

American Conference Institute's  
13<sup>th</sup> Advanced Forum on:

Structuring, Negotiating and Managing

# Pharma/Biotech Collaborative Agreements

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

THE event for your legal,  
business development  
and licensing teams.

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November 17-18, 2009 • Helmsley Park Lane Hotel • New York, NY

“Very good conference. Issues  
were very thorough and on-  
point for current trends.”

– Rob Aboud, GlaxoSmithKline  
prior delegate November 2008

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

- INTEGRATE emerging trends in investment capital and current deal structuring into your product strategies
- ESTABLISH a strong presence in new and emerging markets
- STRENGTHEN market power by ensuring effective due diligence
- MAXIMIZE profitability through skillful negotiations of critical performance terms
- DEVELOP strategies to determine the impact of M&A activity and best position your company for an acquisition
- GAIN greater control by drafting clearly defined termination provisions
- ENSURE effective alliance management
- PROTECT future rights on emerging technologies such as follow-on biologics

## Featuring 2 Post-Conference Master Classes on November 19, 2009

- A** International Collaborative Agreements: Navigating and Managing the Unique Regulatory and Legal Risks of Global Partnerships
- B** The Win-Win Collaborative Agreement: Practical and Ethical Negotiating and Drafting Strategies

### Meet Dealmakers From:

BioCryst Pharmaceuticals  
Bristol-Myers Squibb  
Eisai  
Endo Pharmaceuticals  
Lundbeck  
Merck  
Neogenix  
National Institutes of Health  
New York University  
Sanofi-Pasteur  
Schering-Plough  
Supernus Pharmaceuticals  
Tactical Therapeutics  
VLST Corp.  
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## Seize the opportunity to unlock lucrative new markets this November by meeting the key dealmakers who will become your next business partners

You've seen the headlines – Big Pharma is evolving into Big Biotech, striking strategic alliances with the innovative biotechnology companies who are developing the next generation of therapeutic blockbusters. Now is the time to open up new markets and revenue streams by cultivating relationships with the key dealmakers essential to thriving in this new dynamic. Meet them at ACI's 13<sup>th</sup> **Advanced Forum on Structuring, Negotiating, and Managing Pharma/Biotech Collaborative Agreements**.

Through a series of interactive business and legal intelligence panels and networking breaks, an exceptional speaker faculty consisting of the year's top dealmakers will share strategies and solutions for:

- Capitalizing on shifting trends in the venture capital investment landscape
- Performing effective due diligence to assess the company's market power
- Identifying the best deal structure that will provide the most potential profit
- Anticipating converting a licensing deal into an acquisition
- Drafting critical termination terms
- Negotiating partnerships with start-up innovators and the government
- Positioning your IP to increase your market power
- Defining alliance management priorities

*Featuring Two Master Classes:*

### **International Collaborative Agreements: Navigating and Managing the Unique Regulatory and Legal Risks of Global Partnerships**

New for this year – A comprehensive and interactive class to successfully navigate collaborations in emerging markets. Gain essential knowledge on global partnerships you must master including the specific legal contractual nuances of India, Asia, and the EU, avoiding invalidation of restrictive terms, minimizing tax liability, and negotiating alliances with foreign academic institutions.

### **The Win-Win Collaborative Agreement: Practical and Ethical Negotiating and Drafting Strategies**

The in-demand Master Class you cannot afford to miss – Earn ethics credits while you walk through a negotiation and gain practical insights you can implement into your next agreement to achieve a win-win successful alliance.

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**Register Today to Secure your Place at the Table by Calling 888-224-2480**  
**[www.AmericanConference.com/collaborations](http://www.AmericanConference.com/collaborations) or Fax your Registration to 877-927-1563**

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ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board in the amount of the 11.5 hours. An additional 3.5 hours will apply to workshop participation (A or B), 1.0 of which will apply to legal ethics for workshop B only.

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## DAY 1 – Tuesday, November 17, 2009

8:00 Registration and Continental Breakfast

9:00 **Co-Chairs' Opening Remarks**

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*Alane Barnes*  
General Counsel  
BioCryst Pharmaceuticals, Inc. (Birmingham, AL)

*Timothy Herpin, Ph.D.*  
Head of U.S. Search, Strategic Transactions Group  
Bristol-Myers Squibb (Princeton, NJ)

9:15 **Predicting Future Trends & Reviewing Emerging Strategies From The Year's Top Deals**

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*Timothy Herpin, Ph.D.*  
Head of U.S. Search, Strategic Transactions Group  
Bristol-Myers Squibb (Princeton, NJ)

*Randall B. Sunberg*  
Partner, Chair Life Sciences Transactions  
Morgan, Lewis, & Bockius LLP (Princeton, NJ)

*Thomas Lytle*  
Chief Operating Officer  
Neogenix Oncology, Inc. (Great Neck, NY)

*Beth E. Arnold*  
Partner  
Foley Hoag LLP (Boston, MA)

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

- Analyzing the impact of the 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
- How have the year's mergers and acquisitions impacted licensing agreements?
- Adjusting deal-structuring strategies to account for the pending enactment of follow-on biologics
- 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

10:30 Morning Break

10:45 **Setting the Stage: Conducting Effective & Strategic Due Diligence**

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*Richard B. Murphy*  
Associate Vice President, Intellectual Property  
Sanofi Pasteur (Swiftwater, PA)

*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)

*Michael F. Hurley*  
Partner  
McDermott Will & Emery LLP (New York, NY)

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

- Thoroughly assessing 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

12:00 Networking Luncheon

1:15 **Negotiating Essential Critical Terms with Built-in Milestones to Maximize Profitability**

---

*Paul Thompson*  
Senior Legal Director, Licensing  
Schering-Plough (Kenilworth, NJ)

*Howard S. Schwartz*  
Partner  
DLA Piper (Baltimore, MD)

*Tanya Dobash Berlage*  
Partner and Chair, Life Sciences Practice Group  
Saul Ewing LLP (Baltimore, MD)

*Alex Scott*

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

*Lori Hoberman (Moderator)*

Principal

Fish & Richardson, P.C. (New York, NY)

- 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
  - 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
    - geography
    - 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
- 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
  - profit-share vs. royalty
- Ensuring proper milestones are structured into the agreement to prevent economic losses
- Managing expectations of the parties

2:30 Afternoon Break

3:00 **Integrating M&A Considerations into Your Collaborations Strategy**

*Kingsley L. Taft*

Partner

Goodwin Procter LLP (Boston, MA)

*Matthew B. Zisk, J.D. Ph.D.*

Counsel

Skadden, Arps, Slate, Meagher & Flom LLP  
(New York, NY)

*Kenneth Krisko*

Partner

Cooley Godward Kronish LLP (Reston, VA)

- 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
  - current FTC positions and implications of further acquisitions

4:30 **Networking Reception**



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

5:30 **Conference Adjourns for the Day**

“ The program was well done – a nice balance in gut level legal issues and business considerations arising in all types of alliances.”

– Gary J. Marini, AstraZeneca Pharmaceuticals LP, prior delegate

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8:30 Continental Breakfast

9:00 Co-Chairs' Remarks

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9:10 **Creating and Implementing Critical Termination Provisions**

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*Alane Barnes*

General Counsel  
BioCryst Pharmaceuticals, Inc. (Birmingham, AL)

*Daryn A. Grossman*

Partner  
Proskauer Rose LLP (New York, NY)

*Emily L. Leonard*

Partner  
Covington & Burling LLP (Washington, D.C.)

*Stephen M. Goodman*

Partner  
Pryor Cashman LLP (New York, NY)

- 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

10:30 Morning Networking Break

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

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*Douglas D. Macpherson*

Vice President and Associate General Counsel  
Endo Pharmaceuticals Inc. (Chadds Ford, PA)

*Ron Myers*

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

*Frank S. Vellucci*

Partner  
Chadbourne & Parke LLP (New York, NY)

*Kenneth Krisko*

Partner  
Cooley Godward Kronish LLP (Reston, VA)

*Faye E. Russell*

Partner  
Latham & Watkins LLP (San Diego, CA)

- 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 **Negotiating Collaborative Research Agreements with the U.S. Government and Academic Institutions**

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*Cynthia J. Zarsky*

Senior Director, Research Contracts and Outlicensing  
Merck Research Laboratories (Rahway, NJ)

*John W. Puziss*

Director of Technology Licensing  
Yale University (New Haven, CT)

*Claire T. Driscoll*

Director, Technology Transfer Office  
National Human Genome Research Institute (NHGRI)  
National Institutes of Health (NIH) (Bethesda, MD)

## *Sadhana Chitale*

Associate Director, NYU Office of Industrial Liaison  
New York University (New York, NY)

- 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

## 2:30 Afternoon Break

## 3:00 Anticipating Future Technologies and Incorporating Terms into the Agreement to Protect Future Rights

### *Eileen Smith Ewing*

Partner

K&L Gates 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

## 4:00 Conference Adjourns

## 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 A

### International Collaborative Agreements: Navigating and Managing the Unique Regulatory and Legal Risks of Global Partnerships

9:00 a.m. – 12:00 p.m.

(8:30 a.m. – Registration and Continental Breakfast)

#### *Tanya Dobash Berlage*

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

#### *Peter Homberg*

Partner  
Jones Day (Munich, Federal Republic of Germany)

#### *Sonia Baldia*

Partner, Chair of India Practice Group  
Mayer Brown LLP (Washington, D.C.)

#### *Radhika C. Pereira, B.Sc., LL.B., LLM*

Partner  
Dudhat Pereira and Associates (Mumbai, India)

- Critical review of emerging areas for international deals:
  - where 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
- Uncovering and contrasting the legal and regulatory deal structuring framework and cultures of Asia and the European Union
- Avoiding common pitfalls associated with global agreements:
  - negotiating critical contract terms that conform with the legal requirements of foreign jurisdictions
  - restrictive terms within the licensing agreement that may risk invalidation
- Employing a practical local IP strategy within the agreement to overcome legal inconsistencies between U.S. and foreign jurisdictions
- Partnering with academic and government institutions in the EU
- Protecting your trade secrets while partnering in China and India
- Identifying critical cultural rights including religious rights that must be taken into account before signing the agreement
- Considering current European patent strategies for biological inventions including follow-on biologics (bioequivalents) and minimizing risks associated with EU competition laws when marketing your products in Europe
- Critical tax considerations to limit liability in foreign jurisdictions
- Enforcing the contract and protecting IP rights in India and employing a rules-based performance objective
- Ensuring contractual terms comply with U.S. and foreign import/export controls
- Remedies available for U.S. investors and enforcing foreign judgments

## Master Class B

### The “Win-Win” Collaborative Agreement: Practical and Ethical Negotiating and Drafting Strategies

2:00 p.m. – 5:00 p.m.

(1:30 p.m. – Registration)

#### *Rashida Karmali*

Chief Executive Officer, General Counsel  
Tactical Therapeutics (New York, NY)

#### *Teresa O. Bittenbender*

Patent Attorney  
(Philadelphia, PA)

- Managing expectations and using good-faith negotiation strategies
  - Recognizing respective goals and potentials
  - Identifying benefits and incorporating them into the agreement
- Doing your due diligence to uncover mistakes in a portfolio
- Drafting applicable agreements
- Drafting in an unambiguous manner while still predicting arising issues and unforeseen changes
- Anticipating change
- Real-world examples of successful collaborations
- Avoiding ethical compromises: Examples of potential ethics issues that can arise in the negotiation and performance of agreements
- Keys terms to include to avoid future disputes
- IP-specific drafting strategies
  - Who gets to maintain the IP?
  - Ensuring your contract clauses can adapt to a changing patent landscape
- Getting what you want out of the royalties clause
- Where should royalties be paid: in markets where the patent has issued or filed, in each market in which the product is sold?
- Drafting clauses that protect against competition in non-patent jurisdictions
- Drafting termination provisions
- Restructuring the agreement when necessary

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NAME	POSITION	
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ADDRESS		
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### Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches, refreshments and complimentary membership of the ACI Alumni program.

### Payment Policy

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Venue: Helmsley Park Lane Hotel  
Address: 36 Central Park South, New York, NY 10019  
Reservations: 212-371-4000 or 800-221-4982

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