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2026





Mi Cai, Ph.D.

+1.617.832.1121

mcai@foleyhoag.com

- Assists in preparation and prosecution of U.S. and foreign patent applications in the areas of biotechnology and pharmaceuticals, as well as worldwide patent portfolio development and management. She also assists clients with competitive landscape analyses, freedom-to-operate assessments, IP due diligence review, and non-infringement and invalidity opinions.
- Represents clients ranging from large publicly traded pharmaceutical companies to emerging startups as well as academic institutes
- Advises clients on patent matters relating to a broad range of technologies, including antibodies, nucleic acids, gene therapy, cell therapy, antibody drug conjugates (ADCs), peptides, genetically modified animals, genome engineering technologies, sequencing technologies, diagnostic methods, nanoparticle technology, vaccines, small molecules, medical devices, and related fields. She regularly advises Chinese and US-based biotech companies on cross-border IP matters.

Education

- Boston University School of Law, J.D.
- Washington University in St. Louis, Ph.D., Molecular Cell Biology
- Peking University, B.S., Biological Sciences

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- ❑ China's Biotech Boom
- ❑ IP Due Diligence (DD) Nuts and Bolts
 - Mechanics
 - IP Ownership, Protection, FTO
- ❑ Selected Asia-Specific IP DD Issues
 1. Inventorship & Service Inventions
 2. Inventor Renumeration
 3. Joint Ownership Traps
 4. Clinical Data & IP from IIT & HGR
 5. Foreign Filing License (FFL)
 6. Geopolitical Issues
- ❑ Key Takeaways & Best Practices

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- ❑ Exponential R&D pipeline growth: biosimilar → me-better → FIC
 - ❑ Strength: ADC, bispecific, cell therapy, high-throughput screening & lead optimization
 - ❑ Regulatory innovation (ICH adoption, new tracks) & clinical enrollment speed
 - ❑ Active out-licensing to U.S./EU partners
 - ❑ Evolving deal forms: split-territory, NewCo, co-dev/co-commercialization

China Biotech's Rise



China Biotech's Rise (Cont'd)





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IP Due Diligence (DD) Nuts and Bolts

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- ❑ Evaluate IP portfolio strength, risks, and compliance
 - ❑ Conducted during a business transaction (e.g., licensing, M&A, IPO, investment)
 - ❑ For licensees: evaluate risks, inform decisions, negotiate
 - ❑ For licensors: prepare, value IP, mitigate risks early
 - ❑ Many issues unique to China vs. U.S./EU practice

Ownership

IP Protection

FTO Analysis

- ❑ **Title:** Confirm ownership docs & official records
- ❑ **Scope:** IP covers all target assets?
- ❑ **Strength:** Validity & enforceability
- ❑ **Obstacle:** Third-party blocking IP
- ❑ **Exclusivity:** Patent term + regulatory exclusivity (LOE analysis)

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❑ Ownership & Assignments

- Confirm executed inventor assignments for all named inventors
 - Not merely relying on Chinese law to vest IP title

❑ Hidden Third-Party Interests

- Academic collaborators and hospitals may retain rights
- University collaborations often carry government covenants

❑ Contractual Encumbrances

- Review upstream license, services (CRO/CDMO), collaboration, and MTA terms
- Confirm IP free to transfer (e.g., joint owners' consent)

□ Verify inventorship is correct

- Incorrect U.S. inventorship can invalidate a patent
- Watch: omitted collaborators; over-included executives
- U.S. and China apply different inventorship standards

□ Correction

- Available during U.S. prosecution and post-grant
- USPTO Correction: consent of all named/unnamed inventors (issued patent)
- Court-ordered correction: "notice and hearing of all parties concerned"

- ❑ Does IP cover products/processes in the deal?
- ❑ Patent types: composition, method of use, secondary
- ❑ Identify key patents (e.g., picture claims)
- ❑ Claim scope: too broad = validity risk; too narrow = design-around
- ❑ Geographic scope: key markets & manufacturing sites

□ Validity of granted claims

- Patent eligibility, novelty, non-obviousness
- Written description, enablement, definiteness
- Other: double patenting, inventorship, FFL issues

□ Patentability of pending claims

- Priority disclosure adequacy; intervening art (e.g., applicant's own disclosure)
- Meet US/EP standards, not only CN/KR/JP

□ Enforceability

- Inequitable conduct (duty of disclosure)
- Annuities and maintenance fees

□ Patent terms

- PTA / PTE; terminal disclaimers
- Interaction with regulatory exclusivity (LOE analysis)

□ Strategies

- Existing prosecution history
- CON/DIV for further claims
- Reissue/reexam

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□ What is FTO?

- Freedom to make/use/sell without infringement
- Covers entire process, not just key products

□ Diligence Approach

- Conduct or verify independent FTO analysis
- Analyze blocking patents (non-infringement position, invalidity defense, design-arounds)
- Monitor pending third-party applications

□ Mitigation Options

- Design-arounds, non-infringement/invalidity opinions, licenses

- ❑ Pending and past patent litigations
- ❑ USPTO post-grant: IPR, PGR, reexamination
- ❑ EPO oppositions; UPC actions
- ❑ Derivation allegations
- ❑ Threat assessment: competitors, generic/biosimilar challengers, non-practicing entities (NPEs)

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□ Operational Capture Systems

- Mandatory invention disclosure forms for R&D staff
- Employment/IP agreements (PIIAA) and executed patent assignments in place
- Pre-publication review and FFL compliance protocols



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Selected China-Specific IP DD Issues

1. Inventorship & Service Inventions
2. Inventor Renumeration
3. Joint Ownership Traps
4. Clinical Data & IP from IIT & HGR
5. Foreign Filing License (FFL)
6. Geopolitical Issues

- ❑ U.S. and China apply different inventorship standards
 - US: conception; claim-by-claim basis
 - China: creative contribution to the “substantive features”; holistic approach
- ❑ China “Service Invention” Rules
 - Employer owns employee inventions by law *but* only if employment relationship is established
 - 1-year post-employment invention capture risk from key employees’ prior employment

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- ❑ Inventor award & compensation: statutory defaults (eff. Jan. 20, 2024)
 - Art. 92: agreements/equity; Art. 93: one-time award; Art. 94: ongoing
 - **Note:** Both Korea and Japan have employee-invention compensation regimes.
- ❑ Company Policy
 - Written scheme to override statutory defaults
- ❑ Risk Mitigation for Licensees/acquirers
 - Confirm valid scheme; obtain indemnification
 - Non-payment ≠ patent invalidity (monetary only)
 - Unpaid claims survive M&A as contingent liabilities

U.S.

Each co-owner may practice and grant non-exclusive licenses without consent or accounting.

No single co-owner can grant exclusivity alone.

Enforcement usually requires all co-owners to join.

China

Co-owners may practice alone and grant non-exclusive licenses without consent.

Royalties from non-exclusive licenses must be **shared**.

Exclusive licensing requires all co-owner consent.

Deal Takeaway

Never leave co-ownership to default law. Contract for licensing control, revenue sharing, enforcement joinder, sublicensing limits, and assignment of all inventor/co-owner rights.

TRACK 1

Investigational New Drug (IND)-Based ISTs

Industry-Sponsored Trials • under NMPA (China's FDA)

Purpose: Drug approval & registration

Scope: Full modality range (small molecule, antibody, Cell and Gene Therapy (CGT), etc.)

Similar to U.S.: Yes — standard IND → Phase I/II/III → approval

TRACK 2

IITs (IND-Free)

Investigator-Initiated Trials • under National Health Commission

Purpose: Clinical research (exploratory, not registrational, but possible translational application)

IND-free IITs: Select novel biomedical tech (e.g., CGT) — **unique to China**

- ❑ China's Human Genomic Resources (HGR) Regulations:
 - ❑ Regulate cross-border transfer of genomic materials and info,
 - ❑ Mandate joint patent ownership arising from international collaboration using Chinese HGR

□ Diligence Points

- Clarify ownership/control of clinical datasets
- IITs and HGR may create ambiguous data/IP rights
 - Industry owning all foreground IP **vs.** co-owning IP with exclusive license from hospital to industry
- HGR compliance assessment

□ The Problem

- Both U.S. and China FFLs required for co-inventors
- China's FFL request must be in Chinese and takes weeks
- No U.S.-style provisional application in China

□ Common Workaround

- U.S. FFL → 1st PCT at CNIPA in English → 2nd PCT (12 mo.) claiming priority to 1st PCT → national phase

□ Critical Pitfall: U.S. Patent Term

- 1st PCT may start 20-year clock if it designates U.S. and its priority claim is improperly handled
- Safeguard: exclude U.S. from 1st PCT; claim foreign priority to 1st PCT

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- ❑ BIOSECURE Act (signed Dec. 18, 2025)
 - Sweeps in Department of Defense §1260H “Chinese military companies”
 - US Office of Management and Budget (OMB) list within 1 yr; ~5-yr off-ramp period
- ❑ Export Control
 - China laws may restrict tech transfers
 - Dual-use / biological materials may need permits



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Key Takeaways & Best Practices

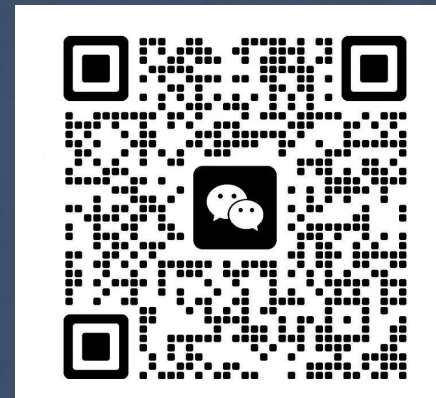
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- ❑ Audit portfolio: map claims vs. products/pipeline
 - ❑ File in key markets (U.S., EU, CN, JP, etc.) per strategy
 - ❑ Proactively conduct FTO before partners ask
 - ❑ Confirm ownership of all collaboration IP
 - ❑ Prepare English-language data package at source level
 - ❑ Build compliance record: FFL, inventor compensation, HGR, etc.

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- ❑ Assemble bilingual, multidisciplinary diligence team early
 - ❑ Conduct independent scientific and regulatory validation
 - ❑ Request source-level documentation, not just summaries
 - ❑ Require reps/indemnities for Asia-specific risks
 - ❑ Treat unexplained ambiguity as a diligence signal



1 617 832 1121

WeChat: kuailemizi



Questions?