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How to Prevent Legal Pitfalls in Early-Stage Biotech Deals

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Abstract

Companies in the life sciences sector share a number of particularities not routinely encountered in other industries: long product development cycles, equity based financing, complex intellectual property portfolios, and reliance on strategic alliances or partnering. These particularities influence early-stage biotechnology transactions, i.e., transactions involving product candidates up to and including phase II clinical trials or companies with such products as their principal assets.

In early-stage biotechnology transactions, the parties often have access to limited or no public information about the target company, its products or other assets. A diligent evaluation of the target company, its technology and key assets, is therefore of the utmost importance when it comes to acquisitions, financing, or technology transfer and collaborations. Such an evaluation must cover all relevant legal issues:

You can prevent legal pitfalls by identifying and addressing legal issues in time. This will help to achieve the long-term goals the transaction partners are seeking.

An efficient, well structured schedule leading to the conclusion of the transaction agreement should always be carefully worked out in advance. For all legal issues, it is essential to establish a step-by-step procedure which can be divided into the following four phases:

1. **Pre-Evaluation Phase**, i.e., the phase in which the parties agree to evaluate a potential transaction but do not at this stage disclose to each other any proprietary information;

2. **Evaluation Phase**, i.e., the phase in which the parties provide each other with (proprietary) information about their businesses and assets to allow the other party to carry out a factual evaluation to enable them to decide whether and on what terms the transaction should proceed;

3. **Transaction Phase**, i.e., the phase in which the parties negotiate and agree upon the detailed terms and conditions of the transaction agreement;

4. **Implementation Phase**, i.e., the phase in which the arrangements provided in the transaction agreement are put into practice.

In each of these phases we recommend that an agreed timetable and specific opt-out scheme is followed.

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Key Considerations in the Pre-Evaluation Phase:

- Identify and characterize the contractual party (e.g., research institution, pharmaceutical company, investor, competitor)

- Identify the contractual party's interests in the transaction (e.g., scientific or commercial, strategic or financial, long-term or short-term)

- Define the subject matter of the transaction (e.g., IP, biological material or processes, asset deal, share deal)

- Anticipate the basic structure of the transaction (e.g., licensing, collaboration, acquisition, capital investment)

- Assess the need to obtain or grant exclusivity during the evaluation phase

- Identify any specific aspects in view of confidentiality requirements (e.g., know-how transfer to competitors, non-disclosure obligations for public companies)

- Implement Disclosure Agreement

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Key Considerations in the Evaluation Phase:

- Corporate & Commercial Matters:

- Who is the real decision maker on each side (management, board, shareholders)? Are all these players aligned?
- What is the risk that the contracting party may not perform during the life of the agreement (financially or scientifically)?
- Define scope of due diligence (restricted, for license or collaboration, full, in case of share deal)
- Also a restricted due diligence must include all commercial agreements (e.g., manufacturing, distribution, supply, licensing) and co-operation agreements (e.g., research grants, co-development agreements) regarding a specific compound

- IP Matters:
  - Identify the relevant IP rights (patents, trademarks, design, copyright, proprietary know-how)
  - Analyze the ownership of / entitlement to the relevant IP rights
  - Characterize the legal status of the relevant IP rights
  - Review and assess the (long-term) IP strategy
  - Freedom-to-operate analysis
  - Identify the reach-through issues
- Regulatory Issues:
  - Identify and analyze the regulatory restrictions in the relevant field of technology
  - Review and assess the (long-term) product approval strategy

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Key Considerations in the Transaction Phase:

The considerations analyzed in the Pre-Evaluation Phase and Evaluation Phase need to be properly reflected in the transaction agreement and, *inter alia*, can be critical to

- Evaluate the appropriate business partner
- Design the optimal transaction model, financing structure, corporate structure and/or tax structure

- Implement commercial terms which accurately reflect the economic potential and risks
- Duly reflect the results of the due diligence
- Agree on reasonable information, inspection and audit rights
- Secure the legally enforceable transfer of rights (ownership rights, license rights etc.)
- Properly protect inventions and innovative concepts
- Properly allocate ownership / control over IP rights
- Secure appropriate IP and regulatory strategies
- Properly define milestones
- Prepare an exit strategy in case collaboration / partnering does not work

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Key Considerations in the Implementation Phase:

Signing the transaction agreement does, factually, not mean the accomplishment but the beginning of the transaction. The implementation of the transaction agreement needs to be observed in order to allow the parties to make accurately timed adjustments, if required:

- Is the agreement followed in practice?
- Are common decisions properly documented (e.g. minutes of steering committee)?
- Is proof and notice of non-compliance sufficiently documented?
- Is there a minimal common structure in case of a critical control shifting (e.g. many shareholders are selling their shares)?
- Are calculations for royalties, participation in sales etc. directed by a robust process?

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