

Negotiating Third Party Manufacturing Agreements

How to reach an agreement that really fits your needs?

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VISCHER

MANY PHARMACEUTICAL AND biotechnology companies do not have own production facilities. They rely on third party manufacturers to provide them with the required quantities of agents or products needed for drug development. An effective and good working relationship between the developing company (the client) and its third party manufacturer is essential. Thus, negotiating a manufacturing agreement should provide a solid basis for such an effective and good working relationship.

A beneficial working relationship between a manufacturer and a client usually goes through three different stages of co-operation:

1. The parties evaluate the cornerstones of their co-operation and try to put down their mutual understanding in a project plan or term sheet.
2. The parties convert the project plan or term sheet into a legally binding agreement.
3. The parties ensure compliance with the agreement by regularly monitoring certain aspects of their co-operation, such as timelines, required disclosures, etc.

Evaluating Your Needs and Establishing a Project Plan

At the very beginning of a potential co-operation, the client should scrutinize the services of several manufacturers and determine which manufacturers are adequately qualified to provide the requested services. In some specific areas, there might be just a few manufacturers that have the necessary experience and thus are able to provide the requested services. Choosing the appropriate partners right from the beginning will most likely spare the developer unnecessary frustration in the course of negotiation and co-operation.

When comparing different manufacturers, the project plan or term sheet usually serves as a sort of checklist to make sure that the CMO and the developing company have a common ground from a business point of view. Once the appropriate manufacturer is identified, the term sheet will be extended to include details about the manufacturing process, specifications, batch sizes, technology transfer, pricing, and timelines. However, legal provisions such as liability, war-

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ranties, and payment terms should only be included in the term sheet if both parties are assisted by counsel. Otherwise, a party might unwittingly concede some rights or incur some duties.

Converting the Understanding into a Manufacturing Agreement

After approval of the product plan or term sheet, either the developing company or the manufacturer will have to prepare a first draft of the manufacturing agreement. The party preparing the first draft starts gets to start with an advantage. Use this advantage and draft — or get someone to draft — an agreement that fits the situation at hand. If you revert to a lawyer, trouble him with the full details and he will come up with an appropriate agreement. Never simply send over templates you have not read in their entirety. If you start drafting with an unsuitable template, you might offend the other party, lose time and give away the advantage of being the first mover. Consequently, make sure that your draft includes all issues touched on in the term sheet. In addition to those issues, the manufacturing agreement will in particular address the following issues:

Framework Agreement

Does the developing company intend to give several similar work orders to the manufacturer under a given legal framework? Or is it preferable to have a custom-made manufacturing agreement for each batch or product? If the parties enter into a framework agreement, the question arises whether a termination notice will affect a specific work order, the framework agreement, or both the framework agreement and all outstanding work orders. Sooner or later, terminating the framework agreement usually entails a break-off of the relationship between manufacturer and client. The standard solution for this issue is that after termination of the framework agreement, outstanding work orders are continued under the same conditions, but neither new work orders nor change orders will be accepted.

Fees and Payment Terms

Does the client have to pay the CMO on a time-spent basis or only upon receipt of the required products? How many advance payments will be made and at which milestones? By changing the balance between advance payments and final payment, the parties can allocate certain risks and benefits between developing company and manufacturer. Manufacturing a new product usually requires a major commitment by the CMO to prepare its employees and facilities. Substantial advance payments for every batch make it more attractive for the manufacturer to agree to short lead times and to satisfy excess demand. On the other hand, the client will need protection in case of delay or defects of the products.

Early Termination

What shall be the consequences of an early termination? Will the majority of the fees be owed anyway or does the client only have to pay for the services actually rendered? Will the

manufacturer have to deliver a final report even in case of early termination, and what shall its contents be? Depending on the nature of a drug development project, the risk of early termination varies significantly. Early-stage development projects might fail completely or run out of funds. Pharmaceutical companies might acquire more advanced projects and wish to transfer manufacturing to their own plants. It is well worth it to determine how technology transfers should look like and how the manufacturer will be compensated for giving away substantial know-how and experience. Further issues to be addressed include fixing the consequences of a termination for breach, insolvency, change of control or similar transactions.

Intellectual Property Rights

Who shall be the owner of any improvements developed during the manufacturing process? What kind of improvements are linked to the manufacturing and should therefore be owned by the manufacturer? What kind of improvements are linked to the product and should therefore be owned by the product company? A clear-cut solution will make life easy for both parties. In other cases, both parties may want to have their share in a particular improvement. To avoid conflicts, the rights and obligations of each party relating to joint patent rights should be described in detail. In other cases, licenses allow allocating to each party exactly the rights it needs. Licenses can be restricted to certain countries or certain fields of use; they can be exclusive or non-exclusive, royalty bearing or royalty free, limited or unlimited in time. Thus, licenses are likely to satisfy the needs of both parties — a situation that almost never occurs when IP rights are transferred in their entirety.

Warranties

What happens if the product does not conform to the product company's expectations? Will the manufacturer have to produce another batch or pay for somebody else to do it? Who shall be liable for loss of sales caused by a delay? In case of an early-stage project, it might not even be possible to specify all parameters of the product. Therefore, the manufacturer is not necessarily obliged to deliver a product complying with all specifications; in this case, a manufacturer might just be obliged to use its best efforts to meet the developing company's expectations. Negotiating appropriate warranties usually takes much of the time the parties spend discussing their project. Parties that know exactly what they expect will move much faster through the tedious warranty section.

Limitation of Liability

Delaying or stopping a promising drug development project might lead to huge damages. A CMO's liability must be reasonable compared to the earnings under the manufacturing agreement. Consequently, most manufacturing agreements provide for caps on liability and exclude certain types of damages such as lost profits. A client, however, should keep in mind that the potential liability can still really hurt a CMO — otherwise, its project will only have low priority in case of capacity overload.

Confidentiality

Should all information exchanged be treated as confidential or just what is clearly marked as confidential? What is the permitted use of the confidential information? What happens to knowledge and experience that stays in the heads of your employees? The less you are protected by enforceable IP rights, the more important confidentiality provisions become. If you do not have any IP rights at all, you even might want to push for contractual penalties, liquidated damages, or fast-track arbitration. Parties that negotiate a manufacturing agreement will have entered into a confidentiality agreement before. You can certainly incorporate such previous agreements by reference, but make sure that they still provide adequate protection: The sections addressing the scope of exchanged information, the permitted use and the timelines often have to be modified. Also, do explicitly mention a previous confidentiality agreement in the boilerplate clause in the miscellaneous section, which states that the manufacturing agreement contains the *entire* understanding of the parties.

Regulatory Issues

What are the legal, regulatory, and safety standards that apply to manufacturing, storing, shipping, and using the product? Who will be responsible for organizing insurance, transportation, and customs clearance? If regulatory affairs managers and lawyers liaise, these issues can be settled quickly. Furthermore, you can avoid doing the same work twice by clearly dividing what needs to be in the manufacturing agreement and what comprises part of the quality agreement frequently required by regulatory authorities.

Governing Law and Jurisdiction

A common default rule that applies in many countries to international manufacturing agreements provides for the application of the laws of the country of the manufacturer and the jurisdiction of the courts where the defending party is located. Assessing the scope and validity of a manufacturing agreement under foreign law may be cumbersome and require hiring local counsel, which costs both time and money. Sometimes, parties feel more comfortable to agree on the laws of an independent country. Also, referring to international arbitration rules — such as the Rules of International Arbitration of the International Chamber of Commerce — greatly enhances equality among the parties and significantly reduces the

importance of the place the proceedings will occur.

Annexes

What kind of annexes and exhibits will be needed? Make sure to negotiate the main agreement, its annexes and the quality agreement at the same time. Otherwise, you are likely to rediscover in the annexes the unfavorable provisions deleted from the main agreement.

If you receive a first draft of a manufacturing agreement from the other party, make sure that these points are clearly addressed. You — and your lawyers — should then thoroughly examine the draft and ask for modifications to accommodate your specific needs and expectations. While drafting the agreement, keep in mind that, in case of a dispute, a judge or even an arbiter deciding on a dispute under the agreement will not have the same knowledge about your business that you have. Thus, when describing what you expect from the other party, be precise, comprehensive, and generally understandable. Try to scrutinize your assumptions and do not be afraid of spelling out self-evident technical issues in the agreement. This will both bring forward varied interpretations between the parties and help you in case of later disputes or litigation.

Monitoring Compliance

Signing a manufacturing agreement and starting to co-operate on a day-to-day basis is quite an achievement for any drug development project. This does not mean that the manufacturing agreement should be filed away and forgotten. Despite frequent provisions providing for contact persons, project managers and steering committees, the day-to-day co-operation needed to advance to project occurs rather informally. However, the manufacturing agreement regularly asks for formal actions such as filings, deliveries, reports, notices, or declarations. It is essential that both the developing company and the manufacturer track the project and live up to any such administrative provisions. If a party fails to perform such administrative tasks, this might result in forfeiture of rights under the agreement or even lead to liability for damages due to breach of contract. Observing such provisions usually enhances communication between the parties, allows identification of critical issues at a time when a resolution is still possible, and might even spur on future projects and collaborations. ■