大成 DENTONS

Anatomy of Pharmaceutical Licensing, Development and Commercialization Transaction in China (II)

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We analyzed the legal definition and common structure of cross-border pharmaceutical licensing transaction in our article of Anatomy of Pharmaceutical Licensing, Development and Commercialization Transaction in China (I), we also discussed some key legal provisions of pharmaceutical licensing agreement. In this article, we will further discuss and analyze the terms of intellectual property rights in pharmaceutical licensing, development and commercialization transaction.

01. Due Diligence on Intellectual Property

License-in transaction could be deemed essentially as an asset transaction in which by paying a certain consideration to the Licensor, the Licensee obtains the intellectual property rights and R&D data related to drug R&D technology to continue the follow-up development, manufacture and commercialization of licensed pharmaceutical candidates. As the most important target in the transaction, the intellectual property rights of the Licensor play quite an important role. Similar to the M&A transaction, the Licensee generally needs to conduct due diligence on the Licensor's intellectual property rights, such as the core patents and technical secrets owned by the Licensor, or the patents and technical secrets authorized to Licensor, so as to confirm the ownership of the Licensor's intellectual property rights (including not limited to patents). Generally speaking, the due diligence of the Licensor's intellectual property will focus on: (1) Ownership of these intellectual property rights; and (2) Freedom to operation of licensed patent.

Due Diligence on Intellectual Property Ownership

The due diligence investigation of intellectual property ownership should focus on whether the Licensor has complete rights to license the intellectual property to the Licensee without any interference. To confirm this point, in addition to confirm that the Licensee is the right holder registered on the intellectual property certificate, it is also necessary to confirm whether there is any

contractual obligation on the rights and obligation allocation concerning these intellectual property rights, such as clinical trial contracts, research and develop agreements. Furthermore, if the patent is generated by the employee of the Licensor when performing his/her labor contract, the Licensor may need to pay certain remuneration to the employee in some jurisdictions. Therefore, the Licensee needs to pay special attention on these points when conducting due diligence.

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Analysis on Patent FTO

The patent freedom-to-operation ("FTO") investigation covers analyzation and investigation on whether there is any risk of infringement of third parties patent rights when using, producing or selling products in the licensed area. FTO investigation is implemented normally as assessment on if any litigation risk against the Licensor's patent in the future. As the free implementation of the licensed patent will be critical importance on its subsequent commercialization, it is very important to ensure the comprehensiveness of FTO investigation. In the due diligence of intellectual property, apart from confirming the ownership of the intellectual property of Licensor, the Licensee usually involves outside legal counsel to conduct FTO on the Licensor's patents, so as to evaluate if any associated risk on the subsequent commercialization of pharmaceutical by the Licensee.

Whether the patent of the Licensor can be freely implemented in the licensed area determines the success of the subsequent commercialization. In practice, the Licensee usually takes the confirmation of patent FTO as the prerequisite for the effectiveness of the licensing agreement or as the condition of upfront payment. The Licensee may also require that if any additional fee is incurred due to the defect on the freedom operation of Licensor's patent, or the patent FTO of the Licensor requires additional authorization from a third party, the Licensee has the right to deduct such fees incurred from the subsequent license fees (mainly payment of Royalties).

02. Scope of the License

Nature of the License

In view of cross-border license-in transaction we served in China, the Licensee usually requires exclusive license right, that is, the right to have an exclusive license for the licensed subject in the licensed area. Normally, the licensed products are in the stage of clinical trials, sometimes in an earlier stage, which means that the Licensee needs to bear uncertainties of commercialization. Even if the drug could be successfully commercialized, it often requires huge expenses from the Licensee and it is a time-consuming process. In order to leverage the risk and reward, the Licensee always insists on an exclusive license right.

Right to Sublicense

The success of pharmaceutical R&D requires joint efforts and cooperation of all relevant parties. If Licensee does not have all the required technology or capacity related to pharmaceutical R&D (such as a start-up biotechnology company), the Licensee may need to subcontract at least part of the R&D work to a third party to continue the follow-up R&D or manufacture activity. In that case the Licensee needs to obtain a right to sublicense. In the following scenarios, the Licensee needs to obtain a sublicense right from the Licensor:

CRO MODEL

CRO (Contract Research Organization) also known as contractual research organization, it refers to the scientific organization that provides professional

services for pharmaceutical enterprises and R&D institutions in the process of drug R&D through contracts. Its target market mainly focuses on the medical statistics and clinical trials of drugs by pharmaceutical enterprises. By selecting an efficient CRO company, the Licensee can obtain clinical research experience, technical support and professional services timely, and also reduce the comprehensive R&D cost.

CMO MODEL

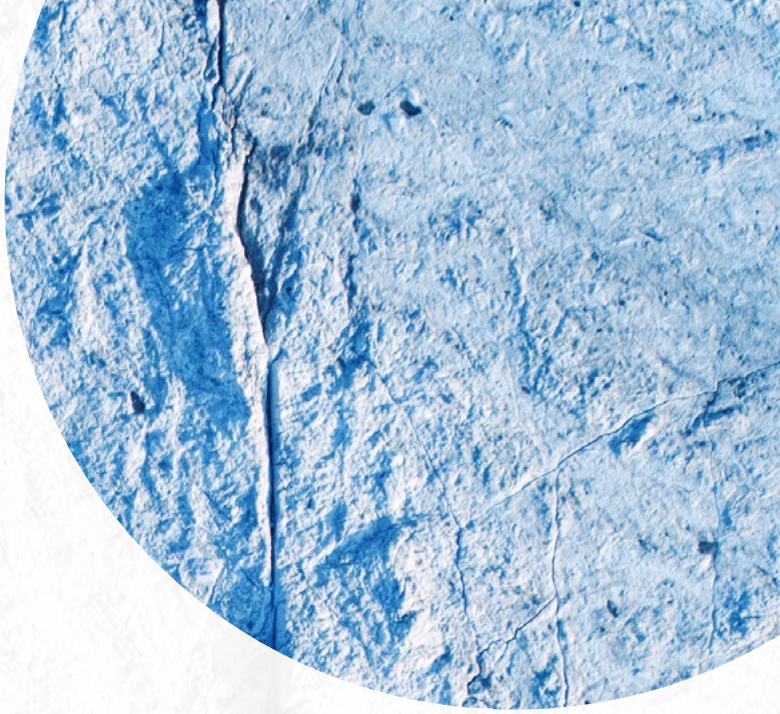
CMO (Contract Manufacture Organization) is entrusted by the Licensee to provide with the process, formula, preparation and synthesis needed in the production of drugs.

CDMO MODEL

CDMO (Contract Development Manufacture Organization) is a kind of customized CRO. Compared with CMO, it is a kind of service upgrade and optimization. It emphasizes more on customized R&D process.

When considering giving the sublicense right to the Licensee, the Licensor will also impose certain restrictions. Typically, these restrictions include:

- Impose certain restriction on the selection of CRO, CMO or CDMO; or require prior consent from the Licensor before the Licensee's choosing of agencies;
- Require the end user of the intellectual property under the sublicense to undertake the obligations of maintaining and keeping confidential the intellectual property to the extent no less than that of the Licensee;
- Require the Licensee to bear joint and several liability for the maintenance and confidentiality of the intellectual property rights of its sublicensee;
- Require the Licensee to deliver a copy of its contract with CRO, CMO or CDMO to the licensor for record after deleting relevant commercial sensitive information.



03. Patent Maintenance and Operation

Upon completion of the authorization through the pharmaceutical licensing-in transaction, the Licensor, as the patentee, still has the obligation to maintain its patent. As the holder of the right of use in the licensed area, the Licensee also has the obligation to provide assistance for the maintenance and operation of the Licensor's patent, such as making reasonable efforts to defend against the infringement of the patent by any third party in the licensed area, and informing the Licensor of the infringement in a timely manner. In the pharmaceutical licensing agreement, both parties also need to agree on the cost sharing of patent maintenance and operation, especially in the scenario of third-party infringement.

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04. Ownership of Derivative Intellectual Property

Under the pharmaceutical licensing-in transaction, the Licensee obtains the license through the transaction and carries out the follow-up R&D, which involves the issue on how to determine the ownership of the intellectual property rights generated in the process of such R&D activity. Intellectual property rights play a key role in the whole transaction, the parties of the transaction need to clearly agree on the ownership of derivative intellectual property rights and document it in the license agreement.

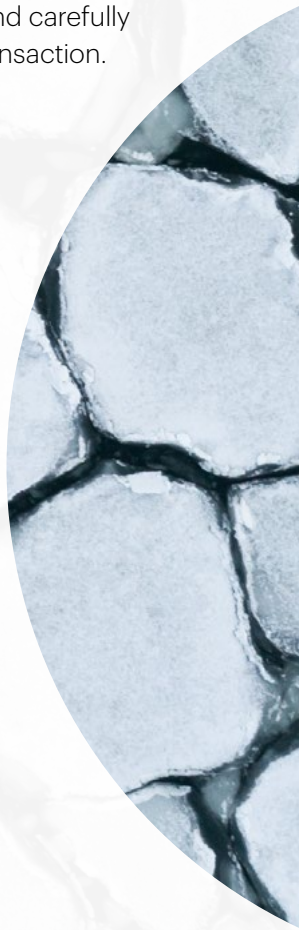
From our previous experience, these derivative intellectual property rights could be owned by the Licensor or by the Licensee, or can be jointed owned by the Licensor and the Licensee as agreed, which depends on the negotiation and the commercial arrangement of the parties for the subsequent commercialization. However, no matter which party owns the derivative intellectual property right, the other party will always ask for free-to-use right or a use right with certain charge for a certain period of time, or for a long term.

In addition, the parties usually stipulate in licensing agreement that when one party generates an invention that may constitute a patent, it needs to notify the other party in time, and provides the corresponding supporting documents or materials to the other party. Both parties shall also discuss and determine whether to apply for a patent and the scope of the patent application through friendly negotiation.

05. No challenge

The prerequisite for the payment by the Licensee to the Licensor is that the licensed subject (i.e. the patent and other intellectual property rights in the licensing transaction) remains valid. Otherwise, the Licensee has the right to terminate the license agreement or stop paying to the Licensor, with requiring the Licensor to bear the corresponding liability for breach of contract. In this circumstance, the Licensee may have the willingness to challenge validity of the patent of the Licensor. Therefore, in the pharmaceutical licensing agreement, the Licensor will often require the Licensee not to challenge its intellectual property rights. If the Licensee initiates or substantially participates in the challenge of the patent of the Licensor, but the challenge fails in the end, the Licensor often requires a right to terminate the license agreement and/or increase the license fee (sales commission).

In summary, the legal provisions in the pharmaceutical licensing agreement related to intellectual property rights play quite important role in the licensing transaction. The parties need to consult with external professionals and carefully planned before proceeding with the transaction.



Key Contact

Hilton Yin
Partner, Shanghai
D +86 21 5878 6513
hilton.yin@dentons.cn

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