

Deal Structuring: Negotiating IP Terms in Development Agreements

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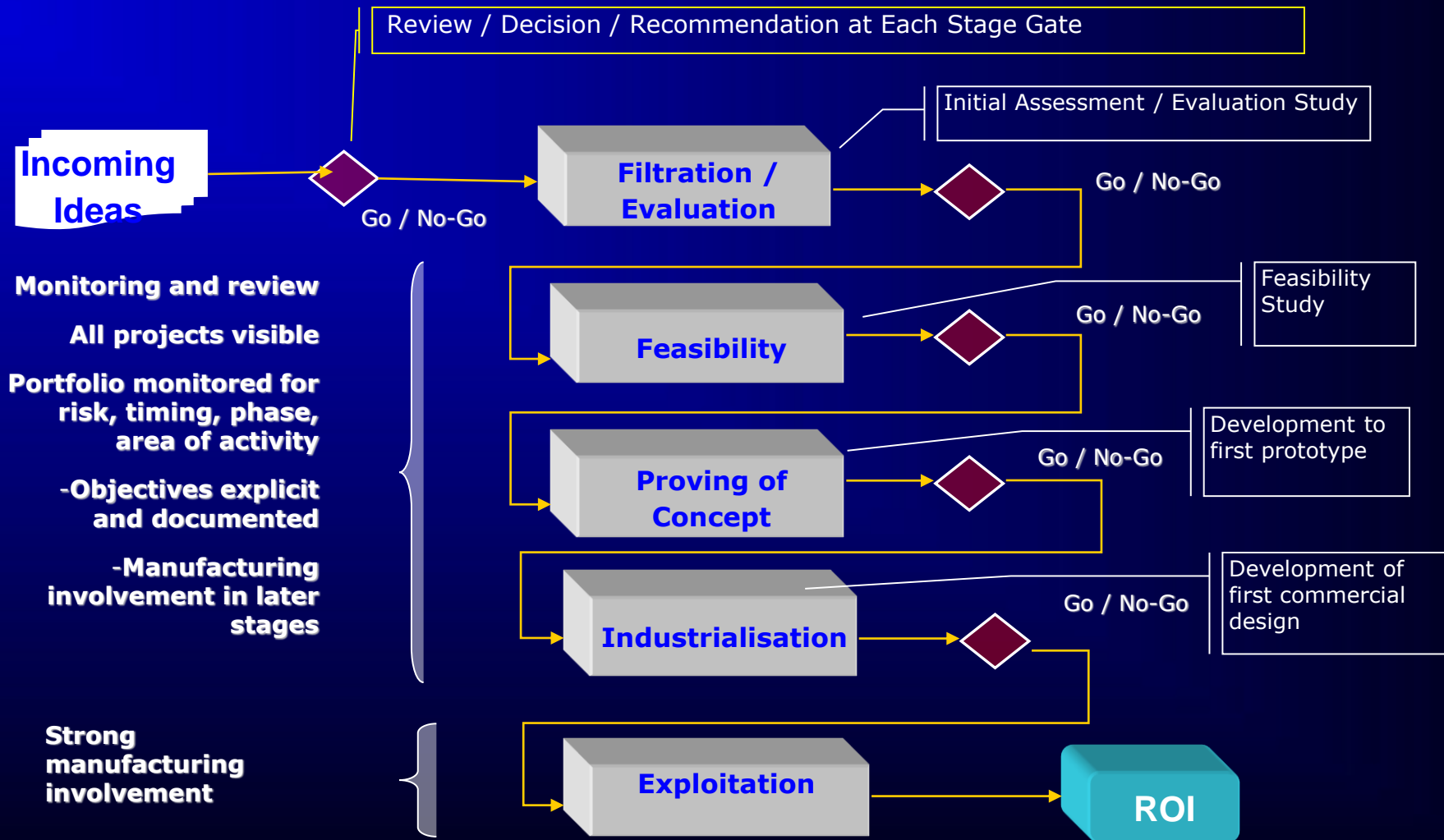
Understanding the Large Company's Challenges

Timelines for product development are very long

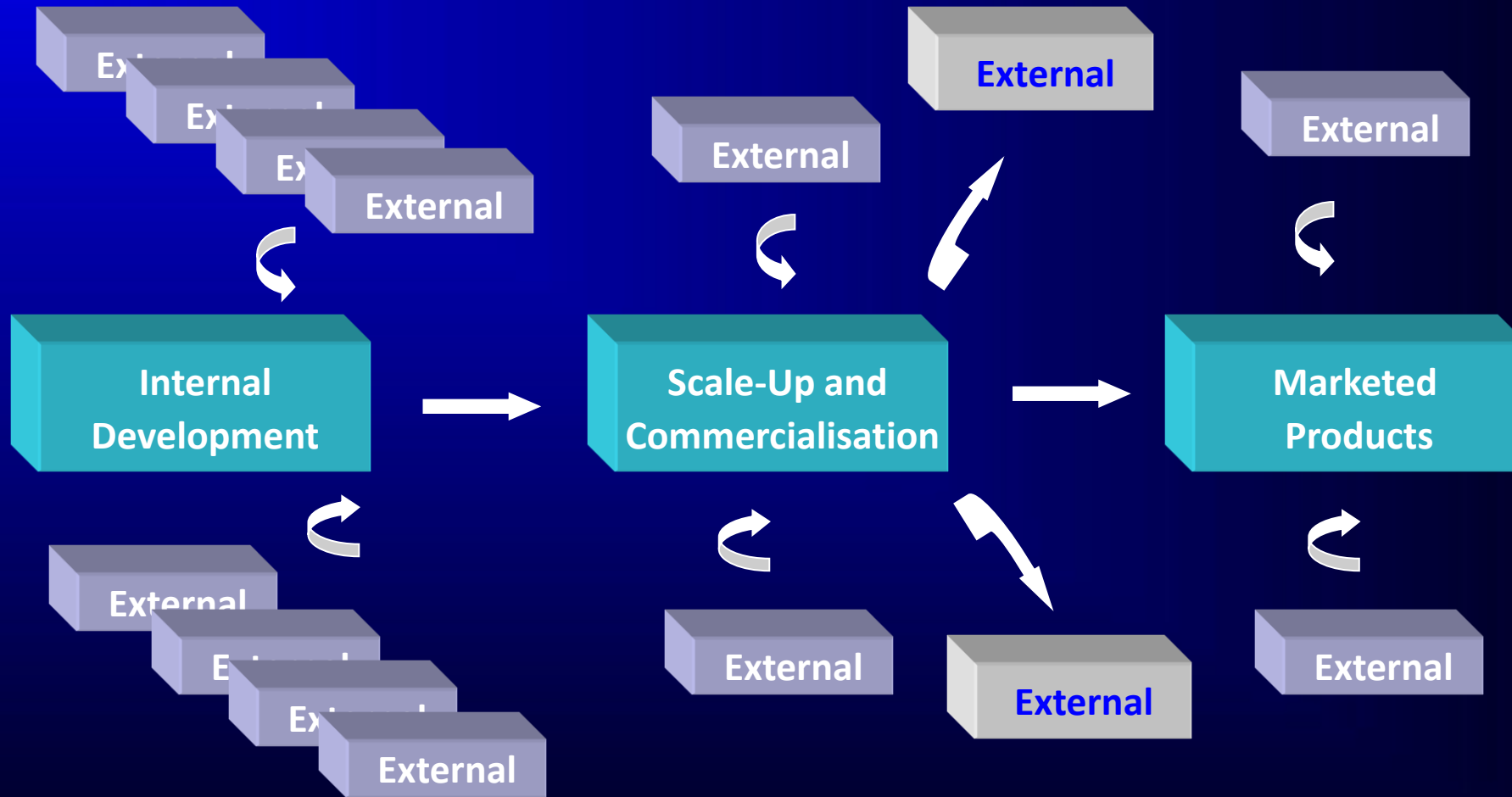
- Pharmaceutical product development is a long process
 - 7 Years in “discovery”
 - 7 Years in “development”
 - 14 Years in total (industry average)
 - The best firms manage 12 years
 - Some individual products - 9 years



Collaborations are progressed through sequential development stages

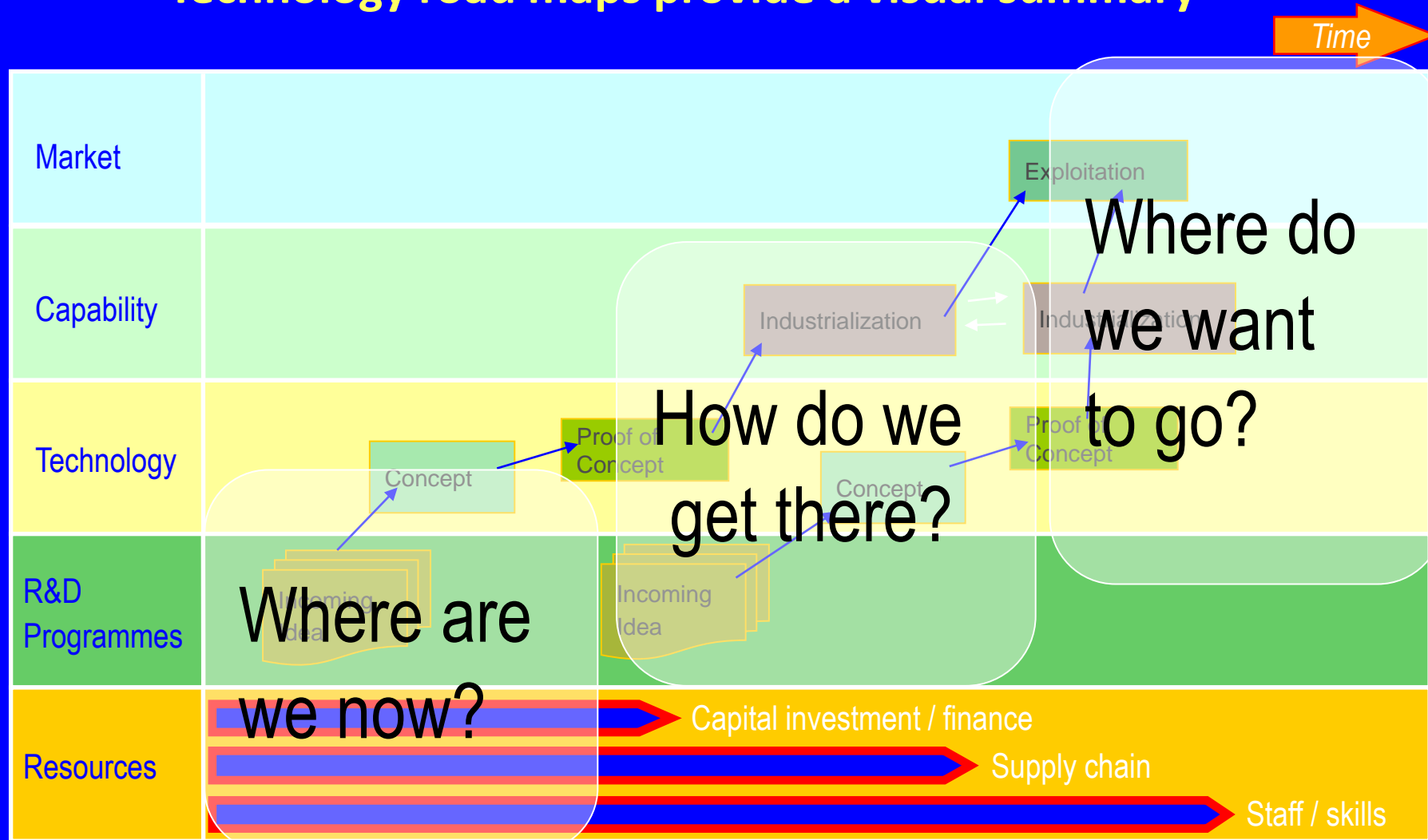


Large firms seek multiple external technology inputs to develop new products – with out-licensing of some technologies



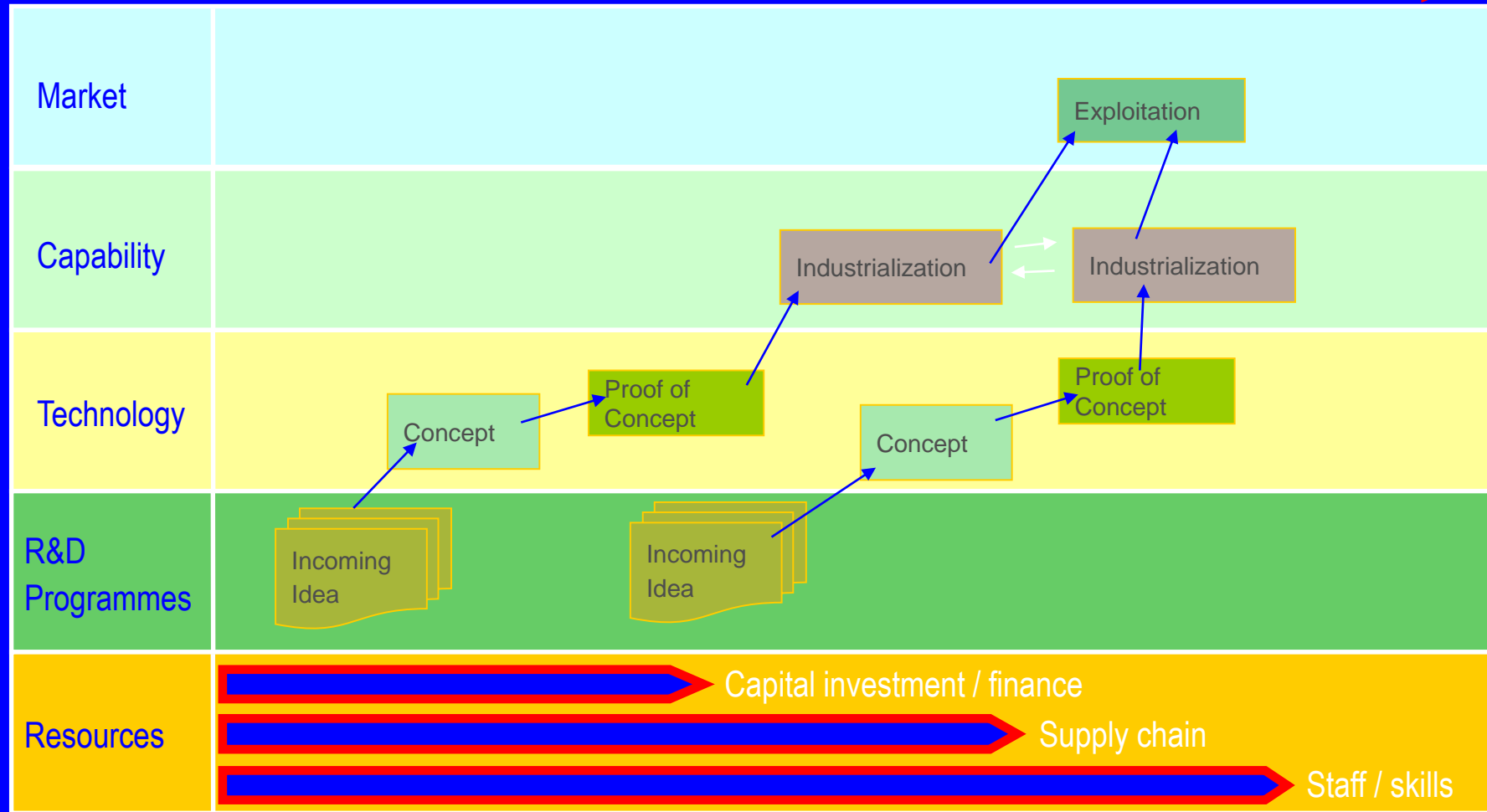
Large companies will have long-term technology strategies

- Technology road maps provide a visual summary

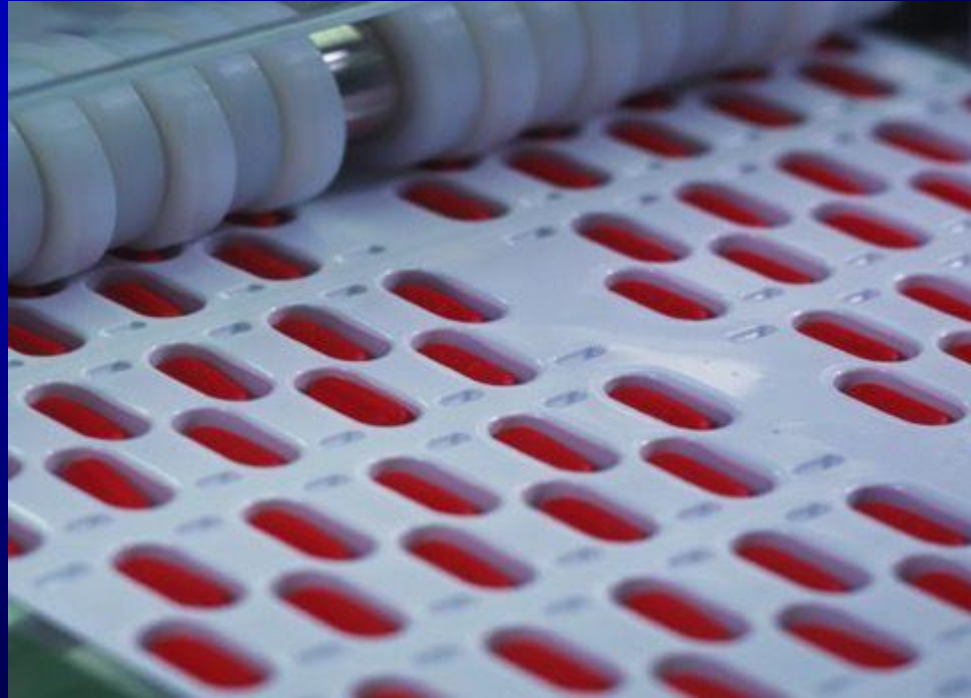


Large companies will have long-term technology strategies

- Technology road maps provide a visual summary



**Technologies must be capable of being developed to a final product –
Large-scale manufacturing issues are important**

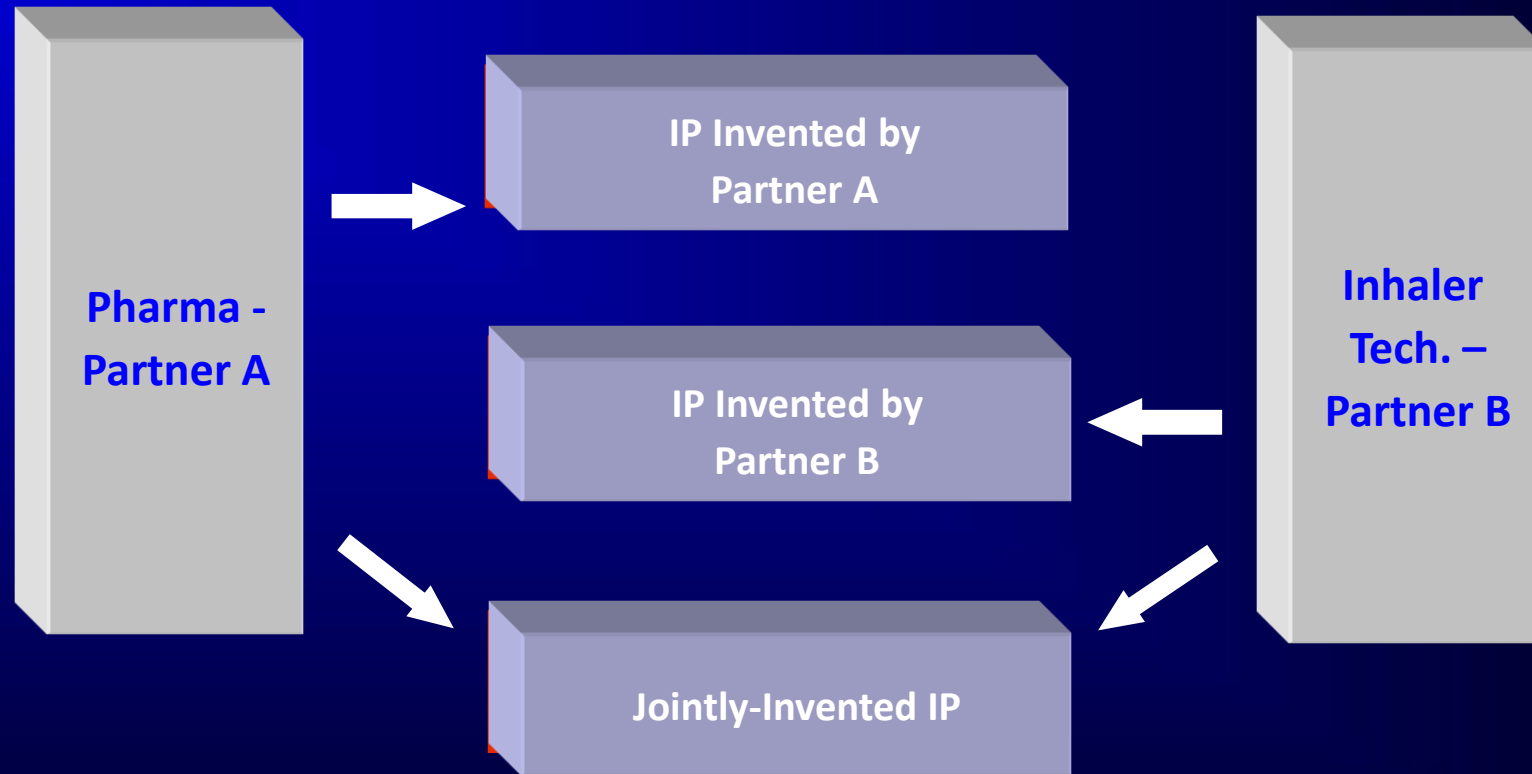


Pharmaceutical Caplet Blister-Packing Line

Standard minimum production threshold for manufacturing is 100,000 dose forms / hour

IP Terms in Collaboration Agreements

How do you allocate foreground (arising) IP? Example: Firm with a respiratory inhaler technology collaborates with a pharmaceutical company



Should Ownership Follow Inventorship?

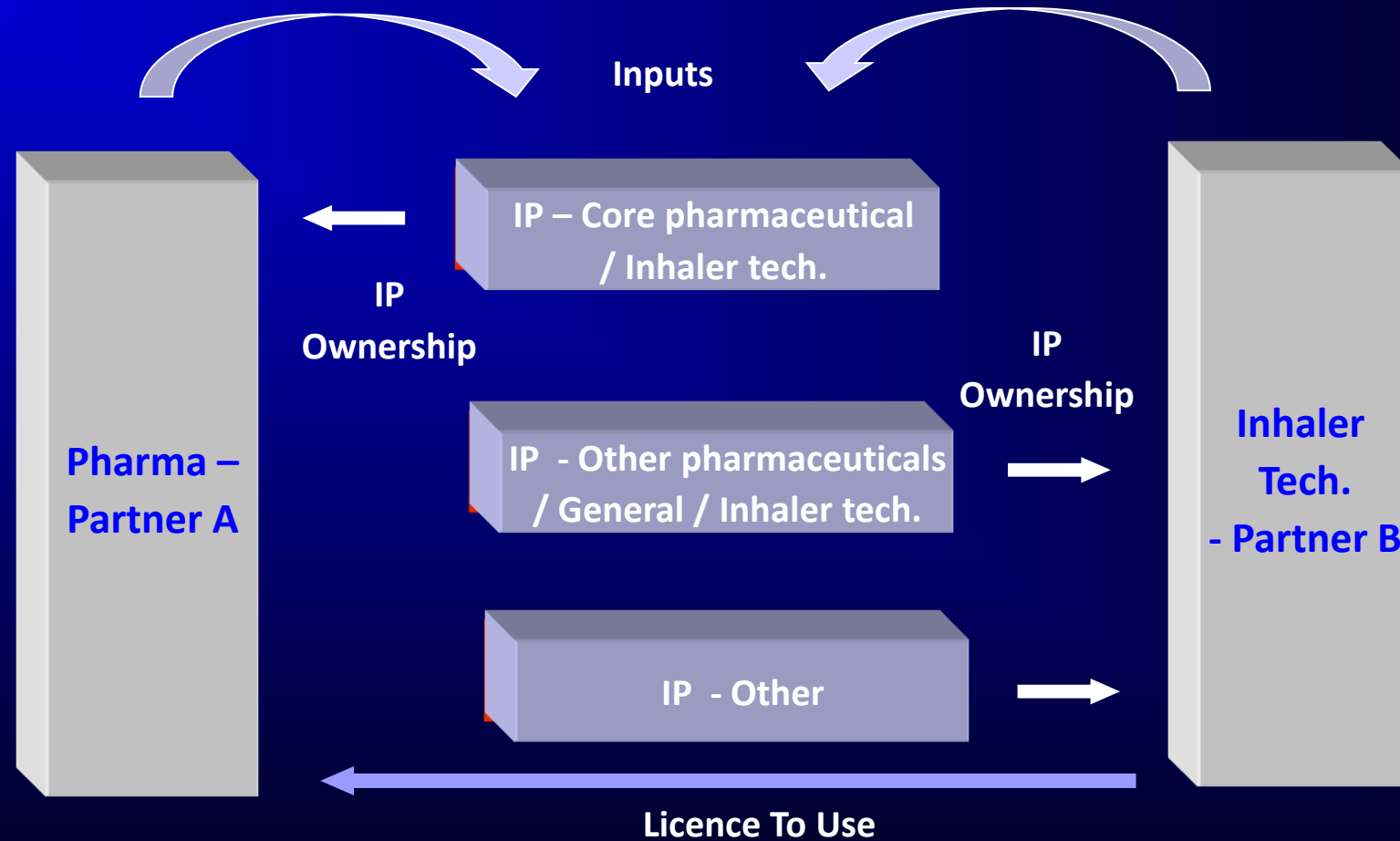
Divide arising (foreground) IP into fields

- **Who should get what?**
 - It depends on a number of factors
 - **Business interests**
 - **Funding for the collaboration**
 - **Critical expertise (e.g. to maintain any patent applications)**
 - **Negotiating position / strength**
- **Use multiple classes (or fields) of IP in each agreement**

Create clarity of ownership and license as is necessary

- **Always “pool” IP within a field**
 - **Never let ownership follow inventorship**
 - **Hinders collaboration and exploitation**
- **Never allow joint ownership of IP**
 - **Ability to use the IP varies across countries**
- **Create licence grants to allow the desired exploitation outcomes**

“Pool” IP and let ownership follow commercial interests



Other key provisions can be extensive

- Sub-licensing rights – Can the rights be passed on to others?
- Rights to improvements – Who owns developments?
- Development and exploitation obligations
 - Does the licensee need to make commitments to licensor?
- Maintenance of patent filings and decision-making
 - For example, on abandonment in minor territories
- Grant-back licence
- Use multiple linked contracts e.g. asset purchase and licence agreements

In major alliances, IP contract provisions should address multiple issues

- Term is typically until expiry of last-to-expire of patents
 - Consider situation with patent term extension rights e.g Supplementary Protection Certificates (“SPCs”)
- Consider rights to data and know-how
 - There may be a know-how licence
 - Step-down rate after patent expiry
 - Data exclusivity provisions affect market access and deal value
 - Europe: 8 years of data exclusivity and 2 years of market exclusivity for new drugs
- State territories
- Patenting obligations / co-operation is standard



**Example -
Biotech – “Big Pharma”: Biomarkers**

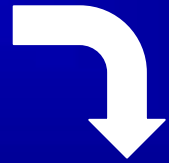
Biotech / Pharmaceutical Company – Biomarkers for flu vaccine performance

- “BIOTECH Enters Into an Agreement With PHARMACO to Identify Biomarkers of Flu Vaccine Performance”
- Anonymised case based on a 2017 press release
- *“Molecular Data Will be Analyzed Using Artificial Intelligence Through BIOTECH’s Platform to Better Understand Influenza Vaccination Response”*

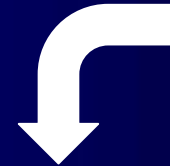
A collaboration to find biomarkers for flu vaccine response



Pharmaco

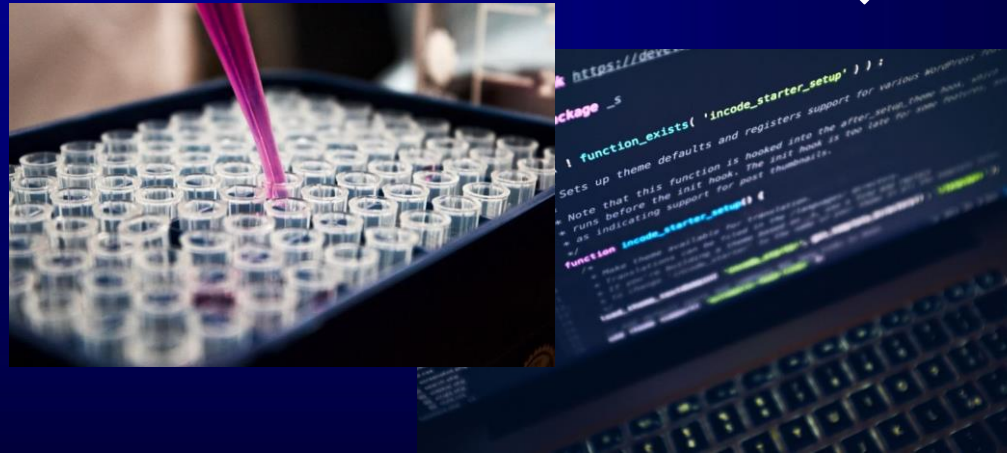


Biotech



Flu Vaccine Expertise

AI System - Drug Response



Search for Biomarkers To Assist New Vaccine Development

Biotech and Pharmaco – Questions

- How would you start to structure an agreement in this situation?
- What is important to each side?
- How would the Biotech perspective differ from the Pharmaco viewpoint?
- What non-IP issues need to be agreed?
- How would you structure the IP terms?

How would you deal with these elements of arising IP?

- **Developments in the AI platform**
- **Insight about the flu vaccine product**
- **Use of the AI engine to assess responses to the flu vaccine**
 - **Biomarker-linked**
 - **Other**
- **Insight on potential new vaccine products**
- **Data that suggests new “discovery” (research) approaches for other types of products**

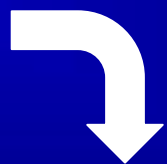
Some ideas on arising IP

- **AI Platform (solely): Biotech**
- **Flu vaccine (solely): Pharmaco**
- **AI Platform and flu vaccine (jointly):**
 - **Biomarker-linked: Pharmaco (with no additional payment)**
 - **Other: Pharmaco, with payment to Biotech on commercialisation / use**
- **Anti-viral vaccines (product class): Pharmaco**
- **All other products: Biotech, with payment to Pharmaco on commercialisation / use**
- **AI Platform and anti-viral vaccines: Pharmaco, with payment to Biotech on commercialisation / use**
- **AI Platform and all other products: Biotech, with payment to Pharmaco on commercialisation / use**

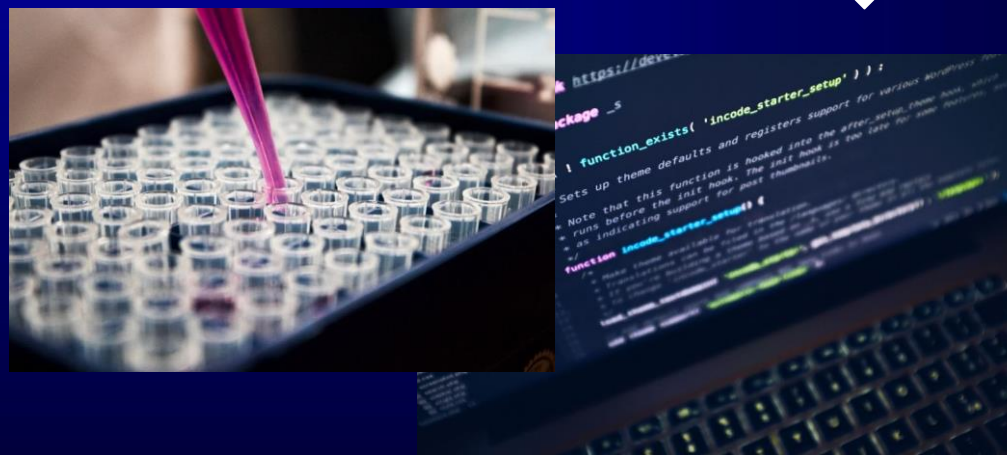
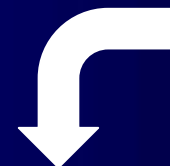
Arrange arising IP In separate “pools” or classes



Pharmaco



Biotech



Flu Vaccine Expertise

IP – Flu Vaccines

IP – AI / Flu vaccine: Biomarker

IP – AI / Flu vaccine: Other (£)

IP – AI / Other Vaccines (£)

IP – Other Vaccines

AI System - Drug Response

IP – AI Platform

IP – AI / Other Products (£)

IP – Other Products (£)

Possible Complexities

- What alliance management challenges might arise?
- What legal issues might arise?
- How could you structure the contract or post-deal management activities to try to avoid disputes?

Key Contract Issues

Use “moral persuasion” language in the contract



Use recitals, descriptive clauses, etc.

Draft royalty and patent maintenance clauses carefully

- Draft royalty and patent maintenance clauses carefully
- E.g to cover any product that is manufactured using any of the claims of any of the patents, or that contains any element that is covered by any claim of any of the patents
- Payment term is usually until the date of expiry of the last to expire of any of the patents (or applications)
- State the applicable rate for use of know-how
 - A step-down rate is often applied



Royalty provisions may be extensive

- Be very explicit as to what products the royalty term covers and set this out at length
 - Definitions can be extensive in pharmaceutical deals
 - Consider promotional samples, discounted supplies, pre-launch supplies, etc
- Include a royalty-audit clause
 - Right to send in an auditor (without cause) at set frequency
 - Counter-parties will expect it
 - Audit at other party's cost if there is a significant discrepancy
 - Specialist firms exist



Consider using price floors and caps

- A specific price (or cap, or floor) may be more practical than an agreement to set a price in the future
 - More legally-specific
 - Less scope for interpretation at a future date
 - “Leave some money on the table” but with the benefit of certainty
- If a costing method is to be used, include a specific method and a worked example in an appendix
 - Used in clinical trial manufacturing agreements
- Be specific about mediation and appeal procedures

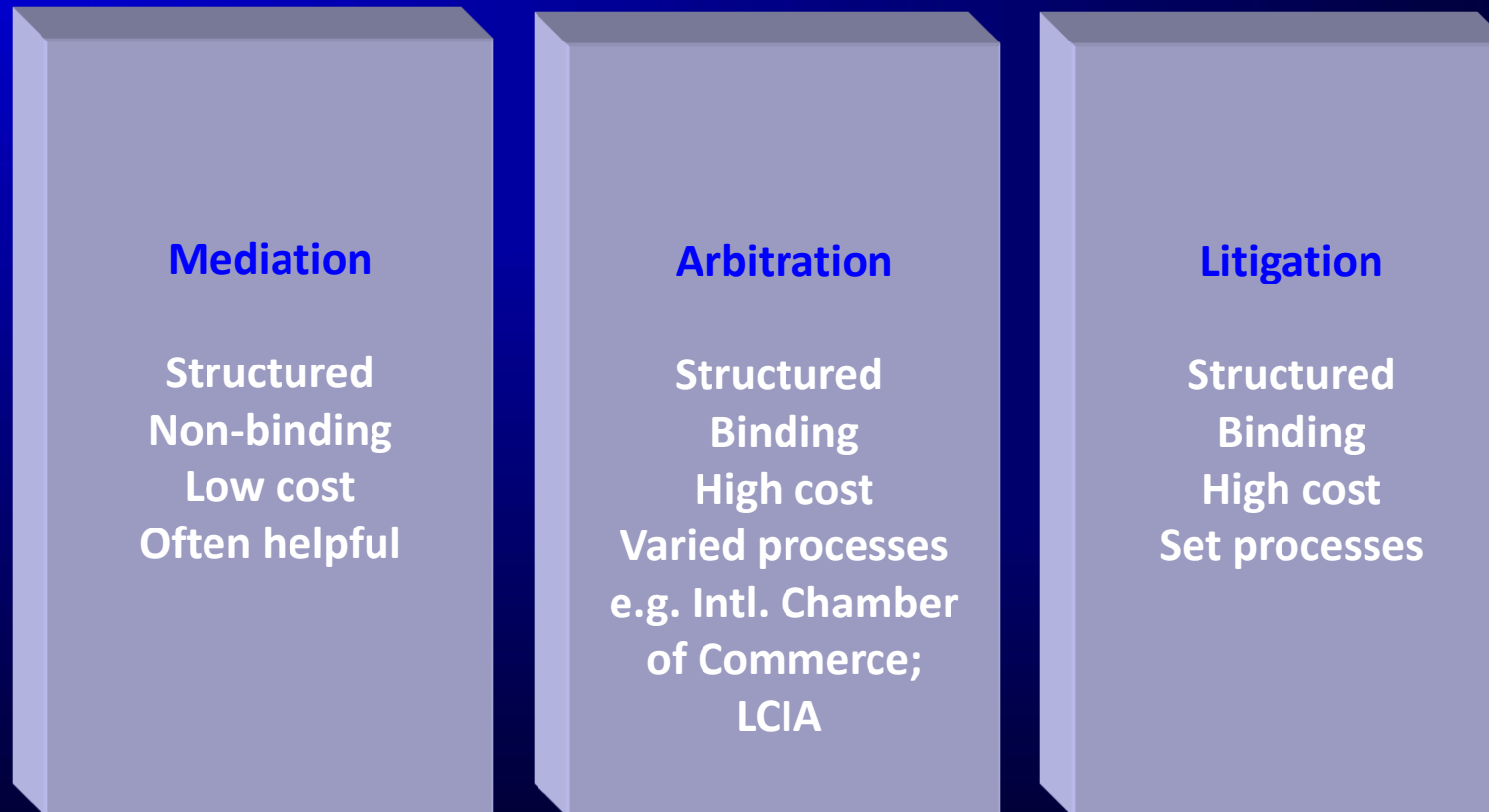


Build escalation and dispute resolution processes into the agreement

- Processes are the same for large alliances and small collaborations
 - Apply active alliance management
 - Monitor
 - Raise potential difficulties early
 - Have an escalation procedure to involve senior management in resolving disputes
 - Make sure that level is appropriate
 - Possible mediation (not arbitration) step
 - Reserve rights for potential litigation

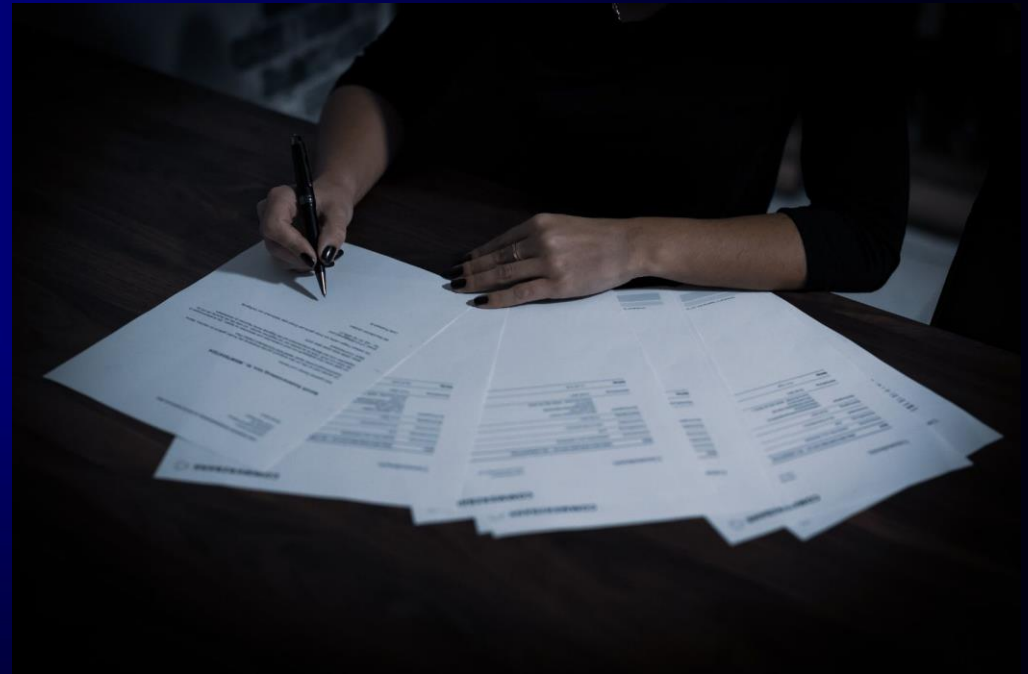


Mediation and arbitration are very different – Consider options carefully



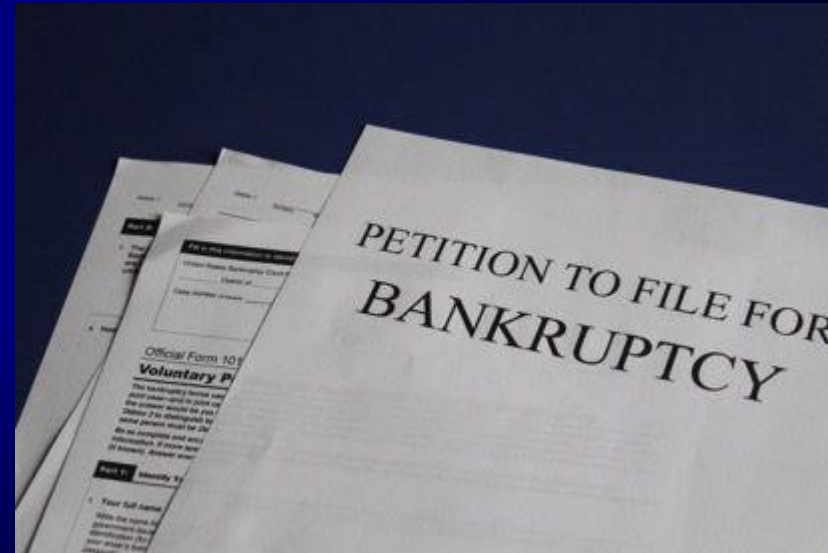
Care is required with indemnities, warranties and representations – particularly in transactional situations

- Always important
- Critical for out-licensing situations
 - IP warranties
 - Equipment warranties
- A major financial risk / liability
 - Often a concern of senior management
- Note that very specific legal language is applied
 - E.g. “indemnify and hold harmless”
- Different to many standard contract clauses (“boilerplate”)



Consider bankruptcy risks – What would happen in a corporate restructuring or bankruptcy?

- There are only limited rights to access IP in bankruptcy situations
- Worry about continued access rights
- Varies with jurisdiction
 - Different practices in different countries
- Powers of receivers / administrators / courts are significant
 - In some countries, officials may set aside contract provisions



Working with Partners

How do you try to avoid problems after deal signature?



Select Partners Rigorously

- Make a realistic assessment of partner capabilities, based on experience
- Consciously assess partner desires and possible future desires
- Ensure that partner selection is regarded internally as a critical activity
- Acknowledge that there are always few (if any) perfect substitutes
 - Options are always highly constrained



Evaluate possible changes in strategic direction

- Make the objectives of the relationship explicit
- Always think 3-4 years ahead
 - What will the situation and pressures on the other company be?
 - What could change in your own firm?
- Include mechanisms for dealing with changes and disputes
 - Steering groups
 - Periodic review
 - Use the right level of individual for steering groups



Raise difficult issues - diplomatically

- How are the project and the relationship developing?
- Were the initial goals explicit?
 - E.g. One firm may wish to learn about another sector. Has this aim been acknowledged in the contract and the project documents?
- What challenges are your goals causing the other party?
- What problems and issues are beginning to emerge?
Does the contract or relationship need to be adjusted?
- Has your senior management's view of the project changed?



Be aware of, and allow for, cultural and personal Factors

- Be sensitive to cultures and to personality styles
 - Consider cultural awareness briefings or formal training
 - Are there critical individuals? How will you deal with these?
- Monitor different evolving perspectives
 - Project leader(s), technical teams
 - Both senior management groups
- Manage the alliance carefully through critical personnel changes
 - Commitment, motivation and interests may change



Key Principles

Negotiate clear contract terms

- Divide foreground IP into fields
- Create clarity of ownership and license as is necessary
- Carefully negotiate licence grants
- Take care with indemnities, warranties and representations
- Build escalation and dispute resolution processes into the agreement



Manage collaborations actively

- Make use of varying degrees of partnership
- Select partners rigorously
- Evaluate possible changes in strategic direction
- Raise difficult issues – diplomatically
- Be aware of, and allow for, cultural and personal factors



Thank You

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