

Making 50-50 Collaborations Work Effectively

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**Advanced Pharma and Biotech IP Licensing:
Creating the Winning Deal**

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

Making 50-50 Collaborations Work Effectively

- **‘One for You, Two for Me...’:**
Protections Against (i) Paying Too Much and (ii) Getting Too Little
- **‘Getting with the Program’:**
Protecting the Development and Commercialization of the Product
- **‘You’re Going the Wrong Way!’:** *Protections Against Disalignment*
- **Discussion Questions**

Making 50-50 Collaborations Work Effectively

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

- ***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

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- **‘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

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

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

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

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

Making 50-50 Collaborations Work Effectively

- ‘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:***
 - Manufacturing and Supply
 - Co-Development and Regulatory Filings
 - Co-Promotion

‘You’re Going the Wrong Way!’: *Protections Against Disalignment*

- ***Lead Party Roles and Responsibilities:***
 - 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:***
 - 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:***
 - 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:***
 - 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

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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

- *Due Diligence*

- CDAs
- Focus on IP and Regulatory Areas
- Understand Encumbrances Created by Other Deals
- Representations and Conditions Tailored to Specific Facts and Issues

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