

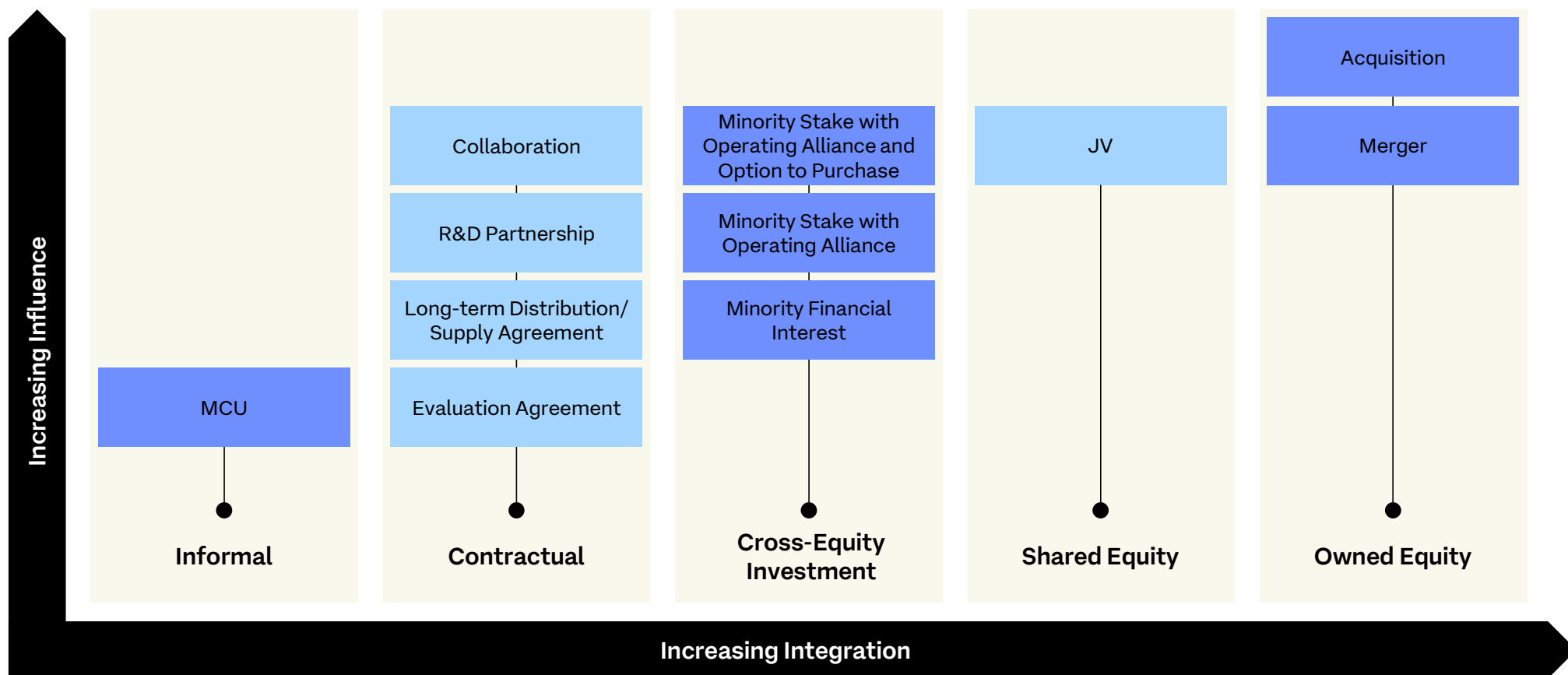
Dodged that Bullet: Navigating Traps in Strategic Commercial/IP Arrangements

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FRESHFIELDS

Transaction Spectrum



Key Drivers of Deal Structure

Financial Terms

Risk Allocation

Pipeline Programs

Accounting Treatment

Control

Tax Efficiency

Financing/Liquidity for Investors

Money Matters

Do you need an inflection
point to raise?

What data do you control?

What data can you share?

Simplicity is your friend!

Why a Collaboration Agreement?

- Licensing offers flexibility that asset or stock transfers don't
- No entity; no new corporate formalities
- Employees retained by their respective parents
- Negotiation of IP ownership and rights for newly developed IP can be complex
- A collaboration should ordinarily be focused on the product – not another product that is tougher to develop – wagering on two products is very risky

Beware of:

Misallocation of IP rights

Inadequately “future-proofed” provisions

Exclusivity overhangs

Competition/Participation limitations

Unclear option structures

Change of control provisions

Full board of director buy-in

CFIUS and foreign regulatory concerns

Allocation of IP Rights

IP definitions

IP ownership and use rights

- Sole and joint ownership
- License rights
 - Same or different buckets of IP?
 - Separate fields of use?

“Future-Proofing” Provisions

- Governance – mechanics and evolution
- Manufacturing/Cost of goods
- Milestones
- Royalties/Royalty deductions/Profit splits
- Termination/Effects of termination

Exclusivity

Exclusivity scope can be value creating or value destroying

- Field → humans and animals
- Indication based
- Clinical development plan

Limited negative covenants may be helpful (or not!)

- Initial window of exclusivity for collaboration to develop its business free from competition
- Narrow “product specific” non-competes

Competition/Participation

Is there a non-compete?

- Does it apply to both parties?
- Limited to specific therapeutic area or molecule type or territory?
- Does non-compete covenant bind affiliates?

Will new partners want to share information?

- Buyer may be competitor of other party

What are the rights to participate and when/how do you get them?

Co-branding and co-promotion

- Co-branding with pharma buyer is different than with small biotech
- Practical implications of co-promoting product with a competitor

Options/ROFXs

- If the company is licensor:
 - Would licensee's option for license sweep in buyer's IP?
 - Would ROFR/ROFN bind buyer?
 - Unintended consequences ...
- If the company is licensee:
 - Does licensor have ROFR/ROFN to something the buyer may want?
- Is an acquiror buying a litigation?

Change of Control Provisions

- By “change of control” we typically mean:
 - a merger, reorganization or consolidation of a party with a third-party which results in the voting securities of the party outstanding immediately prior thereto ceasing to represent at least 50 percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation;
 - a third-party becoming the beneficial owner of 50 percent (50%) or more of the combined voting power of the outstanding securities of a party; or
 - the sale or other transfer to a third-party of all or substantially all of the business or assets of a party to which the agreement between the parties relates.

Change of Control Provisions

- “Typical” provisions – mechanical undifferentiated triggers
 - Any change of control, in which any third-party acquires control
- Variations on triggers
 - Restrict to change of control by a “competitor” to licensee
 - Named competitors only?
 - Tied to collaboration product or product area, not all products
 - Percents and other terms of definition of change of control
 - Time limitation?
 - State of development limitation based on lower need for cooperation post approval?
- Ask: How does this affect value for a buyer?
 - Termination
 - Governance
 - Branding
 - IP provisions
 - Know-how transfer

Restricts Future Transactions

Overly broad change of control provisions (i.e., triggered upon IPO)

- Follow the IPO, collaboration partner sued to milestone payments triggered upon a CiC

Rights not assigned to successors (i.e., limits M&A)

- Acquiror needed to get approval of assignment and deal fell apart

Covenants restricting your ability to assign security rights over IP

- Inability to execute a royalty debt deal

Ability to terminate if you are stopping development

- Creates ghost programs you need to continue to explain

Practical Tips

- Understand the strategic motivation
 - Why are you partnering? Access to IP/technology, expertise (R&D, commercialization), access to customers, access to new markets, sharing of costs, spread the risks, faster time to market
 - Avoid doing a deal just for the sake of doing a deal or desire to create a stock bump
- Choose the right partner
 - Consider financial alignment, ethics, and commitment to patients
- Manage counterparty risks
 - Establish processes to learn about the problems before they grow (ex., detailed schedules with timelines and performance metrics)
 - What happens if a party fails to perform? Schedule changes, liquidated damages, effect on ownership, termination rights
 - Think about disclosure (if a public company) early
- Plan for the long term
 - Review practicality of timelines and budgets over 5–10 year horizon
- Trust your instincts

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