Lessons Learned from BioPharma and MedTech Collaborations

Opportunities and Traps for the Unwary

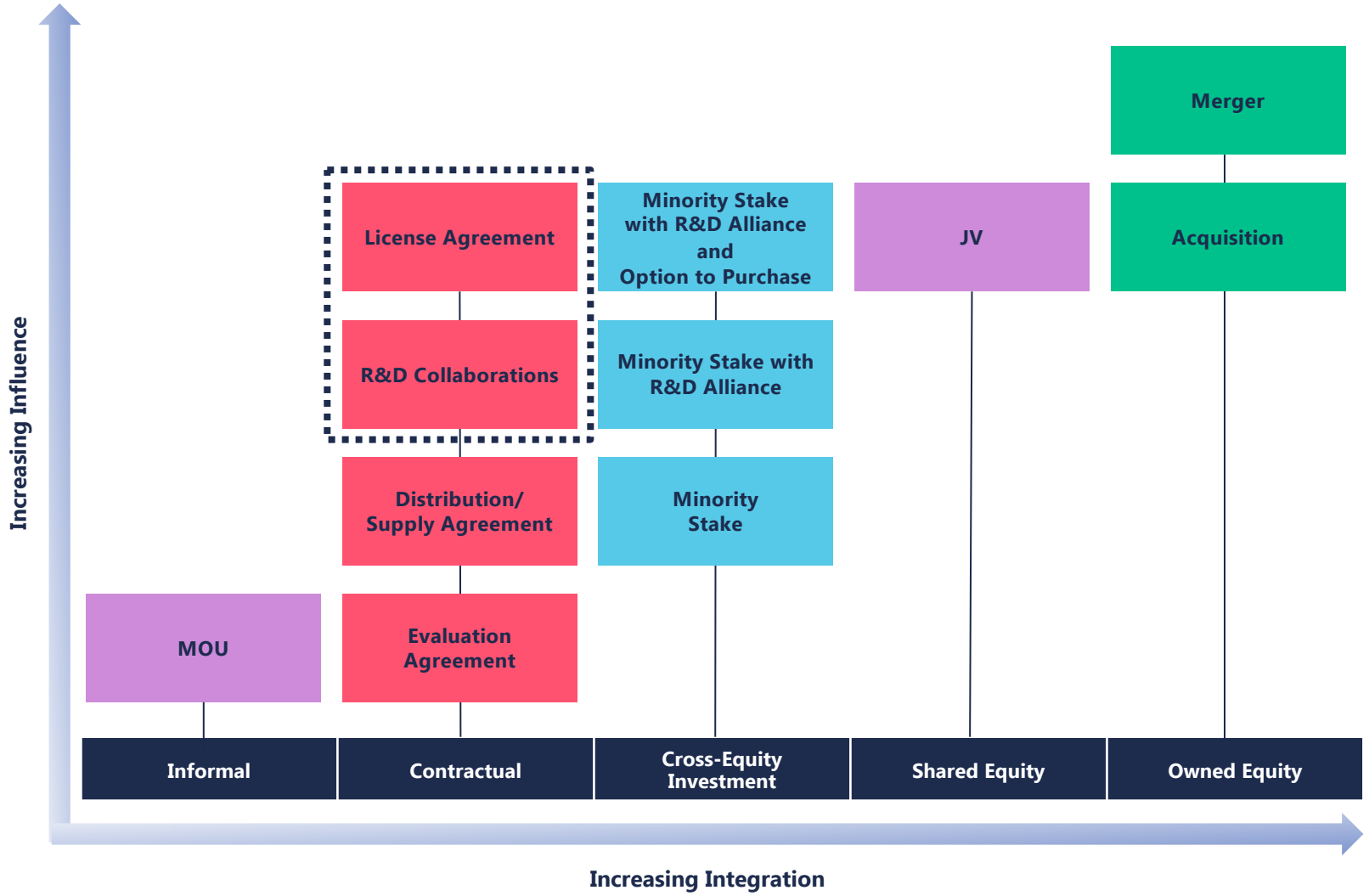
Adam Golden, Vinita Kailasanath, and Kristen Riemenschneider

May 12, 2022

Freshfields

freshfields.us

Life Sciences Deal Types – Transaction Spectrum



What is Biopharma? What is MedTech?

Biopharma

- Cell and gene therapies
  - Vaccines
  - Immunotherapies
  - Stem cell therapies (embryonic, pluripotent, etc.)
  - CRISPR/gene-editing therapies (in vivo and ex vivo)
- Antibody therapies
- Recombinant protein therapies
- Traditional small molecules

MedTech

- Health-focused mobile apps
- Wearables
- Connected biometric sensors
- Smartphone cameras
- Clinical trial patient information collection tools
- In-home connected virtual assistants
- Telemedicine and virtual physician visits
- Electronic health records
- Web-based interactive programs
- Text messaging or email
- Health system disease management apps

Read about 10 Key MedTech Themes for 2022 here

Audience Poll Questions

1. In which industry do you primarily work?

a) Biopharmaceutical

b) MedTech

c) Tech

d) Combination of Biopharmaceutical and MedTech

e) Other

2. How many strategic transactions (M&A, licensing, or other) have you worked on in the past year?

a) 1-2

b) 3-5

c) 6-10

d) More than 10

3. Of those deals, how many were license & collaboration deals?

a) 1-2

b) 3-5

c) 6-10

d) More than 10

IP Licensing Structures

Most collaboration deals involve a license of IP. The license structures can be as creative as the teams who structure them.

Can license any **form** of IP

- Registered IP – Patents, trademarks, copyrights
- Unregistered IP – Copyrights, trademarks, trade secrets, know-how
- Physical devices may be patentable and include software that is protected by copyrights
- In biopharma, critical IP is typically patents and know-how

Can consider IP **owned by multiple parties**

- Can have only one party license IP
- Can have each party license IP to the other ("cross-license")
- Can have parties sublicense IP that they have licensed from someone else (sublicensing)

Can create **territory-based** rights

- Worldwide
- Only certain countries

Can create **field-based** rights

- License to limited field of use
- License to all fields of use

Can create **time-based** rights

- Retroactive grants, present grants
- Perpetual and irrevocable grants
- Future and conditional licenses
- Options to license

Can **limit** extent to which others practice IP

- Exclusive vs. non-exclusive License
- Sublicensable vs. non-sublicensable
- Transferrable vs. non-transferrable

IP Ownership Structures

License & Collaboration Agreements typically allocate IP rights according to the following buckets:

Background IP

- Includes (i) all IP generated by a party before the agreement goes into effect and (ii) all IP generated by such party outside the performance of the agreement
- Ownership usually remains with the party that has created the Background IP, but is often included in the license grant to the licensee

Foreground IP

- Includes all IP generated by either party, or by both parties together, in the performance of the agreement
- Ownership may vary:
  - Each Party owns the Foreground IP created by it; jointly created Foreground IP becomes joint IP; OR
  - All Foreground IP will be owned by licensee (as it likely pays for the development); OR
  - Allocate Foreground IP based on technology concerned (i.e. technology A to party A, technology B to party B)

Improvements Background IP

- Improvements created under the agreement in relation to either party's background IP
- Often: Background Improvement IP is allocated to owner of related Background IP, but:
  - Determining what is an "improvement" and what is independent development is not always easy, and
  - Limitations on grant-back of improvement rights exist under many jurisdictions

Overview of HSR Reporting

The Hart-Scott-Rodino (HSR) Act requires certain transactions to be pre-notified to the US Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ)

- Initial waiting period of 30 days (15 days for a cash tender offer) before transaction consummation
- FTC typically assigned deals in the life sciences sector
- FTC Premerger Notification Office can grant "Early Termination" of the waiting period if requested
  - Grants of Early Termination have been temporarily suspended
  - Once reinstated, Early Termination is not guaranteed
- The waiting period permits FTC/DOJ to evaluate transactions for potential anticompetitive effects and, if warranted, extend the waiting period to investigate further or ultimately seek remedies or sue to block the transaction

Potentially Reportable Transactions:

- Transactions - including exclusive licenses - valued at $101 million* or above might be reportable
- Grant of an option to license is not reportable; however, **exercise** of an option for an exclusive license may be reportable
  - **Practice Tips**: An option to acquire a license can present logistical issues with regard to HSR notification and waiting period process. Consider: timing of filing and ramifications of not obtaining FTC clearance when negotiating an option for an exclusive license.
- Termination of an exclusive license / reversion back to the licensor may also be reportable

*Threshold effective as of February 11, 2022, adjusted annually

Payment and Other Forms of Consideration – Biopharma

Upfront Payment	One-time, non-contingent consideration paid on or shortly after closing
Equity	One-time (often minority) investment (common or preferred stock, convertible promissory note or warrant) in the licensee
Option Fee	Payable upon exercise of an option to license IP
Development/ Regulatory Milestones	Contingent consideration, payable on licensee's accomplishment of specified development milestones (e.g., start of Phase 1, first BLA approval) **Practice Tips:** Define milestone triggers carefully (e.g., what is "successful completion" of a Phase 1")! Define scope of products that trigger the milestones carefully.
Sales Milestones	Contingent consideration, payable on licensee's first achievement of certain cumulated annual net sales target (e.g., $100M of annual net sales).

Royalties	Contingent consideration, payable as a percentage of licensee's net sales of licensed products
	• Percentage is typically tiered, based on annual sales volume
	• Royalty term typically spans for the longest of (per product and country): (i) expiration of last patent covering the product, (ii) expiry of regulatory data exclusivity and (iii) 10/12 years from first commercial sale
	• Often subject to a variety of deductions, e.g., "anti-stacking" amounts paid to license third party IP needed for the licensed product
	  • **Practice Tip:** Consider what the deductions are for (any amounts paid or only royalties paid?) and what amounts they apply to (royalties only or milestones too?)
	  • For multi-component products (e.g., gene therapy), royalty anti-stack calculations can get highly complex.
	• Often also subject to a variety of step-downs (reductions in royalty percentage), e.g., expiration of patents that cover the licensed product (antitrust issues) and entry of generic competition
	  • **Practice Tip:** Consider the aggregate based on specific product. What is "market" is relevant but doesn't always answer the question.

Payment and Other Forms of Consideration – MedTech

MedTech deals can involve any of the same forms of consideration as in biopharma deals, but often also contain more deal-specific value considerations, often in combination, such as:

Value-based Care Models	Payment for the values or outcomes of MedTech solutions, rather than the volume of solutions used. For example, large discounts or rebates if certain clinical or economic outcomes are met.
Discounts Based on Utilization	Access to the MedTech offering at a discounted price based on volume of usage
Per Member/User Fees	Grant of access to technology for a per-member/user fee on a monthly or annual basis
Subscription	Could be at the enterprise level or by class of user or per user. Often maintenance and support are provided on a subscription model.
Profit Share	Depending on how the solution will be used by the collaborators/ each collaborator's members/patients/employees and each collaborator's respective responsibilities in connection with development and commercialization, a profit share (that could vary across channels) could help to incentivize the parties.

Diligence Obligations

In return for granting exclusive rights, and because many payments are contingent on licensee's performance, licensor will typically require that licensee actively develops/commercializes the product

All of these phrases mean different things to different people in different jurisdictions!

In practice, parties usually expressly define "Commercially Reasonable Efforts" in the agreement

Practice Tips:

When drafting a CRE standard, consider:

- What's commercially reasonable?
- Who do you get measured against? Internal standard (your company) vs. external standard (other similarly situated companies in biopharma/MedTech)
- Which factors you should be required to take into consideration, e.g., if you have a competing product that's better, how much money you have to pay under the agreement, or expected profitability of the product

When drafting a CRE requirement, specify the specific obligations to which CRE applies

- Milestones, number of products/indications, specific countries/jurisdictions (e.g. US, EU, Japan)

Diligence Obligations (continued)

What is "commercially reasonable" will always remain vague and a risk for disputes. Therefore:

- **Licensee will try to avoid being caught in breach claims unnecessarily, e.g.:**
  - Consider adding that interim hold of development program for evaluation/decision-making purposes does not constitute breach
  - Require warning notice with long cure periods prior to termination right
  - Require that termination is only effective if confirmed by competent court/arbitration
- **Certain licensors will seek to obtain firm commitments, e.g.:**
  - Maximum time to reach certain development milestones
  - Minimum budgets to invest in development
  - Minimum number of FTEs to work on development
  - Minimum requirements for launch preparation and commercialization

Practice Tips:

- Keep in mind that a requirement to use CRE to perform is not an absolute requirement to perform. For example, licensor may have a CRE obligation to commercialize in a specific country, but may nevertheless elect not to do so if the pricing and reimbursement approval received in such country is too low, therefore making it commercially unreasonable to sell.
- Licensors to consider ways in which you can monitor compliance with CRE obligations, e.g., governance meetings or reporting requirements

Unique Challenges in Structuring MedTech Deals

In many ways, MedTech deals more closely resemble deals in the tech space than the biopharmaceutical space.

Challenges in these deals include:

- Iterative and ongoing development and updates
  - **Practice Tip**: Consider phased development with regular reporting and meeting requirements
- Rights in developed IP and repurposing code
- Shared technology platforms
- Protecting proprietary insights, developments, data
  - **Practice Tip**: Be willing to place limits on know-how exchange (e.g., firewalls and recipient ID)
- Limited utility of many developments without continued access to 3rd party collaborator's platforms and data
- Need for interoperability with other technologies and platforms
- Direct interfaces with patients present both opportunities and challenges
  - Powerful and personalized data source
  - Presentation of information (e.g., correlation vs. causation)
  - Terms of service and privacy policies
  - Discontinuation of products and user and data transitions
- Related issues of content sourcing, data rights, privacy issues, AI, open-source software and cloud technologies

Learn more about Navigating Tech and Data-Driven Collaborations here

MedTech Licensing Considerations

How will technologies relevant to the MedTech offering interact?

- What types of licenses are necessary?
  - Third party software/platforms
  - Any API licenses?
  - Any content licenses?

Where will the included content come from?

- Have all relevant use rights been obtained for third party content?
- Are there any use or technology related limitations on such licenses?

How is open-source software used in the digital health offering?

- All open-source licenses do not pose the same risks
  - **Practice Tip**: Consider periodically scanning developed software for open source

Dealing with the Data in MedTech Deals

Enhanced data analytics/AI is the core of many MedTech offerings. Deal with data separately from other IP – lots of unique issues.

- **Understand the nature of the data in question.**
  - What kind of data is being provided?
    - Does the data include personally identifiable or otherwise protected data? (e.g., GDPR, HIPAA, COPPA)
  - Where is the data coming from?
    - Who controls and collects the data and from where (e.g., user data)?
  - How broad are the data usage rights?
    - What consents are obtained, by whom, and for what uses?

- **Map the data flows**
  - Is the data only shared on an aggregated, de-identified basis?
  - Will each party have ongoing access to the data, or only deliverables at various points?
  - What continuing rights will each party have in the underlying data? Any usage and/or user data? Will these rights continue post-deal?

- **Understand how the database is constructed**
  - Is the data company-specific or is it combined with data from other companies?
  - How are the datasets updated? What quality controls are in place?
  - How valid, unbiased and transparent are the analytics?

Additional MedTech Considerations

MedTech offerings often involve contributions from multiple participants

- How will multiple vendors work together to create and deliver the MedTech offering?
  - Can acceptance testing be delayed until all components are ready?
  - How are updates/improvements managed?
  - Who will play the role of the systems integrator to ensure there are no holes in risk allocation?
    - **Practice Tip**: Governance structures should allow for active and meaningful monitoring and oversight of performance (e.g., ability to monitor performance and revise strategic direction)
  - Can IP/data be shared across vendors?
  - Can acceptance testing be delayed until all vendors' components are ready?
  - Can warranties run from launch rather than from delivery?
  - Are any service level agreements (Cloud-based, SaaS, PaaS) appropriate?
  - Are cloud risks managed?
    - **Practice Tip**: Consider requiring counterparties to adopt best information security practices, including access controls, encryption, business continuity and disaster recovery and incident response plans

- Is each party prepared to satisfy its data security-related obligations?
  - **Practice Tip**: Set forth clear processes and remedies in advance (including communications with regulators and other breach-related notifications)

Learn more about Future Trends in MedTech here

Termination Rights & Effects of Termination

Unlike M&A deals, most licensing deals "live" for an extended period of time – so what happens if the parties change their minds? Consider what happens when you walk away.

- Is the agreement terminated as a whole or only with respect to a particular product/offering or particular country(ies)?
- Who can continue to practice the developed (foreground) technology?
- Has any of your pre-existing technology been affected?
- Do you need continued access to any other party's IP, data or technology, for your rights to be meaningful?
- Consider how termination plays out at each phase of the project (pre-launch vs. post-launch)
- How will you transition customers, patients, data and technology?

Termination for Convenience	• If present, usually only the licensee can terminate for convenience, NOT the licensor • In biopharma deals, usually the licensor tries to limit the right, or require a reasonable notice period **Practice Tip:** Consider bifurcating different notice periods for different stages of the collaboration. For late stage products, termination may trigger a termination fee.
Termination for Patent Challenge	• Usually the licensor requires a termination right in case licensee starts to challenge the validity of the licensed patents **Practice Tip:** Keep in mind that many patent challenge clauses are likely unenforceable.
Deal-specific Termination Rights	• Termination for safety concerns • Termination for bankruptcy of the counterparty (not valid in many countries) • Changed support for the offering
Termination for Material Breach	• Often separate clauses for breach of diligence obligations with longer notice and cure period • Licensee will often request tolling provisions during which agreement doesn't terminate during pendency of dispute

Additional Effects of Termination

Common Effects of Termination (irrespective of termination trigger)

- Original licenses and payment obligations will terminate; complete, transition or wind down any clinical trials/ongoing users
- Licensee may have the right to sell-off remaining inventory
- Exclusivity obligations may survive for some period after termination (a "tail period")
- Could involve a "reversion license" – a transfer or license of the program (including new IP) back to the non-terminating party
- **Practice Tip:** Even though parties getting married don't like discuss divorce, to avoid future renegotiation and disputes, it pays to take the time to get these right!

Special Case: If licensor breaches, and licensee terminates, licensee will lose its license. Poor outcome for licensee…

Licensees often try to negotiate an "alternative remedy" – instead of terminating for breach:

- The license would become perpetual and irrevocable; in MedTech, perhaps an option to access code from escrow
- Milestone/royalty amounts/other ongoing payments would be reduced (typically starts at 50%)
- Licensee would have the right to offset damages against future payments
- Licensee would have the right to step-in to perform certain activities of the Licensor

Licensee arguments:

- The right to terminate is illusory if it means losing rights to the product/offering
- Damages are likely not recoverable due to exclusions of lost profits and other consequential damages
- Also, nobody wants to sue their collaboration partner!

Licensor arguments:

- Arbitrary remedy that will likely bear no relationship to the actual breach or the damages actually sustained by the licensee
- Actual damages would be recoverable

BioPharma Licensed Product/IP Reversion Rights

Reversion License

- Scope of rights granted
- Survival of existing sublicenses
- Consideration in favor of licensee
  - Reverse royalties
  - **Practice Tip:** Consider negotiating upfront vs. negotiating at termination (with dispute resolution procedure if parties cannot agree).
- Critical IP created by licensee that extends patent life cycle
  - Improvements to foreground IP only or background IP too

Context Matters

- Stage of product when agreement is executed
  - Drug/target discovery collaborations
- Scope of technology licensed
  - Cell and gene therapies
  - Component licenses – capsid, promoter, transgene
- Manufacturing technology
- Reason for termination
  - Generally no reversion rights for termination for safety concern

Q&A

Freshfields US Life Sciences Transactions Team

Adam Golden
Partner, Head of US Life Sciences Transactions
New York

Kristen Riemenschneider
Partner, Licensing & Collaborations
Washington, DC

Vinita Kailasanath
Partner, MedTech, Licensing & Collaborations
Silicon Valley

Sebastian Fain
Partner, Corporate/M&A
New York

Mary Lehner
Partner, Antitrust
Washington, DC

Jonathan Zhou
Partner Elect, Corporate/M&A
New York

John Fisher
Partner, Corporate/M&A
Silicon Valley

Damien Zoubek
Partner, Corporate/M&A
New York

Paul Humphreys
Partner, Corporate/M&A
New York

Jeff Jay
Sr. Associate, Licensing & Collaborations
New York

Mina Miljevic
Associate, Licensing & Collaborations
Washington, DC

Tanny Kang
Associate, Licensing & Collaborations
New York

Sora Park
Associate, Licensing & Collaborations
Silicon Valley

Nida Rais
Law Clerk, Licensing & Collaborations
New York

Joshua Samuel
Law Clerk, Licensing & Collaborations
New York

Thank you

DS137420