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Typical Legal Risks in Pharmaceutical Research and Development Contract

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May 2023

With the continuous development of the Contract Research Organization (hereinafter referred to as "CRO") industry, more and more pharmaceutical companies and biotech companies choose to outsource part or even all of their pharmaceutical research and development (hereinafter referred to as "R&D") work to service organizations specializing in pharmaceutical R&D business. Due to the unique characteristic of high investment and high risk in pharmaceutical R&D, and for the benefit of effective risk control, the terms of the pharmaceutical R&D contract shall be detailed and comprehensive, and the rights and obligations of both parties shall be stipulated clearly.

In this article, we will deliberate on the pertinent matters that demand attention from both contracting parties under the pharmaceutical R&D agreement. Additionally, we shall identify issues that may potentially give rise to conflicts, and offer legal advice on possible risk-control methods based on our experience in previous projects.

As a type of technology contract, pharmaceutical R&D agreements can be classified into two categories: the pharmaceutical commissioned development contracts and the pharmaceutical cooperative development contracts. Under the pharmaceutical R&D outsourcing model, pharmaceutical commissioned development contracts are more commonly employed. Therefore, our analysis shall specifically concentrate on the pharmaceutical commissioned development contracts during the pre-clinical stage. It is imperative to note that the pharmaceutical R&D contracts discussed in this article pertain exclusively to the pharmaceutical commissioned development contract.

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I. The Executing and Performing Parties of a Contract

The executing and performing parties of a pharmaceutical R&D contract should be the party entrusted with conducting R&D work and its entrusting counterpart. However, due to the characteristics of technology development, especially for major pharmaceutical R&D outsourcing projects, pharmaceutical enterprises would usually impose special requirements on the experience and credentials of the scientific researchers who actually provide the technology development services in the hopes that specialized scientific research personnel will be in charge of their technology development projects. For this reason, in practice, some pharmaceutical R&D contracts will expressly state that R&D projects shall be carried out by specially designated scientific research personnel of the entrusted party.

The issue that may arise from this is that, if the entrusted party's designated technical personnel for providing the R&D services under the pharmaceutical R&D contract are unable to do so, particularly due to events beyond the entrusted party's control, such as the resignation of the technical personnel, the entrusted party may face the risk of a breach of contract. To avoid such risks, when the entrusting party requests to limit the performing parties to specific technical personnel, the entrusted party may attempt to designate the leader of a research group or a research project as the performing party, so as to avoid including all of the technical personnel's names in the technology development contract, which would reduce the risk of a breach of contract. To further protect the rights and interests of both parties, the parties may consider including a clause in the technology development contract that states that the entrusted party has the right to, within reason, designate scientific researchers with similar qualifications or experience to carry out the contract should the designated technical personnel change due to circumstances outs of the entrusted party's control (including the resignation of the designated personnel). Meanwhile, to ease the entrusting party's concerns or to make the arrangement more acceptable for the entrusting party, the entrusted party may consider offering the entrusting party the right of termination. For instance, if the entrusting party finds the technical personnel that the entrusted party had appointed in replacement unacceptable, the entrusting party has the right to unilaterally terminate the contract within a certain agreed-upon period and shall not be held liable for breach of contract.

II. Term of Contract

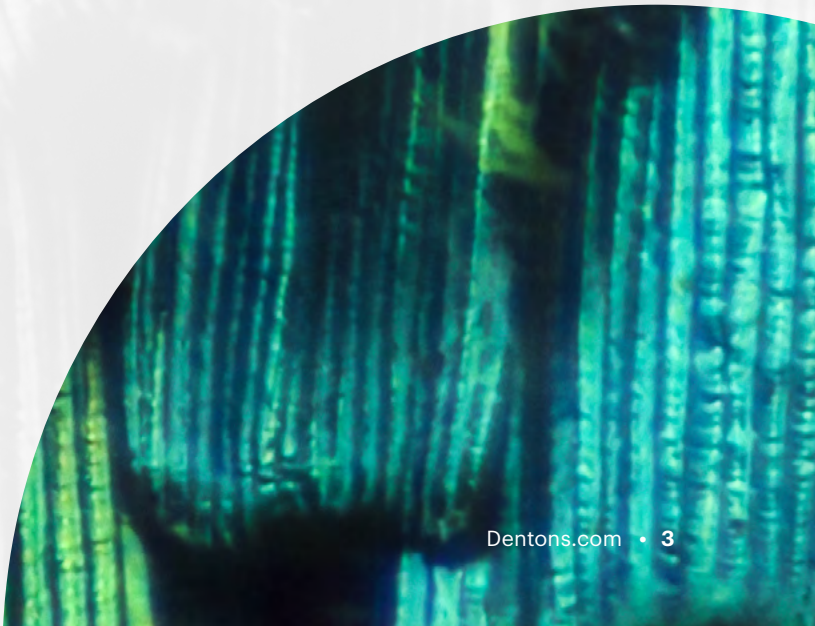
As a customary arrangement, general contracts typically include a deadline for the performance of the contract. Similarly, pharmaceutical R&D contracts usually specify a contractual period that is often associated with the completion cycle of the pharmaceutical R&D project. However, due to the uncertainty in the technology development process, this period is difficult to estimate, which can lead to situations where the contract has already expired, but the technology development project is still ongoing and the contractual obligations have not yet been completely performed. The typical solution is for both parties to the contract not to agree on a fixed contractual period, but to use the project development cycle of the pharmaceutical R&D project as the contractual period, while also specifying a maximum period for the performance of the contract. If the entrusted party is unable to complete the commissioned development project after the maximum period has elapsed, the entrusting party has the right to unilaterally terminate the contract.

For general contracts, the issue of determining the contractual period can be resolved through flexible arrangements that associate the contractual period with the performance of contractual obligations. However, for technology contracts, following China's regulatory requirements for technology contracts and in order for companies to obtain tax benefits, both parties to the contract are required to register the technology contract with the competent technological administration department. One of the pieces of information required for such registrations is the performance period of the contract, which must be a fixed period, or else the registration of the technology contract cannot be completed. Therefore, for pharmaceutical R&D contracts, both parties must also establish a relatively fixed performance period in the contract. To solve this problem, for highly uncertain technology development projects, the contractual parties may consider setting a relatively broad bottom-line period, while also agreeing that if both parties fully perform their rights and obligations before the end of this bottom-line period, the contract shall be terminated on the day of full performance. In addition, mechanisms for adjusting the contractual period may also be included in the contract, such as granting the entrusted party the right to terminate the contract unilaterally, or extend the technology development/contractual period within reason if the technology development services need to be terminated prematurely or extended due to objective reasons (such as changes in laws and regulations or technology development standards/requirements) or due to reasons attributed to the entrusting party.

III. Milestone Payments

Regarding the payment arrangements in pharmaceutical R&D contracts, the contractual parties usually adopt an arrangement that includes an initial payment and milestone payments. For some R&D projects with promising commercial prospects, the parties to the transaction may also reach an agreement on a sales commission after the successful commercialization of the subject of the R&D project. Among these payment arrangements, the payment arrangements for milestone payments and sales commissions can easily lead to disputes and require special attention from the contractual parties. Since the payment arrangement for sales commissions in pharmaceutical R&D contracts is similar to that in pharmaceutical licensing transactions, which we have analyzed in previous articles and will not delve into a further discussion here. Regarding milestone payments in pharmaceutical technology development contracts, the parties to the contract, especially the entrusted party, who is the recipient of the payments, should pay special attention to the following situations:

1. Due to the uncertainty inherent in pharmaceutical research and development, when setting milestones, expressions that refer to the process of pharmaceutical research and development or the full provision of pharmaceutical R&D services should be used, instead of terms that indicate the ultimate outcome of the milestones such as "ensure", "achieve", "attain" or "accomplish".



2. When setting specific milestones, it is preferable to select events that the entrusted party can handle, control, and confirm, while avoiding choosing events that require the entrusting party's cooperation as milestones. For example, in generic drug projects, there may be a scale-up pilot verification phase for trial samples, and this verification often needs to be completed at the entrusting party's production site and requires the entrusting party's cooperation. If the entrusted party sets the completion of the scale-up pilot verification as a milestone that triggers payment, it would be subject to the control of the entrusting party or require information from them to determine/confirm if and when the milestone has been achieved.

3. The contracting parties should also agree that if any event has prevented the achievement of the previous milestone, but the subsequent milestone has been reached, it should be presumed that the previous milestone has been achieved or occurred simultaneously with the subsequent milestone. Moreover, the contract can specify that certain actions or external events by the entrusting party can serve as evidence of a milestone's occurrence. For instance, when the entrusting party provides instructions to the entrusted party to initiate the next stage of R&D work, the previous R&D milestone can be deemed to have been accomplished.

4. If the achievement, occurrence, or confirmation of a milestone is under the control of the entrusting party (such as in the case of product registration application), the pharmaceutical R&D contract should explicitly specify that the entrusting party is responsible for promptly facilitating the achievement of the milestone and informing the entrusted party of its achievement. In the event that the entrusted party has solid evidence indicating that the entrusting party has been indolent to promote the milestone's achievement or that the milestone has already been reached, the entrusted party may request confirmation from the entrusting party as to whether the milestone has been achieved. If the entrusting party fails to confirm within a certain period, the milestone should be deemed to have been reached.

IV. Issues Related to Intellectual Property

When it comes to technology development contracts, especially pharmaceutical R&D contracts, intellectual property (hereinafter referred to as "IP") issues are of great concern to both parties. Confined to the limited length of the article, this article will only discuss these issues from two perspectives: the allocation of intellectual property rights and the agreements on subsequent development rights, which are often included in pharmaceutical R&D contracts.

1) Ownership Distribution

Although the law clearly stipulates how to determine the ownership of IP rights and how to determine the right owner who has the right to exercise the rights if the contracting parties haven't made special agreements on the attribution of IP rights in the commissioned development contract. However, in practice, both parties to the pharmaceutical R&D contract, especially the entrusting party, will make the ownership of IP rights in the R&D contract particularly clear in the contract and insist that the IP rights generated under the R&D contract should be owned by the entrusting party. Although it is difficult for the entrusted party to obtain the ownership of IP rights, the second-best thing is to try to obtain the right to use IP rights, at least within a certain geographical and time range. However, it is not easy for the entrusted party to win over this right of use successfully in the pharmaceutical commissioned development contracts, especially in pharmaceutical R&D contracts for innovative drugs. Due to the sensitivity of IP protection, most of the entrusting parties will not agree to grant the entrusted party the right to use the IPs generated under R&D contracts, but for other types of technology contracts, such as technical service contracts and technical consultation contracts, there's room for both transaction parties to negotiate the allocation of rights through consultation.

In addition, it is worth paying special attention to that if the entrusted party is a scientific research institute, due to the distinctive assessment mechanism of scientific research institutes, scientific research institutes will often request to reserve the "right of authorship" for the patents generated in the provision of R&D services, that is, to be jointly registered as patentees. The right of authorship requested by the scientific research institute as the

entrusted party is only a matter of formalities and will not interfere with the ownership and the use of the patent, nevertheless, in form, after the scientific research institute is registered as a patentee, it is legally acknowledged as the co-owner of the patent. Unless there are other agreements on the distribution of the rights of the patent, the scientific research institute should enjoy the rights granted by law to the joint patent, such as allowing others to use it in the form of a regular license. Therefore, if the entrusted party is a scientific research institute and insists on having the "right of authorship", we suggest that the entrusting party sign a separate written agreement with the scientific research institute to clearly stipulate the arrangement for exercising the rights of the patent.

2) Subsequent Development Rights

In commissioned development contracts, in order to avoid subsequent disputes, the contracting parties often have agreements on the ownership of the technological work products developed by one party on the basis of the technological work products of the project after its completion. However, such agreements on subsequent technological work products should be careful not to fall under the category of "illegal monopoly of technology" and be deemed invalid agreements. According to Article 850 of the Civil Code of the People's Republic of China (PRC), " A technology contract that illegally monopolies technologies or infringes upon others technological work product is invalid." Article 10 of the Supreme People's Court's Interpretation on Several Issues concerning the Application of Laws in the Trial of Technology Contract Disputes (Revised in 2020) stipulates that "the following situations are deemed as 'illegal monopolies of technology' as mentioned in Article 850 of the Civil Code: (1) Restricting one party from conducting new research and development on the basis of the contractual subject technology, or restricting this party from using the improved technology, or the conditions for both parties to exchange the improved technologies with each other being not reciprocal, including such circumstances as requiring one party to gratuitously provide the other party with the improved technology, to transfer the improved technology to the other party non-reciprocally, to gratuitously and solely occupy, or jointly own the IP rights of the improved technology". Therefore, in order to prevent the agreements on the ownership of subsequent technology development products from being deemed as "illegal monopolies of technology", which would subsequently render the agreements void, one should pay attention to the equity of such agreements. If the entrusting party would like to enjoy the ownership of all the subsequent technological development achievements, he should also agree to provide a certain consideration for these products or settle for a right of first refusal, so as to avoid being deemed as non-reciprocal transfer or free possession.

V. Preservation and Processing of R&D Data and Materials

The R&D data and materials generated during the performance of pharmaceutical R&D contracts are generally sent to the entrusting party together with the research results. However, in some cases, the entrusting party only requires a written research report on the final research results or only requires some of the R&D data and materials and decides to leave the remaining data and materials in the possession of the entrusted party. These R&D data and materials may be used in the subsequent pharmaceutical registration filings. Therefore, the entrusting party expects that the entrusted party shall properly preserve these basic R&D data and materials for a period, but the entrusted party is not willing to keep these R&D data and materials for an unlimited amount of time.

For the determination of the length of this preservation period, the parties can make different arrangements in accordance with the relevant provisions of *Good Laboratory Practices for Nonclinical Drug Research*, depending on whether the R&D data and materials are used for registration filings and whether the data and materials should be attributed to the research archives. According to Article 45 of *Good Laboratory Practices for Nonclinical Drug Research*, for the research that is used as the application materials for registration, the archives shall be preserved for at least 5 years after the drug is marketed; for the research that is not used as the application materials for registration (for instance, the terminated researches), its archives shall be preserved for at least 5 years after the date of approval of the summary report; materials that do not fall under the scope of research archives shall be preserved for at least 10 years after they are generated. If the contracting parties cannot agree on the period of time for which the R&D data and information should be kept, the period of time stipulated in the above-mentioned regulation can be used as a reference for mutual compromise. In addition, if the entrusting party would like to request the entrusted party to continue to keep the data and information beyond the above-mentioned period, the entrusted party may request additional fees for the preservation of data and materials.

At the same time, both parties to the contract should also clearly agree on how to deal with the preserved data and materials after the expiration of the data and materials preservation period and how the corresponding costs should be borne. Theoretically, the entrusted party should deal with these data and materials in accordance with the written requirements of the entrusting party. However, if the entrusting party fails to provide clear instructions to the entrusted party on how to deal with these R&D data and materials even after reasonable reminders from the entrusted party, the entrusted party may deal with such data and materials in any way it sees fit and has the right to request the entrusting party to bear the reasonable expenses arising from the disposal of the data and materials.

VI. Non-Competition

In accordance with our practical experience, based on the need to protect IP rights and trade secrets, the entrusting party of pharmaceutical R&D contracts often requires the entrusted party not to engage in the same or similar R&D contracts, especially for some innovative drug projects. However, for the entrusted party, if such restrictions apply to the entrusted party as a whole, the business scope of the entrusted party may be severely limited. Hence, we suggest that the entrusted party clearly limit the obligations of non-competition to the scientific research personnel involved in the project to avoid affecting the entrusted party as a whole. It may also be considered to impose a time limit on the non-competition obligations so that those who exceed this time limit will not be bound by the non-competition obligations.

The above is a summary of the points of friction that often arises in the process of reviewing pharmaceutical R&D contracts and our corresponding suggestions. It should be noted that in accordance with the different stages of pharmaceutical research and development and the different business considerations of both parties to the transaction, the contracting parties should set the corresponding contract terms flexibly depending on specific circumstances.