

International Forum on Biotech Commercialization in Greater China/Asia Pacific



Current Trends and Provisions in Pharma-Biotech Strategic Alliances

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Morgan Lewis
C O U N S E L O R S A T L A W

Morgan Lewis

- 1,200 lawyers in 19 offices worldwide
- Depth, Quality and Experience in Life Sciences
 - Nearly 200 lawyers whose practice and experience are significantly devoted to the life sciences industry
- Extensive Scientific Capability
 - More than 200 professionals with academic backgrounds in life sciences, over 60 of whom have advanced scientific degrees
- Extensive Existing Client Base of Experience
 - Represent over 800 life sciences clients

Representative Pharma-Biotech Strategic Alliances

- **Pharmasset** in its development and commercialization collaboration with **Bukwang Pharmaceuticals** of Korea for the treatment of chronic hepatitis B virus
- **Biovail Pharmaceuticals** in its more than \$100 million product divestiture, strategic collaboration and research and development alliance with **Kos Pharmaceuticals** in the area of cardiovascular disease
- **Shire** in its up to \$500 million collaboration with **New River Pharmaceuticals** for the development and commercialization of a late-stage ADHD compound
- **Schering-Plough** in its acquisition of **Bayer AG's** primary care pharmaceutical product business in the United States and related strategic alliances on oncology products and on Zetia® in Japan
- **Sanofi-Aventis** in the restructuring of its Actonel® collaboration with **Procter & Gamble**
- **Adolor** in its worldwide development and commercialization collaboration for Entereg® with **GlaxoSmithKline Pharmasset** in its \$300 million collaboration with **Roche** to develop and commercialize nucleoside polymerase inhibitors for the treatment of chronic hepatitis C virus infections
- **Aventis** in its up to \$485 million collaboration with **Regeneron** to develop and commercialize VEGF-Trap products, and related equity investment
- **Quintiles** in its co-development and co-promotion collaboration with **Eli Lilly** for Cymbalta®
- **Aventis** in its inhaled insulin strategic alliance with **Pfizer** and related collaboration and licensing arrangements with **Nektar Therapeutics**

Background / "Typical" Deal Steps

- Confidentiality Agreement
- Term Sheet/Letter of Intent
- Due Diligence
- Definitive Agreement(s)
- Consents and Approvals
- Closing
- Implementation



Current Trends and Provisions in Pharma-Biotech Strategic Alliances

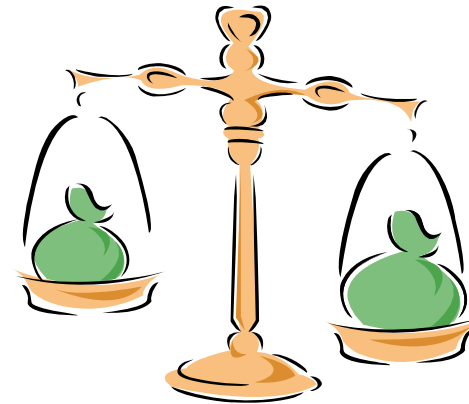
- Financial Provisions
- Development and Commercialization of the Product
- Alignment of the Parties
- Questions & Answers



Current Trends and Provisions in Pharma-Biotech Strategic Alliances

- **Financial Provisions**

- Trend: Biotech wants to receive fair value, while big pharma wants to make sure it doesn't pay too much too soon
- Provisions:
 - Auctions and Bidding Wars
 - Cash Payments
 - Caps on Budgets
 - Payment Reductions
 - Termination



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Financial Provisions

- **Auctions and Bidding Wars**
 - Create Competition in Terms of
 - Money
 - Speed
 - Effort
 - Need for Bidder to Distinguish Itself
 - Criteria and Process for Selection of Winner



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Financial Provisions

- **Cash Payments**
 - Smaller Up-front Fees
 - Smaller but More Milestone Payments
 - FTE Reimbursement for R&D Work
 - Equity Investment



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Financial Provisions

- **Caps on Development and Marketing Budgets**

- Caps on Spending Amounts
- Limits on Number of Years
- Treatment of Overruns
- Mechanism for Annual Resets



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Financial Provisions

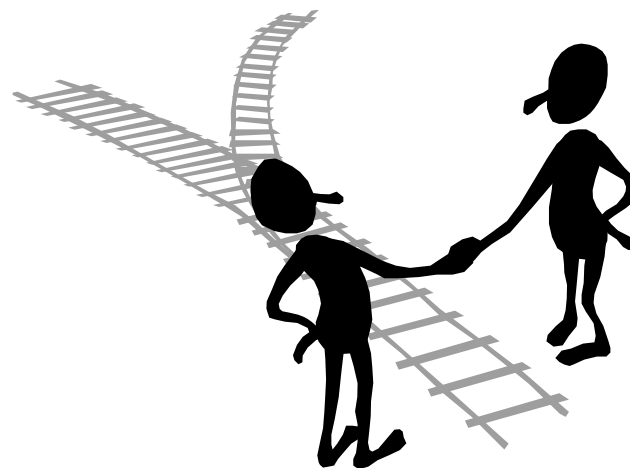
- **Payment Reductions**
 - Royalty Reductions for Generic Competition, Competitive Products and Third Party Royalties
 - Reimbursement of Up-Front Fees or Milestone Payments for Development Delays or Regulatory Problems



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Financial Provisions

- **Termination**

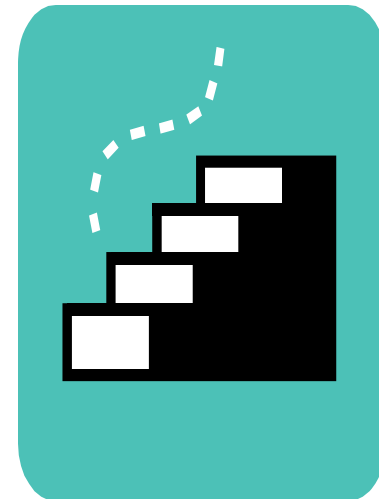
- Ability to Terminate and Cease Further Investment
- Reimbursement Upon Termination for Specific Reasons
- Effects of Termination



Current Trends and Provisions in Pharma-Biotech Strategic Alliances

Development and Commercialization of the Product

- Trend: Biotech wants to see its technology developed and commercialized, but its partner will want flexibility to match its obligations to future events and assessments of product potential
- Provisions:
 - Diligence Efforts
 - Monitoring Progress
 - Ensuring Success
 - Remedies for Diligence Failures



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Development and Commercialization

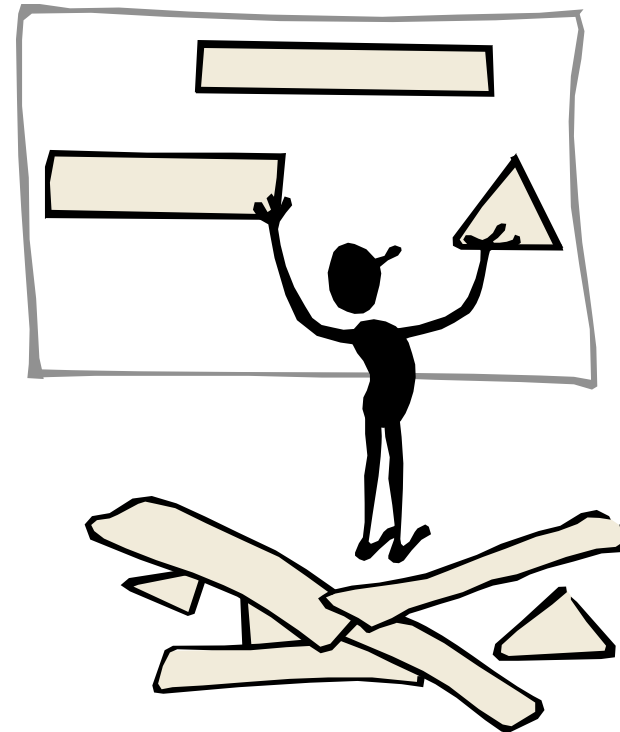
- **Diligence Efforts**
 - Commercially Reasonable Efforts
 - Specific Diligence Provisions
 - Timetables for Achievements



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Development and Commercialization

- **Monitoring Progress**

- Joint Committees
- Periodic Reporting
- Notification Requirements



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Development and Commercialization

- **Ensuring Success**
 - Non-Competes
 - Tie-Breaking Votes
 - Dispute Resolution and Escalation



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Development and Commercialization

- **Remedies**

- Penalties for Delays or Performance Shortfalls
- Termination Rights
- Rights Reversions



Current Trends and Provisions in Pharma-Biotech Strategic Alliances

- **Alignment of the Parties**
 - Trend: Biotechs use the deal to grow capabilities and reputation, and big pharma use the deal as strategic building block
 - Provisions:
 - Downstream Rights
 - Lead Party Roles and Responsibilities
 - Exclusivity
 - Ex-Program Activities
 - Quids



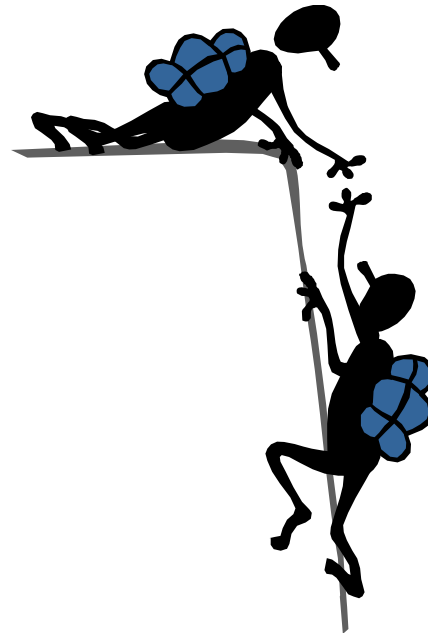
Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Alignment of the Parties

- **Downstream Rights**
 - Manufacturing and Supply
 - Co-Development and Regulatory Filings
 - Co-Promotion



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Alignment of the Parties

- **Lead Party Roles and Responsibilities**
 - Niche Indications for Biotech
 - Prioritization of Indications, Products, Territories and Supply
 - Regulatory Interface
 - Booking of Sales



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Alignment of the Parties

- **Exclusivity**

- Technology and Product Scope
- Duration can be R&D Term or Commercialization
- Exceptions for Internal or Third Party Programs (Carve-outs)



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Alignment of the Parties

- **Ex-Program Activities**

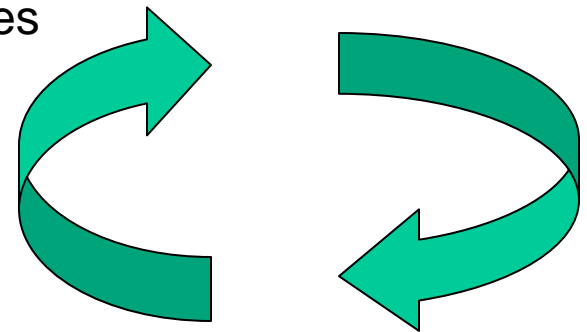
- Use of Collaboration Technology Outside of Program
- Return of Ex-Program Information for Program
- Buy-In Rights
- Royalties or other Reward-Sharing Mechanism



Current Trends and Provisions in Pharma-Biotech Strategic Alliances: Protections Against Disalignment

- **Quids**

- Timing of Selection
- Selection Process or Fix in Agreement
- Stage of Product and Capabilities Needed
- Scope of Rights from Co-Promote to Book Sales
- Independence (or Not) from Collaboration
- Co-Termination with Collaboration



Current Trends and Provisions in Pharma-Biotech Strategic Alliances

Questions
&
Answers

