



**COMMIT**

# Unwinding Life Sciences Collaborations

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# Agenda

- Issues that often prompt the early unwinding of collaborations:
  - Milestones are poorly defined/ambiguous resulting in disagreements as to satisfaction
  - Diligence requirements are onerous and unable to be satisfied
  - Pathway for success of a development stage product changes
  - Parties have different opinions as to the success of the product and the appropriate amount of resources to commit
- Pathways for unwinding collaborations:
  - Termination of agreement
  - Negotiated amendment or restructure of agreement
  - Divestment of the Asset
- Issues to consider in the event of a wind-down:
  - Transition activities of the parties
  - Handling of IP generated during collaboration
  - “Exit” consideration



# Issues that Often Prompt the Early Unwinding of Collaborations





## Issues that Often Prompt the Early Unwinding of Collaborations

- Milestones are poorly defined/ambiguous resulting in disagreements as to satisfaction
  - Example – first patient/first dose in a Phase III Trial and not “successful completion” of a Phase II Trial
- Diligence requirements are onerous and unable to be satisfied
  - Avoid agreeing to complete milestones by a date certain
  - Commercially Reasonable Efforts only standard is preferable
- Pathway for success of a development stage product changes
  - Regulatory path to market becomes more expensive and/or time consuming
  - Strength of IP rights protecting product changes
  - Parties have different opinions as to the success of the product and the appropriate amount of resources to commit



# Pathways for Unwinding Collaborations





# Termination of Agreement

- Does a party have the right to terminate for convenience?
  - What are the penalties?
  - When is the termination effective? Example – termination right language
- Should the parties just mutually agree to amend the agreement to effect the termination?
- Does one party have significantly more leverage?
  - Is one party in breach of the current agreement?
  - Do the existing survival provisions more severely impact one party?
- Is a release required?
  - Does it apply only to claims preceding the settlement date?





## Poorly Drafted Termination Right

- **“After the seventh (7<sup>th</sup>) anniversary date of this License, Licensee may terminate this License with respect to the entire Territory for all Licensed Products on thirty-two (32) months prior written notice (“Termination Notice”) to Licensor (“Termination Notice Period”). Except as otherwise provided below, this License including, without limitation all payment obligations hereunder including any Development Plans that have been accepted as of the date of the Termination Notice, shall continue in full force and effect through the end of the Termination Notice Period.”**
  - Parties intent is ambiguous.
  - Is the License terminable effective as of the 7<sup>th</sup> anniversary date or does the Termination Notice Period shift the earliest effective date of termination to the 8.5 year anniversary date?





## More Precisely Drafted Termination Right

- “Licensee shall have the right to terminate this Agreement from and after one hundred and twenty (120) days following the fifth (5<sup>th</sup>) anniversary of Regulatory Approval of the Product in the United States upon twenty-four (24) months’ prior written notice to Licensor. For clarity, **Licensee may provide written notice of termination to Licensor at any time from or after one hundred and twenty (120) days following the third (3<sup>rd</sup>) anniversary of Regulatory Approval of the Product in the United States, such that this Agreement may be terminated by Licensee effective any time from or after one hundred and twenty (120) days following the fifth (5<sup>th</sup>) anniversary of Regulatory Approval of the Product in the United States.**”
  - Clarification sentence simplifies interpretation and underscores the parties intent







## Negotiated Amendment or Restructure of Agreement (1 of 2)

- In some cases termination is unavailable or undesirable – better for the parties to continue working under new conditions
- Can amend the original agreement or restate it – this allows parties to:
  - Address issues that arose since signing
  - Clarify existing ambiguities
  - Renegotiate now-unfavorable terms (including payment obligations)
- Example – Negotiate an amendment to suspend affirmative obligations under original documents pending completion of prescribed activities (e.g., a pivotal clinical trial)





## Negotiated Amendment or Restructure of Agreement (2 of 2)

- Best practices:
  - Clearly and specifically define new/ongoing obligations
  - Limit representations and covenants regarding any new/ongoing obligations
  - Can include a release for past activities
    - BUT, claims relating to new/ongoing obligations under the restructured collaboration and transition activities would not be extinguished





## Divestment of the Asset

- In some cases, the parties can't break up immediately, but want to limit their ongoing activities – a divestment may make sense
- In this case, the asset is handed back over a prescribed period of time
- Can address:
  - Transition services provided by a party
  - Supply of materials/product
  - Handling of existing inventory
  - IP licensing



# Issues to Consider in the Event of a Wind-down





## Transition Activities of the Parties

- Define the end-point of any post-handback assistance/transition services objectively and with as much specificity as possible
  - **“Transition Period”**: the period, on a country-by-country basis, from the Effective Date until the end of both the MA Transfer Period (Phase 1) and the Supply Transfer Period (Phase 2), but in no event longer than two (2) years from the Effective Date.
- Provide for a period to settle rolling Net Sales royalty deductions that arise post-closing but relate to pre-closing royalties
  - Example – receiving party lowers the price of a product in the market (e.g., reverse “channel stuffing”) and end-users return product sold by party handing back the product to purchase new product at the lower price. Party handing back the product should be entitled to a refund of pre-closing royalties paid on Net Sales under the original agreements, but may not have a right of recovery if they were terminated.





# Handling of IP Generated During Collaboration

- Both parties likely generated IP during the collaboration
  - Who owns it under the original agreement?
  - What is it useful for?
    - IP generated during the collaboration may have utility in other fields/products
  - Who gets to use it?
    - Do you need to negotiate a new license for the non-owning party?
  - How do you untangle the parties' interests so that you don't have overlapping IP interests?
  - May require non-competes





## “Exit” Consideration

- Who had the leverage? Consider any payments which may be necessary to induce renegotiation and/or settlement
  - Lump sum payment (in a settlement, this amount is often some percentage of potential damages anticipated in litigation)
  - Convertible note
  - Equity investment in former partner and/or its affiliates
  - Revised development cost allocations



Thank You

