

NJTC
June 8, 2005



Partnering with Large Pharma

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Partnering with Large Pharma

- “Getting with the Program”: Development and Commercialization of the Product
- “You’re Going the Wrong Way!”: Keeping Your Partner Aligned
- “Money Talks...”: Financial Provisions in Biotech Deals
- Questions & Answers

Partnering with Large Pharma

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

- Issue: Licensor wants to see its technology developed and commercialized, but large pharma may want flexibility to match its obligations to future events and assessments of product potential
- Strategies:
 - Diligence Efforts
 - Monitoring Progress
 - Ensuring Success
 - Remedies for Diligence Failures



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

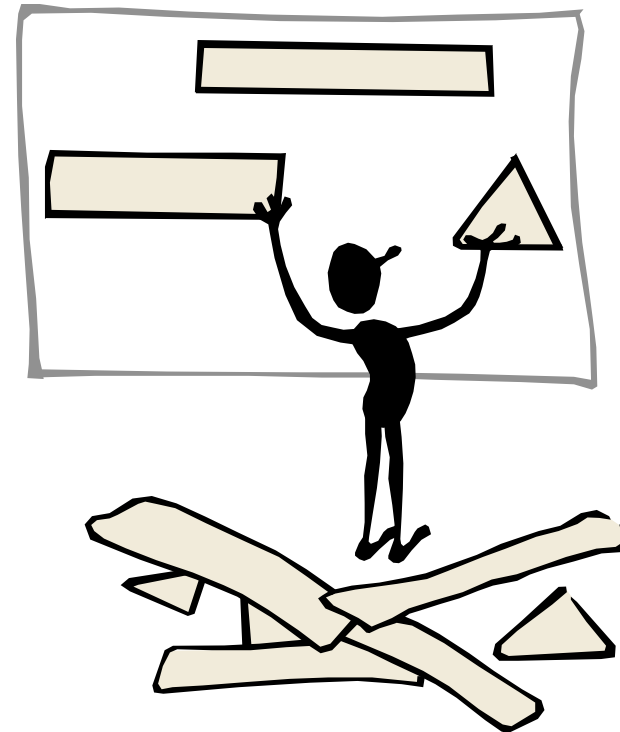
- **Diligence Efforts**
 - Commercially Reasonable Efforts
 - Specific Diligence Provisions
 - Timetables for Achievements



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

- **Monitoring Progress**

- Joint Committees
- Periodic Reporting
- Notification Requirements



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

- **Ensuring Success**

- Non-Competes
- Tie-Breaking Votes
- Dispute Resolution and Escalation



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

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



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

- **Questions for Audience Participation**
 - Do you think that a partnering deal should include all product indications? All fields of use? As the licensor? As the large pharma? Why?
 - Should the large pharma partner be able to have other products in development or on the market in the same indication or field of use as the collaboration product? As the licensor? As the large pharma? Why?

Partnering with Large Pharma

- **“You’re Going the Wrong Way!”: Keeping Your Partner Aligned**
 - Issue: Licensors may use the deal to grow capabilities and reputation, while large pharma may use it for a specific product or strategic area of business
 - Strategies:
 - Downstream Rights
 - Lead Party Roles and Responsibilities
 - Exclusivity
 - Quids



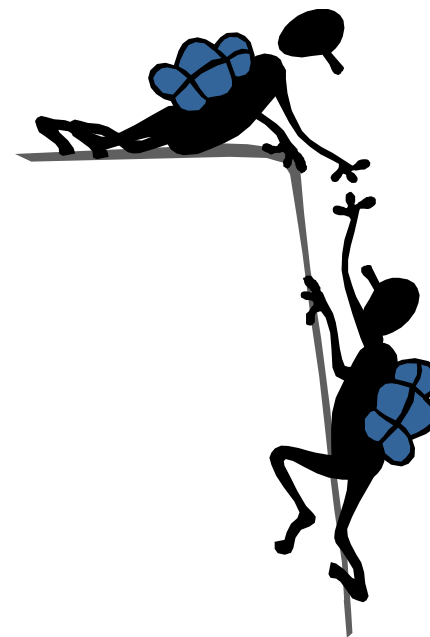
“You’re Going the Wrong Way!”: Keeping Your Partner Aligned

- **Downstream Rights: ‘Who’s got the wheel?’**
 - Large Pharma has present capabilities but Licensor may want to develop ability to grow into a FIPCO
 - Manufacturing and Supply
 - Co-Development and Regulatory
 - Co-Promotion



“You’re Going the Wrong Way!”: Keeping Your Partner Aligned

- **Lead Party Roles and Responsibilities: ‘Don’t panic, I’m in charge now’**
 - Large Pharma has experience, but Licensor wants to play too!
 - Niche Indications for Biotech
 - Prioritization of Indications, Products, Territories and Supply
 - Regulatory Interface
 - Booking of Sales
- *Battle of capabilities or battle of egos*



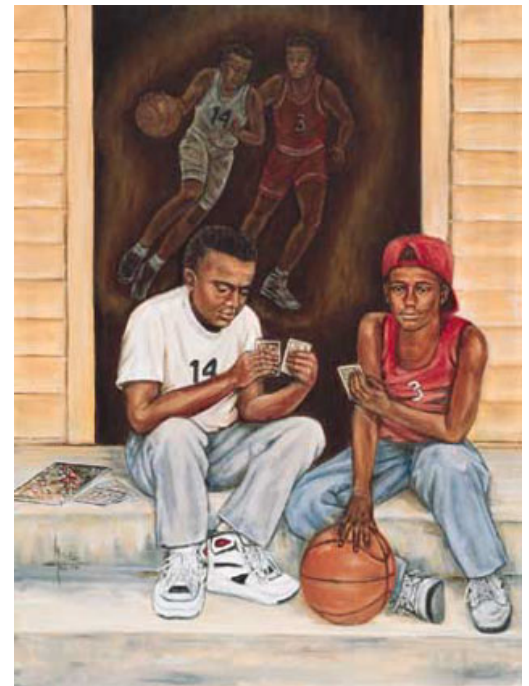
“You’re Going the Wrong Way!”: Keeping Your Partner Aligned

- **Exclusivity: “What’s mine is mine and what’s yours is mine”**
 - Technology and Product Scope – how broad is the deal?
 - Duration can be R&D Term or Commercialization
 - Exceptions for Internal or Third Party Programs (i.e., Carve-outs)



“You’re Going the Wrong Way!”: Keeping Your Partner Aligned

- **Quids: ‘I’ll trade ya... no backsies!’**
 - Every licensor would like a product back, but large pharma isn’t likely to give up a cash cow
 - 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

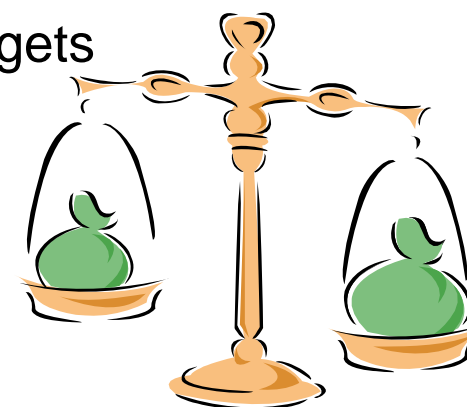


“You’re Going the Wrong Way!”: Keeping Your Partner Aligned

- **Questions for Audience Participation**
 - Should both parties co-promote the collaboration product? As the licensor? As the large pharma? Why?
 - Should the parties be free to use the collaboration technology outside the collaboration? As the licensor? As the large pharma? Why?

Partnering with Large Pharma

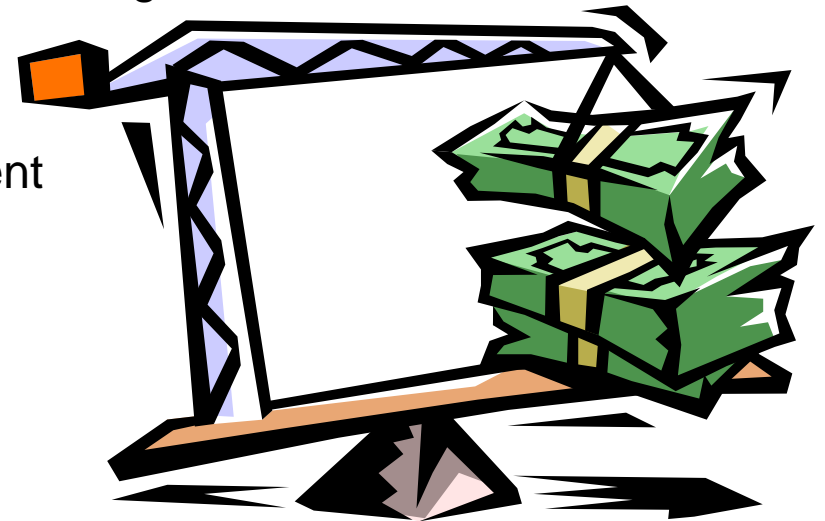
- **“Money talks... but all mine ever says is good-bye”:
Financial Provisions in Partnering Deals**
 - Issue: Licensor wants to receive fair value, while large pharma wants to make sure it doesn't pay too much too soon
 - Strategies:
 - Cash Payments
 - Caps on Development and Marketing Budgets
 - Payment Reductions
 - Termination



“Money Talks...”: Financial Provisions in Partnering Deals

- **Cash Payments**

- Up-front Fees – paying for the past or future success?
- Smaller but More Milestone Payments – spreading out the pain
- Royalties, Sales Milestones or Profit Sharing
- Options Payments
- Acquisition of Inventory and Equipment
- FTE Reimbursement for R&D Work
- Equity Investments



“Money Talks...”: Financial Provisions in Partnering Deals

- **Development and Marketing Budgets**

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



“Money Talks...”: Financial Provisions in Partnering Deals

- **Payment Adjustments**

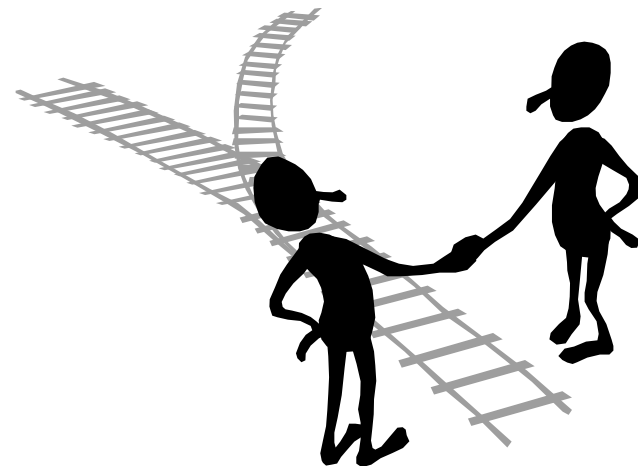
- Adjustments to Milestones based on Indications Received or Labeling at Approval
- Royalty Reductions for:
 - Expiration of Patents or Market Exclusivity
 - Generic Competition
 - Competitive Product Launches
 - Third Party Royalties
 - Rx to OTC Switches
- Reimbursement of Up-Front Fees or Milestone Payments for Development Delays or Regulatory Problems



“Money Talks...”: Financial Provisions in Partnering Deals

- **Termination**

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



“Money Talks...”: Financial Provisions in Partnering Deals

- **Questions for Audience Participation**
 - Would you prefer a larger upfront payment, or defer to larger milestone payments or royalties? As the licensor? As a large pharma? Why?
 - Would you prefer royalties or a profit-split on sales of products from the collaboration? As the licensor? As a large pharma? Why?

Partnering with Large Pharma

Questions & Answers

