國楓律師事務所
GRANDWAY LAW OFFICES

Newsletter

Update June 30, 2025

Update

The CNIPA Issues Notice to Advance Special Actions on Patent Commercialization

On May 30, 2025, the China National Intellectual Property Administration (CNIPA) issued the *Notice on Deepening the Special Actions for Patent Commercialization and Accelerating the Formation of a Long-term Mechanism* (the "Notice"), which took effect immediately.

The Notice requires localities to activate the existing patents of universities and research institutes, promote the industrialization of patents, and enhance the competitive edge of small and medium-sized enterprises and key industries. It emphasizes promoting patent commercialization from both the supply and demand sides and utilizing artificial intelligence to improve transformation efficiency. The document calls for supporting the development of patent-intensive products, improving patent quality enhancement policies, and establishing a long-term mechanism. Localities are required to improve patent management

systems, promote transformation models such as “use first, pay later,” and build an open and collaborative patent commercialization ecosystem.

Third Edition of Guidelines for Data Export Security Assessment Released

On June 27, 2025, the Cyberspace Administration of China (CAC) issued the *Data Export Security Assessment Declaration Guidelines (Third Edition)* (the “Guidelines”), which took immediate effect. The Guidelines clarify the required materials for data export security assessment, the online declaration process, and conditions for extending the period of assessment results.

The Guidelines optimize the application materials and further detail the online application process, including submission of legal representative/handler identification, risk self-assessment report, contract with the overseas recipient, and others. They specify the conditions, process, and required materials for data processors to extend the validity period of security assessments, allowing applications to be submitted within 60 working days before the assessment’s expiration.

Amendment to the Anti-Unfair Competition Law Passed, Strengthening Oversight in the Digital Economy

On June 27, 2025, the 16th session of the Standing Committee of the 14th National People’s Congress voted to adopt the newly revised *Anti-Unfair Competition Law*, which will come into effect on October 15, 2025.

The amended law comprises five chapters: General Provisions, Unfair Competition Acts, Investigation of Suspected Unfair Competition Acts, Legal Liability, and Supplementary Provisions. This revision further improves the rules for fair competition in the digital economy sector, increases regulatory oversight of unfair competition by platforms, and clearly stipulates that platform operators shall not force or indirectly force operators on the platform to sell goods below cost in accordance with their pricing rules, thereby disrupting market competition order.

The amendment also establishes reasonable compliance obligations for platform operators and makes provisions on acts of unfair competition such as infringement of data rights and malicious transactions.

Six Departments Jointly Issue Nineteen Opinions to Boost and Expand Consumption Through Financial Support

On June 19, 2025, the People’s Bank of China, together with other five departments, jointly released the *Guiding Opinions on Financial Support for Boosting and Expanding Consumption* (the “Opinions”), which took effect immediately.

The Opinions present 19 measures aimed at enhancing consumption capability, expanding financial supply, tapping consumption potential, and optimizing the consumption environment. The Opinions emphasize increasing credit support for the service consumption sector, innovating financial products,

improving payment services for consumption, establishing a sound credit system, and protecting rights and interests in financial consumption. Financial institutions are encouraged to innovate credit products, support diversified financing in the consumption industry, and promote the expansion of consumer credit scale.

MOFCOM Launches Pilot Program for Domestic Investment Information Reporting by Foreign-Invested Enterprises

On June 25, 2025, the Ministry of Commerce (MOFCOM) issued Announcement No. 12 of 2025, launching a pilot program for domestic investment information reporting by foreign-invested enterprises (FIEs). The first group of pilot regions includes Jiangsu, Shanghai, Tianjin, Liaoning, Hebei, Hunan, Shaanxi, and Chongqing. The Announcement will take effect on July 1, 2025.

Under the program, FIEs that establish new enterprises, increase capital, or acquire equity interests within China must fulfill their information reporting obligations. FIEs in the pilot regions must submit initial and change reports through the enterprise registration system and report investment information to the competent commerce authorities. Other matters will continue to be handled in accordance with the Measures for Information Reporting of Foreign Investment and Announcement No. 62 of 2019.

NMPA Proposes Ten Measures to Support Innovative Development of High-End Medical Devices

On June 20, 2025, the National Medical Products Administration (NMPA) held a meeting to review and adopt the *Measures for Optimizing Whole-Life-Cycle Regulation to Support the Innovative Development of High-End Medical Devices* (the "Measures").

The Measures set out ten aspects: optimizing special approval procedures, improving classification and naming principles, strengthening the standards system, clarifying registration review requirements, enhancing communication guidance and expert consultation mechanisms, detailing post-marketing regulatory requirements, reinforcing quality and safety monitoring, tracking industry development, advancing regulatory science research, and promoting global regulatory harmonization.

The Measures aim to deepen comprehensive reforms across the full life cycle of drug and medical device regulation, while outlining targeted support priorities in the high-end medical device sector.

Shanghai Lingang Issues Measures for the Administration of Legal Service Vouchers

On June 13, 2025, the Administrative Committee of Lingang New Area of China (Shanghai) Pilot Free Trade Zone released the *Measures for the Administration of Legal Service Vouchers of Lingang New Area of China (Shanghai) Pilot Free Trade Zone* (the "Measures"), which will take effect on July 15, 2025.

The Measures apply to the application, use, redemption, and supervision of legal service vouchers in the Lingang New Area. The recipients of legal service vouchers include small, medium, and micro enterprises and technology innovation teams that meet the positioning requirements of the Lingang New Area. The scope of support covers legal services such as legal consulting, civil and commercial dispute resolution,

intellectual property rights, and investment and financing. Legal service vouchers subsidize up to 50% of the contract amount, with each enterprise eligible for up to three applications per year and a maximum cumulative subsidy of RMB 30,000. The Administrative Committee is responsible for policy formulation, budget management, and supervision. Legal service vouchers may not be transferred or traded, and violators will be held accountable.

GACC Streamlines Export Control Procedures for Dual-Use Items

On June 16, 2025, the General Administration of Customs (GACC) issued the *Announcement of the General Administration of Customs on Matters Concerning Customs Queries over Export Control of Dual-Use Items* (the "Announcement"), which took effect immediately.

The Announcement stipulates that where the consignor of export goods fails to submit the license issued by the national export control authority to customs, and customs has evidence indicating the exported goods may fall under export control, customs shall raise a query with the consignor and issue the Notice of Customs Query on Export Control of Dual-Use Items. The consignor shall submit five materials including a paper customs declaration within 7 working days of receiving the Query Notice, all of which must be sealed with the company stamp and for which the consignor guarantees authenticity.

Upon receipt of the materials, customs will make a determination in accordance with the law or initiate an expert appraisal, and shall dispose of the matter differently based on three scenarios, issuing the *Notice of Customs Query/Expert Appraisal Results for Export Control of Dual-Use Items*.

Article(s)

Legal Challenges and Pathway Design for the Cross-Border Commercialization of State-Owned Biotechnology – From the Perspective of Offshore SPV Structures

by Rachel Chen

The Fourteenth Five-Year Plan positions biotechnology as a "future core pillar of national competitiveness." For state-owned research institutions and commercialization entities, this mandate creates two parallel tasks in tension with one another. First: the strict safeguarding of biosecurity and data sovereignty to ensure human genetic resources, sensitive biological data, and core patents (and their underlying data) do not leave the country. Second: accelerating the capitalization and value appreciation of the results, as clinical development and global financing must be completed within a limited window. The former relies on the strict constraints of the *Biosecurity Law, Export Control Law*, and Foreign Investment Negative List. At the same time, the latter demands rapid integration with international capital markets and global pharmaceutical regulatory systems. The conflict between the red line of safety and the timeliness of the market has given rise to the compromise pathway of 'in-country patenting – Offshore SPV – backhaul control.' Firstly, core patenting and data desensitization are completed in China. Secondly, the Offshore SPV takes over the exclusive licensing rights in a specific region and becomes responsible for international financing. Finally, the SPV repatriates the development outcomes via exclusive reverse-licensing agreements for clinical and industrial use. This paper, through cross-validation

of legal norms and business practices, seeks to provide a set of feasible solutions for the cross-border commercialization of state-owned biotechnology that balances security imperatives and market efficiency.

I. Analysis of Legal Challenges

1. Assessment and Accountability Risks for the Loss of State-Owned Assets

Most biotechnological achievements are still in the preclinical or Phase 1 stage, lacking comparable transaction references and stable cash flow projections. Accordingly, traditional cost- or income-based valuation methods often fail to reflect their future commercial potential fully. The *Law on the State-Owned Assets of Enterprises* and its supporting regulations require transactions involving the transfer or licensing of state-owned assets to undergo valuation and comply with corresponding approval and filing procedures. If the technology's valuation increases exponentially during overseas financing, and if it can be proven that the initial domestic valuation involved gross negligence, intentional undervaluation, or procedural violations, regulatory authorities may impose liabilities under the *Enterprise State-owned Assets Law* and related regulations, with severe cases potentially triggering criminal penalties.

2. Technology Export Controls and Biosecurity Redlines

The *Export Control Law* explicitly defines the licensing of patented technology to foreign entities or the provision of technological materials (including oral, written, or electronic forms) as technology exports. The *Biosecurity Law* and the *Regulations on the Administration of Human Genetic Resources* impose strict controls on the cross-border transfer of data containing Chinese human genetic information. If a company misjudges the sensitive nature of the technology/data or fails to anonymize it sufficiently, it may face severe penalties for "unauthorized export without a license."

3. Negative Lists for Foreign Investment and the Failure of VIE Structures

The latest edition of the *Special Administrative Measures for Foreign Investment Access (Negative List)* explicitly prohibits foreign investment in sectors such as "collection and preservation of human genetic resources," "development and application of genetic diagnosis and treatment technologies," and "development and application of stem cell technologies." In prohibited sectors, the Variable Interest Entity (VIE) structure is commonly viewed as a tool to circumvent foreign investment restrictions, leading to stringent substantive scrutiny of related overseas listings and M&A transactions, which makes approvals extremely difficult. This results in a dilemma where foreign investors have potential investment interest but face practical barriers to entry, while state-owned entities often lack the financial capacity to independently fund large-scale, global, multi-center clinical trials and registration applications.

II. Offshore SPV Structure Design

1. Ownership Separation and Financing Vehicle Rationale

The core strategy is "domestic asset retention (ownership) + offshore financing (licensing revenue)":

- **Domestic Entity**: Retains ownership of core assets (patents, data, etc.) to comply with China's regulatory restrictions on foreign ownership in sensitive sectors.
- **Offshore SPV**: Obtains exclusive rights for commercialization outside Greater China (or Mainland China) and uses the revenue stream as the basis for international equity financing.

- **Investor Rights**: Limited to profit participation from licensing royalties, without direct ownership of underlying core assets, thereby avoiding or significantly mitigating conflicts with China's Foreign Investment Negative List.

2. Round Trip Control and the "Dual Firewall" Mechanism

Golden Share (Special Management Share): A domestic state-owned entity retains a golden share with veto power over the disposal of core assets, major sub-licensing agreements, and change of control events (e.g., SPV acquisition).

IRR (Internal Rate of Return) Excess Profit Sharing:

- **Trigger**: If the project's IRR exceeds a predefined threshold (e.g., 25%), foreign investors must return excess profits to the state-owned partner at a predetermined ratio.

Data Repatriation Clause:

- **Trigger Events**:
  - SPV bankruptcy or insolvency,
  - Unauthorized control transfer (e.g., hostile takeover).
- **Requirement**: All technical documents and data must be repatriated to onshore servers within a specified timeframe.

3. Three-Step Compliance Implementation Framework

Step 1: Sensitivity Classification & Desensitization Processing

- **Red Zone**: Prohibited from cross-border transfer;
- **Yellow Zone**: Apply for export permit after desensitization;
- **Green Zone**: Directly complete registration.

Step 2: Export License Application & Contract Filing

- **Yellow Zone Technologies**: Submit export license applications to Commerce/Technology authorities;
- **Green Zone Technologies**: Complete technical service contract registration.

Step 3: Cross-Border Payment & Tax Compliance Management

- Test fund flows (license fees/dividends/rebates) through cross-border RMB capital pool policy channels;
- Adopt a "license fee + dividend" hybrid payment structure to optimize tax burden and assess PE risk;
- Prepare transfer pricing documentation in accordance with the arm's length principle and fulfill dynamic filing obligations.

III. Key Practical Implementation Steps

1. Data Desensitization Audits and Continuous Monitoring

- **Inventory-Based Management**: Establish a "Red-Yellow-Green" classification system at the project's initiation, jointly verified by technical and legal teams and approved by the compliance committee.

- **Desensitization Effectiveness Verification**: Select regulatory-compliant desensitization technologies and obtain third-party attestation reports.
- **Dynamic Monitoring Clause**: Embed periodic desensitization compliance audits in contracts to ensure continuous data security monitoring.

2. State-Owned Asset Valuation Filings and Revenue Lock-In Mechanisms

- **Multi-Method Valuation**: Conduct parallel assessments using cost, market, and income approaches, with expert validation of clinical scaling factors in the income method.
- **Regulatory Filing Implementation**: Submit valuation reports and SPV structure proposals for approval by the state asset regulator, ensuring that the golden share and IRR excess return mechanisms are properly implemented.
- **Change-of-Control Protection**: Incorporate a buyback price formula in shareholder agreements to prevent undervalued disposal of state-owned equity interests.

3. Fine-Tuning Foreign Exchange and Tax Compliance

- **Foreign Exchange Channel Testing**: Conduct simulations with banks and SAFE to test cross-border fund flows, including license fees, dividends, and rebate payments.
- **Tax Structure Optimization**: Design dual-channel payment mechanisms leveraging tax treaties to reduce the overall tax burden and prevent unintended PE (Permanent Establishment) creation.
- **Transfer Pricing Documents**: Maintain comprehensive records of arm's length transactions to ensure timely and accurate regulatory filings.

IV. Conclusion

The offshore SPV model enables access to international capital while complying with biosecurity and state asset regulations through "ownership separation + return licensing." Successful implementation hinges on: clear legal structure, strict sensitivity classification and desensitization, end-to-end compliance management, and a dynamic policy response mechanism.

Contact Us

davidzou@grandwaylaw.com

www.grandwaylaw.com

23F, S2 Building, Bund Financial Center, 600 Zhongshan No. 2 Road (E), Shanghai, 200010, China