Legal Commentary

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2024 Data Analytics: China Life Sciences NewCo & Licensing Terms[1]

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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[3], 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[4].

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[1] For the Chinese version, please click *2024 年 NewCo 与药械 License-in/out 项目核心条款数据分析与对比*.

[2] Jingjing XU has contributions to this article.

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

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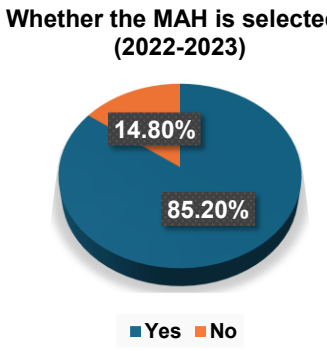
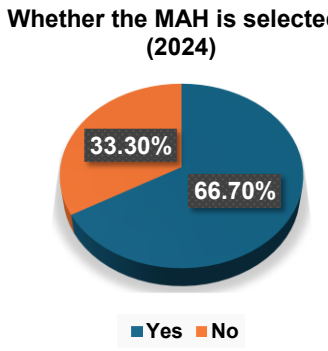
Marketing authorization rights

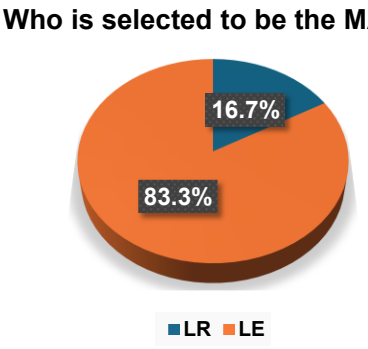
The system of Market Authorization Holders of drugs or the registrants or record filing parties of medical devices (collectively referred to as "**MAH**") plays a crucial role under the regulatory framework for the drug and medical device industries. In 2024, in the vast majority (approximately 66.7%) 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.





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.

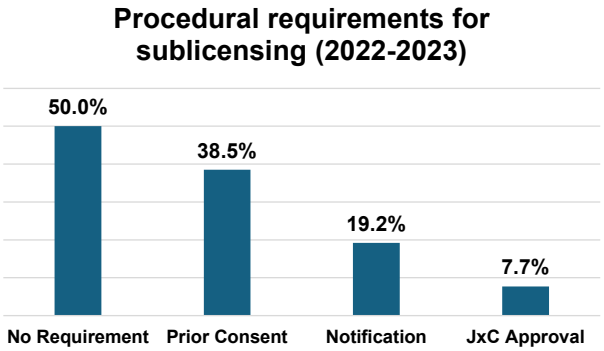
License grant

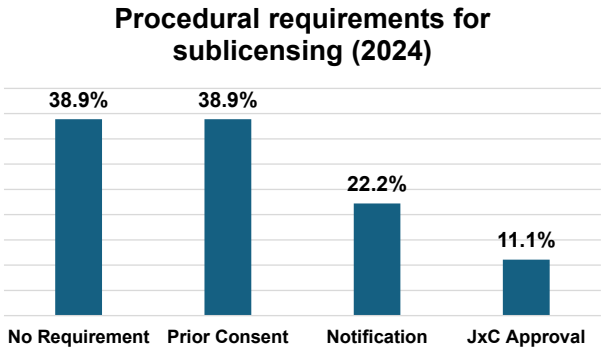
I. Sublicensing

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[5].

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

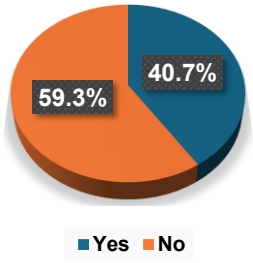
[5] In certain statistics presented in this article, the total percentages may exceed 100% due to the inclusion of multiple overlapping categories in certain agreements.

standardizing the terms of sublicensing.

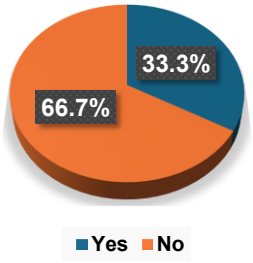
II. Grant-back license

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 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.

Whether there is a grant-back license provision? (2022-2023)

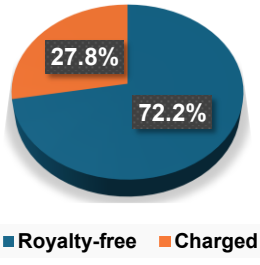


Whether there is a grant-back license provision? (2024)

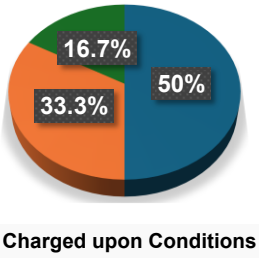


Among agreements with grant-back license provisions, 50% have provided a royalty-free grant-back license, while about 33.3% have provided potential fees based on factors such as whether the Licensor engages in profit-making activities, and approximately 16.7% have not specified any payment terms for 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.

Whether the grant-back license is subject to a fee? (2022-2023)



Whether the grant-back license is subject to a fee? (2024)



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

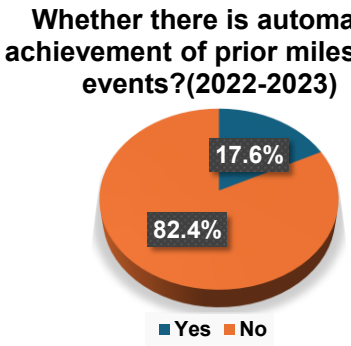
may be attributed to the distinct objectives of NewCo projects. As part of the strategy for securing offshore financing, NewCo projects typically prioritize obtaining investment and generating cash flow, rather than acquiring regulatory data, research data, or intellectual property. Consequently, during negotiations, the parties involved are generally less inclined to invest significant time and resources in grant-back license terms or option rights.

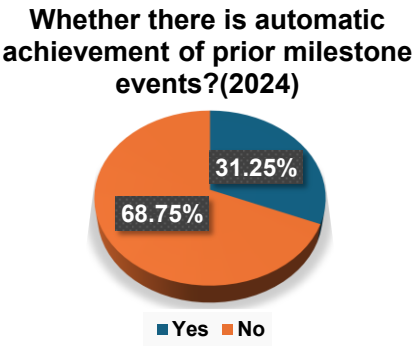
Financial terms

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.

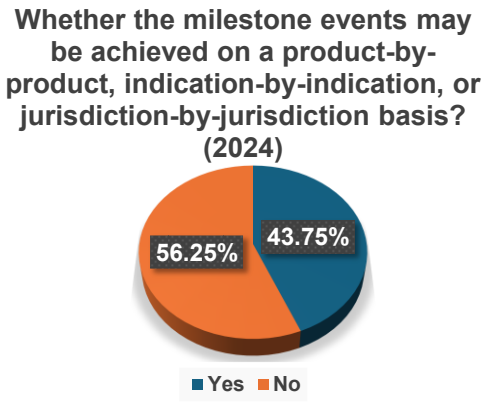




Secondly, regarding milestone events, 43.75% of the projects with agreed milestone payments have set differentiated milestone payment arrangements based on different jurisdictions, products, or indications, to achieve multiple milestone payments. It represents an increase from 29.4% in the previous year. 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.



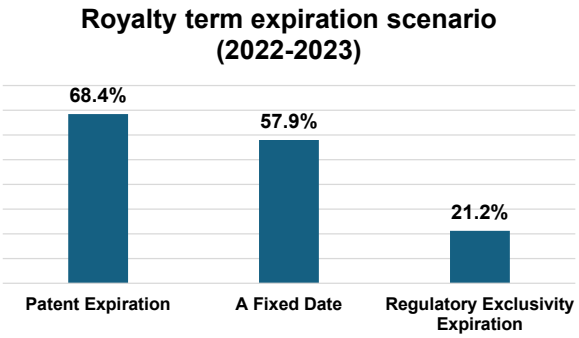
Additionally, different agreements may involve various types of milestones, including, among others, development milestones, sales milestones, milestones regarding patent applications, diligence milestones, regulatory milestones, and milestones for inclusion in the national reimbursement drug list. These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

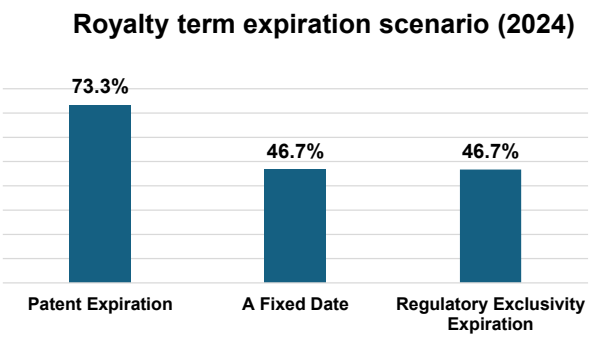
II. Royalty

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.

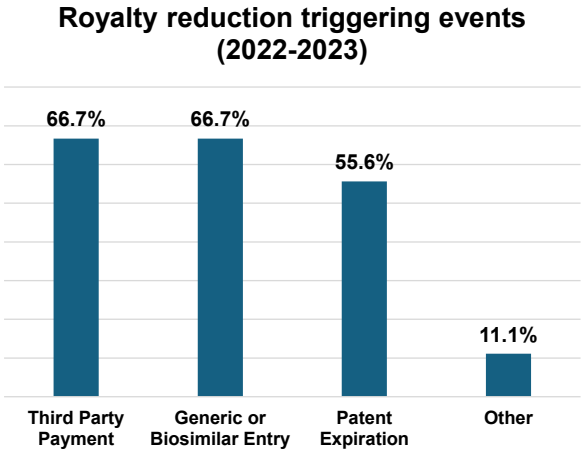
The data above shows little changes compared to previous years. However, it is noteworthy that 60% (compared to 42.1% in previous years) of the projects have incorporated two or more triggering events mentioned above, with the expiration date being the earliest/latest occurrence among these events. Objectively, 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.

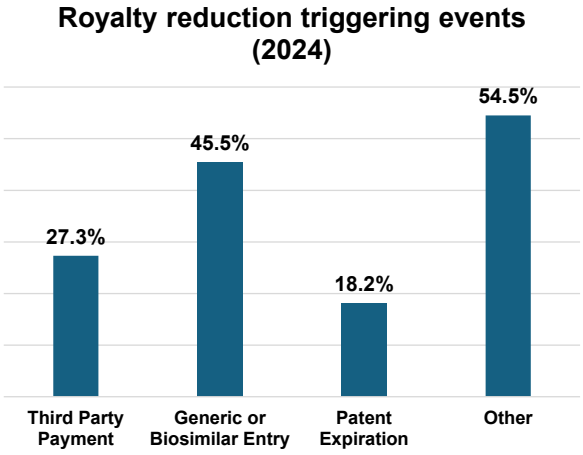




As to the royalty base, almost all projects use net sales as the base for royalty calculation, while there are a few agreements that alternatively use the invoiced amount received by the Licensee for the sales of the licensed product to third party (excluding taxes) as the calculation base. In the previous 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.



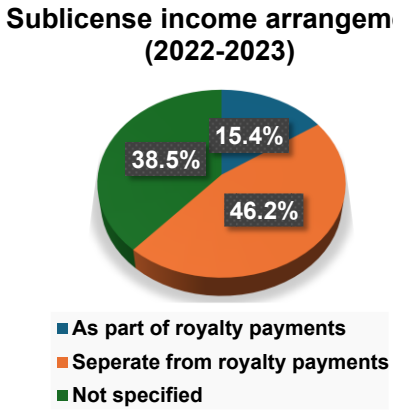


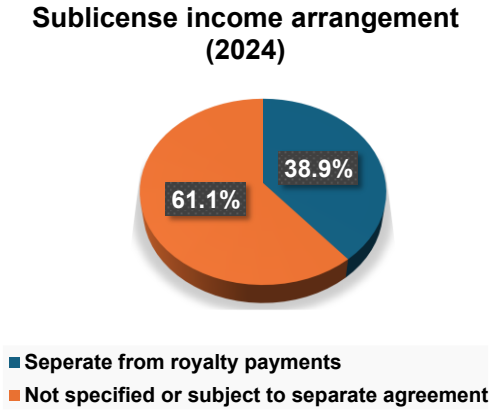
In addition, approximately 63.6% of the projects have set a floor on the percentage of reduction. However, the range of these floors varies significantly, which we understand is closely related to the distribution of the specific products and the bargaining power of the parties involved.

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.



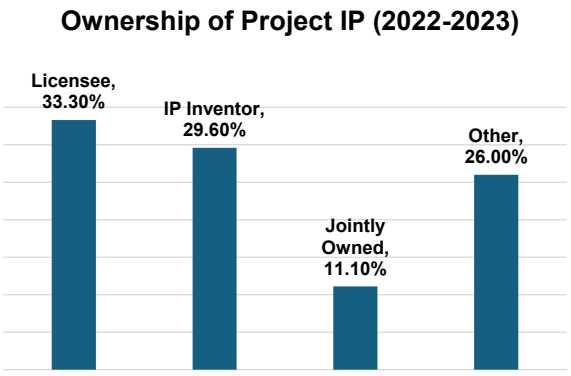


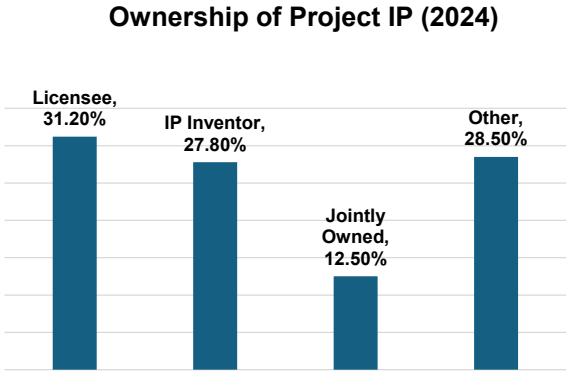
In NewCo projects, 37.5% of the projects have explicitly required sublicense income. The majority of these projects prefer to calculate sublicense income separately and include it (along with other future proceeds, such as upfront payments, royalties, milestone payments, and equity acquisition payments) 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

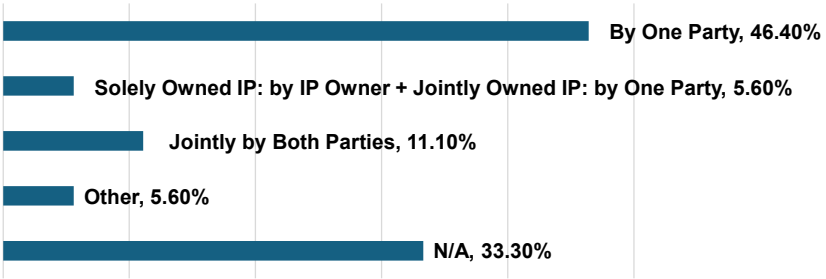
Similarly, the overall trend regarding IP enforcement terms in the projects has shown no significant changes, largely maintaining the patterns observed in previous years.

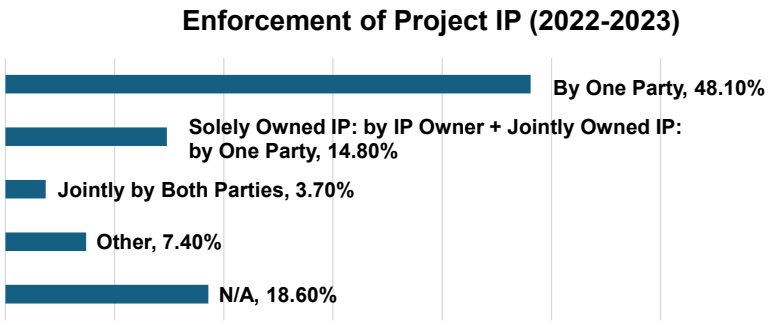
Regarding the responsibilities for enforcing the licensed intellectual property as between the Licensor and Licensee, approximately 52.3% of projects have specified that the Licensor shall bear full responsibility, a slight decrease from 59.2% in previous years. Around 26.4% of projects have assigned 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)

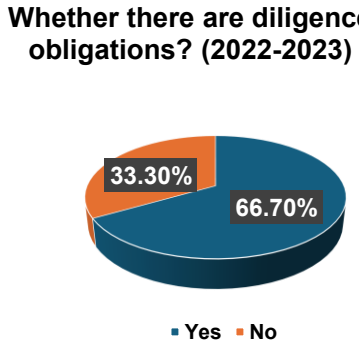


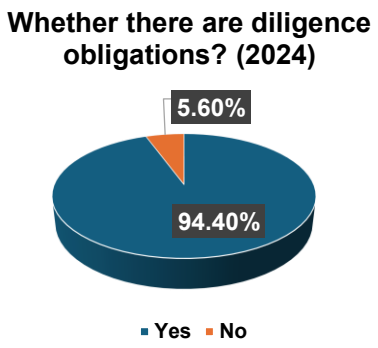


Diligence obligation

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.



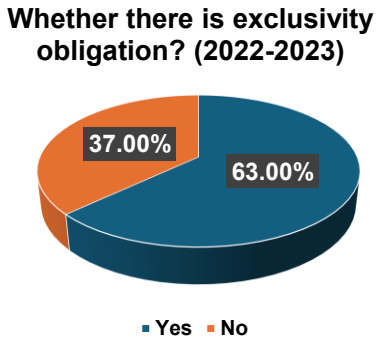


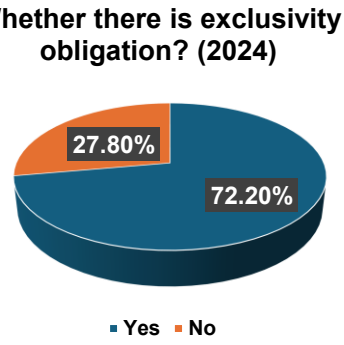
Among projects containing diligence obligation clauses, the majority have adopted the standard of "Commercially Reasonable Efforts", while some others have applied the standard of "Diligent Efforts". In addition to these relatively abstract obligation standards, approximately 22.2% of projects have further 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

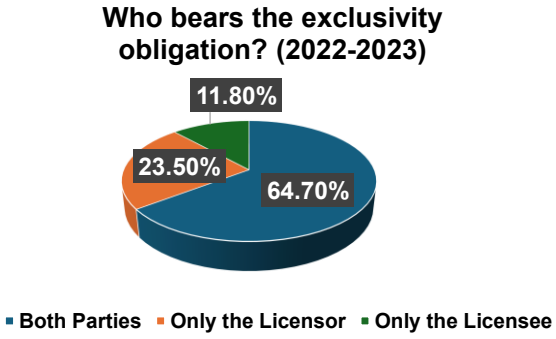
To ensure effective collaboration between both parties in the development and commercialization of the licensed product while maximizing overall returns, licensing agreements typically include explicit provisions

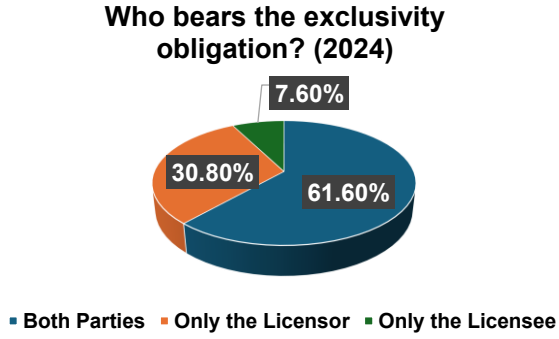
on exclusivity obligations. These provisions are designed to prevent any actions that may adversely affect the rights and interests of the other party. According to statistics, a clear non-compete obligation is stipulated in the vast majority (72.2%) of projects, while approximately 27.8% do not contain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





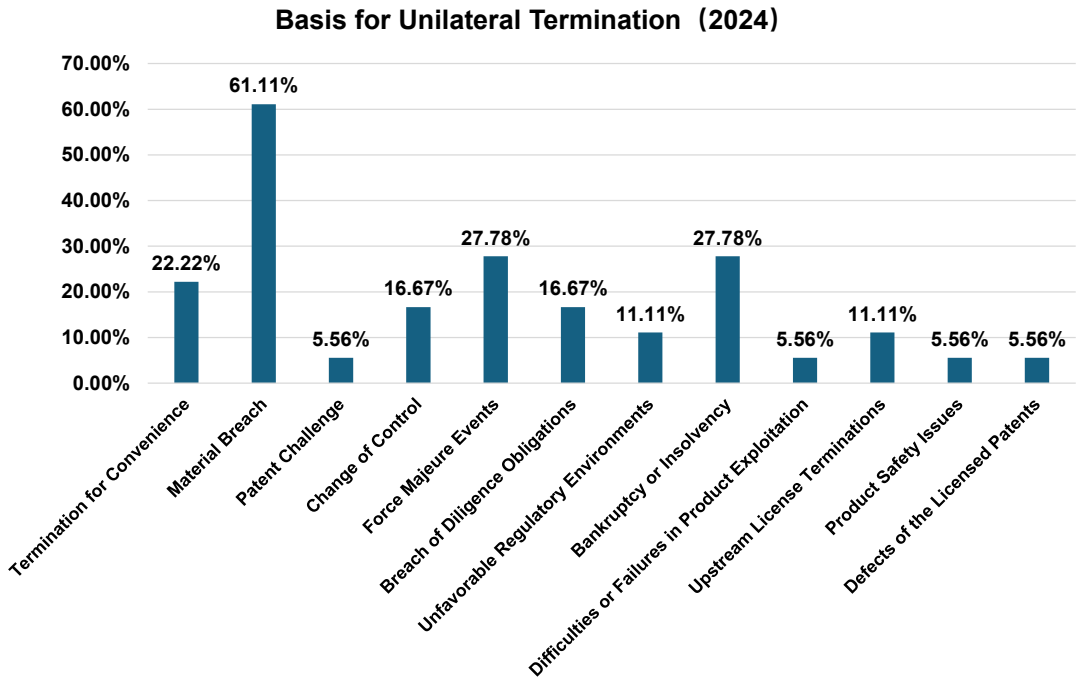
Termination rights

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.

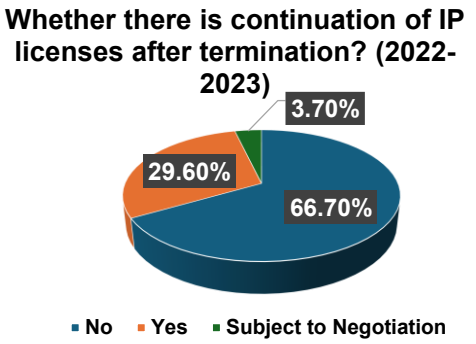
In terms of the grounds for exercising the unilateral termination rights, material breach of the agreement

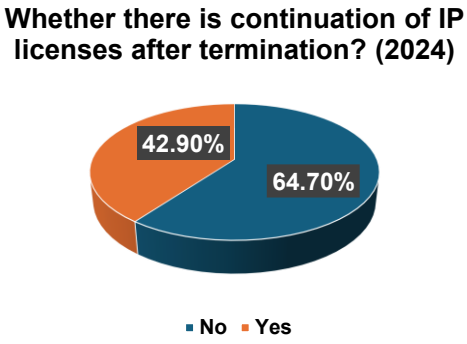
by the other party is the most common scenario, accounting for approximately 61.11% of cases, followed by force majeure events and bankruptcy, accounting for approximately 27.78%. In addition, about 22.22% of projects have provided termination for convenience, and a small number of projects have specified 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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