development
Sunesis Pharmaceuticals, Inc. (South San Francisco, CA)

- Analyzing the impact of the world's current economic state on deal structuring
 - insights on recent deal activity and creative alliances
 - new strategies for protecting IP rights and evolving deal structures
- Shifting trends in venture capital
 - Where is the money coming from?
 - How has the credit crisis changed the investment landscape?
- Increased power of cash-rich Big Pharma and how it's altered the negotiating process
- Lessons learned from the year's top deals
 - getting to the heart of what rights were granted and retained
 - recognizing what the potential pitfalls were
 - how the parties arrived at mutually beneficial terms

10:20 **Morning Refreshment Break** 

10:35 **Conducting Effective & Strategic Due Diligence**

John Wetherell Ph.D. J.D.
Partner, Co-Chair National Life Science Group
Pillsbury Winthrop Shaw Pittman LLP (San Diego, CA)

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

Margaret M. Buck, MLS, JD
Patent Attorney
Lundbeck Research USA, Inc. (Paramus, NJ)

Lauren L. Stevens, Ph.D.
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner
(Palo Alto, CA)

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

- Thoroughly accessing the business need and company's market power
- Preparing an audit of the IP portfolio
- Crafting a due diligence checklist
- Identifying potential partners
 - what makes for a good fit?
 - assessing differing industry perspectives
- Focusing the diligence analysis to take into account time constraints and budget concerns
 - setting clear requirements and milestones
 - knowing when to dig deeper
 - what discoveries should set off alarm bells?
- Discovering potential competitor issues including:
 - checking to make sure that the IP rights are clear
 - potential third-party rights
 - restrictive licenses
- Freedom to Operate reports
 - ensuring that you aren't buying a lawsuit
 - taking into account special business concerns that may lead to increased scrutiny
 - confidentiality concerns and procedures
 - royalty financing
 - fraud and abuse compliance records
 - kickbacks and corporate fraud
 - Sarbanes-Oxley
 - consulting compensation
 - manufacturing concerns: cost of goods, supply arrangement
 - clinical trial strategies
 - prior collaboration and litigation history
 - other ongoing collaborations and resource constraints

Extended Session

12:10 **Networking Luncheon**

1:25 **Negotiating Essential Critical Terms to Maximize Profitability**

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

James C. Snipes
Partner
Covington & Burling LLP (San Francisco, CA)

Jeffrey L. Wade

Executive Vice President and General Counsel
Lexicon Pharmaceuticals, Inc. (The Woodlands, TX)

Tanya Dobash Berlage

Partner and Chair, Life Sciences Practice Group
Saul Ewing LLP (Baltimore, MD)

- Identifying the best deal structure
 - factoring in needs and strengths: what are the companies' business models?
 - treatment of debt or loans that may need to be paid
 - determining the structure that will yield the greatest potential returns
 - straight licensing
 - co-promotion
 - co-commercialization
 - co-development
 - cross-licensing
 - profit-sharing and co-funding
 - out-licensing
- Drafting flexible and simplified terms
 - effectively documenting who owns what and what entities are involved
- Ensuring an equitable share of risk and reward
- Negotiating exclusive and non-exclusive rights: maximizing the value of assets
 - differing agreement terms for diagnostic uses vs. therapeutics
 - options for dividing up control of IP based on:
 - molecules
 - disease indications
 - exclusive geographical restrictions
- Protecting rights on future developments:
 - clinical trials
 - joint improvements
 - preserving freedom to operate
- Drafting terms for mutually beneficial co-promotions
 - setting sales prices and discounts
 - assessing the real value v. the perceived value of a co-promotion deal
 - monitoring/audits of performance

2:40 Afternoon Refreshment Break 🍷

2:50 Developing a Profitable Compensation Structure with Built-in Milestones to Maximize Value

Ron Myers

Vice President, Corporate Development and Legal Affairs
VLST Corp (Seattle, WA)

Cheni Kwok Ph.D., CLP

Senior Vice President, Corporate Development
Poniard Pharmaceuticals (South San Francisco, CA)

Alex Scott

Vice President, Business Development
Eisai Inc. (Teaneck, NJ)

- Inserting creative and flexible terms into the agreement
 - preventing an agreement from becoming too lengthy and complex
- 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
- Selecting the compensation structure that creates the greatest overall project value
 - profit-share vs. royalty
- Ensuring proper milestones are structured into the agreement to prevent economic losses
 - Managing expectations of the parties
- Devising useful valuation models
 - 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

3:30 Structuring the Agreement with an Eye Towards M&A

John Mohr

Senior Vice President, Business Development
CV Therapeutics, Inc. (Palo Alto, CA)

Neil Abdollahian

Senior Director, Business Development
Trius Therapeutics (San Diego, CA)

Jeffrey C. Selman

Partner
Nixon Peabody LLP (Palo Alto, CA)

- Developing an enticing portfolio to attract a buyer
- Anticipating when a deal may turn into an acquisition
 - Preparing an IP audit in advance of negotiations
 - Providing an increased level of security to a buyer
- Determining whether to introduce M&A into the licensing discussion
- Investigating the long-term and short-term goals of the parties
 - to what extent is the potential partner looking to be acquired?
 - assessing whether the company needs external financing that could change the decision makers in the company
- How different financial terms for the collaboration can facilitate or hinder a later acquisition
 - amount paid up front
 - timing of payment stages and incorporating milestones into the agreement
- Selecting appropriate terms for the possibility that the company will be acquired
 - taking the co-developed intellectual property
 - terminating the arrangement
 - retaining other rights in the event of an acquisition
 - right of first refusal on sale of collaborator
 - right of first offer
 - right to participate in any future financing activity

- Protecting the company should a change of control take place
 - trade secrets
 - attorney-client privilege
- Including change-of-control provisions in the initial agreement
 - tips for drafting the provisions to protect the company and account for alternate possible outcomes
 - sample actual language
- Protecting collaborative agreements from antitrust violations
 - current FTC positions and implications of further acquisitions

4:30 Networking Event

Please join the speakers and your peers to continue the day's discussions in a more relaxed setting



5:15 Conference Adjourns for the Day

DAY 2 – Wednesday, July 15, 2009

9:00 Registration and Continental Breakfast

9:30 Co-Chairs' Remarks

9:40 Creating and Implementing Critical Termination Provisions

Thomas E. Duley

Of Counsel

Morgan Lewis & Bockius LLP (San Francisco, CA)
(Former Senior Corporate Counsel and Head of Transactional Group for PDL BioPharma, Inc.)

Judith Ann Hasko

Partner

Latham & Watkins LLP (Menlo Park, CA)

Jonathan S. Dickstein

Partner

Morrison & Foerster LLP (San Francisco, CA)

- Understanding what critical elements must be included in the agreement in regards to the current economy
- Ensuring both parties retain some value to the product at the end of the day
- Clearly defining the circumstances that warrant termination
 - at-will
 - convenience
 - for breach – curable and non curable
 - change of control
 - under what circumstances can you terminate without a breach?
- 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

10:45 Morning Refreshment Break

11:00 Alliance Management: Establishing Governance Structures for Successful Collaborations

Mary Jo Struttmann, MBA, CA-AM

Senior Director, Alliance Management
Astellas US LLC (Deerfield, IL)

Nina Ashton

Vice President, Intellectual Property
Elan Pharmaceuticals, Inc. (South San Francisco, CA)

Andrew A Paul

Senior Counsel
The Procter & Gamble Company (Cincinnati, OH)

- Building a steering committee: assigning parties' roles to ensure a clear decision making process
 - territorial vs. functional allocations
 - assigning the right tasks to the right people in the right organization
 - which qualifications are right for which positions?
- Implementing a dispute resolution mechanism
 - defining voting, veto and tie breaking rights
 - examining options for dealing with ties
 - strategically deciding how to divide up responsibilities
 - negotiating terms when giving up the deciding vote to the other party
 - determining when it makes sense to have joint control
 - factoring in the influence and responsibilities of the parties when determining who decides
 - understanding tensions that arise when responsibility is split
 - assessing risks of giving control to one party
 - negotiating a compromise
- Creating terms to ensure your product is developed and makes it to market
 - moving beyond "commercially reasonable" efforts
 - structuring the deal so the other party is incentivized to develop and/or market the product
 - setting benchmarks and the methods for resolving changing circumstances
 - identifying champions to move the deal forward
 - clarifying who has regulatory responsibility including compliance with recordkeeping and reporting requirements
- Establishing clear milestones and deliverables
- Providing for jointly defending a product
 - contemplating how the parties will defend against lawsuits and patient complaints
 - making the litigation process part of the collaborative agreement
 - execution of joint defense agreements
 - understanding the scope of indemnity provisions
 - managing litigation

12:00 Networking Luncheon

1:15 **Crafting International Business Agreements for Calculated Growth and Sustainability**

Stephen C. Ferruolo

Partner

Goodwin Procter LLP

- Critical review of emerging areas for international deals:
 - what are the hot spots outside the U.S. for development?
- Gaining an increased U.S. presence
- Accounting for decline of international markets and balancing risks with costs when predicting future economic conditions both within the U.S. and in emerging markets
- Enforcing international agreements in China: protecting trade secrets and IP rights
- Strategically aligning with foreign partners for calculated growth
- Avoiding the leading pitfalls associated with international deals
 - weighing the pros and cons of regional v. worldwide deals
 - enforcing licenses abroad
 - focusing on the correct local laws
 - arbitration and handling disputes
 - valuation abroad

2:00 **Afternoon Refreshment Break** ☒

2:15 **Negotiating Collaborative Research Agreements with the U.S. Government and Academic Institutions**

Claire T. Driscoll

Director, Technology Transfer Office

National Human Genome Research Institute (NHGRI),
National Institutes of Health (NIH) (Bethesda, MD)

Brian Cummings

Executive Director, Technology Commercialization

University of Utah (Salt Lake City, UT)

David G. Schetter

Assistant Vice Chancellor for Research (Retired)

University of California, Irvine (Irvine CA)

Bernadette M. Broccolo

Partner

McDermott Will & Emery, LLP (Chicago, IL)

- How is the credit crisis changing business models for drug development?
- What is the impact on licensing with the government?
- Partnering with the government on technologies that serve the public health interest
- Counter terrorism projects and funding for innovative technologies that serve a public health interest
- Investigating the synergies and cultural differences and objectives between industry and academia
 - cultural differences between different universities
 - public vs. private universities and state statutes governing IP transactions
 - understanding the needs of academics
- Crafting agreements with individual scientists or academic departments
 - challenging aspects to communicating and managing faculty

- Defining the three main types of agreements with universities
 - material transfer agreements
 - licensing
 - research collaborations
- Balancing interests in confidentiality v. publication rights
- Demystifying the legal, regulatory and tax restrictions unique to academia that impact the contract terms
 - Bayh-Dole Act – can a university assign patents?
 - NIH Guidelines – the impact of federal funding
 - foundation grant mandates (e.g., Gates Foundation, JDRF)
 - commercial research restrictions (Tax Act of 1986)
 - individual institutional policies
 - working with the IRS regs
 - state fiduciary duties
 - CREATE act
 - limitations to research when investigator leaves
- 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
- Appreciating the difference between government regulations and policies
- Understanding how the nascent nature of the technology coming from academia impacts the deal terms

3:30 **Anticipating Future Technologies and Incorporating Terms into the Agreement to Protect Future Rights**

Ralph A. Loren

Partner

Edwards Angell Palmer & Dodge, LLP (Boston, MA)

- Structuring deals that incorporate follow-on biologics terms into the agreement
 - exploring the future regulatory pathway: what will it look like?
 - what will be the impact on competition and anticipating competitive challenges into the agreement?
 - what essential exclusivity terms can you include before legislation is passed?
- Reviewing other emerging technologies and hybrid technologies including:
 - human cell and tissue-based products
 - nanotechnology
- Negotiating future rights on emerging technologies with the government and research institutions

4:15 **Conference Concludes**

POST-CONFERENCE MASTER CLASS

Thursday, July 16, 2009 | 9:00 a.m. – 12:00 p.m.
8:30 a.m. (Registration and Continental Breakfast)

Collaborations in Troubled Times: Structuring a Deal with a Struggling Counterparty

James C. Snipes

Partner
Covington & Burling LLP (San Francisco, CA)

Amy L. Toro

Partner
Covington & Burling LLP (San Francisco, CA)

The current economic climate has produced a changing dynamic in deal structuring and alliance management. Led by industry experts, this Master Class will walk you through the critical aspects of the negotiating and management processes when forging a strategic alliance during these times of unpredictable market shifts.

Points of discussion include:

- Conducting appropriate IP and financial diligence
- Structuring the deal -- acquisition versus license
- Fashioning protective co-development arrangements
- Ensuring continuity of supply
- Deal structures that protect IP rights in bankruptcy
- Limits on a licensee's protection under the Bankruptcy Code
- Possible deal modifications upon a change of control
- Termination triggers and consequences
- Expedited dispute resolution procedures

WHO YOU WILL MEET

Biotechnology and Pharmaceutical Professionals

- Counsel
- Business development and strategic planning
- Licensing executives
- Alliance managers

Attorneys practicing in the following areas:

- Pharmaceutical, life sciences and health care
- Intellectual property
- Life sciences transactions
- Licensing



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MASTER CLASS

Collaborations in Troubled Times:
Structuring a Deal with a
Struggling Counterparty

July 16, 2009

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