Advanced Pharma and Biotech IP Licensing

Creating the Winning Deal

October 27-29, 2004

JPMorganChase Newport Conference Center
Newport, NJ

"Maximize your IP Assets – Minimize the risks associated with alliances."

Licensing is the fuel that drives innovation and increases the value of your IP assets.

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Conference Chair:

Stephen A. Bent, Partner and Head, Life Sciences Industry Team, **Foley & Lardner LLP**

Speakers:

Douglas Altschuler, General Counsel
Eyetech Pharmaceuticals, Inc.

David Bernstein, General Counsel
US Genomics, Inc.

Jay Bua, President & CEO
Ascend Therapeutics

Dr. Prem O. Das, Director
Office of Technology Licensing
Harvard Medical School

Michael Duffy, SVP, General Counsel and Secretary
Point Therapeutics, Inc.

David J. Earp, JD PhD, Chief Patent Counsel SVP, Business Development
Geron Corporation

Marc S. Friedman, Partner and Chair of Intellectual Property Practice Group
Sills Cummis Epstein & Gross PC

Thomas E. Hartman, Partner
Foley & Lardner LLP

Melodie Henderson, VP, Intellectual Capital and Licensing
Genaissance, Inc.

Robert Hrubiec, VP, Intellectual Property
Cephalon, Inc.

Janice M. Klunder, PhD, Patent Counsel
Millennium Pharmaceuticals, Inc.

Ranan Lachman, Principal
2Value, Inc.

Dr. Leslie MacGregor Levine, Chief Intellectual Property Counsel
PerkinElmer Life and Analytical Sciences

W. Bradford Middlekauff, SVP, General Counsel and Secretary
Medarex, Inc.

Michel Morency, PhD, Shareholder
Greenberg Traurig LLP

Joyce Morrison, VP, Intellectual Property
Xencor, Inc.

Dr. Richard C. Peet, Leader, IP Chemical and Pharmaceutical Practice Group
Foley & Lardner LLP

Ron Pepin, SVP, Business Development
Medarex, Inc.

Ira A. Rosenberg, Partner and Chair of Life Sciences Practice Group
Sills Cummis Epstein & Gross PC

Robert Silverman, Associate General Counsel
Millennium Pharmaceuticals, Inc.

James F. Stern, Partner
Foley & Lardner LLP

Dr. Richard Warburg, Partner
Foley & Lardner LLP

Dr. Stephen P. Weeks, President
First Principals, Inc.

Joseph S. Zakrzewski, VP, Business Development
Eli Lilly and Company

This Event Will Give You and Your Company Cutting-Edge Legal Tips To:

- Protect IP assets while leveraging their full value
- Successfully address pre-contractual considerations for entering into strategic alliances
- Effectively value IP assets using early to late stage valuation methodologies
- Negotiate 'win-win' licensing and JV agreements
- Capitalize on the pivotal relationship between industry and research

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DAY ONE: WEDNESDAY OCTOBER 27, 2004

1:30 pm Registration for Pre-conference Workshop

2:00 pm Workshop Begins

Creating Realistic Governance Structures for Alliances and Collaboration Agreements

This intensive three-part workshop will provide Delegates with cutting-edge legal and strategic advice from a number of senior counsel at one of America's leading law firms. Themes covered will be of interest to younger and established companies entering into new R & D fields and alliances.

Part 1: Getting It Right From the Start – The Initial Phase of Project Development

- Successfully integrating R&D goals with a market-driven business plan
  - Identifying commercialization targets and time frames
  - Mastering the art of linking market projections with IP potential
    - Where there is a crowded technological field
    - Establishing that there is freedom to operate
    - Re-considering the timing/content of patent filings
- Establishing a realistic governance framework in an innovative process – moving from conceptualization to end-product
  - Delineating principles of inventorship versus ownership
  - Documenting and corroborating the evolution of inventions
  - Creating mechanism(s) to coordinate R&D agenda with competing internal priorities
- Synchronizing innovative, regulatory, and public-relations endeavors
- Reaching a consensus on principles of management transition and project termination

Part II: Evolving Toward IPO or Acquisition in the Age of SOX

- Sarbanes-Oxley Act initiatives
  - Revised Nasdaq and NYSE listing requirements
    - Independent directors
    - Audit committees
    - Shareholder approval of equity plans and arrangements
    - Code of Conduct
  - CEO/CFO certifications of financial statements
  - Annual audits of internal controls
  - Prohibitions on loans to officers and directors
    - Planning for an IPO or acquisition
      - Audited financial statements and internal controls
      - Independent directors
      - Update business plan
      - Evaluating in-house management and management employment agreements
      - Clarifying and simplifying ownership of assets
      - Settle ongoing litigation/eliminate other contingencies
      - Eliminate/reduce related-party transactions
      - Change of control provisions

Part III: Organizing (and Reorganizing) to Accommodate Changing Circumstances

- Choice or conversion of entity
- Securities, tax, corporate, and government-funding implications
- Board make-up and governance
- Key executive severance and stay bonus agreements
- Structuring financings
- Identifying, quantifying, and structuring change-of-control provision
- Financial- and legal-housekeeping items

Stephen A. Bent, Partner and Head, Life Sciences Industry Team
Foley & Lardner LLP

Thomas E. Hartman, Partner
Foley & Lardner LLP

James F. Stern, Partner
Foley & Lardner LLP

Facilitated by:

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5:15 pm Conclusion of Workshop and Closing Remarks

DAY TWO: THURSDAY, OCTOBER 28, 2004

8.00 am Registration

8:45 am Opening Remarks from Chair and Conference Welcome

9:00 am Panel Discussion

A Look Ahead by the Experts: Emerging Trends, Developments and Hot Topics in Pharma and Biotech Deal Making

- The rise of biotech companies
- Novel deal structures in in-licensing, co-development and co-promotion
- Where are the deals now?
- Enhancing the value of your IP assets through licensing
- The commercialization of research tools post University of Rochester
- Predicting future trends

Moderator: Stephen A. Bent, Partner and Head, Life Sciences Industry Team
Foley & Lardner LLP

Dr. Richard Warburg, Partner
Foley & Lardner LLP

Ira A. Rosenberg, Partner and Chair of Life Sciences Practice Group
Sills Cummis Epstein & Gross PC

Jay Bua, President & CEO
Ascend Therapeutics

Robert Hrubiec, VP, Intellectual Property
Cephalon, Inc.

David J. Earp, JD PhD, Chief Patent Counsel, SVP, Business Development
Geron Corporation

10:15 am Case Study

Key Success Factors in Funding and Financing Winning Alliances

- Sources of finance and their potential
  - Debt Financing
  - Private Equity Finance
  - IPOs
  - Angels
  - Venture Capital
  - Government Funding
  - Private offerings
- Successfully monitoring capital markets
- Managing who pays for what
- Pricing trends
- Achieving a 'win-win' finance structure
- Attracting large partners and profitable deals

Michael Duffy, SVP, General Counsel and Secretary
Point Therapeutics, Inc.

11:05 am Refreshment and Networking Break

11:30 am Case Study

Pre-Contractual Considerations for Entering into Strategic Alliances

- Determining what your IP rights are from the outset
- Pre-deal considerations
- Best Practices for in-house IP licensing and management
- Due diligence
- Overcoming your own limitations and setting realistic targets
- Determining how to make the right choice about deal structure
  - Lifecycle
  - Co-development agreements
  - In-licensing and cross-licensing
  - Joint ownership and co-promotion
- How choice of deal structure affects IP rights
  - Corporate strategy considerations
- Successfully determining what parties to be involved
- Choosing the role each party will play: manufacturing, promotion, sales, marketing or R&D
- Successful risk assessment and management
- Evaluating your potential partner and their company culture

Janice M. Klunder, PhD, Patent Counsel
Millennium Pharmaceuticals, Inc.

Robert Silverman, Associate General Counsel
Millennium Pharmaceuticals, Inc.

12:30 pm **Luncheon Sponsored By:**

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DAY TWO: CONTINUED

1:45 pm — Case Study

The Art and Science of a Successful Deal

- General license structure
- Creating mutually beneficial deal terms
- Successfully recognizing the value of negotiating rights upfront
- Maintaining the ability to grant sub-licenses
- Creating an effective and workable management structure
- Controlling downstream use of technology
- Successfully avoiding royalty structures that will cause future problems
- Structuring IP rights
- Voluntary and involuntary termination
- Warranties, indemnification and insurance
- Establishing jurisdiction
- Recognizing common pitfalls from the outset

David Bernstein, General Counsel
US Genomics, Inc.

2:35 pm — Case Study

Analyzing the Winning Deal from Start to Finish: A Walk Through a Pharmacogenomics Deal

- Realistic legal strategies
- Market forces and drivers we have to be aware of
- Choosing the appropriate collaborator
- Finding money and investors in today's market
- Efficiently moving from on paper to in practice

Melodie Henderson, General Counsel
Genaissance

3:30 pm — Refreshment and Networking Break

3:45 pm — Case Study

Successfully Partnering with a University or Research Institute: Essential Information

- What to expect when academia partners with industry
- Identifying terms for future inventions and research
- Key issues in structuring transactions between research institutes and universities
  - Licensing research tools
  - Monitoring and controlling IP rights
  - Protecting patent infringement during the course of research
- Sponsored research: pros and cons
- Critical considerations for royalties and the reservation of rights

Dr. Prem O. Das, Director, Office of Technology Licensing
Harvard Medical School

Dr. Leslie MacGregor Levine, Chief Intellectual Property Counsel
PerkinElmer Life and Analytical Sciences

Joyce Morrison, VP, Intellectual Property
Xencor, Inc.

4:45 pm — Keynote Presentation

Making the Grade in Biotech: How Smart Business Decisions and Product Advances Strengthen Your Market Position

The biotech industry has transformed from start-up to an industry that is creating first-class drugs, vaccines and diagnostics. In this session, learn valuable legal strategies to successfully commercialize a new biotech product.

- Seizing opportunities through commercialization
- Securing funding from multiple sources
- Using IP as a vehicle to drive market value
- Meeting industry standards
- Determining outside counsel expectations
- Partnering with big pharma

Douglas Altschuler, General Counsel
Eyetech Pharmaceuticals, Inc.

5:35 pm — Closing Remarks from the Chair

5:40 pm — **Cocktail Reception Sponsored by:**

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DAY THREE: FRIDAY, OCTOBER 29, 2004

7:30 am — **Breakfast Sponsored by:**

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8:30 am — Opening Remarks from the Chair and Re-cap of Day Two

8:40 am — Keynote Presentation

From Pipeline to Partnering: Special Concerns for Pharma and How to Tackle Them Head-on

- First-hand tips for overcoming product pipeline deficiencies
- Licensing and its role in safeguarding your pipeline
- Determining expectations from outside counsel
- Leveraging assets through licensing
- Managing due diligence with finesse and foresight

Joseph S. Zakrzewski, VP, Business Development
Eli Lilly and Company

9:30 am — Case Study

Real Options Analysis: An Effective Tool for Valuing Intellectual Property in Biopharma Deals

One of the greatest challenges in valuing biopharma deals relates to significant intellectual property variables. This session will illustrate how real options analysis provides an effective tool for dealing with patent validity, patent infringement and related intellectual property issues.

- Why value biopharma IP?
- Comparison of valuation methods
  - Net present value
  - Other models
- Understanding and successfully overcoming sensitive IP variables
  - Patent validity
  - Claim scope
  - Patent infringement
- Hypothetical Case Study: valuing a licensing deal (Hypothetical)
  - Options analysis
  - Evaluating potential deal value
- Best Practice approaches for biopharma asset valuation

Dr. Richard C. Peet, Leader, IP Chemical and Pharmaceutical Practice Group
Foley & Lardner LLP

Ranan Lachman, Principal
2Value, Inc.

10:30 am — Refreshment and Networking Break

10:45 am — Interactive Negotiation and Strategy Session

What To Do When There is Trouble on the Horizon: Strategies and Remedies for Resolving Disputes in Licensing Transactions

In this lively, interactive session, Delegates will be given a short hypothetical scenario of a licensing transaction and agreement, and will then be able to watch two skilled lawyer and client teams negotiate the resolution of a licensing transaction gone sour. Issues to be negotiated include:

- Exit strategies: Graceful termination and division of IP assets
- Failure to comply with license terms
- Enforcement of contractual provisions
- Termination
- Dispute resolution procedures
- Jurisdictional problems
- Confidentiality
- Indemnity and other provisions surviving termination

Team A
Marc S. Friedman, Partner and Chair of Intellectual Property Practice Group
Sills Cummis Epstein & Gross PC

Team B
Ira A. Rosenberg, Partner and Chair of Life Sciences Practice Group
Sills Cummis Epstein & Gross PC

12:15 pm — Luncheon

1:30 pm — Case Study

Enhancing the Value of IP through Licensing

- Why license?
  - Valuation through economic means
  - Market dynamics
  - Core competency issues

DAY THREE: CONTINUED

- Using contract provisions that enhance valuation
  - 'Field of Use' limitations as a means of maximizing royalty stream
  - Grant back provisions
  - Patent term extensions
  - Geographical limitations
  - Exclusivity vs. non-exclusivity
- Ensuring that building value is a continuous process

Dr. Stephen P. Weeks, President
First Principals

2:20 pm Case Study

The Current Regulatory Environment and Its Impact on Partnering

- Planning for the future in light of recent developments
- The regulatory and promotional role of government
- The FDA and the Patent Office
- The impact of the Sarbanes-Oxley Act on privately owned pharma and biotech companies

Michel Morency, PhD, Shareholder
Greenberg Traurig LLP

3:05 pm Refreshment and Networking Break

3:15 pm Case Study

A Marriage of Two Equals: Making 50-50 Collaborations Work Effectively

Gain some insight into how to effectively use your legal and corporate know-how to structure a profitable 50/50 collaboration between pharma and biotech firms.

- The courtship: negotiating a 50/50 deal
- The marriage: living with the arrangement
- The pre-nuptial: what happens if things do not work out?

W. Bradford Middlekauff, SVP, General Counsel and Secretary
Medarex, Inc.

Ron Pepin, SVP, Business Development
Medarex, Inc.

4:30 pm Closing Remarks from the Chair

CONFERENCE FOCUS

IP rights are crucial for pharmaceutical and biotech companies. In fact, company share value continues to be dependent upon the drugs, biologics or therapeutics that companies have a patent on and which can be brought to market. The pharmaceutical industry needs a constant pipeline of new products to ensure a future stream of revenue. Biotech also faces a challenge – securing the capital to develop its products. Partnering and licensing agreements bridge the gap and help to increase companies' shareholder value.

Strategic alliances between pharma, biotech and research institutes are not a passing trend – they are here to stay. Whether or not partnering and licensing agreements are successful is largely dependent on both the legal and strategic advice given. In order to truly maximize shareholder value and to avoid future litigation, partnering and licensing agreements must reflect foresight, achieve longevity and take account of the different players involved. By having a thorough knowledge of IP law and the latest deal making developments, in-house counsel will serve their company's best interests. It is essential to also maintain an ongoing relationship with external counsel and to keep abreast of issues such as best practice valuation methodologies and what is happening further afield.

This forum will provide an opportunity for counsel, Intellectual Property and Business Development Officers to share best practices and master the challenges they face because of licensing activities. Up-to-the-minute case studies and presentations will show you how companies are negotiating the best deal and creating profitable long-term partnerships.

With the a flurry of activity on the capital markets for emerging biotech companies and a number of pharma patents expiring every day, can you afford not to attend?

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Foley & Lardner's Life Science Industry Team

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