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Han Kun Newsletter

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Legal Updates

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1. CTA Update: BOI Back Again with New Deadline

Author: Mike Chiang of Han Kun LLP

Summary

Following a ruling by the U.S. District Court for the Eastern District of Texas in ***Smith v. U.S. Department of the Treasury*** on February 17, 2025, the Beneficial Ownership Information (BOI) reporting requirements under the Corporate Transparency Act (CTA) are once again in effect. Subsequently, the Financial Crimes Enforcement Network (FinCEN) has extended the reporting deadline by 30 days, allowing most reporting companies until March 21, 2025, to comply.

Timeline of Events

I. Texas Top Cop Shop Inc. v. Garland

- **December 3, 2024** – The U.S. District Court for the Eastern District of Texas issued a preliminary injunction, temporarily halting CTA enforcement due to constitutional concerns.
- **December 23, 2024** – The Fifth Circuit granted the government's motion for an emergency stay, effectively reinstating CTA requirements, arguing the law is constitutional under the Commerce Clause and imposes minimal compliance burdens.
- **December 26, 2024** – The Fifth Circuit vacated its stay, reinstating the injunction against CTA enforcement to maintain the constitutional status quo while the appeal proceeds.
- **January 23, 2025** – The U.S. Supreme Court granted the government's application for a stay of the injunction in **Texas Top Cop Shop**. However, BOI reporting could not yet be enforced due to a separate injunction in ***Smith v. U.S. Department of the Treasury***, which remained in place.

II. Smith v. U.S. Department of the Treasury

- **January 7, 2025** – The U.S. District Court for the Eastern District of Texas issued an injunction, suspending FinCEN's enforcement of BOI reporting requirements.
- **February 5, 2025** – The U.S. Department of Justice (DOJ) filed an appeal and requested a stay to resume enforcement of CTA.
- **February 17, 2025** – The U.S. District Court for the Eastern District of Texas lifted the injunction, allowing BOI reporting requirements to be enforced again.
- **February 18, 2025** – FinCEN officially announced a **30-day extension**, pushing the compliance deadline to **March 21, 2025**, for most reporting companies.

Impact on BOI Reporting Deadlines

- **Most Reporting Companies:** The new deadline to file initial, updated, or corrected BOI reports is

March 21, 2025.

- **Companies with Later Deadlines:** Entities that already had reporting deadlines beyond March 21 (e.g., those qualifying for disaster relief extensions) should adhere to their original deadlines.
- **Exempt Entities:** Plaintiffs in ***National Small Business United v. Yellen*** (including Isaac Winkles and members of the National Small Business Association as of March 1, 2024) remain exempt from BOI reporting at this time.

FinCEN announced that it will continue to evaluate its options for further deadline modifications and potential rule changes to reduce compliance burdens on low-risk entities, particularly small businesses.

Next Steps for Businesses

1. **Review BOI Filing Obligations:** Ensure your company meets the new **March 21, 2025**, deadline.
2. **Monitor FinCEN Updates:** FinCEN may implement further adjustments based on ongoing regulatory reviews.
3. **File Reports Using FinCEN's E-Filing System:** Reports can be submitted at FinCEN's E-Filing System.
4. **Stay Informed on Legal Developments:** The appeal process is ongoing, and further court rulings may affect compliance obligations.

Conclusion

While the CTA's BOI reporting requirements are now back in effect, the 30-day extension provides businesses with additional time to comply. Companies should act promptly to meet their obligations and stay informed about potential regulatory changes.

2. New Rule for PI Protection Compliance Audit and Implications

Authors: Ting ZHENG | Eryin YING | Shirley LIANG | Hattie ZHANG

On 14 February 2025, the Cyberspace Administration of China ("**CAC**") released the *Administrative Measures for the Personal Information Protection Compliance Audit* (《个人信息保护合规审计管理办法》, the "**PI Audit Measures**") and its FAQ on its official website[1]. Prior to that, CAC presented the consultation draft of PI Audit Measures in August 2023, and the National Cyber Security Standardisation Technical Committee of China proposed a set of national standards on compliance audit requirements in July 2024.

Compliance audit for personal information ("**PI**") protection is an existing requirement derived from Art. 54 of *Personal Information Protection Law* (《个人信息保护法》, the "**PIPL**") and Art.27 of the *Regulation on Network Data Security Management* (《网络数据安全管理条例》, the "**Network Data Regulation**"). The PI Audit Measures serve as implementing rules for these compliance audit requirements and will take effect from 1 May 2025.

We set out below the key requirements under the PI Audit Measures and its implications for foreign funded financial institutions and multinational corporations as PI processors.

Triggers, frequency and methods of two compliance audits

I. Self-initiated audits

- Where a PI processor processes PI of less than ten million individuals, the PI processor shall conduct a self-initiated audit at a frequency that it determines depending on own specific circumstances. We anticipate a compliance audit every three to five years should be reasonable.
- Where a PI processor processes PI of more than ten million individuals, the PI processor will be required to conduct compliance audit at least once every two years.
- In a self-initiated audit, PI processors will have flexibility to determine whether to conduct the audit internally or by engaging an external professional agency.

II. Compulsory audits

- CAC and/or industry regulators may mandate a PI processor to appoint an external professional agency to conduct a compliance audit as soon as possible upon occurrence of any of the following events:

  (1) there is a significant risk in its PI processing activities that severely affects individuals' rights or lacks adequate security measures; or

  (2) its PI processing activities may infringe on the rights of a large number of individuals; or

[1] Official links: https://www.cac.gov.cn/2025-02/14/c_1741233507681519.htm;https://www.cac.gov.cn/2025-02/14/c_1741232792029282.htm.

(3) a PI security incident occurs, resulting in the leakage, tampering, loss, or destruction of PI of over one million individuals or sensitive PI of over 100,000 individuals.

- It remains unclear what precisely constitutes the first two trigger events. The regulators may have discretionary interpretations during the implementation of the compulsory audits.
- There is no specific timeframe for conducting a compulsory audit. The timeframe will be subject to the regulators' discretion case by case, and it may only be extended upon special approval from the regulators.
- In a compulsory audit, PI processors will be required to provide necessary assistance to the professional agency, bear audit costs, conduct the rectification as required by the regulators, and submit the relevant report to the regulators within 15 business days after completion of the audit.
- It remains to be seen which professional agencies will be qualified to conduct compliance audits for PI processors. A PI processor cannot engage the same professional agency to conduct over three consecutive compliance audits for PI protection.

Scope and standards of compliance audits

I. Legal basis and scope

Self-initiated and compulsory audits shall be conducted based on the PIPL, the Network Data Regulation and other laws, administrative regulations applicable to PI processing activities. The *Personal Information Protection Compliance Audit Guidelines* (《个人信息保护合规审计指引》) attached to the PI Audit Measures set out the key aspects that shall be covered in any compliance audit, including but not limited to:

- legitimacy of the basis and rules for PI processing;
- disclosure and explanation of the PI processing rules;
- joint processing and entrusted processing of PI;
- transfer and sharing of PI;
- automated decision-making;
- public disclosure of PI;
- legitimacy of the basis and purpose of image collection and ID devices;
- processing of disclosed PI;
- processing of sensitive PI and minors under the age of 14;
- cross-border transfer of PI;
- protection of data subjects' rights in PI processing activities;
- adequacy of internal organizational setup and measures for data security;

- efficacy of IT measures for data security; and
- training, IT security emergency handling and PIPIA etc.

II. Recommended standards

The 2024 draft of national standards on compliance audit requirements (《数据安全技术 个人信息保护合规审计要求》) provided comprehensive guidelines for conducting compliance audits for PI protection, including detailed standards on implementation procedures and evidence management, as well as capability and independence of auditors. These are recommended standards and may represent best practice in the market. It remains to be seen whether National Cyber Security Standardisation Technical Committee of China would propose new set of national standards based on the PI Audit Measures.

Legal liability for violations

Any breaches of the PI Audit Measures will render a PI processor subject to penalties in accordance with the PIPL and the Network Data Regulation, including but not limited to confiscation of illegal gains, an order to make corrections, suspension or termination of business, fine and revocation of business license. Senior officers may also face personal liabilities.

Recommendations

It's important for all PI processors to comply with the PI Audit Measures. Proper audits will help a PI processor to reduce risks of being challenged or penalized by CAC or industry regulators in data breaches and complaints. It's highly recommended that PI processors should set up PI protection compliance audit systems, procedures and responsible team and take immediate actions to ensure all audit requirements will be fulfilled.

3. U.S. Tariff Updates: Impact on Chinese Businesses

Author: Mike Chiang of Han Kun LLP

The U.S. government has introduced significant trade policy adjustments that will have a direct impact on Chinese exporters, manufacturers, and businesses with operations in Mexico. The key changes include:

1. **Termination of the de minimis exemption for goods from China, Mexico, and Canada** – Shipments from these countries, regardless of value, will now be subject to duties. The exemption remains available for other countries, but further modifications to this policy may be introduced in the future (Note: the termination of the de minimis exemption from goods from Mexico and Canada are temporarily postponed until March 2025).
2. **Increased tariffs on imports from China, Mexico, and Canada** – A 10% tariff now applies to Chinese-origin goods, while Canadian and Mexican imports are subject to a 25% tariff (10% for Canadian energy products) (although the Canada and Mexican tariffs are temporarily postponed until March 2025).
3. **Enhanced customs procedures** – The U.S. government will increase oversight of import documentation, tariff classification, and trade routes to ensure compliance with the updated regulations.

These developments bring new considerations for Chinese businesses trading with or investing in the U.S. market. Below, we outline these policy updates, their potential effects, and recommended strategies for businesses to remain competitive.

Termination of the De Minimis Exemption for China, Mexico, and Canada

Effective Date: February 4, 2025

I. Key Changes

1. Shipments from China, Mexico, and Canada no longer qualify for duty-free entry under the de minimis exemption

- Previously, goods valued at $800 or less could enter the U.S. without duties under the de minimis rule.
- With this exemption no longer in place for these three countries, all shipments, regardless of value, are now subject to tariffs and customs processing requirements (Note: the termination of the de minimis exemption from goods from Mexico and Canada are temporarily postponed until March 2025).

2. De minimis exemption remains in effect for other countries

- Imports valued under $800 from other regions (e.g., ASEAN, EU, South Korea) continue to qualify for duty-free entry.
- However, U.S. authorities may review this policy further, and additional restrictions could be introduced in the future.

3. Enhanced customs review of e-commerce and small-parcel shipments

- E-commerce shipments originating from China (such as those from Shein, Temu and AliExpress) will receive greater scrutiny from U.S. Customs and Border Protection (CBP).
- Any inconsistencies in product classification, valuation, or documentation may result in shipment delays or penalties.

II. Impact on Chinese Businesses

1. Increased costs for online retailers and logistics providers

- Businesses exporting low-value goods to the U.S. can no longer rely on the de minimis exemption to reduce import duties.
- Additional tariffs may impact the pricing strategies of e-commerce platforms and small-parcel shippers.

2. Longer customs clearance times

- CBP's stricter import processing procedures may extend shipment clearance times, affecting delivery commitments for online retailers.
- Fulfillment centers and logistics providers may need to adjust operations to comply with the revised import policies.

3. Greater emphasis on accurate documentation

- Businesses must ensure that all shipments are properly classified under the Harmonized Tariff Schedule (HTSUS) to prevent unnecessary delays.

III. Recommended Actions for Chinese Exporters

- Review and adjust pricing strategies to account for new tariff obligations.
- Ensure accurate customs classification and documentation to minimize risks of delays.
- Consider alternative logistics models, such as bulk shipping or U.S. fulfillment centers, to improve efficiency.
- Stay updated on potential expansion of de minimis restrictions to other countries.

Adjustments to Tariffs on Imports from China, Mexico, and Canada

Effective Date: February 4, 2025 (Mexico tariff delayed until March 2025)

I. Updated Tariff Rates

Country	New Tariff Rate
China	10%

Country	New Tariff Rate
Canada	25% (Delayed until March 2025)
Mexico	25% (Delayed until March 2025)
Canadian energy products	10% (Delayed until March 2025)

II. Key Changes

1. A 10% tariff now applies to all Chinese exports to the U.S.

- The new tariff applies across all industries, requiring exporters to assess cost implications for their U.S. market operations.

2. A 25% tariff on imports from Canada and Mexico (10% for Canadian energy products) – enforcement postponed until March 2025

- While the tariff has been announced, enforcement has been delayed, leaving open the possibility of policy adjustments in the coming months.
- Businesses with manufacturing operations in Mexico should closely monitor negotiations between the U.S. and Mexican governments.

3. Closer examination of supply chain movements

- Shipments that involve third-country processing (such as goods made in China and assembled in Mexico before U.S. importation) may face additional customs scrutiny.

III. Impact on Chinese Exporters and Nearshoring Operations in Mexico

1. Additional costs for Chinese suppliers exporting to the U.S.

- The new 10% tariff structure raises expenses for businesses shipping products directly to U.S. buyers.

2. Uncertainty for companies manufacturing in Mexico

- Many Chinese manufacturers established operations in Mexico to benefit from tariff-free access under USMCA.
- If the 25% tariff is enforced in March, nearshoring operations may become less cost-effective for certain industries.

3. Increased compliance monitoring

- U.S. customs agencies are intensifying their focus on trade route optimization strategies, requiring greater diligence in supply chain planning.

IV. Recommended Actions for Chinese Exporters & Nearshoring Companies

- Monitor developments in U.S.-Mexico trade relations to anticipate tariff risks before March 2025.

- Reassess supply chain strategies, including alternative sourcing and shipping models.
- Explore warehousing or bonded storage solutions to optimize trade flows.

The adjustments to the de minimis exemption and tariff increase on imports from China, Mexico, and Canada represent a significant change in U.S. trade policy. Businesses must act swiftly to address these changes, mitigate risks, and explore alternative trade and supply chain solutions.

4. 2024 Data Analytics: China Life Sciences NewCo & Licensing Terms

Authors: Aaron GU | Duzhiyun ZHENG | Matt ZHANG | Franky YU | Shuwen SUN | Ariel YANG

License-in/out transactions have become a key strategic approach for innovative drug and medical device (including medical aesthetics) companies to expedite the research and development of the products and expand market presence. According to statistics, the total deal value of business development (BD) transactions in life sciences sector in China has reached a historic high of over 60 billion US Dollars in 2024. The proportion of license-out transactions continues to rise[2], highlighting the strong momentum of China's biopharmaceutical industry in its global expansion.

Our team has been 100% dedicated to the legal work in the life sciences, biopharmaceutical, and healthcare fields, including corporate matters, regulatory compliance and transactions. We were honored to have the privilege of assisting in numerous significant license-in/out and NewCo projects in 2024. In light of our practical experience, we have systematically outlined our insights into the NewCo model adopted by China's Biotech companies (please refer to: *Six Key Insights into China Biotech's NewCo Model*) and have provided a thorough analysis of the prevailing trend of such NewCo model in the international expansion of pharmaceutical companies (please refer to: *Insights into China Biotech's New Approach: Spin-off-NewCo Model*). Furthermore, we have also conducted a specialized study on license-in/out transaction terms from the perspective of the lifecycle of drugs and medical devices (please refer to: *Anatomy of Licensing Deals from China Regulatory Perspective*).

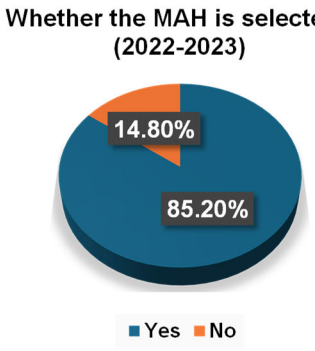
At this very beginning of the new year, in order to enhance industry's understanding of the key terms of license-in/out projects, we have reviewed the key licensing and NewCo projects handled in 2024 and referred to our analysis presented in the article *2022 – 23 Data Analysis on China Life Sciences Licensing Key Terms*. In this article, we will present a comparative analysis across seven key dimensions, including marketing authorization rights, license grant, financial terms, intellectual property, diligence obligation, exclusivity, and termination rights, to highlight key trends and considerations in current licensing and NewCo transactions, providing valuable insights for the industry's future development and long-term strategies[3].

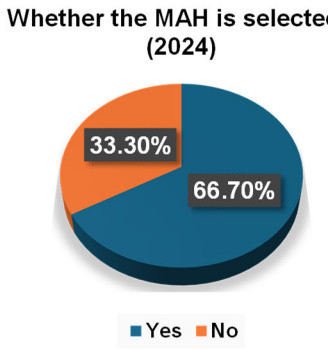
Marketing authorization rights

The system of Market Authorization Holders of drugs or the registrants or record filing parties of medical devices (collectively referred to as "**MAH**") plays a crucial role under the regulatory framework for the drug and medical device industries. In 2024, in the vast majority (approximately 66.7%) of license-in/out projects, the collaborating parties have explicitly stipulated the MAH in the agreements, while the rest approximately 33.3% of the projects have not specified the MAH.

[2] Please refer to: http://vip.stock.finance.sina.com.cn/q/go.php/vReport_Show/kind/lastest/rptid/790620929724/index.phtml.

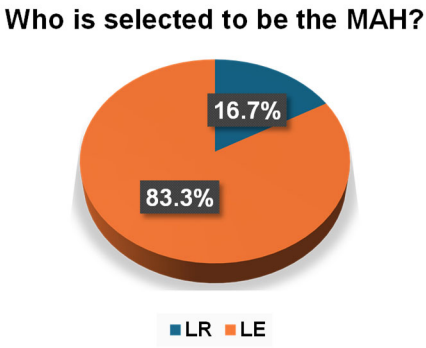
[3] This report is an important work product and copyright of Han Kun and should be treated as confidential information of the





The data above largely reflects a continuation of the patterns we observed in 2022 – 2023, i.e., where the MAH arrangement is explicitly stipulated in a majority of projects, while such MAH will be determined at a later stage in the remaining cases. Similarly, among cases where MAH is not specified, collaborating parties may defer MAH arrangements due to the product being at early stages, such as Pre-IND, or the MAH will be negotiated and selected based on the progress of the specific project. These findings align with our conclusions drawn from the 2022 – 2023 statistics.

Among cases where MAH is specified, 83.3% of them specify that the licensee ("**Licensee**") will be the MAH within the licensed territory, while 16.7% stipulate the licensor ("**Licensor**") will be the MAH. As observed in previous cases, the Licensee may also be granted the right to designate its affiliates or third parties to assume the role of the MAH in some agreements. This demonstrates a flexible and diversified approach to the arrangement of regulatory matters, where the Licensee is not necessarily always the MAH in licensing transactions.



Based on the NewCo projects we have handled, the parties tend to defer the designation of MAH. We understand that this approach allows the collaborating parties in NewCo projects to retain flexibility in adjusting the MAH in response to future market developments and strategic needs, while also retaining opportunities for potential pipeline licensing.

License grant

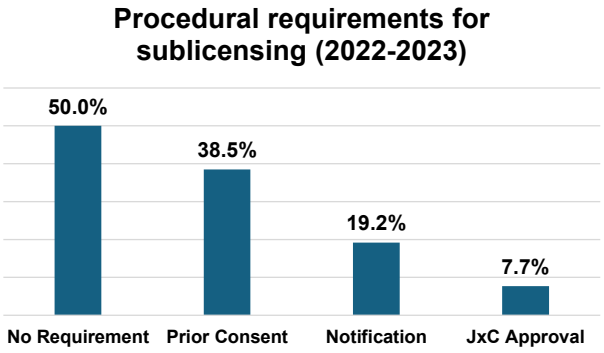
I. Sublicensing

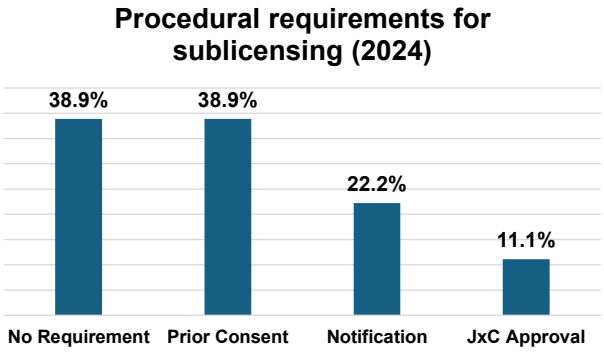
In all the reviewed license-in/out projects, the Licensee is granted the right to sublicense the licensed technology. Approximately 5.6% of the projects stipulate that the Licensee can only grant sublicences

through limited tiers, with sublicensees ("**Sublicensees**") prohibited from granting further sublicenses; around 16.7% of the projects have specified the categories of eligible Sublicensees, such as affiliates or designated third parties (CROs or CDMOs). The proportion of projects with explicit restrictions on Sublicensees has increased compared to in previous years (with the proportion of 3.8%). This trend may indicate the Licensor's long-term vision with regard to its expectation of the potential of the product and the development capabilities of the collaborating party.

Additionally, around 22.2% of the projects provide that the Licensor (typically in writing) shall be notified prior to sublicensing, while about 38.9% require prior written consent from the Licensor. Approximately 11.1% of the projects stipulate that the sublicensing shall be approved by the joint project committee (JxC), and around 38.9% impose no procedural restrictions on sublicensing. Among projects with procedural restrictions, approximately 27.8% apply a combination of various restrictions, such as different procedures for different categories of Sublicensees[4].

We have also compiled the data in the previous article, which reflects the extent of control the Licensor exercises over the Licensee's sublicensing rights. The data in 2024 is generally consistent with that of previous years. However, our observations indicate that licensing transactions are subject to more stringent sublicensing restrictions. Notably, there has been an increase in agreements requiring prior licensor consent, notification, or JxC approval, coupled with a decline in the proportion of projects without any procedural requirements.





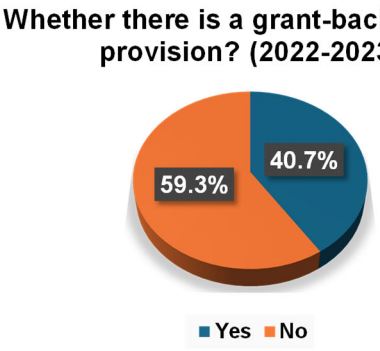
With the increasing number of outbound activities, we believe that, with the assistance of professionals, the parties will be able to engage in more thorough negotiations, thereby further refining and standardizing the terms of sublicensing.

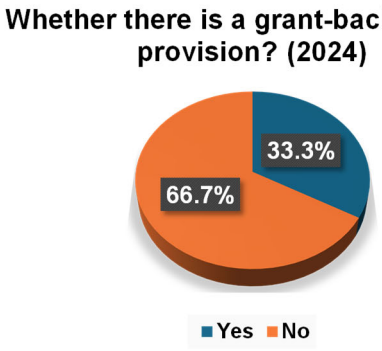
II. Grant-back license

For commercial considerations, Licensors may require the Licensee to grant-back rights to newly developed intellectual property (e.g., improvements) to ensure that the Licensor can reasonably use relevant technology beyond the scope of the license. As in previous years, projects with clearly defined grant-back license terms have continued to represent a minority, accounting for 33.3% in 2024, a decrease from 40.7% the previous year. We understand that this trend may be closely related to

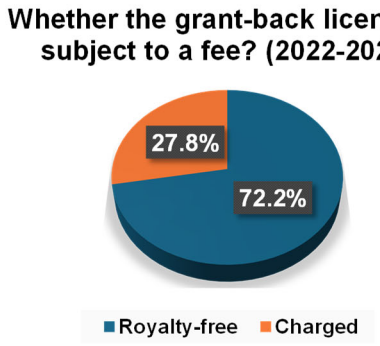
[4] In certain statistics presented in this article, the total percentages may exceed 100% due to the inclusion of multiple overlapping categories in certain agreements.

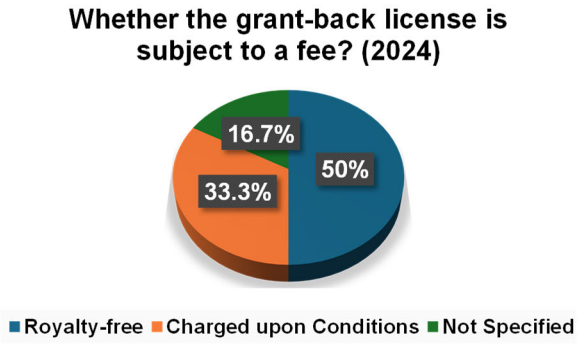
the objectives of the collaboration and the nature of the business, such as whether the Licensor is engaged in other development activities in similar fields or has plans to market the same product outside the licensed territory.





Among agreements with grant-back license provisions, 50% have provided a royalty-free grant-back license, while about 33.3% have provided potential fees based on factors such as whether the Licensor engages in profit-making activities, and approximately 16.7% have not specified any payment terms for the grant-back license. Within the agreements, a variety of categories of grant-back licenses are observed, including exclusive, non-exclusive, and conditional licenses. However, no project has granted Licensors any option right for the grant-back license. From our understanding, compared to the primary objectives of the licensing transaction, the grant-back license is not the major concern for the Licensor, and granting an option right may potentially extend the negotiation period, hindering transaction efficiency and complicating cost control.





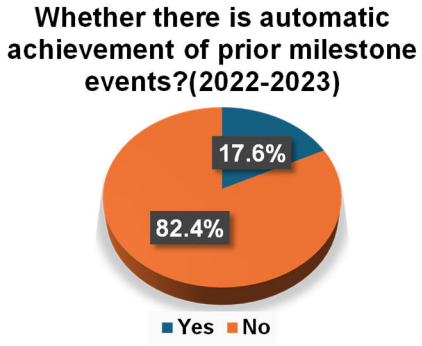
For the NewCo projects, the data shows that only 25% have included grant-back license provisions, which is slightly lower than the 33.3% observed in traditional license-in/out projects. This discrepancy may be attributed to the distinct objectives of NewCo projects. As part of the strategy for securing offshore financing, NewCo projects typically prioritize obtaining investment and generating cash flow, rather than acquiring regulatory data, research data, or intellectual property. Consequently, during negotiations, the parties involved are generally less inclined to invest significant time and resources in grant-back license terms or option rights.

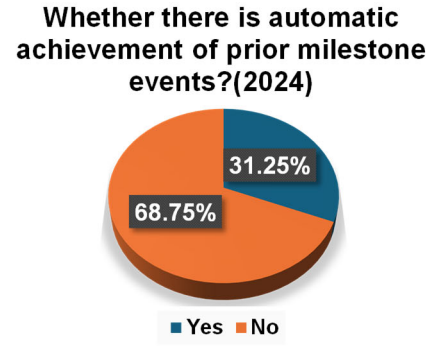
Financial terms

I. Milestone payment

In the License-in/out projects analyzed, the vast majority have incorporated milestone payment terms. For more clarity on the specific arrangements of these terms, we have conducted a more detailed analysis of the relevant provisions.

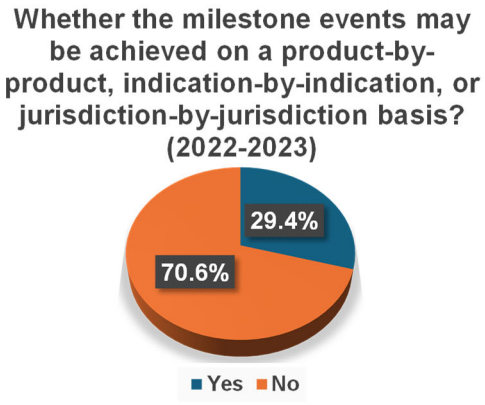
Firstly, in terms of the automatic achievement mechanism of prior milestone events, 31.25% of the projects with agreed milestone payments have included this mechanism, compared to only 17.6% in previous years. This increase reflects a growing trend over the past two years. As a relatively uncommon provision, the rising rate not only reflects improvements in the negotiating experience and capabilities of the parties involved, but also indicates that participants are becoming more sophisticated in designing transaction structures and risk allocation mechanisms.

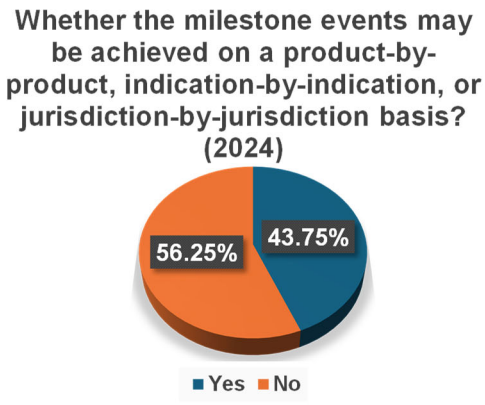




Secondly, regarding milestone events, 43.75% of the projects with agreed milestone payments have set differentiated milestone payment arrangements based on different jurisdictions, products, or indications, to achieve multiple milestone payments. It represents an increase from 29.4% in the previous year. This shift reflects the growing capabilities of both parties in licensing transactions and indicates refinement of deal terms to better align with the objectives of the parties.

However, it is important to note that differentiated milestone payment arrangements may not always enable the Licensor to achieve revenue more quickly in practice. Taking sales milestones as an example, the arrangements typically require net sales to be calculated separately for each jurisdiction, product, or indication. This approach can extend the time required to trigger a milestone and may lead to lower cash flow efficiency compared to calculating net sales as a whole. Therefore, the design and selection of terms shall be carefully considered based on a systematic evaluation of the transaction elements, including commercialization pathways, market penetration expectations, and risk tolerance. In this regard, parties with commercial insight can select different strategies for negotiation based on their business objectives and actual circumstances.





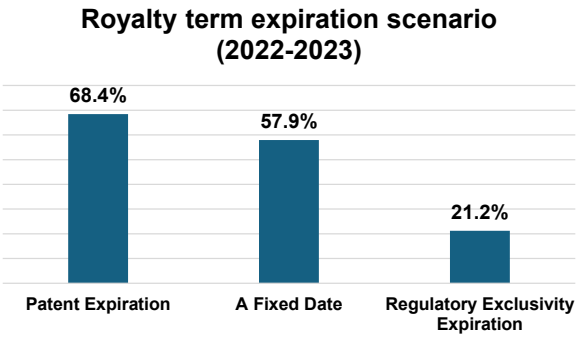
Additionally, different agreements may involve various types of milestones, including, among others, development milestones, sales milestones, milestones regarding patent applications, diligence milestones, regulatory milestones, and milestones for inclusion in the national reimbursement drug list. These milestone terms can be established individually or in combination, depending on the specific needs of the parties in the transaction.

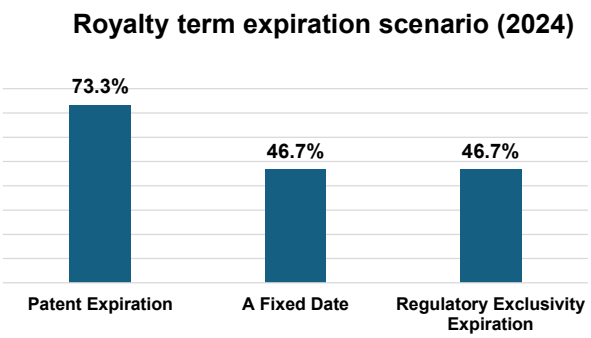
II. Royalty

Approximately 83.3% of the projects have included provisions for royalties. We have conducted further analysis on key elements such as the royalty terms, bases, and reductions of these projects.

Regarding royalty terms, the start date is typically the first commercial sale of the licensed products, while the expiration date of such terms varies. According to the statistics, approximately 73.3% of projects set the expiration date of the last-to-expire valid claim as one of the expiration events. 46.7% of projects set a fixed period as one of the expiration events. 46.7% of projects set the expiration date of all regulatory exclusivity as one of the expiration events. Additionally, some agreements have defined the expiration date of royalty terms as the date of first commercial sale of a generic equivalent of the licensed product in the territory or the expiration date of the orphan drug status of the licensed product.

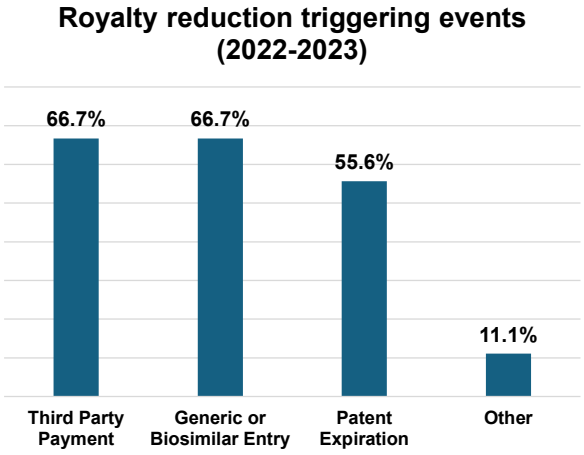
The data above shows little changes compared to previous years. However, it is noteworthy that 60% (compared to 42.1% in previous years) of the projects have incorporated two or more triggering events mentioned above, with the expiration date being the earliest/latest occurrence among these events. Objectively, compared to projects with a single triggering event, this approach offers greater diversity, flexibility and bargaining power and conditions for both parties. By implementing various strategies, both parties can enhance their chances of reaching consensus, which to some extent reflects the overall improvement in industry transaction experience and negotiation skills.

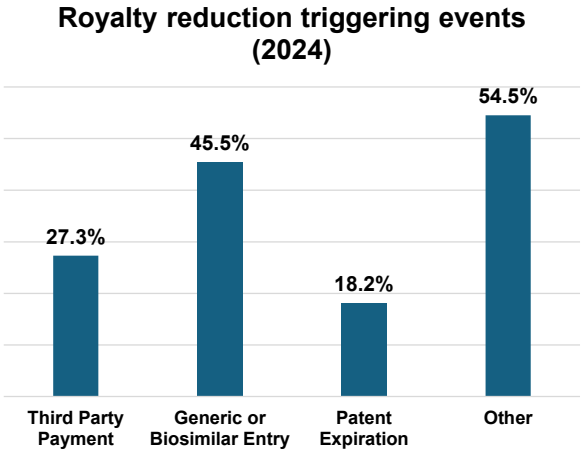




As to the royalty base, almost all projects use net sales as the base for royalty calculation, while there are a few agreements that alternatively use the invoiced amount received by the Licensee for the sales of the licensed product to third party (excluding taxes) as the calculation base. In the previous statistics, there are instances where gross sales are used as the calculation base, but choosing net sales as royalty base remains the predominant industrial practice.

In terms of royalty reductions, most common triggering events may include patent expiration, presence of generic or biosimilar products and third-party payments. Notably, the proportion of other triggering events has increased (accounted for 54.5%), such as the expiration of data exclusivity, the inclusion of the product in the national reimbursement drug lists or reductions due to the U.S. Inflation Reduction Act.



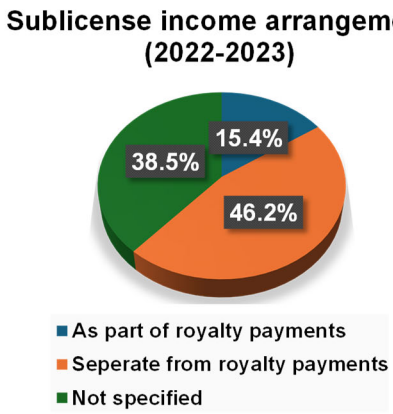


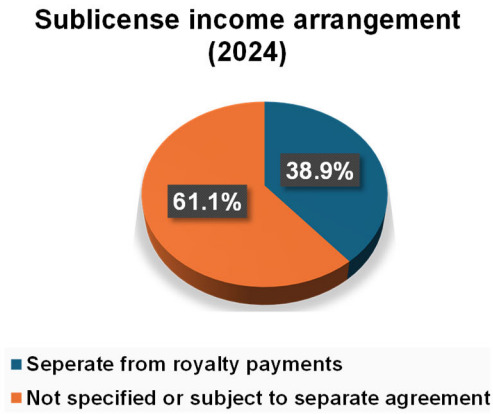
In addition, approximately 63.6% of the projects have set a floor on the percentage of reduction. However, the range of these floors varies significantly, which we understand is closely related to the distribution of the specific products and the bargaining power of the parties involved.

III. Sublicense income

In practice, there are typically two methods for calculating sublicense income: one is to include such income in the royalty base (usually net sales) for calculation, while the other is to separately obtain a share from the sublicense income. However, a significant number of projects (61.1%) have not explicitly defined the allocation method for sublicense income. All of the projects establishing the sublicense income have adopted the approach of separately calculating the share from the sublicense

income. We understand that this approach is likely more favored in practice compared to including it in the net sales for calculation.



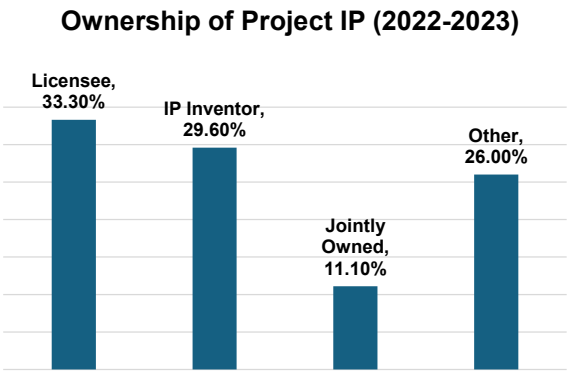


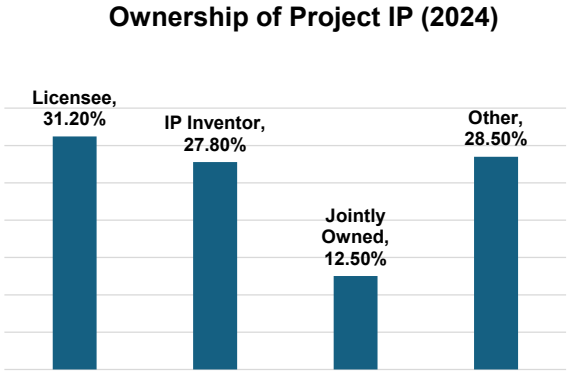
In NewCo projects, 37.5% of the projects have explicitly required sublicense income. The majority of these projects prefer to calculate sublicense income separately and include it (along with other future proceeds, such as upfront payments, royalties, milestone payments, and equity acquisition payments) into the profit-sharing calculations. This approach aligns with the characteristics of traditional License-in/out transactions.

Intellectual property

I. Ownership of Project IP

Compared to previous years' statistics, the pattern of intellectual property ownership terms remains consistent, with only slight variations. For example, the proportion of projects that explicitly specify exclusive ownership by the Licensee has decreased slightly from 33.3% to 31.2%. The proportion of projects adopting the principle that the project intellectual property ("**Project IP**") shall be owned by the inventor remains steady at 27.8%, compared to 29.6% in previous years. The proportion of projects explicitly agreeing on joint ownership has increased slightly to 12.5%, up from around 11.1% previously. Additionally, the proportion of projects with customized, category-specific rules has increased from 26% to 28.5%. Such flexible arrangements are more common in complex scenarios, such as cross-licensing and co-development projects.





Overall, the intellectual property ownership terms closely align with those in previous years, reflecting a market consensus on the IP ownership rules. While there have been minor adjustments in the proportions of some specific categories, no new allocation models that deviate from traditional frameworks have emerged.

II. Responsible party for IP enforcement

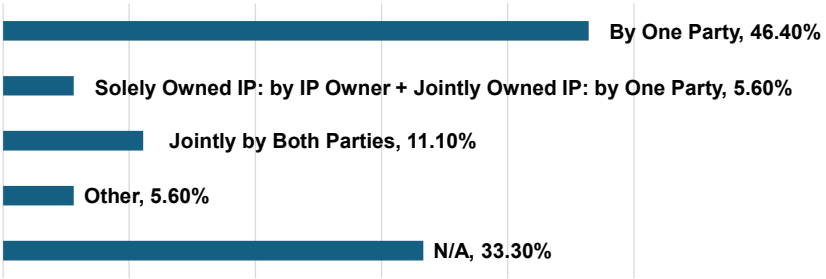
Similarly, the overall trend regarding IP enforcement terms in the projects has shown no significant changes, largely maintaining the patterns observed in previous years.

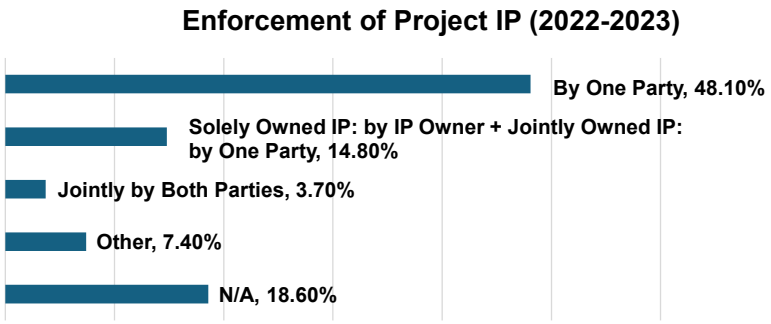
Regarding the responsibilities for enforcing the licensed intellectual property as between the Licensor and Licensee, approximately 52.3% of projects have specified that the Licensor shall bear full responsibility, a slight decrease from 59.2% in previous years. Around 26.4% of projects have assigned full responsibility to the Licensee, which is consistent with the previous year's 25.9%. Projects that do not explicitly designate a party responsible for IP enforcement account for approximately 18.1%, a slight increase from 14.9% in the previous year.

In terms of the enforcement of intellectual property and the ownership structure of the Project IP, approximately 46.4% of projects stipulate that one party is fully responsible for all Project IP, a slight decrease from 48.1% in previous years. The proportion of projects that distinguish between sole and joint ownership of Project IP, with each party responsible for the portion they solely own and the cooperating parties responsible for the jointly owned portion, has decreased. The proportion of projects where both parties jointly manage the enforcement of the Project IP has increased. Additionally, other methods of enforcement allocation (such as assigning responsibility by jurisdiction or having one party responsible for applications while the other covers expenses) have remained consistent, while the percentage of projects with no clear designation of the enforcement party has risen.

Regardless of the changes in the minor details of IP enforcement terms, the overall trend continues to follow the patterns observed in previous years.

Enforcement of Project IP (2024)

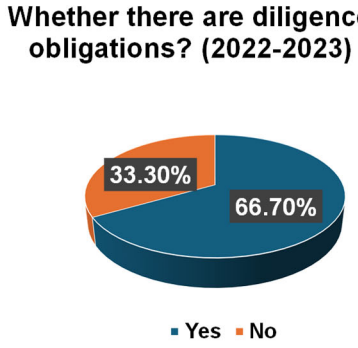


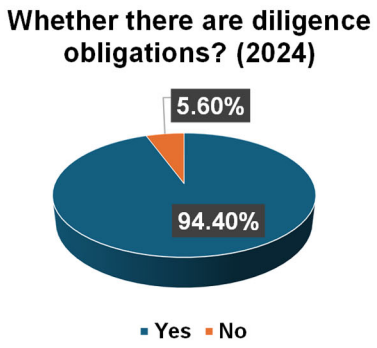


Diligence obligation

In order to ensure that the licensed product can be successfully and timely marketed to achieve commercial value, the agreements typically include a diligence obligation for the Licensee (or both parties in co-development projects) regarding product research and development and commercialization.

According to statistics, approximately 94.4% of projects have included a provision for diligence obligations, while about 5.6% do not explicitly address such issue. This proportion has increased significantly compared with previous years, and this trend to a certain extent reflects a long-term perspective of the Licensor. On the one hand, Licensor places greater emphasis on the future prospect of the product and prefers to find a suitable collaborator rather than focusing solely on the amount of upfront payments. On the other hand, it reflects Licensor's consideration of the opportunity cost associated with the licensed product. If the product fails to progress, licensor may, through a termination right associated with the diligence obligation, end the cooperation and continue the development independently or with a third party.



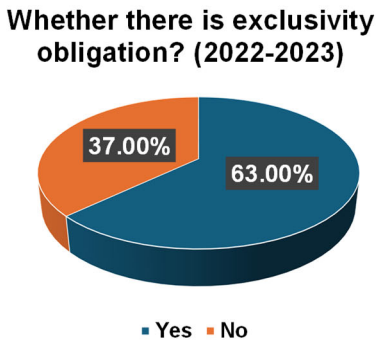


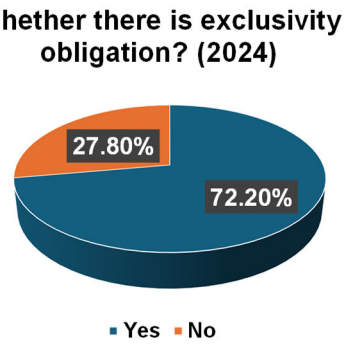
Among projects containing diligence obligation clauses, the majority have adopted the standard of "Commercially Reasonable Efforts", while some others have applied the standard of "Diligent Efforts". In addition to these relatively abstract obligation standards, approximately 22.2% of projects have further specified concrete diligence obligations, such as establishing particular diligence milestones, which are designed to incentivize the Licensee to actively advance the development and commercialization process.

Exclusivity

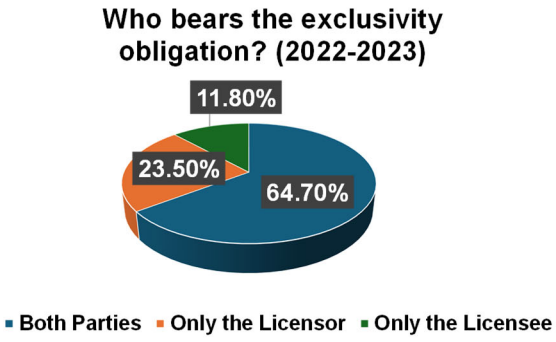
To ensure effective collaboration between both parties in the development and commercialization of the licensed product while maximizing overall returns, licensing agreements typically include explicit provisions

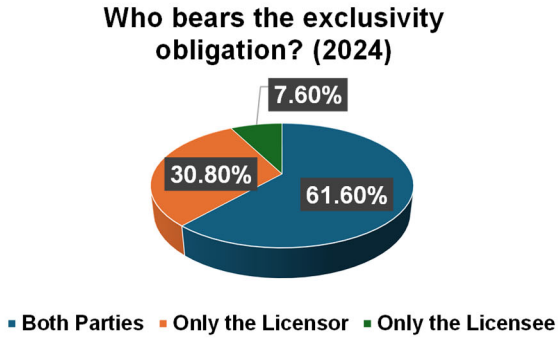
on exclusivity obligations. These provisions are designed to prevent any actions that may adversely affect the rights and interests of the other party. According to statistics, a clear non-compete obligation is stipulated in the vast majority (72.2%) of projects, while approximately 27.8% do not contain such provisions, which marks an increase in proportion compared to previous years.





Among the agreements that incorporate exclusivity obligations, approximately 61.6% involve mutual exclusivity obligations for both parties; about 30.8% have an exclusivity obligation solely on the Licensor; and around 7.6% impose this obligation solely on the Licensee. Overall, this distribution remains largely consistent with previous years, with mutual exclusivity obligations continuing to be the predominant arrangement. We understand that the agreement on exclusivity obligations is closely related to the bargaining power of the parties and has a profound impact on the future business strategies and operations. Therefore, we strongly recommend that all parties carefully evaluate their actual commercial needs and attach great importance to the negotiation and drafting of these provisions.





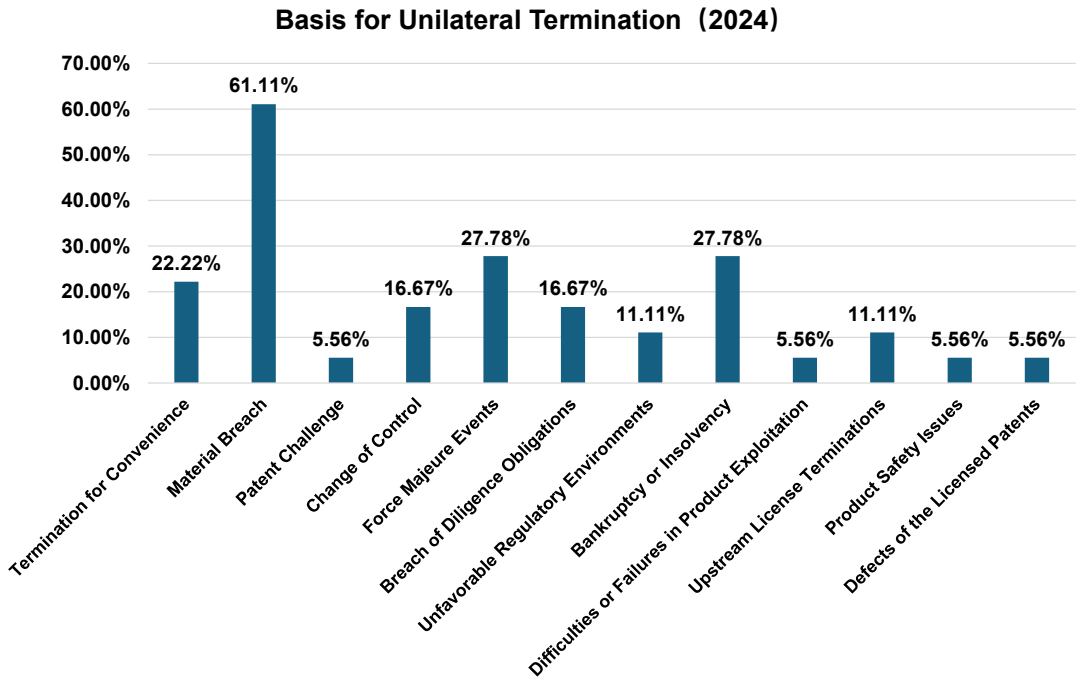
Termination rights

I. Unilateral termination right

The proportion with regard to the inclusion of unilateral termination rights has remained largely consistent with previous years, showing no significant shifts in overall trends. In most projects, both parties are granted unilateral termination rights, regardless of whether the grounds and conditions for exercising such rights are reciprocal. However, in a limited number of projects, only the Licensor holds the unilateral termination right.

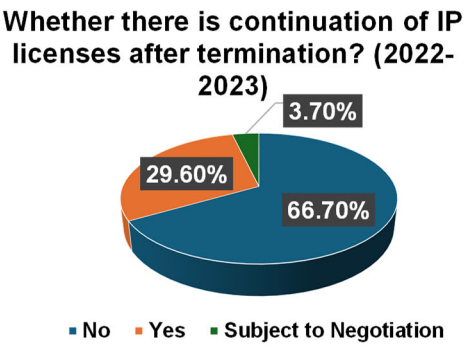
In terms of the grounds for exercising the unilateral termination rights, material breach of the agreement

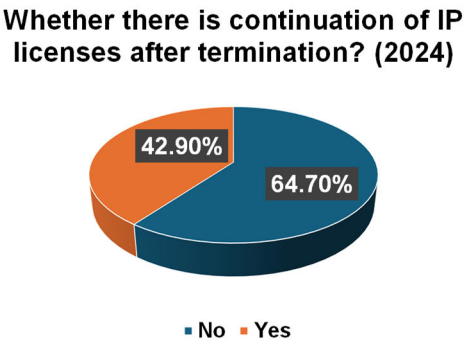
by the other party is the most common scenario, accounting for approximately 61.11% of cases, followed by force majeure events and bankruptcy, accounting for approximately 27.78%. In addition, about 22.22% of projects have provided termination for convenience, and a small number of projects have specified causes for termination include breach of diligence obligations, patent challenge, and change of control. In practice, multinational pharmaceutical companies (MNCs) frequently incorporate unilateral termination rights without cause in their agreements. Typically, when a high upfront payment has been made, the Licensor may seek the flexibility to terminate the license at any time.



II. Termination consequences

Generally, a license granted under a license agreement automatically terminates upon termination of the agreement. According to the statistics, in more than half of the projects, parties have expressly agreed not to continue granting the license upon termination. However, depending on its nature and the scenario of termination, approximately 42.9% of projects have expressly provided that some or all of the licenses will continue to be effective after termination of the agreement, marking an increase in proportion compared to previous years. Among the projects with continued licensing arrangements, the majority are co-development projects, and it is mainly because after the termination of such projects, one of the parties may still require access to the technology of the other party to proceed with the subsequent development and commercialization activities.





Comparative summary of license-in/out transactions (2022 – 2023 vs. 2024)

According to the statistics, the structure of licensing transactions in 2024 has remained largely consistent. However, transaction participants have become increasingly experienced, leading to more refined negotiation strategies and a stronger emphasis on long-term perspectives.

Firstly, the structure of core terms remains stable. For example, the MAH is usually held by the Licensee, and clauses such as the setting of milestone payments and the calculation of royalties based on Net Sales continue to be prevalent. At the same time, clauses such as deductions from Net Sales and sub-license revenue allocation have also maintained some stability.

Secondly, the complexity of the terms of the agreement has increased with the accumulation of transaction experience and the gradual development of the negotiation in a more detailed and specialized direction. For example, the proportion of agreements incorporating automatic achievement mechanism of prior milestone events has increased, as has the frequency with which financial terms are negotiated either comprehensively or separately by product, indication or jurisdiction. Additionally, the proportion of agreements specifying royalty terms at multiple intervals has also risen.

In addition, there has been a clear shift towards long-term strategic thinking in licensing transactions. For example, the proportion of projects specifying diligence obligations or diligence milestones has increased. This indicates that the parties to the transaction are not only concerned about the amount of the upfront payment, but also the long-term development potential and market prospects of the product. This long-termist thinking is also reflected in the rise of the NewCo model, which tends to lay out the groundwork for the distribution of future revenues in advance, by setting up new companies or co-operation structures to ensure that the parties can continue to benefit in the future. The emergence of this model further confirms the importance that counterparties place on the long-term value of their products, as well as forward planning for future market changes.

Overall, while the fundamental principles of licensing transactions have remained relatively stable in recent years, the approach to negotiation and the design of agreement terms have become more diversified and specialized. This evolution reflects the growing experience of the parties involved and the changing market landscape. Additionally, the gradual embrace of the long-term strategic thinking has provided new directions for the future development of licensing transactions.

NewCo vs. traditional license: comparative analysis of key terms

Compared with traditional license-in/out transactions, the design of the terms in NewCo projects is more comprehensive: while license-in/out agreements usually focus on the terms of the licensing terms, NewCo transactions not only cover pipeline spin-offs, but also take into account multiple terms such as equity investments, operations and governance of the project company, change of control and revenue sharing.

Regarding the design of licensing terms, traditional license-in/out agreements typically require the specification of clear and detailed licensed objects. In contrast, at the early stage of NewCo projects, where future parties remain uncertain on the objects and some pipeline spin-offs occur solely within the company group, the licensing terms are often expressed in a broad and general manner.

In addition, unlike License-in/out transactions, where negotiation efforts often focus on provisions like grant-back licenses, MAH allocation, and diligence obligations, NewCo projects typically prioritize revenue-sharing structures, defining the scope of earnings, exclusivity and equity interests. This approach reflects NewCo projects' emphasis on financial returns rather than stringent technical constraints at early stages. However, in certain cases, NewCo projects may still incorporate detailed licensing provisions depending on the project's specific needs and the bargaining power of the parties involved.

Conclusion

This article offers an updated review of data and trends from previous years across seven critical areas: marketing authorization rights, license grant, financial terms, intellectual property, diligence obligation, exclusivity, and termination rights. Furthermore, it provides a comparative analysis of the emerging NewCo model with traditional License-in/out transactions from the perspective of contractual provisions.

We recommend that, when negotiating and drafting future project agreements, companies and practitioners may carefully consider these insights above while bearing in mind that the terms and conditions of licensing transactions are not predetermined. While past practices may serve as valuable guidance, agreements must be tailored to address specific commercial needs and negotiation dynamics, so as to facilitate successful collaboration between parties.

Important Announcement

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