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How to negotiate a deal

Key legal considerations on drug licensing (licensing-in/out) transactions

Drug licensing transactions (licensing-in/out) have become more and more popular for pharmaceutical and biotechnology enterprises to enrich their drug R&D product pipelines or commercialization. Companies have also set up their own business development team to find suitable targets or partners in the market. Meanwhile, the continuous popularity of drug licensing transactions makes the parties, especially a Licensee, encountering more competition and difficulty in negotiating a deal. On one hand, the Licensee is expected to spend huge expenses on market research, and it is also time consuming to find suitable targets; on the other hand, the Licensor has increasingly stringent requirements on the terms and conditions of the transaction. The difficulty of finding a suitable target is determined by the supply-demand relationship on the market rather than the parties to a single transaction, but the parties can negotiate the terms of the transaction to achieve a transaction arrangement satisfactory to both parties. For the parties in a drug licensing transaction, as they need to cooperate closely for a long term in various stages such as licensing, R&D, manufacture and commercialization, the allocation of interests and obligations between the parties is also extremely complicated. Consequently, it is not easy to achieve a transaction arrangement satisfactory to both parties.

This article will walk you through the key legal considerations on drug licensing transactions and share with you our experience on how to achieve a deal based on our previous projects and the latest transaction trends.

I. Structure of drug licensing transactions

In a drug licensing transaction, whether in license-in or license-out, the parties will first negotiate a deal structure. The deal structure determines the basic framework of rights and obligation allocation between the parties. Some licensors would like to have more cash to support their operation or product R&D; some licensors may wish to work closer with licensees on licensed products; if the Licensee has adequate capacities and complementary advantages with the Licensor, both parties may establish a closer and long-term comprehensive relationship of cooperation. To satisfy demands of each party to the transaction, the Licensor and the Licensee should negotiate and determine the deal structure prior to the proceeding of the transaction. In a drug licensing transaction, there are typically three following deal structures:

1. The first one is the traditional transaction in cash: the Licensee obtains all kinds of intellectual property rights, know-how and R&D data of the target drugs of the Licensor by paying cash to the Licensor. Such payment will normally be comprised of an upfront payment, milestone payments and royalties.

Under this structure, by way of agreement, the Licensor and the Licensee cooperate and allocate the rights and obligations in different stages of drug R&D, manufacture and commercialization. This structure is generally applicable to the transaction which is limited to a single target drug. The Licensor intends to convert the target drug into cash quickly in a short term. Compared with the other two, the risk of the Licensor under this structure is controllable. Consequently, the Licensor can only obtain royalties after successful commercialization of the target drug.

2. The second one is collaboration at equity level: the Licensor and the Licensee cooperate in the development of the target drug through collaboration at equity level. This kind of cooperation can be in the form of joint venture established by both parties to cooperate on the development of R&D product(s) or in the form of cross-shareholding between the Licensor and the Licensee to achieve comprehensive cooperation on the development of multiple targets. Unless the Licensor and the Licensee have the same strength and are familiar with each other, they will consider cross shareholding directly. Otherwise, in most cases, the Licensor and the Licensee may hope to set up a separate joint venture on a single target so as to establish limited equity cooperation.

   Compared with cash transactions, such a deal structure is more flexible, and the parties will establish a closer cooperation. From the perspective of products, the parties may cooperate on a single product as well as multiple products. On the allocation of risk and profits, although the Licensor get a relatively small upfront payment and bear the risk of failure in the target R&D, the Licensor may share more profits upon success of the cooperation, which includes profits from drug commercialization and the equity appreciation, especially the equity appreciation if the joint venture can be successfully listed in the capital market. If the Licensor and the Licensee have quite similar capacities in terms of capital, R&D and commercialization, etc., and that both parties have the intention of long-term cooperation, this equity cooperation model will become the optimal option for the parties.

3. The third one is a mix of the two aforesaid models: the Licensor and the Licensee can cooperate by way of licensing agreement as well as have collaboration at the equity level. This mixed model integrates the characteristics of both cash transaction model and equity transaction model. Under this mixed model, not only can part of the Licensor's cash demand be satisfied, but the Licensor's benefits of equity appreciation can also be guaranteed. From the Licensee's perspective, the Licensee can also obtain the Licensor's licensing, the Licensor's support for the target product and other products or businesses by paying a smaller upfront fee at the early stage.

The deal structure of a drug licensing transaction determines the subsequent framework and negotiation process of rights and obligations allocation between the Licensor and the Licensee. It is usually the first key issue to be solved by the parties in a drug licensing transaction. The Licensor and the Licensee may discuss and choose different deal structures based on their commercial considerations.

After the deal structure is settled, the Licensor and the Licensee will also bargain for the scope of licensing, the ownership of intellectual property rights, and the rights and obligations allocation in the process of drug R&D, manufacture and commercialization.

II. Scope of licensing

In addition to the deal structure, the scope of licensing will also have a significant impact on the parties. The licensing scope mainly includes the licensed territory, indication and field of the target drug.

1. The comprehensive strength of the parties and the applied business model will be the decisive factors in determining the scope of licensing. The Licensee would definitely like to obtain a broader territory, indication and field; however, the final determination of the licensing scope still depends on the R&D and commercialization capacities of the Licensee and the actual needs of the Licensor. Nevertheless, there are still room for the parties to negotiate. Especially for the possible future cooperation with the Licensor, the Licensee can try to obtain some priorities if there is any future cooperation with the Licensor.
2. For the territory, at the beginning of cooperation, the Licensor may not be able to fully acquire the Licensee's R&D capacity globally. It will only consider giving the Licensee a relatively small territory. In this case, the Licensee may try to argue for some conditional rights to expand the territory in the future. For example, the Licensee may try to argue that if they can obtain certain milestone approvals of licensed products within a shorter time of period, it will then have the right to require the Licensor to expand the territory. Surely enough, the Licensor will also require additional license fees and impose some limitations on the rights of the Licensee if the territory is expanded.
3. The Licensee may also try to obtain the right to expand the indication and field of the target drugs. The Licensee may try to negotiate priorities for expansion of the licensed indication and field. The Licensee may also try to obtain priorities for other products of the Licensor in the licensed territory. In some transactions, the Licensee can even obtain an exclusive negotiation with the Licensor concerning the contemplated transaction for a certain period of time.

III. Ownership of intellectual property rights

In a drug licensing transaction, whether it is license-in or license-out, the core asset is intellectual property. Therefore, the ownership and use of intellectual property generated in the collaborative R&D activities will become an important focus of the parties.

Generally speaking, the ownership allocation of intellectual property rights can be categorized into two models: one is that the intellectual property rights are owned by either the Licensor or the Licensee; the other is that intellectual property is jointly owned by both parties. However, it may become quite complicated for the parties to negotiate either of them.

1. Under the first model, the intellectual property belongs to either party. There is no doubt both parties will argue for the ownership of the intellectual property. From the perspective of the Licensor, since the subsequent intellectual property generated via collaborative activities is usually derivatives from the Licensor's previous intellectual property, considering the decisive role of the Licensor's early intellectual property rights in the subsequent intellectual property rights, the Licensor will insist that such prospective intellectual property rights should belong to the Licensor. Especially when the target drug is a quite competitive product in the market, the Licensor's position on such matter will be quite firm.

   From the perspective of the Licensee, the subsequent intellectual property rights are mainly generated from the continuous investment of the Licensee in R&D activities with its financial support. Without the subsequent investment of the Licensee, especially capital investment, these prospective intellectual property rights cannot be generated. Based on such argument, the Licensee will claim its ownership of the intellectual property. When the negotiation powers of both parties are quite equivalent, it is difficult for either party to convince the other party about the ownership of intellectual property rights. To take the second best, both parties may consider the following compromises:

   i) To categorize the intellectual property, such as dividing intellectual property into product related intellectual property and process related intellectual property and dealing with the ownership of these two types of intellectual property, respectively. Another classification is based on the licensed territory. For example, the Licensee is the owner of the intellectual property in the territory, while the Licensor is the owner of the intellectual property in other areas.

ii) To secure the other party's right of long-term, free use of the intellectual property.
For example, when intellectual property rights belong to one party, the other party often requires a free right to long-term use. Of course, the owner of the intellectual property will also put some limitations on the other party's use of the intellectual property, such as limiting the scope of use, not using the intellectual property in the business competing with the owner's, or not cooperating with the competitors of the owner, etc.

2. Under the second model, the intellectual property belongs to both parties. Although the joint ownership model can effectively solve the disputes, the next issue both parties will likely encounter is how to decide the use of such intellectual property. The right to decide the use of intellectual property and the allocation of benefits generated by the use of intellectual property will become a key issue of subsequent negotiations between both parties.

   The general logic is that since intellectual property rights are jointly owned, the right to use intellectual property rights should also be jointly decided by both parties, and the benefits generated by the use of these intellectual property rights should also be equally allocated between both parties. However, this arrangement will have an impact on the efficiency of the use of intellectual property rights. As a compromise, both parties may consider the allocation of the decision-making power on the right of use. For example, in the licensed territory, the Licensee has the right to decide the use of intellectual property. Of course, such right of the Licensee is often subject to some constraints. For example, the Licensee should perform reasonable due diligence on the sublicensee and bear joint and several liabilities with the sublicensee for the use of intellectual property rights; the Licensee can only use the intellectual property rights in certain R&D fields, not in business competing with the Licensor's; and the interests generated by intellectual property licensing should be equally shared by the parties, etc.

IV. Other key negotiations

In addition to negotiations on the points listed above, the parties to the licensing transaction may also need to negotiate and determine the subsequent R&D, manufacture and commercialization of the licensed products, such as:

1. At the R&D stage: the general principle is that the Licensee is mainly responsible for R&D activities in the territory, and the Licensor should provide reasonable support for the Licensee's R&D activities. However, for specific R&D activities, there are still many issues that need to be negotiated and determined by both parties. For example, whether the Licensee has the right to outsource some R&D activities? If it is necessary for the Licensee to do so, does the Licensor have the right to approve such outsourcing? Or does the outsourcing R&D institution need to sign relevant legal documents to ensure the compliance and confidentiality of its R&D? Or does the Licensee only need to inform the Licensor of the relevant information about such outsourcing in advance?

   In addition, since the Licensor is more familiar with the R&D technology and data, in the start-up stage of drug R&D, the Licensee often requires the Licensor to provide certain technical consulting and support, and even may require the Licensor's R&D personnel to provide on-site support. In this case, does the Licensee need to pay additional consideration to the Licensor? Generally speaking, the Licensee may consider such intellectual support as an incidental service necessary for the Licensor to complete the transfer of licensed technology and R&D data. Therefore, no additional fee should be charged. However, the Licensor may object and insist that when the Licensee conducts transactions, it should ensure that it has sufficient

R&D personnel, technology and ability to support the subsequent R&D of the licensed target, and that it should not rely on or require too much for the Licensor's technical support. Even if the Licensor is willing to give the Licensee some free technical support, the Licensor will make an agreement on the scope and time of such free technical support. For anything exceeding the agreed scope or time, the Licensee still needs to pay additional fees to the Licensor.

2. At the drug manufacture stage: drug manufacture includes the manufacture of investigational drugs and new drugs after commercialization. For the manufacture of investigational drugs, since the Licensor has invested in the manufacture of investigational drugs and obtained corresponding approval prior to the licensing transaction, and that the demand for investigational drugs will be quite limited, from the perspective of economic efficiency, the Licensor is generally responsible for the production of investigational drugs. The Licensee needs to make sure there will be detailed agreements on the supply and pricing mechanism of investigational drugs in the license agreement.

   The Licensor and the Licensee may pay more attention to the production and supply rights of new drugs after commercialization. When determining the allocation of such right, the territory for commercialization obtained by the Licensee and its possible proportion in the sales of such drugs within the global region will determine whether the Licensee has the right to manufacture. If the commercial territory obtained by the Licensee accounts for a large proportion in the global region, the Licensee is more likely to obtain the manufacture right. Otherwise, the Licensor may retain such right, especially when the Licensor licenses the licensed drug to different licensees in other territories. Under such scenario, in order to ensure the unity of drug quality and supply, the Licensor often insists on the right to manufacture. Meanwhile, the Licensee may require a corresponding reduction in the proportion of royalties paid to the Licensor, because it has paid a purchase price to the Licensor for purchasing the drugs.

3. At the commercialization stage: The drug commercialization here specifically refers to the sales stage after the drug is put onto the market. At the commercialization stage, the Licensor and the Licensee should first solve the problem: which trademark will be used for the drugs? Generally, the Licensor will insist that its existing trademark should be used here. If the Licensee has sufficient reasons to believe that the existing trademark of the Licensor is inappropriate or that there is a need to register a new trademark for the sale of drugs in the territory, the Licensor may also use a newly registered trademark. However, the ownership of the trademark and the goodwill generated from the sale of drugs will belong to the Licensor.

   At the drug sales stage, the Licensee should generally pay a proportion of royalties to the Licensor based on the volume of the sales as part of the consideration for the transaction. For such payment, the Licensee may try to require a right of deduction under certain circumstances, such as any loss of the Licensee caused by the Licensor's breach of its representations and warranties, defects in the licensed intellectual property, any additional fees paid by the Licensee for the free implementation of the Licensor's patent in the territory, or emergence of any generic drug of the target product in the territory. If the Licensor agrees to make a deduction, it usually puts a cap on such deduction so as to put some limitations here.

The successful conclusion of a drug licensing transaction depends on various factors, such as the market, regulatory environment, business arrangements between the parties and rights and obligations allocation between them. Some of these can be settled via design of deal structure or mutual agreement in transaction documents. If the parties can make some preparations in advance concerning the possible negotiation points of a drug licensing transaction, it will definitely enhance the possibility of success of the transaction.

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