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# **ASIA LIFE SCIENCES**

**Considerations for Cross-Border Strategic  
Licenses and Collaborations for Asia Based  
Life Sciences Companies**

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# Presenters



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# Considerations for Cross-Border Strategic Licenses and Collaborations for Asia Based Life Sciences Companies

- **Topics Covered:**

- General Industry Trends in Life Sciences Transactions
- Cross-Border Transactions & General Challenges
- Cross-Border Strategic Collaborations and Licenses
  - Intellectual Property Rights related Issues
  - Payment & Tax Related Issues
  - Governing Law & Dispute Resolution Related Issues
  - Other Regulatory Compliance Related Issues





# General Overview

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# Industry Trends in Life Sciences

- Growth in the life sciences sector has remained relatively strong
- While recent M&A and investment activity has been slower, the number of licensing and collaborations between life sciences companies have remained robust
- Scale of cross-border and domestic licensing deals in Asia have been expanding, and according to an article published by Deloitte in May 2022, licensing deals have become the most sought-after business development model in China's pharmaceutical industry
- According to the 2021 Annual BD Deals Report for China Pharmaceutical Industry released by MyBio Capital, there were 174 publicly reported cross-border drug licensing deals involving Chinese enterprises. This included 133 License-in deals and 41 License-out deals (compared to 84 in-license deals and 6.8 out-license deals in 2019, respectively)
- National and local governments around the world are tightening regulations and have also moved to more protectionist postures with respect to domestic healthcare industries.

# Cross-Border Transactions

- Cross-Border Transactions
  - Transactions where parties (e.g., buyer and seller, licensor and licensee, customer and service provider, etc.) are not based in the same country
  - Can include variety of types of matters:
    - Licensing and Collaborations
    - Joint Ventures
    - M&A
    - Financing
    - Distribution Agreements
    - Etc.

# Common Issues in Cross-Border Transactions

- Unfamiliarity with local laws and regulations / compliance risk (e.g., export restrictions, bribery and corruption, data protection)
- Agreeing on governing law / conflict of laws
- Enforcement of awards or judgement
- Complex or unfavorable tax issues
- Intellectual property rights protection
- Practical challenges (e.g., language barrier, time zone, cultural differences between parties / lawyers)
- Etc.

# Cross-Border Strategic Licenses and Collaborations

- Cross-Border Strategic Licenses and Collaborations
  - Involves parties that are not based in the same country
  - Involves grant of licenses under certain intellectual property rights
  - May or may not involve collaborative efforts
  - Scope of the relevant territories may be limited (e.g., China, Japan, Korea, etc.) or may be global
  - Issues discussed may be relevant for other commercial transactions involving parties based on different countries, e.g., services agreements, distribution agreements, MTAs, SRAs, etc.



# Cross-Border Strategic Licenses and Collaborations

- Sample Anatomy of a Cross-Border Strategic Licenses and Collaborations
  - Definitions
  - Management of Collaboration Activities / Governance
  - Licenses / Exclusivity
  - Territory Specific Terms (e.g., U.S., Asia, RoW)
  - Development, Regulatory, Supply and Commercial Provisions
  - General Payment Provisions
  - Intellectual Property Rights
  - Confidentiality; Publication
  - Term and Termination
  - Representations and Warranties
  - Indemnification; Liability
  - Miscellaneous Provisions (e.g., Governing Law, Jurisdiction, etc.)



# Intellectual Property Rights & Scope of Licenses

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# Intellectual Property Rights

- Intellectual Property Rights
  - Rights given to persons over the creation of their minds, e.g., inventions, literary and artistic works, designs, symbols, names and images
  - Oftentimes, a life sciences company's most valuable asset
  - Intellectual Property Rights are protected in law, e.g., via patents, trademarks, copyright and trademarks
  - Essential to ensure that intellectual property rights are well-defined and protected in the *relevant* jurisdictions

# Intellectual Property Rights

- Ensure that patent rights exist in the relevant jurisdictions
  - Ensure that there is, or will be patent protection
    - Conduct diligence to confirm patent applications have been, or will be filed
    - Obtain first right to prosecute patent rights in relevant jurisdictions
    - Contractually obligate the other party to seek/maintain patent protection in relevant jurisdictions, and/or get backup rights
  - Ensure that assignment of relevant intellectual property rights generated under the license/collaboration will happen
    - Specify the relevant IP inventorship/ownership rules, e.g., “inventorship will be determined in accordance with U.S. patent law, and ownership will follow inventorship”
  - Ensure employment agreements are in place (e.g., via diligence or reps/covenants)

# Intellectual Property Rights

- Academic Agreements
  - May enter into material transfer agreements or sponsored research agreements, which eventually lead to a license agreement with an academic party
  - Non-U.S. academic institutions may assign to a sponsor intellectual property created by them using funds from such sponsor
  - U.S. academic institutions will likely push back on assigning to a sponsor any intellectual property created by them using funds from such sponsor, but may be willing to grant non-exclusive licenses to such IP

# Scope of Licenses

- In territory specific collaborations/licenses, consider if the scope of the license grant is appropriate
- For example, consider the following two license grants:
  - Licensors grants licensee an exclusive license under Licensors patent rights to research, develop, manufacture, and commercialize a Licensed Product in China
  - Licensors grants licensee an exclusive license under Licensors patent rights to research, develop, manufacture, and commercialize a Licensed Product in or for China
- The latter would give greater flexibility to a licensee to be able to use CROs and CDMOs outside of China, as long as the ultimate purpose is for exploitation of Licensed Product in China



# Take Away – IP Rights

- Make sure that the licensor actually has IP rights to grant
  - Diligence IP portfolio
  - Include reps and warranties regarding ownership, employee assignments, etc.
- Make sure that IP rights are protected in relevant jurisdictions
  - Get first right to prosecute in relevant jurisdictions (or comment rights and back-up rights)
  - Include obligations on licensor to diligently prosecute in the relevant jurisdictions
- Make sure the territorial scope of the license grants are appropriate
  - Carefully consider whether each of the research, development, manufacturing, and commercialization licenses should be exclusive in the relevant territory



# Regulatory Compliance

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# Regulatory Compliance

- Regulatory Compliance
  - Adherence to laws, regulations, and guidelines created by government legislations and regulatory bodies applicable to an organization based on the industry and jurisdiction in which it operates
  - Cross-border licenses/collaborations in the life sciences industry involve a complex regulatory framework, including product approvals, clinical trials, intellectual property rights, and data privacy laws, among other matters

# Regulatory Compliance – Applicable Laws

- Applicable Laws & Regulatory Authorities
  - Generally, “Applicable Laws” and “Regulatory Authorities” are broadly defined
    - “Applicable Laws” means **all** federal, state, local, regional, national, and supranational **laws**, statutes, ordinances, codes, guidelines, rules, regulations, judgments, decrees, directives, injunctions, orders and permits of or **from any** court, arbitrator, **Regulatory Authority** or Governmental Authority **having jurisdiction over or related to the subject items** and that are in force as of the Effective Date or come into force during the term of this Agreement
    - “Regulatory Authority” means **any** national, international, regional, state or local regulatory agency, department, bureau, commission, council or other **governmental entity with authority** over the distribution, importation, exportation, Manufacture, use, storage, transport, clinical testing, pricing, sale or reimbursement of any Licensed Product in the Territory.

# Regulatory Compliance – Applicable Laws

- Include general compliance provisions as a catch call
- Consider specifying relevant laws and regulatory bodies to ensure common understanding between the parties
  - [Party 1] shall ***conduct all activities in compliance with all Applicable Laws***. For clarity, with respect to each activity performed under the Research Plan, each Party shall comply with the regulations and guidance of the applicable Regulatory Authorities in the Territory, including ***NMPA and PMDA***. Without limiting the foregoing, in connection with this Agreement, Each Party will comply with all Applicable Laws dealing with government procurement, conflicts of interest, ***corruption or bribery***, including, if applicable, the ***U.S. Foreign Corrupt Practices Act of 1977***, as amended, the ***UK Bribery Act***, and any ***laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions***.

# Regulatory Compliance – Clinical Trials / Marketing Approvals

- In the US, foreign companies can generally conduct clinical trials and obtain marketing approval
- In certain Asian countries, a local partner or representative may be required for foreign companies seeking to obtain marketing approval or looking to conduct clinical trials



# Regulatory Compliance - Data/Privacy

- Value of data continues to grow for pharma, biotechs, and device companies
- Legislatures are focusing on data, increasing data risks and liabilities
- Differing jurisdictions may have differing rules governing protection of data/personal information
- Failure to comply with data-related laws can result in material liability, including contractual liabilities, civil and, in some cases, criminal penalties
- Consult data/privacy subject matter expert
  - Not atypical to have a separate data transfer agreement governing rights/obligations to data that will be transferred

# Regulatory Compliance – Foreign Investments

- Cross-Border Strategic Licenses and Collaborations may contemplate investment in a company by a foreign entity
- Investment in a company by a foreign entity may be subject to the purview of applicable regulatory bodies
- Even in the absence of investment, certain legislation may have been drafted broadly enough to arguably encompass licenses/collaborations under the purview of relevant regulations meant to cover foreign investments
- CFIUS reviews in the U.S. can take longer than 90 days to run its course, and the review process for other jurisdictions may also take months
- Consider early in the process to get input from subject matter experts and develop a coordinated approach between parties

# Regulatory Compliance - Antitrust / Competition Law

- Antitrust clearance may be required for “competitor collaborations” in the U.S., and similar clearance may be required outside of the U.S.
  - “Competitor Collaboration” comprises a set of one or more agreements, other than merger agreements, between or among competitors to engage in economic activity, and the economic activity resulting therefrom
  - Tests can take into consideration various factors such as size of the transaction, market share or revenue, and each jurisdiction may have its own differing test
- Time period for getting clearance may be in the order of months
- Consider early in the process to get input from subject matter experts and develop a coordinated approach between parties

# Regulatory Compliance - Export Controls and Trade Sanctions

- Import/export restrictions may apply to transfer of technical data and/or materials
- Consequences of non-compliance may be significant, including loss of export privileges, heavy fines and even prison sentences
- The regulations/laws may not be clearly defined
  - Have a clear overview of products and activities that might be sensitive
  - Follow the frequent updates in regulatory requirements
  - Implement controls & prevention mechanisms
  - Create record-keeping procedures

## Take Away - Regulatory Compliance

- Identify material issues early – novel issues may take time to analyze and timeline for getting clearance may be longer than expected
- Get input from subject matter expert
- Develop a coordinated approach with counterparty



# Choice of Law & Dispute Resolution

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# Choice of Law

- Choice of Law Clauses
  - Allows the parties to designate which state or country's laws will govern the interpretation of the contract, even if the contract was signed in or parties reside in differing states/countries
  - Generally advisable to pick a jurisdiction the parties are connected to – where the parties are located, or where activities will take place
  - Issue in cross-border transactions because the two parties are connected to different jurisdictions and activities may take place in multiple jurisdictions

# Choice of Law

- Considerations for Choice of Laws
  - Does the forum chosen have a clear and well-developed body of law?
  - Does the law of that particular jurisdiction respect party autonomy and freedom of contract?
- Generally, all international conventions and treaties provide that choice-of-law agreements selecting the law governing international commercial contracts are presumptively valid and enforceable
- New York / Delaware law, Law of England and Wales, Hong Kong and Singapore choice of law provisions are common

# Dispute Resolution - Litigation

- Litigation
  - Courts generally presume the validity of forum-selection clauses. A party opposing enforcement must make a strong showing that enforcement would be unreasonable or unjust to rebut the presumption. If the forum-selection clause is valid, then the defendant does not need “minimum contacts” with the forum state for the court to have personal jurisdiction
- Consider:
  - Are the courts in that jurisdiction accessible to foreign parties and capable of deciding on international business matters?
  - Is it beneficial for judgements to be appealable?
  - Will we want to take advantage of features of litigation, e.g., compelling testimony, issuing summary judgements, joining non-signatories in multiparty disputes?

# Dispute Resolution - Arbitration

- Arbitration
  - Procedure in which a dispute is submitted to one or more arbitrators who make a binding decision on disputes
  - General benefits of arbitration:
    - Confidentiality
    - Procedural flexibility
    - Ability of the parties to select arbitrators

# Dispute Resolution - Arbitration

- Arbitration
  - International arbitration offers additional benefits for cross-border disputes:
    - A forum selection clause which submits a dispute to arbitration is widely enforceable
    - Recognition and enforcement of arbitral awards
    - Avoidance of a foreign court where an adversary may benefit from a 'home court' advantage
  - International arbitration remains the preferred method for resolving cross-border disputes

## Take Away – Choice of Law / Dispute Resolution

- New York / Delaware law, Law of England and Wales, Hong Kong and Singapore are common governing law choices in cross-border strategic licenses/collaborations
- Litigation and arbitration each have advantages and disadvantages as a dispute resolution mechanism for cross-border strategic licenses/collaborations
- International arbitration remains a preferred method for resolving cross-border commercial disputes



# Payment / Tax

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# Payment / Tax

- Relevant payments in a Strategic License/Collaboration may include:
  - Upfronts / annual license fees
  - Reimbursement for R&D / Patent Prosecution expenses
  - Milestone payments
  - Royalties
  - Profit Share
  - Equity Investment
- For Cross-Border Strategic Licenses and Collaborations, it is essential to understand and comply with relevant tax laws and currency exchange & remittance related regulations. You'll want to be sensitive to tax treaties in place with between countries that can affect withholding tax requirements.



# Payment / Tax

- Consider:
  - Will payment be made in USD?
  - Are there any restrictions on currency exchange or remittance of payment?
  - Which entity will be making payment? Does it make sense to consider payment being made by a different entity (e.g., U.S. subsidiary of a relevant party) to get around any tax / currency issues?
  - Are there any value added taxes, withholding taxes, or other similar taxes? Is there business alignment on who will be responsible for such taxes?
  - Is there an equity component as part of the consideration?

## Take Away - Payment / Tax

- Identify/understand the risks
- Confirm business understanding with client
- Consult with a subject matter expert (e.g., tax) to implement business understanding
- Include contractual provisions to deal with potential uncertainty
  - e.g., If at any time legal restrictions prevent the remittance by Licensee of all or any part of Licensed Product Royalties due on Net Sales in any country, Licensee shall have the right and option to make such payment either by depositing the amount thereof in local currency to an account in the name of Licensor in a bank or other depository selected by Licensor in such country



# Other Practical Considerations

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# Other Practical Consideration

- Communication styles:
  - Direct vs. indirect
- Approach to contracting & negotiation:
  - Emphasis on reciprocity
  - Cooperative vs. competitive
- Decision-Making
  - Additional time may need to be built in to account for formal approval process by stakeholders
- Emphasis on Formality
  - Wet ink signatures may be required, and countersigned executed agreements may need to be mailed to the other parties

## Take Away - Other Practical Consideration

- Be mindful of cultural differences
- Be respectful, and to the extent possible and practical, adopt customs or approach of counterparty
- Get input from local counsel



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# Biography



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Ben Rho counsels life science, healthcare, and technology companies on transactional matters, including advising clients on negotiating and structuring acquisitions, divestitures, joint ventures, corporate partnering, licensing, and other complex collaborations. Drawing on his background and experience in patent law, Ben brings an awareness and appreciation for intellectual property and science related issues that can arise in intellectual property focused transactions.

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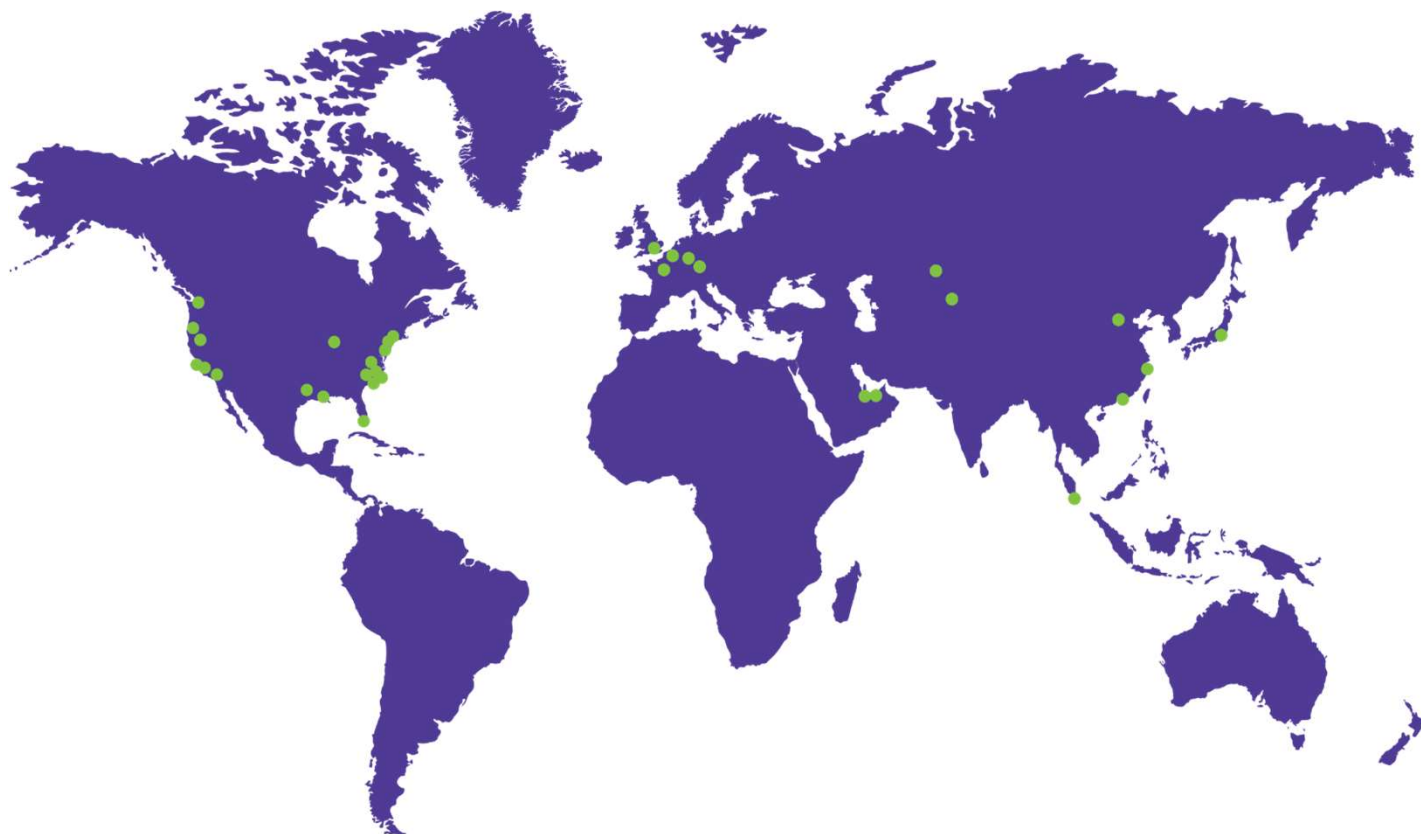


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