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Legal Analysis of CMO Contracts

Min ZHU | Effy SUN

On May 26, 2016, the State Council promulgated the Pilot Program for the Drug Marketing Authorization Holder System, announcing implementation of the marketing authorization holder ("**MAH**") program in 10 pilot provinces and cities. Within the pilot areas, drug MAHs may entrust qualified contract manufacturing organizations to manufacture market-authorized drugs, regardless of whether the MAH possesses production capacity. Before this, MAHs were only allowed to use contract manufacturers in the case of insufficient production capacity.

Contract manufacturing can effectively integrate the production capacity of pharmaceutical companies, promote the development of high-quality pharmaceutical enterprises and facilitate the rational allocation of industry resources. Regulators are also vigorously promoting contract manufacturing. Whether the contract manufacturing is MAH-related or general in nature, contract manufacturing organization contracts ("**CMO Contracts**") lay a foundation for cooperation between principals and contract manufacturers, and play a key role in protecting all parties' interests and guaranteeing drug production quality. Based on our experience in helping clients to handle contract manufacturing matters, and our extensive study of various litigation cases and agreements, we consider the following CMO Contract terms to significantly impact the rights, obligations and responsibilities of contracting parties, and therefore require special attention when negotiating and concluding such contracts:

Quality Agreements

Drug quality agreements are an indispensable supplemental document to CMO Contracts, which may be signed separately or included as an annex. The contents of these two documents are obviously different. CMO Contracts mainly deal with procedural matters, such as production cooperation methods, rights and obligations of the parties, production plans, packaging and shipping, production transfers and contract termination conditions. Quality agreements mainly address matters related to quality control and management, such as product quality and safety obligations, production process change management, quality control

and clearances, and liability for damages from product defects. CMO Contracts and drug quality agreements complement and are indispensable to each other in a manner similar to the relationship between GMP operating procedures and process specifications.

Quality agreements are, unfortunately, often missing from domestic CMO transactions. Since domestic pharmaceutical companies fail to fully understand the importance of quality agreements, they rarely sign a separate quality agreement. The quality standards and quality control management and control provisions included in CMO Contracts also tend to be very simple and far from sufficient. This causes trouble if disputes subsequently arise between the parties.

Intellectual Property Rights

Intellectual property rights provisions mainly provide for the licensing and use of technical secrets, patents and trademarks of contract manufactured drugs. The following issues should be clearly stipulated in these provisions.

Ownership of Contract/Cooperative Research Products: Some CMO Contracts not only provide for contract manufacturing, but also contain provisions relating to contract or collaborative research. The parties should expressly agree upon the ownership of the products from the research. Absent such an agreement, the products of contract research belong to the developer, and the products of collaborative research are jointly owned among all parties to the cooperative research. Furthermore, if a party refuses to apply for a patent related to a research product, other parties cannot apply for that patent. However, if a party waives its right to apply for a patent related to a research product, other parties can apply for the patent and the waiving party may implement the patent free of charge.

Technical Improvement Rights and Ownership of Those Rights: Contract manufacturers implement and use the principal's technical secrets and may create new intellectual property rights during drug manufacturing. Considering drug patents or technical secrets lie at the core of a pharmaceutical company's competitiveness, the parties should clearly agree upon whether the contract manufacturer has the right to amend and improve/develop the patents, technical secrets and other project information provided by the principal. If the contract manufacturer is granted a right to make improvements, the parties should further agree on the ownership and handling of such improvements, including but not limited to the right to apply for patents, whether the improvement can be protected as a trade secret, and whether the improvement can be disclosed or licensed to any third party.

Intellectual Property Infringement: Principals must ensure that formulas, technical and quality documents, trademarks and packaging that it provides do not infringe on the rights of a third party, including intellectual property rights. Unless otherwise agreed by the parties, the principal will be held fully liable for damages if a contract manufacturer is sued for infringement

of a third party's legitimate rights and interests due to its use in the production process of a patent, technical secrets or trademarks in accordance with the contract. If the contract manufacturer also provides any intellectual property for purposes of performing the contract, it should make the same representations and warranties as above.

It practice, however, we often see that intellectual property terms are still missing from domestic CMO Contracts, despite being of great concern to foreign pharmaceutical companies.

Confidentiality Provisions

CMO Contracts may involve various type of confidential information. In order to avoid disputes arising between the parties with respect to determining which technical drug content and intellectual property rights are subject to confidentiality provisions and to better protect the interests of both parties, CMO Contracts should define the scope of confidential information as clearly as possible, either by providing a definition that includes several express examples or itemizing all information that is deemed confidential in an annex attached to the CMO Contract. Many technical secrets, including but not limited to drug formulas, ingredient descriptions, production processes and procedures, quality standards and inspection records may be regarded as confidential information related to the CMO Contract, which will be subject to the approval of the parties based upon actual circumstances.

In addition, technical drug information is generally considered a trade secret unless a patent has been applied for with respect to that information. In judicial practice, in deciding whether certain information is to be protected as a trade secret, the court will consider several factors including whether such information is "unknown to the public," whether it "has economic benefits and practicability" and whether "the information owner has taken protective measures." In particular, the third factor is most important judgement criteria, and is also the focus of disputes. There was a case in which the judge denied certain information as confidential trade secret information on grounds that the information owner failed to take protective measures with respect to such information. We recommend that relevant provisions be drafted carefully by referring to the Supreme People's Court's judicial interpretations on unfair competition civil cases and based upon the actual circumstances of the project.

In China, domestic pharmaceutical companies have not paid enough attention to the protection of confidential information. Even confidentiality provisions contained in CMO Contracts tend to be poorly drafted, and are sometimes simply a standard boilerplate term reading as "any party shall not disclose the content of this contract and any information including the technical information related to the drug hereunder to any third party." This is far from enough in practice for CMO transactions, which are complex and often involve substantial technical secrets.

Rescission

CMO Contracts may be terminated by operation of law or through the maturity of any agreed terms. In both cases, the conditions for termination should be clearly provided in the contract. With respect to termination by the operation of law, in order to avoid misunderstandings and to mitigate the burden of proof in litigation, we recommend that CMO Contracts restate the statutory causes for termination as provided in the Contract Law and specify those actions that are regarded as committing a "delay in performing significant obligations" or "other breaches of contract." Although CMO Contracts generally stipulate that the contract manufacturer should have a Drug Production License and a GMP certificate to become a qualified contract manufacturer, there have been cases where judges held that the absence of such a license or certificate does not necessarily constitute a legal cause for termination of a CMO Contract.

However, the burden of proof for statutory contractual termination is relatively high. Furthermore, in the process of contract manufacturing, either party may undergo commercial adjustments, production transfers or become unqualified to engage in contract manufacturing due to administrative punishment. In such cases, a party may wish to terminate the CMO Contract and seek new partners to ensure the continuation of normal business operations. To ensure the right to exit, we recommend CMO Contracting parties to obtain as many rights to terminate as possible. Causes that can result in the termination of CMO Contracts include but are not limited to personnel requirements and staffing, compliance and regulatory control, document management systems, GMP supplier quality assurance programs, environmental requirements, raw material controls, test controls, unqualified products (defects) and the investigations thereof, product manufacturing and release, product complaints and packaging and shipping.

Contract Amendments

In most cases, the MAH and the contract manufacturer would prefer to form and maintain a long-term cooperative relationship, because the termination of a CMO Contract requires significant manpower, material and financial resources to transfer production. Provided the circumstances related to the contract manufacturing have not undergone any significant changes and the contracting parties are willing to continue performing the contract, the parties may agree to allow for amending the CMO Contract, including the terms and methods for making amendments. In fact, amendment clauses are as important as termination clauses, which together constitute a complete mechanism to protect the parties' rights and interests.

In practice, many CMO Contract items may need to be changed in various ways, such as product formulas, manufacturing processes, quality standards and requirements, manufacturing process quality control and quality operation systems (such as key quality personnel are subject to administrative penalties due to bad management, etc.). In addition, since the healthcare law and policy are undergoing significant reforms, the performance of CMO Contracts may also be impacted by many unpredictable macro-environmental factors.

In light of this, we recommend the parties to reasonably anticipate such changes and agree upon the relevant means of handling them in the CMO Contract, provided the overall cooperation framework and core interests of the contracting parties are not harmed. In practice, it is a test of the drafter's ability to properly align the termination and amendment provisions in CMO Contracts.

Default Liability Provisions

For a CMO Contract, the importance of default liability provisions can never be overemphasized. Since common and stable business practices have yet to be established in the CMO industry in China, and the macro-environment of the pharmaceutical industry in China is undergoing rapid and dynamic change, CMO Contracts must include certain penalty and control mechanisms to protect the contracting parties' legitimate rights and interest. Based upon actual circumstances, the parties may agree upon default provisions with respect to the following matters: contract assignment, delayed delivery, unqualified products, insufficient order quantities, intellectual property rights, confidentiality liability, non-competition, price payment, self-dealing, maintenance of quality systems and contract manufacturing plans that are affected by administrative penalties, etc.

Correspondingly, CMO Contracts should further provide reasonable relief entitled to non-defaulting parties in the event of a default. Remedies for default mainly include penalty and liquidated damages, which will be decided by the parties based upon the actual circumstances of the project. If a penalty is provided as a remedy for breach, when a default arises, the non-defaulting party may directly claim against the defaulting party for payment of the penalty. The challenge for the drafter is how to determine a reasonable amount for the penalty beforehand. However, if liquidated damages are chosen as a remedy, the non-defaulting party will be obliged prove that its losses were suffered due to the default. This means that the non-defaulting party will be subject to a greater burden of proof in litigation.

Generally, for some unquantifiable acts of default, such as changes that occur to the quality systems and delayed return of articles or materials, the parties may agree on a fixed penalty amount. Penalties for quantifiable acts of default may be determined based upon the value of the products involved, such as delays in product delivery and unauthorized sales or unauthorized contract assignments.

Production Transfers

A party may wish to transfer drug production to a new contract manufacturer or relocate the project to a new location because of the termination of a CMO Contract due to substantial breach of contract, or because of the adjustment to a party's strategic or business plans. Therefore, CMO Contracts should clearly provide for the transfer of production, in particular

with respect to the following matters:

a) Assistance obligations. The contract manufacturer should be required to designate an appropriate person who is responsible for answering questions from the principal or the new contract manufacturer selected by the principal. In addition, the contract manufacturer should provide all written documents in its possession that are necessary for manufacturing qualified products, such as test records, government approval documents, audit and inspection information, technical parameters and product standards.
b) Term setting. The process of transferring production is long and complex, and may involve a significant handover work. In order to ensure a smooth and orderly transfer process, CMO Contracts should provide a sufficient transition period, normally 12-24 months, based upon actual project circumstances. In addition, CMO Contracts should also stipulate for a continuous supply of products during the transition period.

Transferring production is very different in China's overall industry environment compared to other countries. For example, domestic CMO Contracts often fail to clearly stipulate with respect to the allocation of transfer costs if the production transfer is necessary due to reasons attributable to the contract manufacturer. In other countries, the CMO business model is relatively mature and the principal and contract manufacturer have equal footing in their cooperation. In the case of transferring production, the transfer costs would be allocated between the parties according to their degree of fault. However, in China, as MAH has been recently launched and is still in an early stage, the contract manufacturer is often in a strong position. By contrast, the principal is in a relatively weaker position in the arrangement. This requires the principal to fight even harder to protect its rights when drafting CMO Contracts.

Purchases of Insurance

Currently, an insurance policy is a necessary document to apply for a MAH certificate. Therefore, whether required by a CMO Contract or not, the principal must purchase the relevant insurance as a MAH. However, there is no clear stipulation with respect to whether contract manufacturers need to purchase insurance. The CMO Contract should clearly set forth whether the contract manufacturer needs to purchase comprehensive liability insurance or property damage insurance related to its own production facilities and equipment, or is obliged to purchase the clinical trial liability insurance, drug quality and safety liability insurance or additional drug recall cost insurance related to the contracted drugs. The premium is determined by considering various factors, including but not limited to the amount of cover, expected sales, variety and destination of the contracted drugs.

In other countries, both the principal and contract manufacturer are required to purchase the relevant insurance, and the CMO Contracts clearly stipulate the minimum limit of liability for the

occurrence of a single insured event, as well as the aggregate liability limitation for all insured events.

Summary

Generally speaking, both CMO Contracts and quality agreements are complicated transaction documents that cover wide range of issues. CMO Contracts concluded by foreign pharmaceutical enterprises and experienced domestic pharmaceutical companies always come in the form of several dozen pages, which is in stark contrast with the leaner contracts prepared by some domestic enterprises. This article is too brief to fully address all legal issues related to CMO Contracts. In practice, many legal issues should be analyzed on case by case basis based upon the actual progress of the project. Nonetheless, we recommend that parties reach CMO Contracts that are as detailed and clear as possible before the project commences.

Important Announcement

This Legal Commentary has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

If you have any questions regarding this publication, please contact **Mr. Min ZHU（+8621-6080 0955; min.zhu@hankunlaw.com**）