

The background of the slide is a close-up, high-magnification image of several red blood cells. The cells are a deep red color and have a biconcave, disc-like shape. They are slightly out of focus, with one cell in the foreground being sharper than the others. The lighting creates a sense of depth and texture on the surface of the cells.

**Morgan Lewis**

**THE LIFE SCIENCES  
GROWTH SERIES**

**Timely Issues Relating to Transactions with  
Chinese and other Foreign Investors**

**Carl Valenstein, Stephen Paul Mahinka and Todd Liao**  
**March 21, 2019**

© 2018 Morgan, Lewis & Bockius LLP

# **INTRODUCTION AND AGENDA**

# Introduction and Agenda

- Early stage life sciences companies are generally looking to raise capital with the exception of certain well-funded companies started by serial entrepreneurs or with wealthy friends and families.
- There are many foreign investors, particularly Chinese venture capital and strategic investors, looking to invest in US life sciences companies. The Chinese government has actively directed and supported the biotech industry as part of its Made in China 2025 policy and current five-year plan.
- Often the financial investments are coupled with strategic partnerships including licensing, collaboration/co-development agreements and joint ventures to build the Chinese market and acquire technology, products and talent abroad.
- There are special issues to be considered before engaging in a transaction with a foreign investor.
- This presentation will focus principally on Chinese investors, although many of the issues have general application to other foreign investors.

## Introduction and Agenda (Cont.)

- The issues to consider include the following:
  - Background investigation on foreign investor
  - Export control, sanctions and FCPA compliance
  - US government funding restrictions
  - National security reviews (CFIUS)
  - Transactional issues, including choice/conflicts of law, dispute resolution, tax planning, foreign regulatory issues and IP protection with respect to the transactional documents
- Carl Valenstein will address background investigation, export control, sanctions, US government funding restrictions.
- Stephen Paul Mahinka will address national security reviews (CFIUS)
- Todd Liao will address transactional issues, including choice/conflict of law, dispute resolution, foreign regulatory issues and IP protection

## Background Investigations on Foreign Investors

- It is critically important to do a background investigation on your foreign investor to understand their source of funding, financial and commercial resources, ownership and control, investment authority, reputation and regulatory status (e.g. are they subject of any US sanctions or export restrictions or a company of concern in prior CFIUS filings )
- The current “trade war” with China has implications for Chinese investment in US biotechnology and transactions by Chinese investors have been blocked on national security grounds. See *China’s Biotechnology Development; The Role of US and other Foreign Engagements. A report prepared for the US-China Economic and Security Review Commission* (February 14, 2019)
- Third party services can be used (e.g. World Check) as well as references checked. In larger transactions involving more strategic relationships, investigative firms can be engaged to do more than a public records search but this can be expensive.
- Contractual representations, warranties and covenants are no substitute for a background investigation.

## Export Controls and Sanctions

- It is important for the US company to understand the export control status of any technology or equipment that might be exported as part of the transaction. Note that exports can be made in the US by giving a foreign investor or its representatives access to certain technology in the US. So-called “deemed exports” can occur with hiring non US citizen or permanent resident alien employees. Sufficient lead time should be allowed for obtaining any required export licenses.
- The US has for many years maintained multilateral-based (Australia Group) controls on technology and related equipment used in bio-warfare/bio-defense (ITAR), as well as dual-use biological materials, including certain human, animal and plant pathogens, toxins and genetically modified organizations. The CDC maintains separate controls on so-called “select agents.”
- As will be discussed in more detail with respect to national security reviews (CFIUS), it is important to determine if the US company has any “critical technologies” defined currently by reference to the NAICS codes, ITAR, CDC and EAR lists, but subject to expansion under an on-going regulatory review process to add certain “emerging and foundational” technologies.

## Export Controls and Sanctions (Cont.)

- As part of the background investigation, the US company should have confirmed that the foreign investor is not subject to US sanctions or export restrictions by reference to various US government lists (e.g. Consolidated Screening Lists).
- Note that China is prohibited jurisdiction for ITAR-controlled items and many EAR controlled items require an export license for China or for a deemed export to Chinese nationals in the US. There are also Chinese companies/persons on the denied or blocked persons lists.
- Export control issues can arise in license and collaboration agreement, joint ventures, during due diligence and with the visit/employment in the US of non US persons.
- These determinations are often confirmed with representations, warranties and covenants in the transactional documents.

## FCPA

- The Chinese life sciences industry has generated the highest number of FCPA investigations and enforcement cases, particularly in the medical device industry because of a number of factors:
  - The counterparties are state-owned hospitals or research institutions and doctors/scientists may be considered foreign government officials for FCPA purposes
  - The low pay in China of these persons
  - The complexity of the Chinese regulatory process and the prevalence of bribery notwithstanding efforts of the Chinese government to prohibit it.
- Certain foreign investors are government owned and controlled and their representatives are considered foreign government officials. A good background investigation should have revealed this information, as well as the overall compliance history and reputation of the foreign investor.



## FCPA (Cont.)

- With transactions that involve strategic partnerships that go beyond a straight investment by a foreign investor in the US company, care must be taken that no funds transferred to the foreign investor or its representatives violate the FCPA anti-bribery provisions or will be used by the foreign investor or its representatives in violation of the FCPA with respect to foreign government officials, which could create liability for the US company.
- Tailored FCPA representations, warranties and covenants should be included in the transactional documents and FCPA training provided to relevant US company and foreign investor personnel.

## US Government Restrictions

- If the US company has any grants, contracts or other sources of funding from the US government, the relevant agreements must be checked for compliance with any provisions applicable to a potential investment by or a strategic partnership with a foreign investor.
- US government rights under the Bayh-Dole Act may require manufacturing in the US, although waivers may be granted in certain situations.
- The NIH and FBI have begun to visit recipients of NIH funding to determine if there is any risk that US funded intellectual property is being stolen or improperly transferred outside of the US by foreign investors or researchers.

## Background on CFIUS and the Defense Production Act of 1950

- The Committee on Foreign Investment in the United States (“CFIUS”) has historically reviewed transactions involving the acquisition of control by a foreign person of a US business that pose threats to national security under the Defense Production Act of 1950.
- These reviews have historically been on a voluntary basis by parties submitting a joint filing, although CFIUS has had the right to require review of certain non-notified transactions and for the first time ever intervened before closing to block a Broadcom hostile takeover.
- Before 2016, CFIUS had blocked or forced the divestiture in only a small number of foreign investments, principally involving Chinese SOEs with military connections, and proposed mitigation terms in a slightly larger number of cases to address national security issues. The number of blocked or withdrawn transactions involving Chinese investors has increased dramatically as part of the Trump Administration’s trade war with China, but Chinese transactions are still being cleared.
- Risks are largely on foreign persons who often condition an investment on clearance by CFIUS.

## Summary of FIRRMA – Substantial Expansion of CFIUS

- On August 13, 2018, the President signed into law the Foreign Investment Risk Review Modernization Act of 2018 (“FIRRMA”).
- FIRRMA makes significant changes to both CFIUS powers and operations, particularly the assertion of jurisdiction over certain non-controlling investments involving “critical technologies.”
- FIRRMA was accompanied by the Export Control Reform Act of 2018, extending controls over licensing of certain IP, and including new coverage of “emerging and foundational technologies.”
- FIRRMA requires CFIUS to adopt implementing regulations within 18 months of enactment and authorizes CFIUS to adopt interim regulations, which CFIUS did on October 11, 2018 with the Pilot Program Regulations.
- Consequently, important for Chinese investors to make two decisions:
  - Is the transaction required to be filed (mandatory Declaration)?
  - Is it advisable to file, in view of the U.S. business products or technology (Joint Voluntary Notice)?

## Summary of Mandatory Pilot Program – Focus on Critical Technologies

- The Pilot Program Regulations became effective on November 10, 2018 and, in limited cases require certain transactions to be cleared with CFIUS or fines can be imposed on the parties up to the value of the transaction.
- All foreign countries are treated equally—China is not singled out, but Chinese investments are clearly a major focus of CFIUS' concern.
- If a transaction constitutes a “Pilot Program Covered Transaction,” then a filing with CFIUS is required at least 45-days before the closing of the transaction.

## Summary of Mandatory Pilot Program

- The Declaration, a shortened form to be used for mandatory filings, requires extensive seller information.
- Penalty for not filing a Declaration when required is up to the value of the transaction.
- The new mandatory feature and potential sanctions will necessitate more front-end due diligence on transactions.
- For the time being, filing fees are not being required but it is anticipated that fees will be introduced in the near future (as authorized per FIRRMA, to be the lower of \$300,000 or 1% of the value of the transaction).
- Even if a transaction is not a Pilot Program Covered Transaction, it may still be a “covered transaction” for purposes of CFIUS review, and a Joint Voluntary Notice may be advisable.

## How to tell if a transaction is a Pilot Program Covered Transaction?

A “Pilot Program Covered Transaction” is defined as either:

- (a) A “pilot program covered investment” or
- (b) “any transaction by or with a foreign person that could result in foreign control of any pilot program US business, including such a transaction carried out through a joint venture”

## How to tell if a transaction is a Pilot Program Covered Transaction?

A “pilot program covered investment” is the acquisition of an equity interest (including a contingent equity interest), direct or indirect, in an unaffiliated pilot program covered business that could not result in control (i.e., a non-controlling investment) but affords that foreign person:

- (a) access to any material non-public technical information in the possession of the pilot program US business;
- (b) membership or observer rights on the board of directors or equivalent government body of the pilot program US business or the right to nominate an individual to a position on the board of directors or equivalent governing body of the pilot program US business; or
- (c) Any involvement, other than through voting of shares, in substantive decision making of the pilot program US business regarding the use, development, acquisition or release of “critical technology.”



## How to tell if a transaction is a Pilot Program Covered Transaction?

A “pilot program US business” means any US business that produces, designs, test, manufactures or develops a “critical technology” that is:

- (a) Utilized in connection with the US business’s activity in one or more “pilot program industries”; or
- (b) Designed by the US business specifically for use in one or more “pilot program industries.”

# How to tell if a transaction is a Pilot Program Covered Transaction?

A “pilot program industry” is defined as any of the 27 industries identified in Annex A to the regulations by reference to the NAICS codes. Note that the NAICS codes are broad and prepared for statistical purposes and there is no agency charged with responsibility for a final determination if an industry is covered.

➤ Current NAICS Code Industries

- Aircraft Manufacturing (336411)
- Aircraft Engine and Engine Parts Manufacturing (336412)
- Alumina Refining and Primary Aluminum Manufacturing (331313)
- Ball and Roller Bearing Manufacturing (332991)
- Computer Storage Device Manufacturing (334112)
- Electronic Computer Manufacturing (334111)
- Guided Missile and Space Vehicle Manufacturing (336414)
- Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing (336415)
- Military Armored Vehicle, Tank and Tank Component Manufacturing (336992)
- Nuclear Electric Power Generation (221113)
- Optical Instrument and Lens Manufacturing (33314)

# How to tell if a transaction is a Pilot Program Covered Transaction?

## ➤ Current NAICS Code Industries

- Other Basic Inorganic Chemical Manufacturing (325110)
- Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing (336419)
- Petrochemical Manufacturing (325110)
- Powder Metallurgy Part Manufacturing (332117)
- Power, Distribution and Specialty Transformer Manufacturing (335311)
- Primary Battery Manufacturing (335912)
- Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing (334220)
- Research and Development in Nanotechnology (541713)
- Research and Development in Biotechnology (except Nanotechnology) (541714)
- Secondary Smelting and Alloying of Aluminum (331314)
- Search, Detection, Navigation, Guidance, Aeronautical, and Nautical Systems and Instrument Manufacturing (3354511)
- Semiconductor and Related device Manufacturing (334413)
- Semiconductor Machinery Manufacturing (333242)
- Storage Battery Manufacturing (335911)
- Telephone Apparatus Manufacturing (334210)
- Turbine and Turbine Generator Set Units Manufacturing (333611)

## How to tell if a transaction is a Pilot Program Covered Transaction?

- “Critical Technologies” is defined in the Pilot Program regulations as:
  - (a) technology covered by the International Traffic in Arms Regulations (ITAR);
  - (b) technology covered by the Commerce Control List (CCL) of the Export Administration Regulations (EAR);
  - (c) controlled nuclear related technology;
  - (d) select agents or toxins; or
  - (e) “emerging or foundational technologies” to be added in the future by the Department of Commerce, under the Export Control Reform Act of 2018, which definition will also be used by CFIUS.
- To be a mandatory filing, the US business must be both within a listed NAICS Code and meet one of the above criteria.

## How to tell if a transaction is a Pilot Program Covered Transaction?

- The Department of Commerce has issued a notice of opportunity to comment (Nov. 19, 2018) on a potential list of emerging and foundational technologies, which is very wide-ranging, including the following areas:
  - Biotechnology, including nanobiology, genomic and genetic engineering, and neurotech
  - Artificial intelligence, including neural networks, genetic programming, computer vision, expert systems, speech and audio processing, machine translation, audio and video manipulation technologies, AI cloud technologies
  - Position, navigation, and timing technology
  - Microprocessor technology, including advanced computing technology, memory-centric logic
  - Data analytics technology
  - Advanced computing technology

## How to tell if a transaction is a Pilot Program Covered Transaction?

- Quantum information and sensing technology
- Logistics technology
- Additive manufacturing (3D printing)
- Robotics, including swarming technology and molecular robotics
- Brain-computer interfaces
- Hypersonics, including flight control algorithms
- Advanced materials, including biomaterials
- Advanced surveillance technologies, including faceprint and voiceprint technologies

## Practical Consequences If Subject to Mandatory CFIUS Filing

- If a transaction is a Pilot Program Covered Transaction, you must file with CFIUS at least 45-days before the closing and be prepared for delays if CFIUS determines it must review through the Joint Voluntary Notice process, which could take up to an additional 105 days of review (or more in a complex case, through required re-filings).
- Need to negotiate special contractual language to address the risks of CFIUS review and the potential for required mitigation or blocking.
- When CFIUS filing fee is introduced, contractual language needed to allocate cost.
- May need to consider “no mandatory filing required” representations in agreement.
- Even if the transaction is not a Pilot Program Covered Transaction subject to mandatory filing, the parties, particularly the foreign person, should consider if it wants to condition the transaction on clearance with CFIUS if it constitutes a covered transaction under the existing regulations. The foreign person bears the risk of a required divestiture or onerous mitigation conditions.

## Effects on Timing of Closing and Agreement Provisions

- A transaction can be closed before or during CFIUS review
- Extensions of review period or re-filing demands within sole discretion of CFIUS
- Need to consider provisions in deal agreements to address potential issues
  - Possible closing during CFIUS review
  - Whether to make a CFIUS filing only a condition or a condition precedent
  - Inclusion of break-up / reverse break-up fees
  - Contract rep that no mandatory filing is required (because, e.g., no “critical technology” / not a “pilot program covered transaction” / not “critical infrastructure” / target does not maintain or collect personal data of U.S. citizens)
  - Contract rep that investor is not a “foreign person”



## CFIUS Remedies

- CFIUS can and often does impose monitoring responsibilities, by outside entities
- In addition to divestiture, CFIUS can impose mitigation conditions, including
  - Prevention of foreign entity access to data, technology, or participation in decision-making of the U.S. business
  - Prevention of acquiring a board or observer seat
  - Prevention of technology transfer

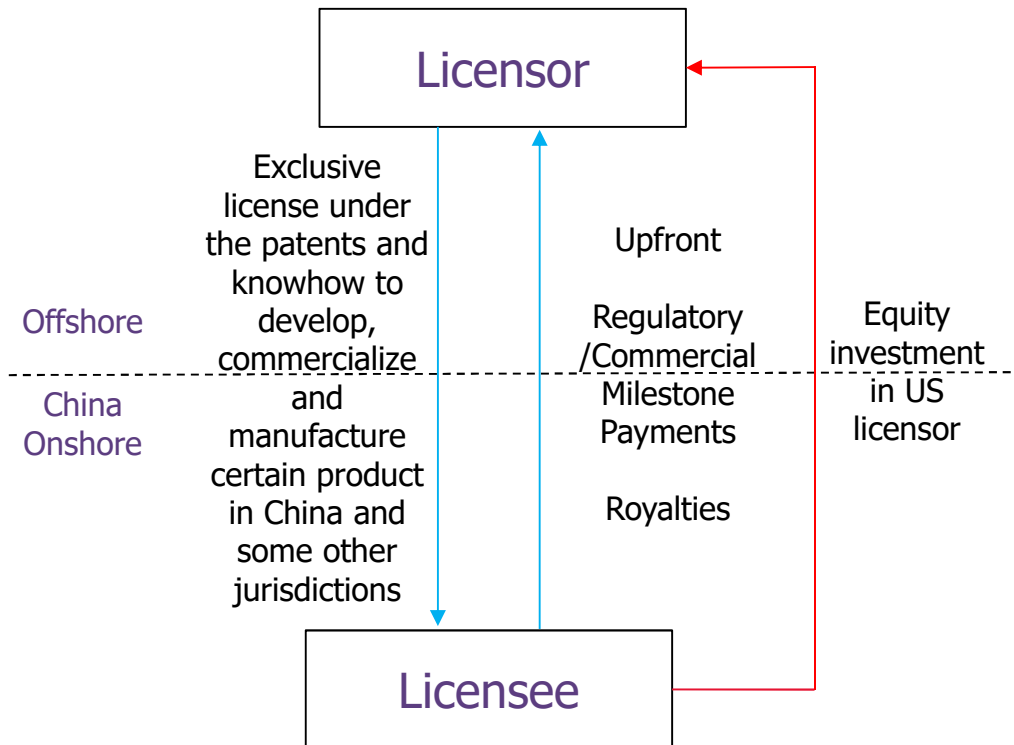
## Transactional Issues - General

- Choice of Law:
  - VC Financing Documents: typically follow the governing law of US financing documents
  - License & Collaboration Agreements: typically follow the governing law of US license agreements
  - Offshore JV for China home market: Hong Kong law is more preferred
  - Onshore JV for China home market: PRC law
- Dispute Resolution:
  - VC Financing Documents: international arbitration (e.g., US, Hong Kong, Singapore)
  - License & Collaboration Agreements: international arbitration
  - Offshore JV for China home market: international arbitration
  - Onshore JV for China home market: international arbitration, China International Economic and Trade Arbitration Commission or Shanghai International Arbitration Center

## Transactional Issues - General

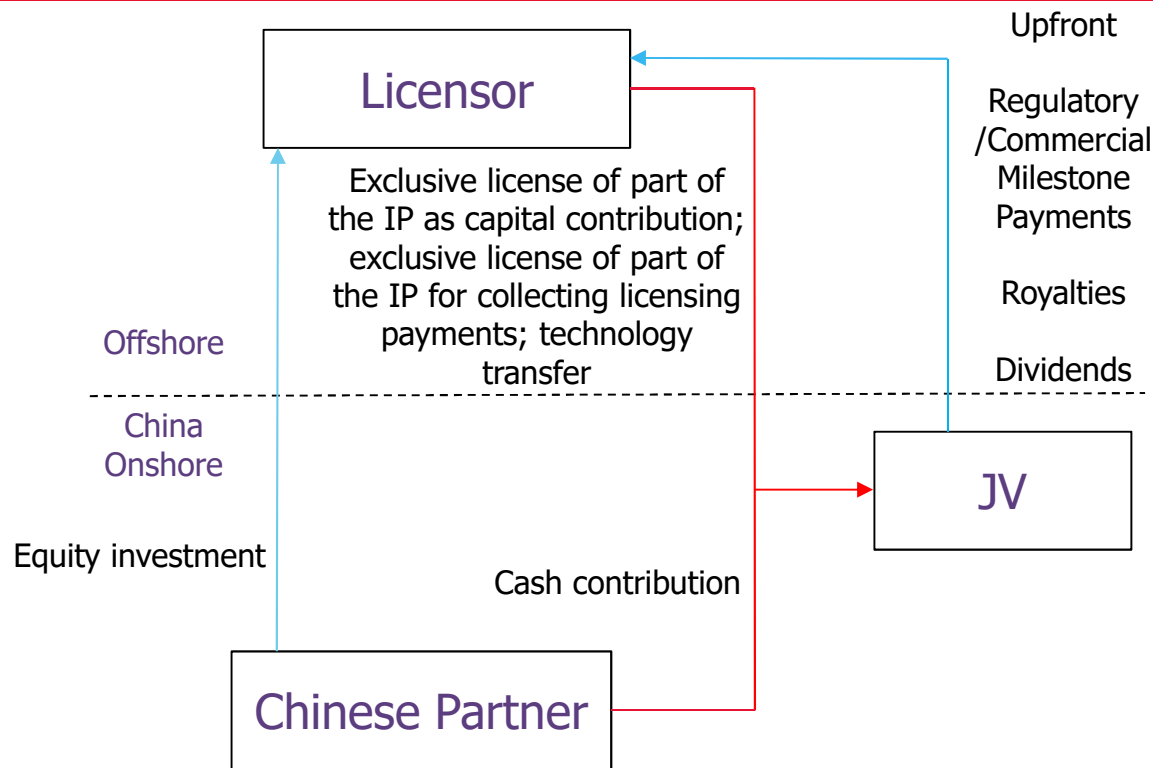
- Foreign Regulatory Issues
  - To repatriate funds from China to make equity investments overseas, Chinese investors need to complete prior filings with the National Development and Reform Commission and the Ministry of Commerce, and to obtain the foreign exchange registration with the State Administration of Foreign Exchange (or its designated local banks), for each such investment.
  - US companies should request the Chinese investor to start with the filing procedures in China as soon as possible, and/or review the filing/registration certificates if the Chinese investor already has funds outside of China.
- IP Protection:
  - Apply for patents in China if the parties will develop and commercialize the products for the China market through licensing, collaboration and/or JV arrangement.
  - License & Collaboration Agreements: Registration of IP import agreement with the Ministry of Commerce in China.
  - While Shanghai Free Trade Zone allows foreign investor to make equity contribution to a China onshore JV by exclusive IP license (supported by IP valuation report), some other provinces and cities in China may only accept IP transfer as an eligible form of equity contribution to a China onshore JV.

# Licensing + Equity Investment



- Some Chinese licensees would participate in financing of the US licensor, while taking the China right of a certain product

# Licensing + JV + Equity Investment in Licensor



Morgan Lewis

- Some Chinese partners would make equity investment in the US licensor, while taking the China right of a certain product through a JV
- JV will be the local entity to develop, commercialize and manufacture the licensed products in China
- IP license (as opposed to IP assignment) as a form of capital contribution is recognized in the Shanghai Free Trade Zone, but not many other cities or provinces in China
- JV may or may not make payments under the exclusive license, depending on the valuation of relevant IP and the cash contribution from the Chinese partner

## Biography



**Carl Valenstein**

Boston, MA

T +1.617.341.7501

[carl.valenstein@morganlewis.com](mailto:carl.valenstein@morganlewis.com)

Carl Valenstein focuses his practice on domestic and international corporate and securities matters, mergers and acquisitions, project development, and transactional finance. He counsels extensively in the life science, telecom/electronics, and maritime industries, and he has worked broadly in Latin America, the Caribbean, Europe, Africa, Asia and the Middle East. He is the co-chair of the International Section of the Boston Bar Association and co-chairs the firm's Cuba Initiative. He is a frequent speaker at conferences on a variety of international compliance and transactional topics.

**Morgan Lewis**

# Biography



**Stephen Paul Mahinka**

Washington, D.C.

T +1.202.739.5205

[stephen.mahinka@morganlewis.com](mailto:stephen.mahinka@morganlewis.com)

Stephen Paul Mahinka is a partner in the Washington, D.C. office of Morgan, Lewis & Bockius LLP, and a member of the firm's CFIUS Working Group. Mr. Mahinka is a former leader of the firm's Antitrust Practice, founder of its FDA Practice, and co-founder and former chair of its Life Sciences Industry group. He is responsible for many of the firm's filings before the Committee on Foreign Investment in the United States (CFIUS), and has represented both foreign buyers/investors and domestic sellers of U.S. businesses in reviews, obtaining clearances for over 50 transactions in recent years, and has analyzed hundreds of proposed transactions. These CFIUS clearances obtained include transactions in the life sciences, energy (both conventional and renewable), technology, defense, and transportation industries. He has substantial experience in negotiating Foreign Ownership, Control, and Influence (FOCI) and other mitigation agreements that may be presented as conditions for clearance of a proposed transaction. Mr. Mahinka has published over 90 articles on CFIUS, FDA, and antitrust issues, and is a co-author of several books, including the ABA Antitrust Section's *Pharmaceutical Industry Antitrust Handbook* (2<sup>nd</sup> ed. 2018), *Food and Drug Law and Regulation* (3<sup>rd</sup> ed. 2015), and *Life Sciences Mergers and Acquisitions* (2008). He is a graduate of Johns Hopkins University, *Phi Beta Kappa*, and of the Harvard Law School, where he was Executive Editor of the *Harvard International Law Journal*.

**Morgan Lewis**

## Biography



**Todd Liao**

Shanghai

T +86.21.8022.8799

[todd.liao@morganlewis.com](mailto:todd.liao@morganlewis.com)

Todd Liao works with clients on a wide range of financial transactions and legal issues involving China. He frequently works with multinational corporations on cross-border mergers and acquisitions, foreign direct investment and investment financing, disposal of Sino-foreign joint ventures and assets, and the structuring of complex commercial transactions. Todd also handles intellectual property (IP) work, specifically assisting clients with managing their trademark portfolios. He is admitted in New York only.

In addition, Todd counsels on matters related to the US Foreign Corrupt Practices Act (FCPA) practice in China and throughout the Asia-Pacific region. He advises multinational corporations regarding compliance with the FCPA and other regulatory compliance matters including policies and practices, gifts, travel and entertainment policies and violations, third-party due diligence issues, managing and conducting investigations of alleged FCPA violations, whistleblower investigations, and employee disciplinary actions. He also conducts FCPA training in multiple languages.

**Morgan Lewis**

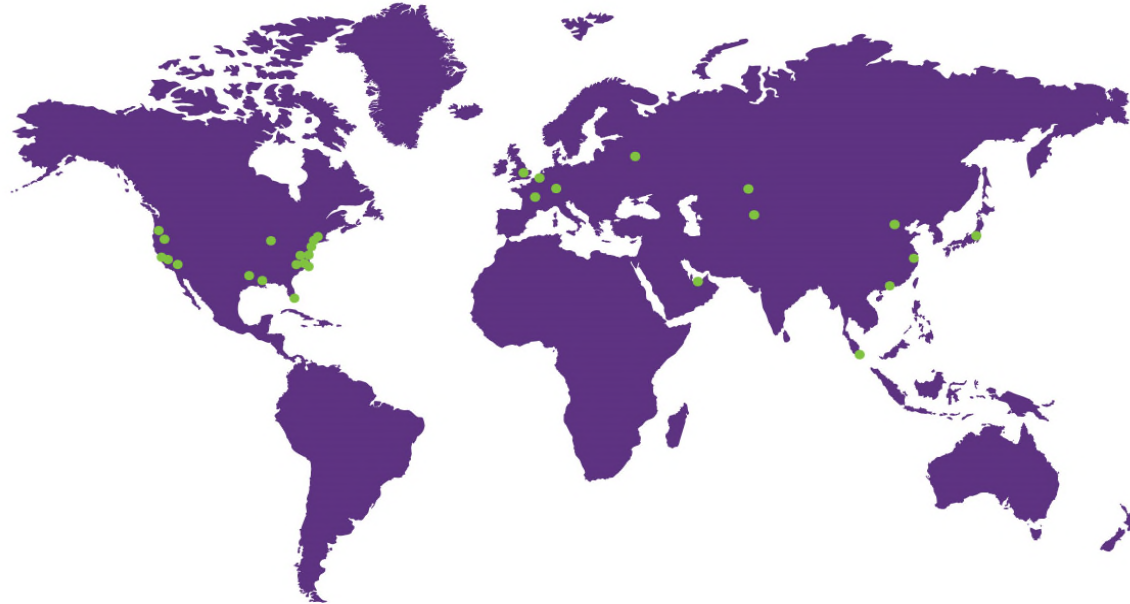


## Our Global Reach

Africa  
Asia Pacific  
Europe  
Latin America  
Middle East  
North America

## Our Locations

Almaty	Chicago	Houston	Orange County	Shanghai*
Astana	Dallas	London	Paris	Silicon Valley
Beijing*	Dubai	Los Angeles	Philadelphia	Singapore
Boston	Frankfurt	Miami	Pittsburgh	Tokyo
Brussels	Hartford	Moscow	Princeton	Washington, DC
Century City	Hong Kong*	New York	San Francisco	Wilmington



# Morgan Lewis

\*Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan Lewis operates through Morgan, Lewis & Bockius, which is a separate Hong Kong general partnership registered with The Law Society of Hong Kong as a registered foreign law firm operating in Association with Luk & Partners.

# THANK YOU

© 2018 Morgan, Lewis & Bockius LLP  
© 2018 Morgan Lewis Stamford LLC  
© 2018 Morgan, Lewis & Bockius UK LLP

Morgan, Lewis & Bockius UK LLP is a limited liability partnership registered in England and Wales under number OC378797 and is a law firm authorised and regulated by the Solicitors Regulation Authority. The SRA authorisation number is 615176.

Our Beijing and Shanghai offices operate as representative offices of Morgan, Lewis & Bockius LLP. In Hong Kong, Morgan Lewis operates through Morgan, Lewis & Bockius, which is a separate Hong Kong general partnership registered with The Law Society of Hong Kong as a registered foreign law firm operating in Association with Luk & Partners.

This material is provided for your convenience and does not constitute legal advice or create an attorney-client relationship. Prior results do not guarantee similar outcomes. Attorney Advertising.

**Morgan Lewis**