American Conference Institute’s

Structuring, Negotiating and Managing Win-Win Pharma and Biotech Collaborative Agreements

Allocating Risk, Responsibilities & Rewards in In-Licensing, Co-Development & Co-Promotion Deals

NEW SESSIONS this year on:

- ALLOWING for future M&A opportunities
- VALUATION and COMPENSATION structures
- ASSESSING value of multiple indications
- DEVELOPING methods to ensure the product makes it to market
- CASE STUDY: MedImmune v. Genentech

July 16-17, 2007
InterContinental Mark Hopkins, San Francisco, CA

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Washington University

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Master Classes – Wednesday, July 18, 2007

A Negotiating Industry/University Collaborations: Ethical and Practical Strategies for Maximizing Return on Investment

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

Plus, hear valuable insights from leading experts in the field on how to:

- PROTECT intellectual property rights
- MINIMIZE risks through effective due diligence
- NEGOTIATE research agreements with universities
- DEVELOP effective governance processes
- DRAFT termination provisions
- OVERCOME antitrust violations
- ANTICIPATE the impact of generics
- AVOID the top ten pitfalls associated with international deals
Pipelines are drying up...collaborative agreements are becoming more complex...costs of new drug development are skyrocketing...billions of dollars are at stake...

In today's increasingly competitive market, both pharmaceutical and biotech companies must rely on licensing and collaborative deals to ensure their survival. Biotech companies are more sophisticated and many larger companies are looking for new strategies to fill their dwindling pipelines.

**Develop a winning business strategy**

Selecting the right partners, deal structure and compensation analysis are crucial to the success of the deal and an assessment of these factors must be done early in the process. With bigger and more costly deals, you also need to be aware of the potential antitrust implications. In addition, as more of these deals morph into M & As, you need to adjust your negotiation strategies accordingly.

**Ensure your agreements lead to positive outcomes**

Developing a workable governance structure is essential to a successful deal along with creating a plan to make certain the product is developed and sold. And should the deal fall through, as many do, it is imperative that you have protected your IP and drafted termination provisions that allow both parties to walk away with their assets intact.

Also, add significant value to your experience by attending one of our Master Classes: one focusing on Negotiating Industry/University Collaborations: Ethical and Practical Strategies for Maximizing Return on Investment and the other focusing on The "Win-Win" Collaborative Agreement: Ethical and Practical Negotiating and Drafting Strategies. Each of these thorough and hands-on sessions will be led by experts in the field who will give you practical and detailed instruction on how to negotiate and draft the most effective and ethical collaborative agreements.

Take this opportunity to get the most updated and comprehensive information and advice regarding collaborative agreements while you network with your peers and colleagues. Register now 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/pharmabiocollab.

**AGENDA-AT-A-GLANCE**

**MONDAY, JULY 16, 2007**

- Adapting Negotiation Strategies to Allow for Future M & A Opportunities
- Strategically Planning the Deal
- Gauging Value and Structuring Compensation in the Face of Increased Competition for Early-Stage Products
- Leveraging and Safeguarding IP Rights During Negotiations
- Exploring the Potentially Damaging Impact of MedImmune v. Genentech
- Ensuring the Agreement Includes Flexible and Scalable Methodologies for Assessing the Value of Multiple Indications
- Fine-Tuning Due Diligence Processes to Identify and Minimize Risks
- Successfully Negotiating Collaborative Research Agreements with Academic Institutions

**TUESDAY, JULY 17, 2007**

- Guaranteeing Effective Governance Through Clear Decision-Making Procedures
- Creating Terms to Ensure the Product is Developed and Makes it to Market
- Drafting the Prenup: Addressing the Critical Importance of Termination Provisions
- Overcoming Potential Antitrust Violations When Structuring the Collaboration
- Incorporating Foreign Laws and Business Practices Into Transnational Collaborative Agreements
- Making an Early Assessment of the Impact of Generics and Regulatory Matters on the Collaboration

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DAY 1 – Monday, July 16, 2007

7:15  Registration and Continental Breakfast

8:15  Co- Chairs’ Opening Remarks

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

Sean O’Connell
Senior Director, Corporate Development
Gilead Sciences, Inc.
(Foster City, CA)

8:30  Adapting Negotiation Strategies to Allow for Future M & A Opportunities

Sergio Garcia
Partner, Co-Chair Life Sciences Group
Fenwick & West LLP
(San Francisco, CA)

William J. Newell
Executive Vice President
Aerovance, Inc.
(Berkeley, CA)

Benjamin Perkins
Managing Director, Pacific Growth Equities
(San Francisco, CA)
- Deciding when it is appropriate to include M & A discussion in the collaboration negotiation
- Preserving confidentiality disclosures for potential M & A, not just licensing
- Reducing future tax consequences
- Minimizing the sting to the acquirer of an existing collaboration
- Making the target company more desirable for acquisition or funding
- Developing practical strategies to ensure that the collaboration does not lead to the ultimate demise of the smaller company

9:30  Strategically Planning the Deal

Larry Kahn
Vice President, Business Development
InterMune Inc.
(Brisbane, CA)

James Farrington
Partner
Wiggin & Dana LLP
(Stamford, CT)
- Choosing the right partner – evaluating compatibility of corporate cultures and each company's goals
- Assessing needs and strengths: What is your company's business model?
  - understanding your business's unique selling proposition before soliciting a deal
  - making your company look more attractive
- Getting to the heart of the reasons behind the deal
- Selecting the appropriate deal structure
  - straight licensing
  - assessing the real value v. the perceived value of a co-promotion deal
  - co-development
- Developing strategies for maintaining the scope of rights and exclusivity in the collaboration
  - different methods for deciding when exclusivity kicks in

10:30  Morning Coffee Break

10:45  Gauging Value and Structuring Compensation in the Face of Increased Competition for Early-Stage Products

Michael McCully
Director and Senior Analyst
Recombinant Capital
(Walnut Creek, CA)

Pamela A. Simonton
Senior Vice President
Patents & Licensing, Exelixis Inc.
(South San Francisco, CA)
- Predicting future market forces and trends in order to create an analysis of product valuation
- Avoiding compensation payments based on market forecasts
- Devising useful valuation models
  - for early 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
- Ensuring that expectations about the deal are driven by realistic valuations based on models
- Positioning assets for maximum valuation
- 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

11:45  Leveraging and Safeguarding IP Rights During Negotiations

Kenneth G. Chahine PhD, JD
President and CEO
Avigen, Inc. (Alameda, CA)

Ralph A. Loren
Partner
Edwards Angell Palmer & Dodge LLP (Boston, MA)
- Streamlining the methods for identifying the IP rights at issue
- Drafting simplified agreement terms that appropriately define IP ownership
  - effectively documenting who owns what
  - clinical trials
- Overcoming doubts or uncertainties about a new technology
- Finding ways to more quickly determine the options and come to terms on dividing up control of existing IP rights
  - molecules
  - indications
  - geography
- Protecting future developments and improvements
  - joint improvements
  - preserving freedom to operate
- Resolving litigation consequences
  - minimizing risks for patent infringement suits
  - determining who pays for litigation costs
  - dividing up the rewards from successful suits
  - drafting successful limitations of liability clauses
  - including appropriate indemnification provisions
- Developing controls to protect trade secrets and proprietary information from unfair competition

12:45  Networking Lunch
2:00 Exploring the Potentially Damaging Impact of MedImmune v. Genentech

Thomas J. Kowalski
Partner
Frommer Lawrence & Garb LLP
(New York, NY)

Shane M. Popp
Manager, Legal
Agensys, Inc.
(Santa Monica, CA)

This recent decision raises a number of crucial issues relating to both existing licensing arrangements as well as ways to structure future agreements such as how can you protect yourself from infringement suits while at the same time not create problems with patent abuse and misuse? Are provisions prohibiting challenges to the validity of the patent permissible in a collaborative agreement and, if so, how can they be structured so that they aren't considered “stumbling blocks” under Lear, Inc. v. Adkins? How does the increased risk of litigation affect pricing considerations? In this section, an experienced panel of experts will address the recent ruling and analyze the anticipated impact on licensing and collaborative agreements.

2:45 Ensuring the Agreement Includes Flexible and Scalable Methodologies for Assessing the Value of Multiple Indications

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

- Preserving the right to pursue multiple indications for the product
- Identifying the circumstances where indication splitting is feasible
- Where are these deals occurring?
- What products are included?
- Maximizing value and protecting interests in developing opportunities in other areas
- Developing viable economic tracking systems to retain indications
  - Database management tracking
  - Methodology for statistical sampling
  - Sales metrics
  - Independent assessment
- Integrating the criteria and assessment into the collaboration agreement

3:00 Afternoon Refreshment Break

3:45 Fine-Tuning Due Diligence Processes to Identify and Minimize Risks

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

- 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?
- Creating a flexible and useful due diligence checklist
- Resolving due diligence matters relating to patents and competitors
- 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
- Successfully identifying practices that might lead to potential business risks and compliance problems early in the process
- Sarbanes-Oxley
- Manufacturing concerns
- Clinical trial strategies

4:30 Successfully Negotiating Collaborative Research Agreements with Academic Institutions (Academia is From Venus, Business is From Mars)

Sally O’Neill, Esq.
Manager, Industrial Contracts Office
Stanford University Office of Technology Licensing
(Palo Alto, CA)

Jon Kratchevil, Esq.
Business Development Director
Washington University
(St. Louis, MO)

Mark Alfenito
EVP Corporate Development
KaloBios Pharmaceuticals Inc.
(Palo Alto, CA)

Mark D. Hankins
Vice President, Business Development
Cardinal Health, Inc.
(Woodstock, IL)

Moderator
Emily Leonard
Partner
Covington & Burling
(Washington, DC)

- Investigating the synergies and cultural differences and objectives between industry and academia
- Cultural differences between different universities
- Crafting agreements with individual scientists or academic departments
- Understanding the needs of academics
- Defining the three main types of agreements with universities
  - Material transfer agreements
  - Licensing
  - Research collaborations
- 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, JDFR)
  - Commercial research restrictions (Tax Act of 1986)
  - Individual institutional policies
  - Working with the IRS regulations
  - State fiduciary duties
  - Limitations to research when investigator leaves
- Effectively negotiating contested issues with academic institutions:
  - Ownership of IP
  - Rights to improvements
  - Exclusive commercialization rights
  - Sublicensing provisions
  - Pricing issues
  - Indirect costs for sponsored research
  - Allocation of risk
- Appreciating the difference between government regulations and policies
- Understanding how the nascent nature of the technology coming from academia impacts the deal terms

5:45 Conference Adjourns to Day 2

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DAY 2 – Tuesday, July 17, 2007

7:30  Registration and Continental Breakfast

8:45  Co-Chairs’ Remarks

Emily Leonard  
Partner, Covington & Burling (Washington, D.C.)

Sean O’Connell  
Senior Director, Corporate Development  
Gilead Sciences, Inc. (Foster City, CA)

9:00  Guaranteeing Effective Governance Through Clear Decision-Making Procedures

Kenneth A. Clark  
Partner  
Wilson Sonsini Goodrich & Rosati (Palo Alto, CA)

Jeffrey Wade  
Executive Vice President & General Counsel  
Lexicon Genetics Inc. (The Woodlands, TX)

- Assigning parties’ roles and responsibilities to ensure a clear decision-making process
  - territorial v. functional allocations
  - assigning the right tasks to the right people in the right organization
  - which qualifications are right for which positions?
- Preventing the deal from collapsing by utilizing a dispute resolution ladder that works
  - defining voting, veto and tie breaking rights
  - options for dealing with ties
    - one person, one vote
    - joint steering committees
  - allowing one party to break ties in different circumstances
  - ensuring the ultimate governing body is clear
  - knowing when to escalate the dispute
  - making a final decision in a cost effective and speedy manner
- Strategically 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: ceding certain roles but dividing up others (e.g., budget, voting on major changes)
- Allocating intricate and vital regulatory and compliance tasks
- Maintaining good relationships between the parties to ensure resolution when disagreements arise
- Drafting an intelligent, viable and simplified structure for dispute resolution into the agreement

10:15  Creating Terms to Ensure the Product is Developed and Makes it to Market

Kirk Schumacher  
General Counsel  
Seattle Genetics Inc. (Bothell, WA)

Glen Y. Sato  
Partner  
Cooley Godward Kronish LLP (Palo Alto, CA)

- M oving beyond “commercially reasonable” efforts
  - structuring the deal so the other party is incentivized to develop and/or market the product
    - striking a balance between carrot and stick approaches
    - what happens if they don’t move it forward?
  - Keeping control of IP in a practical sense to ensure continued progression of development
  - Setting benchmarks and the methods for resolving changing circumstances
    - ensuring clarity on who is responsible and that they have the freedom to do what needs to get done
    - avoiding overly burdensome provisions
  - Clearly defining key parameters for monitoring the process
    - developmental obligations
    - specific deadlines with tasks
    - milestone payments
    - marketing/sales figures
    - funding and pricing commitments
  - Case studies: Creative solutions and specific examples that worked

11:15  Drafting the Prenup: Addressing the Critical Importance of Termination Provisions

John E. Wehrli  
Partner  
Latham & Watkins LLP (Menlo Park, CA)

Kingsley Taft  
Partner  
Goodwin Procter LLP (Boston, MA)

- Justifying why it is imperative to include termination when negotiating the agreement
  - ensuring both parties retain some value to the product at the end of the day
  - looking at how the right termination provisions impacted real deals
- Spelling out the circumstances that warrant termination
  - at-will
  - convenience
  - for breach – curable and non curable
  - change of control of parties
  - under what circumstances can you terminate without a breach?
- Defining the scope of termination rights
  - agreement in its entirety
  - by product or compound
  - by country or territory
- Deciding who walks away with what
  - reversion rights
  - related compensation considerations
  - ownership of IP rights – who retains them in the event of termination?
  - partial termination issues
  - obligations to transfer programs
    - manufacturing programs
    - contracts
    - relationships with suppliers, vendors, customers
  - IP, clinical data – what do these include?
- clinical programs
- Determining the effects of termination on existing sublicenses

Overall, 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  
Assistant General Counsel, AstraZeneca Pharmaceuticals LP
12:15 Networking Lunch

1:30 Overcoming Potential Antitrust Violations When Structuring the Collaboration

J. Thomas Rosch, Commissioner
Federal Trade Commission
(Washington, D.C.)

Paul T. Denis
Co-Chair, Antitrust/Competition Practice Group
Dechert LLP
(Washington, D.C.)

- Structuring deals that maximize value and minimize antitrust risk
- Managing the most common triggers for antitrust review
  - potential competition and pipeline products
  - innovation effects
  - exclusive in-licenses
  - antitrust-sensitive royalty agreements
  - impact on generics
  - non-compete provisions
  - equity or late stage deals

- Deciding when a Hart-Scott-Rodino filing is necessary
  - value of the deal and size of the parties
  - requirements and timing of the filing

- Complying with DOJ and FTC guidelines for IP licensing and collaborations among competitors
- Avoiding “tying” in violation of the Sherman Act with out-licensing deals
- Ensuring that arrangements will not be seen as a mask for market division or price fixing
- Responding to FTC/DOJ investigations

2:30 Afternoon Refreshment Break

2:45 Incorporating Foreign Laws and Business Practices Into Transnational Collaborative Agreements

David Hull
Partner
Covington & Burling LLP
(Brussels, Belgium)

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

Stefan Schuppert
Partner
Lovells
(Munich, Germany)

- Avoiding the top ten pitfalls associated with international deals
  - protecting IP when manufacturing in another country
  - guarding trade secrets
  - weighing the pros and cons of regional v. worldwide deals
  - structuring royalties to account for complicated tax issues
  - addressing transfer pricing
  - enforcing licenses abroad
  - paying attention to local laws
  - arbitration and handling disputes
  - valuation abroad
  - antitrust violations

- Managing specific considerations with deals in the EU and Asia
  - distinguishing how the markets are different
  - protecting IP rights
  - negotiating licenses and co-development agreements
  - approving/recording cross-border licenses
  - securing rights to “improvements”
  - settling disputes
  - enforcing agreements
  - techniques
  - brewing inter-country disputes

4:00 Making an Early Assessment of the Impact of Generics and Regulatory Matters on the Collaboration

Robert A. Dormer
Partner
Hyman, Phelps & McNamara, P.C.
(Washington, D.C.)

- Protecting against generics earlier in the agreement
- Anticipating what is on the horizon for biogenerics
- Changing the deal to account for generics
  - royalty reductions
  - diligence on patents
  - competitive analysis
- Increasing sensitivity in Washington regarding FDA safety and efficacy issues
- Understanding the current FDA rules and framework
  - confidential data issues
  - reps and warranties
  - complying with the law
  - how to get the right compliance assurances
  - exclusivities
  - orphan approvals
  - pediatric
  - Hatch Waxman exclusivities
  - Hatch Waxman on patent term extension
- Drafting an agreement that complies with current regulatory standards
  - approval and post approval
    - follow-up issues with the applications
    - who owns/writes/takes control of post market studies?
    - pharmacovigilance
    - who handles complaints?
  - manufacturing
    - enforcement
    - who deals with the FDA?
    - auditing
    - FDA inspection, who responds?
  - labeling and promotion issues
    - who owns/writes/takes control of post market studies?
    - pharmacovigilance
    - who handles complaints?
  - manufacturing
    - enforcement
    - who deals with the FDA?
    - auditing
    - FDA inspection, who responds?
  - labeling and promotion issues
    - who owns/writes/takes control of post market studies?
    - pharmacovigilance
    - who handles complaints?

4:45 Conference Concludes

The seminars were excellent. Topics were well covered and the discussions were well-led and informative

Michael Shih
Senior Counsel, Eisai Inc

The topics were timely, interesting and full of information

Christopher L. Curfman J.D., Ph.D.
Needle & Rosenberg
Negotiating Industry/University Collaborations: Ethical and Practical Strategies for Maximizing Return on Investment

9:00 a.m. – 12:00 p.m. (Registration at 8:30 a.m.)

Sally O’Neil, Esq.
Manager, Industrial Contracts Office, Stanford University
Office of Technology Licensing (Palo Alto, CA)

Sara Nakashima
Licensing Associate, Stanford University Office of Technology Licensing (Palo Alto, CA)

Pharma and biotech companies face ever-increasing pressure to innovate. Expiring patents on blockbuster drugs, shrinking development pipelines, and reluctant capital markets have caused university partnerships – long a mainstay for these industries – to take on new luster. However, these often complex deals can be challenging to negotiate and draft. This Master Class will provide special insights on the art of negotiating and drafting these deals. Experienced practitioners will discuss differing drivers and motivators for each party as well as provide expert insight into key negotiation and drafting strategies that meet everyone’s needs and uphold ethical standards. Points of discussion will include:

- Negotiating in good faith
- Understanding each party’s goals and how to reach them
  - pinpointing the benefits collaboration offers to big pharma, biotech, and universities
  - understanding university objectives
  - drive for research support
  - freedom to meet traditional university goals of education and research
  - intellectual rewards (publication rights)
  - protection if the relationship ends (rights to buy back)
  - limits on field of use
- Royalty structures: where do these structures collide between industry and university?
  - royalty mitigation issues
  - royalties from sublicense v. royalties from sales
- Understanding other ROI mechanisms used by universities and nonprofit institutions
  - equity
  - payments from sales-based income such as milestones and the effect on the license
  - financial rewards for success (compensation if product is a “blockbuster”)
  - back-end protection against equity dilution of university stakeholdings
- Revenue stream buyouts
- Licensing: exclusive, non-exclusive, and transferability of rights
- Drafting an agreement that works in both the long- and short-term without compromising ethics
- Walk-through of “must-have” and “should get” provisions in form agreements
- Avoiding common and not-so-common pitfalls and ethical dilemmas in the real world of agreement negotiation and drafting
- What happens if more than one institution is involved?
  - identifying the contrasting goals and priorities
  - expectations of multiple partners to the deal
  - how does government funding impact the deal?
  - publication rights
- Staying ahead of the publication curve
  - “fast publication” on the Internet
  - terms industry should get for prepublication review
  - university obligations to monitor faculty publications actively
  - real-world remedies for breach of publication obligations
- Maximizing and obtaining rights to improvements
- Avoiding common and not-so-common pitfalls and ethical dilemmas in the real world
  - use of an institution’s name in connection with the private company

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

1:30 p.m. – 4:30 p.m. (Registration at 1:00 p.m.)

Thomas J. Kowalski
Partner
Frommer Lawrence & Hoag LLP (New York, NY)

Mark D. Hankins
Vice President, Business Development
Cardinal Health, Inc. (Woodstock, IL)

With so many unknowns in potential in-licensing, co-development, and co-promotion deals, finding the “win-win” solution – and addressing ethical issues – is often the toughest part of getting the deal done. This Master Class will walk you through the key aspects of negotiating and drafting that are essential to successful agreements. The workshop leaders will show you how to negotiate terms and draft clauses that anticipate and can adapt to change and accommodate competing interests. Plus, this Master Class will address ethical questions that arise during these negotiations. Points of discussion will include:

- Good-faith negotiation strategies
  - recognizing respective goals and potentials
  - identifying benefits and incorporating them into the agreement
  - recognizing cultural differences of the parties
- Drafting adaptable agreements
  - real-world examples of successful collaborations
  - how to anticipate change
- How to avoid ethical compromises
  - real-world examples of potential ethics issues that can arise in the negotiation and performance of agreements
- IP-specific drafting strategies
  - who gets to maintain the intellectual property?
  - 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?
  - only in markets where the patent has issued (or is filed)?
  - in each market in which the product is sold?
- Drafting clauses that protect against competition in non-patent jurisdictions
- Drafting termination provisions
  - how do you protect yourself against excessive costs?
  - how do you determine a fair royalty rate?

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July 16-17, 2007
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