

# **Protecting Your Downside While Maximizing Your Upside: *Protective Provisions in Biotech Deals***

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# Protecting Your Downside While Maximizing Your Upside: *Protective Provisions in Biotech Deals*

- **‘One for You, Two for Me...’:**  
*Protections Against (i) Paying Too Much and (ii) Getting Too Little*
- **‘Getting with the Program’:**  
*Protecting the Development of the Product*
- **‘Wandering Eye for the Biotech Guy’:** *Protections Against Disalignment from Goals Not Core to the Collaboration*
- **Discussion Questions**

# Protecting Your Downside While Maximizing Your Upside: *Protective Provisions in Biotech Deals*

- **‘One for You, Two for Me...’:  
*Protections Against (i) Paying Too Much and (ii) Getting Too Little***
  - Issue: Biotech wants to receive a fair deal for its product, while big pharma wants to make sure it doesn’t pay too much too soon
  - Protective Actions and Provisions:
    - Auctions and Bidding Wars
    - Due Diligence
    - Cash Payments
    - Caps on Development and Marketing Budgets
    - Payment Reductions
    - Termination

**‘One for You, Two for Me...’:  
*Protections Against (i) Paying Too Much and  
(ii) 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 (i) Paying Too Much and  
(ii) Getting Too Little***

- ***Due Diligence***
  - CDAs
  - Focus on IP and Regulatory Areas
  - Representations and Conditions Tailored to Specific Facts and Issues

**'One for You, Two for Me...':  
Protections Against (i) Paying Too Much and  
(ii) Getting Too Little**

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

**‘One for You, Two for Me...’:  
Protections Against (i) Paying Too Much and  
(ii) 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 (i) Paying Too Much and  
(ii) 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

**‘One for You, Two for Me...’:  
Protections Against (i) Paying Too Much and  
(ii) Getting Too Little**

- ***Termination***

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

# Protecting Your Downside While Maximizing Your Upside: *Protective Provisions in Biotech Deals*

- **‘Getting with the Program’:**  
***Protecting the Development 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
    - Monitoring Progress
    - Ensuring Success
    - Remedies for Diligence Failures

# **‘Getting with the Program’: *Protecting the Development of the Product***

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

# **'Getting with the Program': *Protecting the Development of the Product***

- ***Monitoring Progress***
  - Joint Committees
  - Periodic Reporting
  - Notification Requirements

# **‘Getting with the Program’: *Protecting the Development of the Product***

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

# **'Getting with the Program': *Protecting the Development of the Product***

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

# Protecting Your Downside While Maximizing Your Upside: *Protective Provisions in Biotech Deals*

- **‘Wandering Eye for the Biotech Guy’: *Protections Against Disalignment from Goals Not Core to the Collaboration***
  - Issue: Biotechs may want to use the deal to grow capabilities and reputation, and big pharma may want to use the deal as a strategic building block
  - Protective Provisions:
    - Downstream Rights
    - Lead Party Roles and Responsibilities
    - Exclusivity
    - Ex-Program Activities
    - Quids
    - Clawbacks on Rights

# ***‘Wandering Eye for the Biotech Guy’: Protections Against Disalignment from Goals Not Core to the Collaboration***

- ***Downstream Rights***
  - Manufacturing and Supply
  - Co-Development
  - Co-Promotion
  - Conversion Options

# ***‘Wandering Eye for the Biotech Guy’: Protections Against Disalignment from Goals Not Core to the Collaboration***

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

# ***‘Wandering Eye for the Biotech Guy’: Protections Against Disalignment from Goals Not Core to the Collaboration***

- ***Exclusivity***
  - Technology and Product Scope
  - Duration can be R&D Term or Commercialization
  - Exceptions for Internal or Third Party Programs

# ***‘Wandering Eye for the Biotech Guy’: Protections Against Disalignment from Goals Not Core to the Collaboration***

- ***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

# ***‘Wandering Eye for the Biotech Guy’: Protections Against Disalignment from Goals Not Core to the Collaboration***

- ***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

# Protecting Your Downside While Maximizing Your Upside: *Protective Provisions in Biotech Deals*

## ***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