American Conference Institute's **17th Advanced Forum on**

Life Sciences Collaborative Agreements and Acquisitions

Maximizing Opportunities and Rewards in M&A, Licensing, Partnering Deals, and Strategic Alliances

February 27 – 28, 2013 | The Carlton Hotel | New York, NY

Co-Chairs

Robert Aboud
Vice President, Head of Business Strategy
GlaxoSmithKline
(King of Prussia, PA)

William Mongan
Executive Director of U.S. Business Development
AstraZeneca
(Wilmington, DE)

Receive Frontline Deal Making Guidance from Experts Representing

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Leading licensing, business development, and M&A executives, seasoned in-house counsel, and top IP professionals will share their hard-won insights and first-hand experiences on how to:

- INCORPORATE the right takeaways from recent deals into your business development strategies
- MINIMIZE risks with effective due diligence systems and effective partner selection
- STRUCTURE deals that are able meet both parties' goals
- DRAFT termination provisions to effectively avoid problems with deals that do not work out
- UTILIZE contract research organizations and other entities to limit R&D expenditures
- EVALUATE and EXECUTE milestone based compensation structures
- RESOLVE issues in collaboration with universities
- NEGOTIATE acquisitions that satisfy your business objectives

U.S. Federal Trade Commission Spotlight:

Hear **Christine White, Staff Attorney for the Northeast Office of the FTC**, address antitrust issues associated with life sciences transactions in the exclusive session, **Mitigating Antitrust Risks Associated with Life Sciences Alliances and Agreements**

Gain Added Learning Value at the Post-Conference Workshops: March 1, 2013

A Interactive Working Group Session: An In-Depth Review of Collaborative Agreements for Alliance Management Professionals and Attorneys

B The Master Class on Conducting Thorough and Effective Due Diligence Analysis for Life Sciences M&A and Strategic Alliances

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Learn the Art of the Deal and Succeed in a Multi-Billion Dollar Market

As life sciences companies seek to combat ever-rising R&D costs, it is essential for every life sciences company to have the most effective negotiating strategies to ensure that the deal covers all contingencies essential to the collaboration. And as pharmaceutical pipelines dry up and innovation is more diffusely spread across the sector, effectively collaborating with other entities is more critical to success than ever before. With so much on the line, everyone involved in the deal making process from counsel and intellectual property leaders to business development executives and alliance managers need expert advice and instruction.

At *American Conference Institute's* **17th Advanced Forum on Life Sciences Collaborative Agreements and Acquisitions**, a seasoned faculty of business development, licensing, and alliance management executives from top life sciences companies like **Pfizer, AstaZeneca, GlaxoSmithKline, Sanofi Pasteur, Novartis,** and **Bayer** will help you enable your company to advance its key growth strategies. In just two days, these experienced professionals will share:

- In-depth analysis of recent trends in collaboration
- Valuable strategies for managing fruitful alliances
- Best practices for structuring deals to maximally benefit all parties
- Tips for working with academic institutions
- Methods for crafting effective termination provisions, and much more

You will also receive expert instruction on avoiding antitrust problems directly from the **Federal Trade Commission**, mitigating the effects of patent reform on deal making, spreading and limiting risk, and exposing deal-killing IP problems before they wreak havoc.

In addition, exclusive post-conference workshops will cover:

- Strategies for executing due diligence procedures, like managing legal risks associated with collaborations, comparing differing metrics used in M&A deals, and crafting checklists to perform effectively IP diligence.
- Best practices for contract drafting in an interactive review and strategy session where attendees can compare redacted collaborative agreements to share effective techniques based on what has and has not worked.

Take this opportunity to get the most current and comprehensive information and advice regarding strategic partnering agreements in an environment that will provide valuable networking opportunities.

Register now for this timely event by calling **888.224.2480**, by fax at **877.927.1563**, or register online at **www.americanconference.com/Collaborations**.

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Who You Will Meet

✓ Biotechnology, Pharmaceutical, and Device Professionals
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- Licensing and IP Executives
- Alliance Managers
- General and Corporate Counsel

✓ Attorneys Practicing in the areas of:
- Life science transactions
- Intellectual Property
- Licensing

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DAY 1 Wednesday, February 27, 2013

8:00 Registration and Continental Breakfast

9:00 Co-Chairs' Opening Remarks

Robert Aboud
Vice President, Head of Business Strategy
GlaxoSmithKline (King of Prussia, PA)

William Mongan
Executive Director of U.S. Business Development
AstraZeneca (Wilmington, DE)

9:15 Analyzing Recent Trends in Deal-Making and Deciphering Their Implications for Your Next Collaborative Agreement

Steven Bernitz
General Partner, Head of BioPharma Practice
Extera Partners, LLC (Cambridge, MA)

Louisa Daniels
Vice President & Assistant General Counsel
Pfizer, Inc. (South San Francisco, CA)

- Addressing increased cost pressure in the life sciences industry
- Analyzing current market information and deal drivers
- Developing a strategy in light of decreased appetite for risk
  - How have drug development failures impacted a willingness to take on risk?
- What an increased focus in patenting manufacturing methods means for deal making
- Considering the FDA's recent caution in drug approval and adopting strategic decisions in light of this institutional hesitance
- What are large pharmaceutical companies doing to achieve deal flow?
- Assessing the future of strategic investment by big pharma
- How have alternative investment vehicles affected the availability of funds for collaborations?
- Reflecting on changing development time horizons and what they mean for investment in new ventures
- Reviewing lessons learned from this year's top deals
  - Recognizing what the potential pitfalls were
  - How did the parties arrive at mutually beneficial terms?

10:15 Coping With Tectonic Shifts: Understand How the America Invents Act and Recent Case Law Impact Deal-Making for Life Sciences Companies

Jennifer Camacho
Shareholder
Greenberg Traurig P.C. (Boston, MA)

D. Brian Kacedon
Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. (Washington, DC)

This session features essential insights into how the newly implemented America Invents Act (AIA) and recent blockbuster court decisions like *Mayo v. Prometheus,* the *en banc Akamai* decision, and the ongoing *Myriad* saga will affect strategic alliances and acquisitions in the life sciences sector. Discussion will include:

- Identifying the provisions of the AIA that will affect collaborative agreements
  - Determining what the new first-to-file regime will do to R&D systems
  - How will the new opposition procedures affect effectiveness of existing patents?
  - Managing the effects of expanded prior user rights
  - Analyzing the AIA's treatment of joint research agreements
  - Addressing changes to inventor importance in filing
  - What effect will the broader prior art standard have on collaboration?
- Identifying the effect AIA provisions will have on IP licensing
- Understanding the practical takeaways impacting strategies for business development
- Coping with the *Prometheus* decision
  - How will this case impact collaboration to develop new diagnostic methods?
  - Revisiting the usefulness of patents for diagnostic methods following *Prometheus*
- Exploring solutions to the seemingly-endless *Myriad* epic
  - What can be done to ameliorate the effects of a worst-case scenario?
  - How can agreements be structured to minimize reliance on DNA patents?

11:15 Morning Coffee Break

11:30 Utilizing Well-Crafted Agreements that Develop Fruitful Collaborations and Produce Maximum Benefit

John Hurvitz
Partner
Covington & Burling, L.L.P. (Washington, DC)

Vincent Andrews
Associate General Counsel
Eisai, Inc. (Woodcliff Lake, NJ)

- Developing sound agreement governance mechanisms
  - Ordering the command and control structure between companies
  - Cost and profit-sharing arrangements
  - Prioritizing activities and avoiding internal competition
- Addressing differences between partners in product development strategies
  - How aggressive should product development be?
  - Avoiding conflicts when one party is interested in exploring multiple indications for the same product and the other is reluctant
- Exploring creative deal structures
  - Considering the increased complexity seen in agreements
  - Option-based agreements
  - Using milestones frequently
- Utilizing earn-outs instead of a license with royalty payments
  - What are the advantages and disadvantages of this structure?
  - What are the duties associated with an earn-out not seen in a traditional license agreement?

12:30 Networking Lunch

1:45 **Employing a Smart Risk-Limiting Strategy that Satisfies All Parties**

Paul Stewart
President & Chairman
Pasco Ventures, L.L.C. (Indianapolis, IN)

Melissa Bradford-Klug
Vice President, Business Development & Licensing
Pharmaceutical Products
Covidien (Hazelwood, MO)

- Addressing the regulatory environment and its impact on appetite for risk
  - Delineating the perceived risk associated with each stage of clinical trials
- Assessing the current risk/benefit ratio for engaging in a collaboration
- Considering the macro risk environment
  - How do parties take larger risk concerns into account when allocating risk in life sciences deal making?
- What do licensing arrangements require in the current risk-averse environment?
- Analyzing risk-sharing arrangements
  - What has changed compared to the recent past with partner demands for risk sharing?
  - What are the new incentives for parties being asked to take on more risk?

2:45 **Seeking and Acquiring New Sources of Research Funding in Leaner Times**

Robert Aboud
Vice President, Head of Business Strategy
GlaxoSmithKline (King of Prussia, PA)

Tushar Patel, Ph.D.
Senior Director and Head, External Research
Eisai, Inc. (Woodcliff Lake, NJ)

- Seeking and employing non-traditional sources of funding for R&D
  - Patient-advocacy groups
  - Government grants
  - Qualifying drug therapeutics provision of the ACA
- Charting the movement away from using VC-funded biotechs for new projects
- Exploring the use of platform deals to arrange for research funds
- What is the source of the cash crunch in research ventures?

3:45 **Afternoon Refreshment Break**

4:00 **Overcoming Defects in IP that have the Potential to Derail Life Sciences Transactions**

Jeffrey Lewis
Partner
Patterson, Belknap, Webb, & Tyler, L.L.P. (New York, NY)

Matthew Zisk
Partner
Skadden, Arps, Slate, Meagher & Flom, L.L.P. (New York, NY)

Intellectual property professionals see the same issues crop up time and time again – unforeseen IP issues that threaten to destroy potential partnerships or acquisitions. In this session, experienced IP experts will share their thoughts on challenges that, when unearthed, have the potential to undermine deals. Topics to be discussed include:

- Ferreting out when IP rights are overstated by a partner company or acquisition target
  - Making certain the target can convey clear title and what to do when they cannot in order to keep the deal on track
  - Uncovering whether the target's patents have been properly maintained in compliance with statutory requirements
- Employing techniques for clearly documenting what entities are involved and who owns what
- Detecting previous licensing activity
  - Verifying the right of target to sublicense IP acquired from target's prior agreements
  - Resolving who invented what and which rights have been granted to third parties
  - Addressing concerns related to the target's other research agreements
- Determining when use restrictions will adversely impact the business reasons for a partnership
- Identifying the IP and patents at issue and projecting how the target's prior agreements can affect the value and terms of the transaction
- Avoiding pending litigation risks
- Addressing the effects the AIA might have on patent value

5:00 **Conference Adjourns**

DAY 2 Thursday, February 28, 2013

8:15 **Continental Breakfast**

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

9:15 **Mitigating Antitrust Risks Associated with Life Sciences Alliances and Agreements**

Christine White
Staff Attorney, Northeast Regional Office
U.S. Federal Trade Commission (New York, NY)

Joshua Soven
Partner
Gibson, Dunn, & Crutcher, L.L.P. (Washington, DC)

- Conducting a baseline legal risk assessment
- Identifying potential antitrust risks
  - Deciphering the criteria the FTC uses in its analysis
  - Verifying the deal early on to save time
- Establishing what information is needed to comply with FTC filing requirements
  - Presenting complete information to aid in the FTC's review
  - Determining what assets must be disclosed
  - Understanding the factors the FTC uses to review a deal

- Recognizing the antitrust issues associated with licensing and co-development agreements
  - What are some common antitrust issues that crop up in drug licensing agreements?
  - What are the typical pitfalls in agreements that will trigger FTC investigation?
- Surveying recent enforcement initiatives

10:15 Morning Coffee Break

10:30 Integrating M&A Metrics into Your Business Development Strategy

Kimberly Audet Cornwell
Senior Director, Legal Affairs and General Counsel
Sanofi Pasteur (Cambridge, MA)

William Mongan
Executive Director of U.S. Business Development
AstraZeneca (Wilmington, DE)

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

- Analyzing the current M&A market and divining what types of deals are on the horizon
- Evaluating valuation trends and any disparities between perceived value and the price paid for companies
- Determining whether potential collaborators are interested in being acquired
- Executing a proactive audit ahead of various types of negotiations
- Recognizing financial terms for a collaboration that could facilitate or hinder a later merger or acquisition
- Selecting appropriate terms for the possibility that a partnership may lead to merger or acquisition
- Incorporating change-of-control provisions into the initial agreement
  - Drafting provisions to protect the company and account for alternative outcomes

11:30 Effective Alliance Management: Avoiding Missteps and Producing Workable Solutions for the Inherent Challenges of Life Sciences Collaborations

Karen Denton
Director, Alliance Management
Bayer Healthcare Pharmaceuticals (Pine Brook, NJ)

Bradley Prosek
Senior Director
Cubist Pharmaceuticals (Lexington, MA)

- Reviewing failed agreements that led to litigation between parties
  - Determining where things went wrong
  - Analyzing whether problems that arose were tied to negotiated terms
  - Were there clearly assigned rights?
  - What kinds of exclusive rights were granted?
- Evaluating terms in distribution agreements that might cause problems
- Exploring provisions that grant rights in product development and marketing
  - Anticipating when these terms can derail alliances
- Promoting good conduct by parties
- Assigning roles to parties to facilitate a clear decision making process
  - Allocating roles by territory or by function
  - Ensuring that the correct parties receive appropriate roles in an alliance
- Assessing the risks and benefits of delegating control to one party
- Determining when joint control is sensible
- Implementing a dispute resolution mechanism
  - Defining voting, veto, and tie breaking rules
- Crafting terms to ensure that the product comes to market
  - Setting benchmarks and methods for adapting to changing circumstances
  - Using the right people to move the deal forward
  - Overcoming regulatory hurdles with sound quality and recordkeeping systems
- Employing best practices for establishing clear milestones and deliverables
- Establishing methods for response to lawsuits and complaints

12:30 Networking Lunch

1:45 Entering into Collaborative Research Agreements with Academic Institutions

Timothy Howe, Ph.D.
Vice President, Legal Affairs, General Counsel and Head
Acquisitions and Licensing Transactions
Sanofi Pasteur (Swiftwater, PA)

Rachel Carson, Ph.D.
Associate Director of Technology Transfer
The Johns Hopkins University (Baltimore, MD)

Viviane Martin, Ph.D.
Associate Director, Office of Technology Development
Penn State College of Medicine (Hershey, PA)

- Identifying common difficulties in negotiating with universities
  - Who has the authority to negotiate?
  - Devising successful negotiating strategies
- Crafting agreements with individual academics and departments
- Managing research collaborations involving multiple universities
  - How does unequal bargaining power between universities impact their behavior?
- Crafting an effective strategy to manage faculty
- Exploring the current status of IP management at universities
- Balancing tensions between confidentiality interests and publication rights
- Bargaining effectively to address contested issues with universities
  - Determining who owns the IP
  - Who has the responsibility for patent costs covering joint inventions?

- Addressing licensing issues
- Negotiating pricing issues
- Delineating allocation of risk

- Setting the terms of royalties
  - How will deal terms look for agreements covering nascent technologies?
- Defining the main types of agreements with universities
  - Material transfer agreements
  - Licensing
  - Research collaborations

2:45 **Knowing When to Leave: Drafting Critical Termination Provisions**

Thomas Gillespie
IP Transactional Counsel
Emergent Biosolutions (Rockville, MD)

Daryn Grossman
Partner
Proskauer Rose, L.L.P. (New York, NY)

- Guaranteeing that all parties retain some value to the product regardless of a collaboration's outcome
- Defining circumstances that warrant termination with clear language
  - At-will conditions
  - For convenience
  - Upon breach, both curable and non-curable
  - Change of control provisions
  - Determining when termination without breach is possible
- Employing unwind provisions to ensure a smooth transition
  - Including reversion rights
  - Related compensation considerations
  - Clarifying ownership of IP rights in the event of termination
  - Obligations to transfer programs
- Analyzing the effects of termination on existing sublicenses
- Utilizing strategies for enforcing cooperation in the event of termination
- Reviewing how termination provisions have affected deals in the past
- Identifying areas of conflict that can lead to litigation and grasping how the right termination provisions impact relative positions in lawsuits
- Outlining strategies for enforcing cooperation in the event of termination

3:45 **Afternoon Refreshment Break**

4:00 **Winning Strategies for Collaborating with Contract Research Organizations that Deliver Superior Results**

David Ibbiken (Invited)
Senior Legal Counsel
PRA International (Charlottesville, VA)

Fahd M.T. Riaz
Partner
Morgan, Lewis, & Bockius, L.L.P. (Philadelphia, PA)

Collaboration with contract research organizations (CROs) is becoming more common as life sciences companies attempt to limit the costs of drug development. While this type of outsourcing has many advantages, it presents a great many pitfalls as well. In this session, experienced professionals will share best practices on collaborating with CROs, examine some cases where CRO collaborations have gone well, others that have not worked out, and help you adapt to this more and more broadly employed type of alliance.

- Working with contract research organizations to externalize research needs
- Addressing the interests of CROs
- Negotiating limitations on liability with CROs
- Outsourcing clinical trials to "low cost" countries
- Establishing milestones in contracts with CROs

5:00 **Conference Concludes**

Friday, March 1, 2013

A Interactive Working Group Session

8:00 **Registration and Continental Breakfast**

9:00 **An In-Depth Review of Collaborative Agreements for Alliance Management Professionals and Attorneys**

Y. Jerry Cohen
Partner
Cohen, Tauber, Spievack, & Wagner P.C. (New York, NY)

Samuel Davenport
Member of the Firm
Mintz Levin Cohn Ferris Glovsky & Popeo, P.C. (Boston, MA)

As a skilled professional who handles the drafting and negotiating often complex collaborative agreements, this interactive and practical workshop will provide you with a nuts-and-bolts discussion of the underlying business, technical, and legal issues that often drive a life sciences collaboration.

During the workshop, each participant will have the opportunity to bring a redacted collaborative agreement and have seasoned experts guide the group through the good, the bad, and the ugly terms of each contract. Presenting a rare chance to work with your peers and discuss hypothetical contract situations, mock negotiations, and best practices in contract terms, this session will leave you armed with practical strategies on how to solve problems that face even the most experienced counsel and business development executives. Featuring advanced discussions on:

- Creating terms to help ensure your collaborative product is developed and effectively marketed
  - Tailoring effective deal-specific terms for incentivizing the other party
  - Setting benchmarks and methods for adapting to changed circumstances

- Avoiding terms in agreements that can be potential product killers
- Understanding what safeguards must be included in the agreement in regards to the current economic environment
- Identifying contract hazards to avoid
- Negotiating boilerplate clauses: dispute resolution mechanisms, choice of law, and waivers
- Required responses in the event of a breach
- Making the most of risk allocation provisions: indemnification, liability, and warranty coverage
- Negotiating 101 for small and large players: what strategies are available based on your market position?

12:00 Workshop Concludes

12:00 Networking Lunch for Attendees of Both Workshops

B Master Class

1:15 Registration

2:00 **Conducting Thorough and Effective Due Diligence Analysis for Life Sciences M&A and Strategic Alliances**

Kimberly Parker
Vice President, Corporate Counsel and Legal Site Head
Novartis Vaccines and Diagnostics (Cambridge, MA)

Anita Varma
Partner
Ropes & Gray, L.L.P. (Boston, MA)

When negotiating an acquisition or alliance, the diligence review team must ensure that there will be no impediments to executing the deal. This in-depth workshop will help you make informed decisions regarding how the anticipated deal will increase the company's overall value. With a focus on the legal risks that may occur when the diligence process fails to identify areas of concern, an expert faculty of diligence professionals will share best practices to help your next diligence inquiry run smoothly and protect your company's bottom line.

Comparing the Different Metrics Used in M&A Deals:

- Investigating the ways companies are structuring M&A deals
  - Straight-forward asset purchases
  - Staged acquisitions
  - Hybrid acquisitions
  - Partnerships with built in options
- Scrutinizing how deals are tailored to meet both parties' objectives
  - Two-step vs. one-step vs. multi-step acquisitions
  - Milestone-based M&A
  - Partnering with equity investment
  - Spinoffs
  - Reverse spinouts
- Navigating challenges raised by the increasing incorporation of options into deals
  - Grasping different option structures and timelines
  - Analyzing how asset shares are valued in cases of stock purchases
- Determining when change-of-control provisions are appropriate for nontraditional M&A

Managing the Legal Risks Presented by Life Sciences Collaborations:

- Finding and utilizing appropriate resources for your inquiry into:
  - FCPA/anti-corruption/anti-kickback concerns
  - Labeling and marketing violations
  - Products liability risks
  - Manufacturing and employment issues
- Tips for the legal diligence team
  - Assembling the right people on the team
  - Identifying the needs/wants/must-haves and deal-breakers
  - Determining the appropriate level of exposure
- What to do if legal issues are uncovered
  - Taking remedial action
  - Knowing when to walk away

Crafting a Practical Checklist that Addresses both the Business Objectives of a Deal and an IP Assessment:

- Ensuring that the driving force behind the deal and the objectives of the diligence review team are properly aligned
  - Knowing what the deal makers are looking for and what "IP due diligence" means to the parties
  - Avoiding runaway IP diligence disconnected from the strategy of the deal
- Determining the appropriate scope and depth of the IP due diligence necessary for :
  - Large-scale M&A
  - Purchase of a division or a product
  - Co-promotion or co-development alliance with purchase options
- Confirming that non-patent IP is not overlooked
  - Appropriately valuing trade secrets
  - Assessing corporate security issues
- Updating due diligence checklists based on the type of transaction being executed
  - Adjusting to the size of the deal
  - Evaluating the scope of the patent portfolio
  - Identifying challenges in examining enforceability of international IP components
  - Establishing the documents to request and review with respect to early-stage research progress and clinical trials
- Including analysis of the competition in the patent review

5:00 Workshop Concludes

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