

LES Annual Meeting – October 17-21, 2004 Boston – Marriott Copley Place



Biotech and Pharma M&A and Collaborations: Protecting the Deal and Preserving Your Upside

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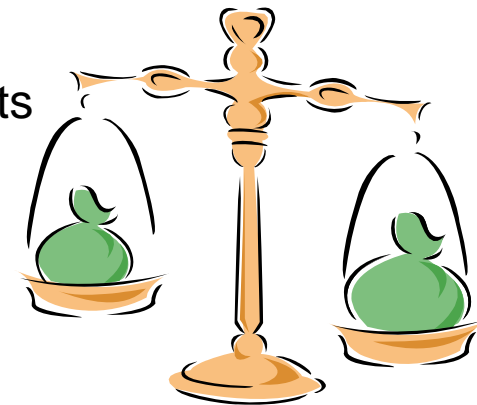
Biotech and Pharma M&A and Collaborations: Protecting the Deal and Preserving Your Upside

- “One for You, Two for Me...”: Protections Against (1) Paying Too Much and (2) Getting Too Little
- “Getting with the Program”: Protecting the Development and Commercialization of the Product
- “You’re Going the Wrong Way!”: Protections Against Disalignment
- “Pick Your Medicine!”: Transaction Structures
- Questions & Answers



Biotech and Pharma M&A and Collaborations: Protecting the Deal and Preserving Your Upside

- **“One for You, Two for Me...”: Protections Against (1) Paying Too Much and (2) Getting Too Little**
 - Issue: Biotech wants to receive fair value, while big pharma wants to make sure it doesn't pay too much too soon
 - Protective Actions and Provisions:
 - Auctions and Bidding Wars
 - Cash Payments
 - Caps on Development and Marketing Budgets
 - Payment Reductions
 - Termination



“One for You, Two for Me...”: Protections Against (1) Paying Too Much and (2) Getting Too Little

- **Auctions and Bidding Wars**

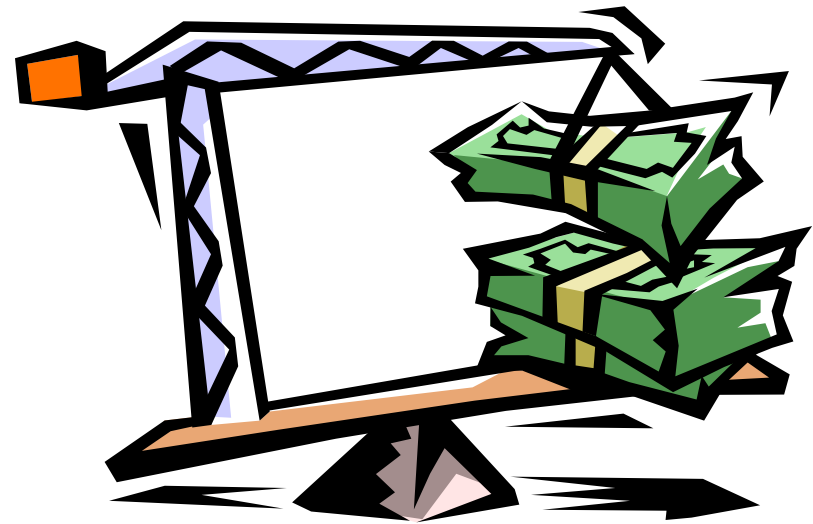
- Create Competition in Terms of Money, Speed and Effort
- Need for Bidder to Distinguish Itself
- Criteria and Process for Selection of Winner



“One for You, Two for Me...”: Protections Against (1) Paying Too Much and (2) Getting Too Little

- **Cash Payments**

- Smaller Up-front Fees
- Contingent Value Rights in M&A
- Smaller but More Milestone Payments
- FTE Reimbursement for R&D Work
- Equity Investment



“One for You, Two for Me...”: Protections Against (1) Paying Too Much and (2) Getting Too Little

- **Caps on Development and Marketing Budgets**

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



“One for You, Two for Me...”: Protections Against (1) Paying Too Much and (2) Getting Too Little

- **Payment Reductions**

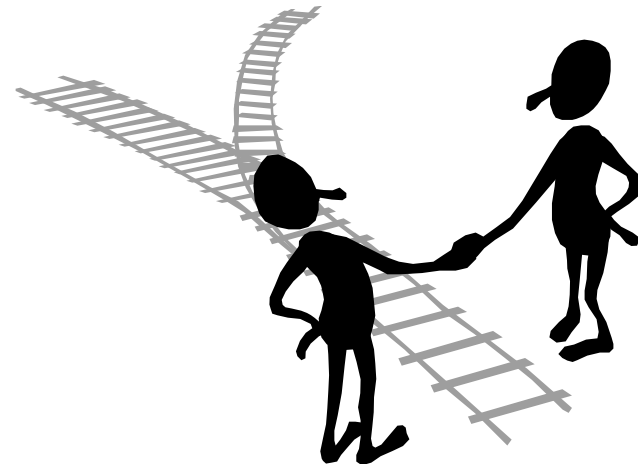
- Royalty Reductions for Generic Competition, Competitive Products and Third Party Royalties
- Reimbursement of Up-Front Fees or Milestone Payments for Development Delays or Regulatory Problems
- In M&A, CVR Payments can be in Tiers Depending on Product Achievements



“One for You, Two for Me...”: Protections Against (1) Paying Too Much and (2) Getting Too Little

- **Termination**

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



Biotech and Pharma M&A and Collaborations: Protecting the Deal and Preserving Your Upside

“Getting with the Program”: Protecting the Development and Commercialization of the Product

- Issue: 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
- Protective Provisions:
 - Diligence Efforts
 - Monitoring Progress
 - Ensuring Success
 - Remedies for Diligence Failures



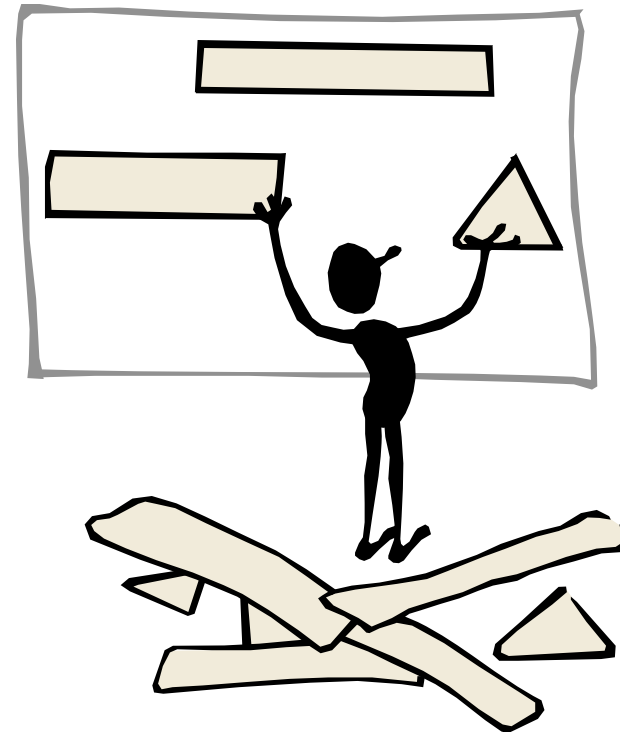
“Getting with the Program”: Protecting the Development and Commercialization of the Product

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



“Getting with the Program”: Protecting the Development and Commercialization of the Product

- **Monitoring Progress**
 - Joint Committees
 - Periodic Reporting
 - Notification Requirements
 - In M&A, Board Committees



“Getting with the Program”: Protecting the Development and Commercialization of the Product

- **Ensuring Success**
 - Non-Competes
 - Tie-Breaking Votes
 - Dispute Resolution and Escalation
 - In M&A, Governance Agreement



“Getting with the Program”’: Protecting the Development and Commercialization of the Product

- Remedies
 - Penalties for Delays
 - Termination Rights
 - Rights Reversions



Biotech and Pharma M&A and Collaborations: Protecting the Deal and Preserving Your Upside

- **“You’re Going the Wrong Way!”: Protections Against Disalignment**
 - Issue: Biotechs use the deal to grow capabilities and reputation, and big pharma use the deal as strategic building block
 - Protective Provisions:
 - Downstream Rights
 - Lead Party Roles and Responsibilities
 - Exclusivity
 - Ex-Program Activities
 - Quids



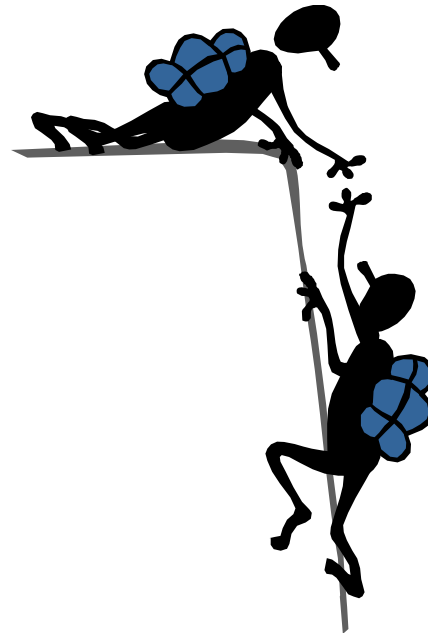
“You’re Going the Wrong Way!”: Protections Against Disalignment

- **Downstream Rights: ‘Who’s got the wheel?’**
 - Manufacturing and Supply
 - Co-Development and Regulatory Filings
 - Co-Promotion



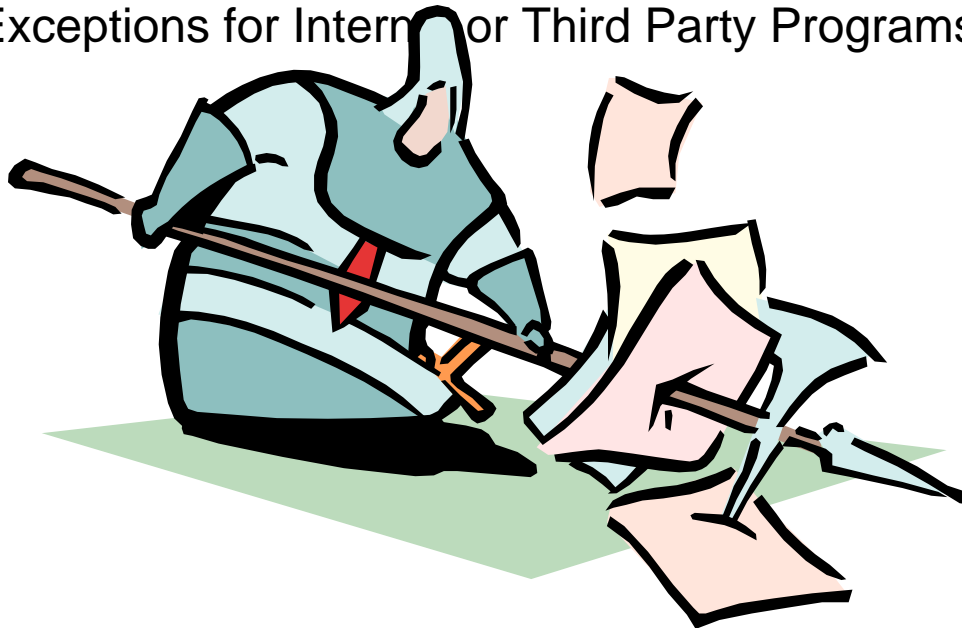
“You’re Going the Wrong Way!”: Protections Against Disalignment

- **Lead Party Roles and Responsibilities: ‘Don’t panic, I’m in charge now’**
 - Niche Indications for Biotech
 - Prioritization of Indications, Products, Territories and Supply
 - Regulatory Interface
 - Booking of Sales



“You’re Going the Wrong Way!”: Protections Against Disalignment

- **Exclusivity: “What’s mine is mine and what’s yours is mine”**
 - Technology and Product Scope
 - Duration can be R&D Term or Commercialization
 - Exceptions for Internal or Third Party Programs (Carve-outs)



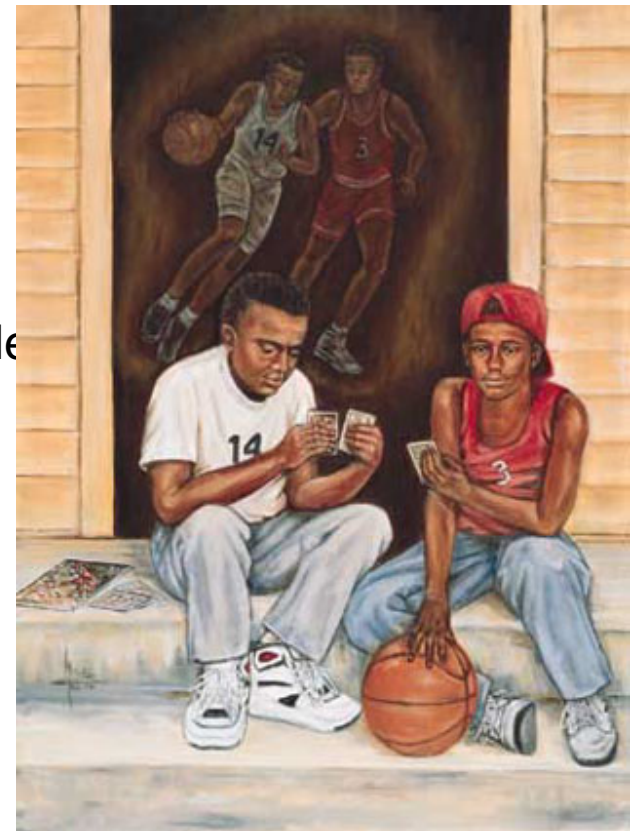
“You’re Going the Wrong Way!”: Protections Against Disalignment

- **Ex-Program Activities: ‘I’m committed, but can I see other people?’**
 - Use of Collaboration Technology Outside of Program
 - Return of Ex-Program Information for Program
 - Buy-In Rights
 - Royalties or other Reward-Sharing Mechanism



“You’re Going the Wrong Way!”: Protections Against Disalignment

- **Quids: ‘I’ll trade ya... no backsies!’**
 - Timing of Selection
 - Selection Process or Fix in Agreement
 - Stage of Product and Capabilities Needed
 - Scope of Rights from Co-Promote to Book Sale
 - Independence (or Not) from Collaboration
 - Co-Termination with Collaboration



Biotech and Pharma M&A and Collaborations: Protecting the Deal and Preserving Your Upside

- **“Pick Your Medicine!”: Transaction Structures**
 - Issue: How to select the best structure for:
 - Licenses
 - JV’s
 - Acquisitions



“Pick Your Medicine!”: Transaction Structures

LICENSES

Benefits:

- Access specific technology or compounds with no additional baggage
- Familiar structure that can be custom tailored
- High level of focus over asset

Challenges:

- Competitive marketplace has driven the price of these transactions up
- Level of retained rights desired by licensor



“Pick Your Medicine!”: Transaction Structures

JOINT VENTURES

Benefits:

- Access to assets/expertise that are “not for sale”
- Expand into market segments which complement core business - without the cost of an acquisition
- Leverage internal and partner’s expertise



Challenges:

- Increased management time required vs. outright ownership
- Complexity of separate legal entity which requires it’s own operational and financial goals
- JV directly competing with one or both of the parent companies
- Exit strategy needs to be aligned with JV purpose

“Pick Your Medicine!”: Transaction Structures

ACQUISITIONS

Benefits:

- Unilateral management control over the business
- Business is consolidated into the Company’s “Business Processes” - planning, reporting, resource allocations, etc.

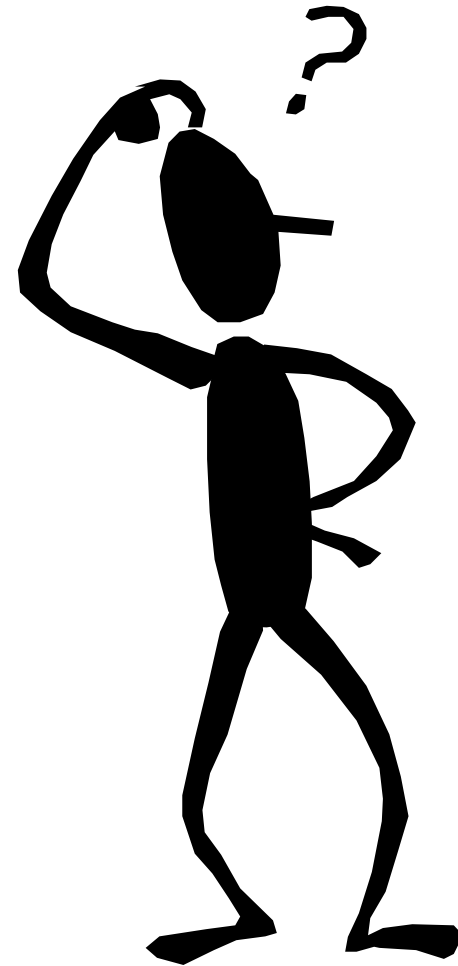
Challenges:

- Non-core assets
- Management time to effectively integrate acquisition into the business
- Ability to retain key employees
- Potential short term accounting/earnings issues



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Questions & Answers



Biotech and Pharma M&A and Collaborations: Protecting the Deal and Preserving Your Upside

Discussion Questions

- Protective Ways to Choose a Partner
- Protection Through Due Diligence: Hot Areas
- Protections Against Being Acquired by Your Collaboration Partner

Discussion Questions

Protective Ways to Choose a Partner

- Existing Relationships
- MTAs
- Feasibility Studies
- Scientific Alignment
- Cultural Fit

Discussion Questions

Protection Through Due Diligence: Hot Areas

- Patents and other IP
- Other Collaborations and Licenses
- FDA/Regulatory
- Equity/capitalization
- Litigation/Risks
- Change-in-Control/Approvals

Discussion Questions

Protections Against being Acquired by Your Collaboration Partner

- Standstill Provisions
- Equity Investments
- Changes in Valuation from Deal
- Post-Signing New Programs and Deals