Morgan Lewis

REPORT

LIFE SCIENCES INDUSTRY

KEY TRENDS AND DEVELOPMENTS FOR ASIA-BASED INVESTORS

2023

www.morganlewis.com

LIFE SCIENCES INDUSTRY: KEY TRENDS AND DEVELOPMENTS FOR ASIA-BASED INVESTORS

With the consequences of the global pandemic still reverberating throughout the Asia-Pacific region, governments and businesses in the area continue to focus on the life sciences industry. From startups to global multinational companies, there is a broad acknowledgment that with consumer demand and growth potential, there are significant opportunities for dealmaking and investments.

In this compilation of key takeaways from Morgan Lewis's Asia Life Sciences Webinar Series, we review hot topics and key updates in the life sciences industry for those operating in Asia, both looking to invest in and outside of the regions, from the impact of US-China relations, trends for the startup community, and what to know about outbound investment from Asia, among other areas:

- Navigating the US-China Relationship and CFIUS
- Cross-Border Collaborations
- Employer Guide for Life Sciences Startups in Japan, China, and the US
- What Asian Investors in US Life Sciences Startups Should Know
- US Government Enforcement: Focus on Asian Life Sciences Companies
- Conclusion

NAVIGATING THE US-CHINA RELATIONSHIP AND CFIUS

In August, the US government issued an executive order as well as an advanced notice of proposed rulemaking introducing a proposed regime regulating select US outbound investment in sensitive technology companies in China, currently limited to semiconductors and microelectronics, quantum information technologies, and artificial intelligence (AI). See our LawFlash for further details and analysis of this action. On the same day, China's Ministry of Commerce issued a statement expressing "serious concern" about the restrictions that would occur under the proposed program and reserving the right to take countermeasures.

Against this backdrop of a significant increase in foreign direct investment (FDI) in the US life sciences industry, which includes medtech and biopharmaceutical companies, Chinese FDI has declined considerably since its peak year of 2016. However, according to a report by the US-China Investment Project, Chinese venture capital investment in the US life sciences industry remains remarkably resilient, partly due to the Chinese government's "Made in China 2025" initiative and other industrial policies.

As demonstrated by cases before the Committee on Foreign Investment in the United States (CFIUS), there is heightened scrutiny of Chinese investment in the US biotechnology industry, particularly with respect to transactions that may affect the US supply chain or critical or leading technology.

The determination of whether CFIUS clearance is required or recommended will generally turn on whether a company has "critical technology" or "sensitive personal data," and whether the noncontrolling transaction has been structured in a way to wall off foreign investors from such critical technology and sensitive personal data.

What Is Considered Critical Technology?

- Determining whether a life sciences company has "critical technology" can be a fact-intensive exercise, as it involves ascertaining if an export license would be required for the foreign investor(s) in question, and many emerging companies have not classified their technology or equipment for export control purposes.
- The analysis is generally more complicated for biopharmaceutical companies, particularly in the biologics space, than for medtech companies.
- CFIUS counsel have detailed checklists that they use with their life sciences company clients to guide them in making the classifications, but sometimes it is necessary or advisable to obtain a formal classification from the US government.

What Is Considered Sensitive Personal Data?

- "Sensitive personal data" is broadly defined as personal, financial, and healthcare information of US citizens, including identifiable data that is in applications for insurance, nonpublic email, or messaging among users of a US business' products or services, biometric data, geolocation data, and personnel security clearance data. It also includes genetic data.
- "Identifiable data" will be treated as sensitive personal data if it is maintained or collected by a US business.
- To narrow the scope of genetic data covered, and following concerns expressed by the life sciences industry regarding proposed rules, CFIUS limited the definition to "the results of an individual's genetic test, including any related genetic sequencing data."

Strategies

Structuring transactions so that CFIUS would not have jurisdiction can be legitimate and generally is not considered evasion (e.g., a license or collaboration agreement with no equity investment).

Another approach in venture deals is to use the standard National Venture Capital Association screening language to avoid holding CFIUS triggering rights (e.g., more than 9.9% ownership, no board or observer rights, no access to material nonpublic technical information or rights to substantive decision-making) until the transaction is cleared by CFIUS.

A company may want to consider filing if the closing should be conditioned on CFIUS clearance because of the national security risk profile, such as its engagement with critical technologies, critical infrastructure, and sensitive personal data (TID); supply chain concerns; a foreign government as an investor; US government nexus through contracts, funding, or governmental or military customers; or a watched technology, among other concerns.

If a decision is made not to file a voluntary notice with CFIUS, the parties should prepare for non-notified outreach by CFIUS, which is almost automatic for Chinese investment in the life sciences industry. CFIUS can issue an interim order blocking the transaction to prevent the parties from proceeding with a transaction pending the completion of CFIUS review.

Key Takeaways

In any transaction involving a foreign person and a US biotechnology business, there is a potential CFIUS issue that should be analyzed promptly, given the complexity of the rules.

Companies planning to seek foreign investment or offering themselves for sale to foreign persons should conduct self-CFIUS due diligence to identify the CFIUS concerns early on because such concerns may

affect the transaction structure. Companies should also consider the implications for future US governmental funding of taking on foreign—particularly Chinese—investors.

International investors into the United States and purchasers should conduct CFIUS due diligence and a risk assessment of how to address CFIUS and other national security issues and the overall deal completion risk that they present.

Due to the geopolitical risks linked with Chinese investors, we are increasingly seeing a trend of requests from sellers to add certain protective clauses in the transaction document, such as the "reverse breakup fees" clauses related to a CFIUS review result, as well as clauses whereby, regardless of whatever mitigation measures CFIUS may impose, the buyer will need to do all they can to cooperate and comply with the mitigation requests from CFIUS.

We covered this in further detail in our webinar What Chinese Life Sciences Companies Need to Know Under US-China Tension. To learn more about upcoming programs and receive our latest publications related to US-China trading policy and the global impact, subscribe to our US-China Trading Policy & Global Impact mailing list.

CROSS-BORDER COLLABORATIONS

Against the backdrop of a slower merger and acquisition (M&A) market, collaborations between biotech companies and pharma companies have remained robust, particularly those focusing on innovation and collaboration for value creation. According to a recent article, the scale of cross-border and domestic licensing deals in Asia has been expanding, with licensing deals becoming a sought-after business development model in China's pharmaceutical industry. Cross-border transactions can take various forms, such as licensing and collaborations, joint ventures, and financing and distribution agreements. However, when undertaking any cross-jurisdictional agreement, there are some key areas to consider.

Intellectual Property Rights

For a life sciences company, intellectual property (IP) rights are often the company's most valuable asset, and without protection, these assets can be vulnerable and subject to exploitation by other third parties. It is important to ensure that a licensor has IP rights to grant and run appropriate due diligence on an IP portfolio. Where possible, include robust representations and warranties regarding ownership and employee assignments, particularly for early-stage biotechs.

Given the international nature of these deals, IP rights should be protected in relevant jurisdictions covered by the collaboration. Get first right to prosecute in relevant jurisdictions and include obligations on the licensor to diligently prosecute in the relevant jurisdictions.

It is also important to ensure that the territorial scope of license grants are appropriate and to carefully consider whether each of the research, development, manufacturing, and commercialization licenses should be exclusive in the relevant territory.

Regulatory Compliance

Cross-border licenses and collaborations in the life sciences industry involve a myriad of complex regulatory frameworks in the broadest sense. They encompass product approvals, clinical trials, IP rights, data privacy laws, export and trade provisions that differ depending on the jurisdiction in which activities take place, or in which companies operate, among others. It is key to identify material issues early, as some novel issues may take time to analyze, having a knock-on impact on the timeline for getting clearance.

Choice of Law/Location for Dispute

If problems turn into a dispute, it is important to ensure that an agreement includes detailed dispute resolution mechanisms, such as arbitration or litigation, and specify the applicable law and jurisdiction. New York, England and Wales, Hong Kong, and Singapore are popular common governing law choices in cross-border strategic licenses and collaborations.

Litigation and arbitration each have advantages and disadvantages as a dispute resolution mechanism; however, international arbitration remains a preferred method for resolving cross-border commercial disputes.

Payment/Tax

The types of payments involved in a cross-border license or collaboration is the same as domestic agreements; these can include upfront or annual license fees, reimbursement for research and development expenses, patent prosecution and maintenance-related expenses, milestone payments, royalties, profit shares, and equity investments. It is important to identify and understand the risks and consult tax experts as well as include contractual provisions to deal with potential uncertainty.

Other Practical Considerations

Being mindful of cultural differences, particularly in communication styles is essential in cross-border deals. Be respectful, and to the extent possible and practical, adopt the customs or approach of the counterparty.

Learn more about Considerations for Cross-Border Strategic Licenses and Collaborations for Asia-Based Life Sciences Companies in our webinar session.

EMPLOYER GUIDE FOR LIFE SCIENCES STARTUPS IN JAPAN, CHINA, AND THE UNITED STATES

The life blood of many life sciences startups is their assets—employees, ideas, and innovations. A key focus for these companies is how to best protect those assets. In Japan, China, and the United States, there are underlying fundamentals in the employment law approach for startups to be aware of and effectively utilize, such as the use of confidentiality agreements; however, there are also important differences to note when doing business in each of these jurisdictions. Below, we take an illustrative look at these potential issues for emerging companies to consider.

Japan

For life sciences startups entering Japan, there are employment law tools that can help protect company assets, similar to the United States and China. There are a number of protective provisions that employers may choose to utilize, including confidentiality provisions; the right to approve any concurrent employment; prohibition against using or bringing any IP belonging to others; work for hire and assignment of invention provisions; and noncompetes, nonsolicits, and nondisparagements. These can be documented in an employment agreement or in separate agreements as discussed below.

Unlike the United States, there is no concept of at-will employment (an employer's ability to dismiss an employee for any reason or no reason at all, and without notice, as long as the reason is not discriminatory) in Japan. Employers in Japan may only terminate for cause and the threshold for justifying a termination for cause is very high. Japan’s employment environment is largely employee

friendly. Because of the limited ability to dismiss employees, most employee exits are the result of mutually agreed separations between the employer and the employee.

Using fixed-term agreements and including robust probationary provisions are potential solutions. Hiring directors or independent contractors rather than employees are also well-used alternatives to avoid some of these issues with employee terminations.

For startups engaging in cross-border matters, it is important not to use employment contracts from other jurisdictions where they may originally operate, as some core employment concepts are different in Japan. In addition to employment-related agreements, work rules carry equal weight with agreements and often specify working hours, overtime, wage calculations, and termination provisions. There are also labor management agreements with unions or employee representatives which also govern the employee relationship. Once the terms of employment have been set, there are restrictions on negative changes in employment terms and conditions, which often require employee consent.

The recording and proper payment for hours worked by employees are closely monitored and employers have an obligation to ensure proper tracking and payment. The proper characterization and payment of overtime premiums are also heavily regulated.

In addition, Japan has stringent data privacy legislation, similar to the European Union's General Data Protection Regulation, and employers are required to protect the personal information of employees in accordance with the Act on the Protection of Personal Information (APPI), which was significantly amended a few years ago. If an employing entity in Japan needs to transfer any employee personal information outside of the company or Japan, including to affiliates of the employing entity, there are a number of alternative approaches to complying with the APPI.

China

While China's employment law regime has developed a great deal in the last 15 years, it is relatively young when compared to the United States and many other jurisdictions. That said, like many countries, China continues to grapple with newer phenomena, such as the gig economy and startup company environment.

At the start of the employment relationship, it is important to set out the core expectations and obligations of employers with respect to protecting IP and how employees engage in business with the fundamentals, such as an employment contract, data export considerations, and a noncompete agreement. Like Japan, China does not have at-will employment, and terminations for cause are challenging to sustain from an evidentiary perspective. Further, restrictions on negative changes in employment terms and conditions also require employee consent in China and may require employee consultation more broadly.

Expansive data protection laws and potential triggers for China's new Anti-Espionage Law are important to consider. The data protection regime covers employee data, third-party personal and sensitive personal data, such as patient and clinical testing data, and "important data" or data related to national security, such as data potentially with respect to military hospitals. If a multinational company learns of nonpublic and sensitive information that relates to China's national security, sharing this data outside the China entity and particularly across borders could implicate the new Anti-Espionage Law.

Also worth noting is that, generally, healthcare professionals in China are government officials. There could be anticorruption risks that require robust policies and monitoring of conduct. Control of samples and third-party interactions with the personnel at laboratories, testing centers, and suppliers should also be key considerations.

Another issue for startups is that equity is regulated and requires filing and approval with the State Administration of Foreign Exchange (SAFE). Before a company is listed or if the equity plan is not filed and approved by SAFE, there is no effective and legally enforceable way to grant equity to Chinese nationals or employees of the China entity.

United States

Central to the protection of assets in the United States are the effective use of three key tools.

Invention Assignment Agreements

An invention assignment agreement is a legal contract that gives an employer certain rights to inventions created by an employee or consultant during the employment or consulting relationship. These require detailed disclosure of prior and future inventions; a definition of what future inventions will belong to the employer, including details on "assignment" (legal transfer) of ownership rights; and cooperation in the patent process.

Employees or consultants can be required to sign an invention assignment agreement as a condition of employment or engagement. However, some states limit the extent to which an employer can require an employee to give up rights—for example, California, Delaware, Illinois, Kansas, Minnesota, North Carolina, and Washington have exemptions to the extent the invention did not rely on the use of the employer's resources and was created during the employee's personal time.

Confidentiality Agreements

These are legally binding contracts that require parties to retain confidentiality for a defined time. Even if confidentially agreements are executed, care should be taken to protect confidential information, such as by using passwords, setting up need-to-know access, as well as the use of restricted USB drives.

Restrictive Covenant Agreements

Nonsolicits

These are a legal contract an employee or consultant signs agreeing not to solicit employees and/or customers for the benefit of a competing business for a stated period of time after the relationship ends. These may limit solicitation of employees and/or customers. To be enforceable, nonsolicits must be reasonable in scope and duration and be tailored to protect legitimate business interests.

Noncompetes

These are legal contracts an employee or consultant signs agreeing not to start a competing business to work for a competitor for a stated period of time after the relationship ends. The Federal Trade Commission has proposed a rule banning noncompetes. Broadly, this rule would ban noncompetes with "workers" or any person "who works, whether paid or unpaid, for an employer," and applies to explicit and de facto noncompetes. It requires rescission of existing noncompetes with notice to workers—the only exception being in connection with the sale of business—for noncompetes applicable to "substantial owners," which is defined to mean those owning more than 25% of business.

What Should Employers Do?

- Take inventory of current agreements (including nondisclosure provisions) and ensure no "de facto" noncompetes in the form of nondisclosure agreements.

- If noncompetes become unavailable in the case of M&A transactions, consider earnouts or staged purchases and retained equity stakes in business post-departure with tail/sunset repurchases.
- Employ protocols and other security measures to protect confidential and sensitive information.
- Use appropriate confidentiality, invention assignment, and restrictive covenant agreements.
- Regularly review for enforceability and sufficient protections.
- Prepare for potential ban on noncompete agreements.

Learn more about employment law issues affecting emerging life sciences companies in our webinar Piloting Through the Pathways of Employment Law: An Essential Guide for Emerging Companies, part of the Asia Life Sciences Webinar Series 2023.

WHAT ASIAN INVESTORS IN US LIFE SCIENCES STARTUPS SHOULD KNOW

The dynamic life sciences venture capital scene presents investors with a high-risk, high-return proposition. There can be many challenges, such as limited sources of revenue and capital, to early-stage companies often without products on the market yet, there can also be significant opportunities, including expanding into new markets and jurisdictions, and expanding the scope for innovation and value creation in the life sciences sector. As investors are becoming increasingly global, the following are some key considerations for Asian investors.

Intellectual Property

In the life sciences startup scene, entire business models can be built around a product. It is therefore critical to consider protecting IP at the outset before significant resources are invested. Amid a litigious landscape in the United States, businesses require robust patents to use as offensive and defensive tools with competitors.

Due Diligence and Patent Portfolios

IP due diligence often revolves around a freedom to operate (FTO) review to evaluate risk and other companies' patents to determine if the target company overlaps with existing patents, including the United States and those from outside the United States. There should be diligence around each claim within a patent, of which there can be several, which determine its scope of each claim's rights. However, it is worth noting that less can be more, as it is the quality of the claim and the claim construction that are important, rather than volume. There is a risk that if a patent is too broad, or even too narrow, others could supersede it.

Day-to-Day Oversight

US venture investors often maintain close contact with private companies in a portfolio. There could be a combination of a regular cadence of board meetings, visits to physical onsite locations, and frequent communication with executive management.

Investors in Asia may experience some challenges in maintaining close contact given time zones and geographic distance. Often, Asian investors have a local team wherever the target company is in the United States. Language and cultural differences are also a consideration, particularly in technical

conversations with scientists, where it is key to have an interpreter that is a field specialist. "Deemed exports" in export controls regulations may also prevent investors from access to certain information.

Regulatory Framework

Life sciences is a heavily regulated industry, making it important to understand regulations and impact they will have.

Partnerships And Collaborations

Partnerships and collaborations are an integral part of the life sciences industry, from partnering with a larger company to develop a drug or medical device or private companies leveraging resources of a large pharmaceutical or medical devices company with leverage for distribution.

Other Sources of Capital

Government funding for early work is common, particularly for research. It can be nondilutive and often does not need to be paid back. However, some capital—such as from academic institutions and other government grants—come with obligations attached, including march-in rights.

CFIUS

As discussed above, CFIUS scrutiny of US investments by non-US investors has intensified in recent years, based in part due to recent legislative developments. Participation by a non-US investor may cause a transaction to fall within the jurisdiction of CFIUS, and if so, the transaction could be restricted, blocked, or significantly delayed if CFIUS believes that a transaction raises US national security concerns.

Learn more about investing in US life sciences startups in our webinar Investing in Life Sciences Startups in the US – Key Issues and Considerations, part of the Asia Life Sciences Webinar Series 2023.

US GOVERNMENT ENFORCEMENT: FOCUS ON ASIAN LIFE SCIENCES COMPANIES

The US Department of Justice (DOJ) has shown increased interest in enforcing the Foreign Corrupt Practices Act (FCPA) in the life sciences sector. The FCPA prohibits the payment of any kind of bribe, kickback, or thing of value to a foreign government official. DOJ has focused particularly on China, which has seen the highest proportion of enforcement actions since the FCPA's enactment.

US enforcement authorities, notably DOJ and the Securities and Exchange Commission (SEC), continue to focus on charging companies and individual corporate executives, with corruption offenses continuing to be a focal point in this enforcement regime. Other countries, including the United Kingdom, Brazil, France, and Singapore, often investigate similar conduct in parallel with the United States.

Self-Disclosure Policy

DOJ announced a new Voluntary Self-Disclosure Policy on February 22, 2023, standardizing the definition of what it means to voluntarily self-disclose and offering improved consistency and predictability as to the benefits and consequences of self-disclosure. DOJ expects companies to meet a high bar to qualify as having voluntarily self-disclosed misconduct, with the three key aspects including voluntary disclosure, timely disclosure, and substantive disclosure. To earn the benefit of such disclosure, the company must also cooperate with government investigations and fully remediate.

Compensation Clawback

In March 2023, DOJ launched a pilot program whereby every corporate resolution the Criminal Division entered into would require the resolving company to implement employee compensation improvements. Under this new pilot program, companies may be able to reduce criminal fines by attempting to claw back compensation from individual wrongdoers. Even if a company were unsuccessful in recouping these funds, if the company initiated the process to recoup such compensation before the time of resolution, an additional fine reduction may be warranted.

Third Parties

Third parties that may be engaged include consultants, finders, introducers, advisors, agents, joint venture partners, local sales agents, and distributors. Under the FCPA—and many other antibribery regimes—a company may be held liable not only for the corrupt actions of its employees but also for the corrupt actions of a third party acting on the company's behalf. Before engaging a third party, the best practice is to have established protocols for due diligence.

Companies can mitigate third-party risk by vetting third parties to determine the likelihood they will take corrupt action, monitor for red flags, and escalate and address any red flags.

Key Compliance Takeaways from FCPA Resolutions for Asian Life Sciences Companies

- A problematic corporate culture can undermine otherwise reliable compliance program structures.
- Acknowledge the need for enterprise-wide policies, processes, and training to be implemented in each business and each country in which the company operates or does business.
- Failure to integrate subsidiaries or apply values and norms of US-based companies poses serious risk, including long-lasting reputational damage.
- Compliance programs and internal control systems not only need to identify red flags, but also ensure that action is taken to address detected issues. Unless a compliance program and its reinforcing controls are reassessed from time to time, they may be allowing problematic transactions to slip through undetected, despite an outward appearance of effectiveness.
- The biggest transactions deserve the same level of scrutiny and controls, if not more, than more routine transactions.
- Prompt remediation matters, especially when it comes to monitored risks.
- Acknowledge the need to demonstrate not only that a compliance program has been implemented, but also that it has been tested and is effective.

These issues were discussed in further detail in our webinar session US Government Enforcement: Recent Developments and Issues in Investigations.

CONCLUSION

The fast-moving Asia life sciences scene is complex and should be considered in conjunction with the global ecosystem of the sector as it presents both significant cross-border opportunities and a multitude of challenges to navigate. It is therefore prudent to consider the ever-changing geopolitical landscape and legal developments in this highly regulated sector.

CONTACTS

If you have any questions or would like more information on the issues discussed in this report, please contact any of the following:

Boston

Carl A. Valenstein	+1.617.341.7501	carl.valenstein@morganlewis.com

Miami

Kimberley E. Lunetta	+1.305.415.3439	kimberley.lunetta@morganlewis.com

San Francisco

Byunghwi Rho	+1.415.442.1275	ben.rho@morganlewis.com
Benjamin H. Pensak	+1.312.324.1719	benjamin.pensak@morganlewis.com
Nancy Yamaguchi	+1.415.442.1242	nancy.yamaguchi@morganlewis.com
Scott D. Karchmer	+1.415.442.1091	scott.karchmer@morganlewis.com

Shanghai

K Lesli Ligorner	+86.21.8022.8777	lesli.ligorner@morganlewis.com
Todd Liao	+86.21.8022.8799	todd.liao@morganlewis.com

Washington, DC

Janice H. Logan, Ph.D.	+1.202.739.5234	janice.logan@morganlewis.com
Justin D. Weitz	+1.202.739.5932	justin.weitz@morganlewis.com

ABOUT US

Morgan Lewis is recognized for exceptional client service, legal innovation, and commitment to its communities. Our global depth reaches across North America, Asia, Europe, and the Middle East with the collaboration of more than 2,200 lawyers and specialists who provide elite legal services across industry sectors for multinational corporations to startups around the world. For more information about us, please visit www.morganlewis.com.