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Make The Service Agreement Work For You And Your CDMO

Proper knowledge of the applicable rules and legal challenges, as well as ways to ensure the enforcement of proprietary rights, requires companies to invest in negotiating and drafting robust and balanced CDMO service agreements. The purpose of this article is to provide practical tips for drafting these vital legal agreements.

Tips For Both The Principal And The CDMO

Define The Scope Of The Services

Clearly identify, apart from the manufacturing task, the scope of the services to be provided by the CDMO. In particular, specify who is responsible for:

- generating and gathering the regulatory documentation: this will determine who is responsible when the competent authority requests additional data (and therefore studies) in order to have the product authorized/certified/registered or if the product is eventually not authorized/ certified/registere
- compliance of the product with the law of the country where the product will be eventually placed on the market: this will determine who is responsible if the product is eventually found not in compliance with the applicable law and, therefore, possibly subject to a recall from the market. If the CDMO is responsible, then it should further be specified whether the CDMO — before the competent authorities — remains a mere factual manufacturer of the product or whether it is considered the legal manufacturer; and
- the supply/check of conformity of raw materials from third parties: this will have an impact on which party can be held liable in case of delays in the supply of raw materials or deficiencies in the raw materials.

Regulate IPR (Intellectual Property Rights)

Usually, the parties will not only generate results that can be protected by IPR (so-called “foreground IP”), but they will also use previously developed IPRs (whether owned by the CDMO or the principal, the so-called “background IP”). Therefore, it is important to specify who shall be the owner of the foreground IP and to provide for a clear regime of licensing/usage rights of the background IP.

Further rights and obligations of the parties should be clearly defined (in particular, insofar as it concerns inspections/audit rights, transfer technology rights and obligations, the right for the principal to appoint additional/other manufacturers, the rules in case of changes to the manufacturing process, and the effects of termination).

In cases of joint ownership, the agreement should also regulate the decision-making process (i.e., who decides, and how, when it comes to the protection and exploitation of IPRs).

Identify The Laws And Guidelines With Which The CDMO Must Comply

As it is common that the CDMO manufacture products that are intended to be placed on the market in a country different from the country where the products were originally manufactured, it is important to identify which laws apply.

Specify What Happens In Case Of Changes To The Manufacturing Proces

Changes to the manufacturing process have significant consequences: they may require significant financial investments, may require amendments to the regulatory documentation, and might cause a temporary suspension of the production. Therefore, the service agreement should specify:

- whether the CDMO is authorized to voluntarily introduce changes to the manufacturing process
- whether the CDMO is obliged to introduce changes to the manufacturing process upon request from both the principal and/or the competent authority; and
- who should pay for such changes, particularly when the changes are not voluntarily introduced by the manufacturer.

Provide For Appropriate Confidentiality Clauses

Both parties may have to disclose confidential know-how under the service agreement. Appropriate and rigorous confidentiality clauses (including restrictions on use and disclosure — also within each company, by way of confidentiality clubs — as well as ownership) should be provided to ensure confidentiality. A particular issue with such confidential know-how may arise when the CDMO uses its own proprietary processes in the manufacturing/development of the products. In such cases, it may not be willing to disclose or license these processes to the principal or to any other manufacturer. This generates a multitude of legal issues:

- what if the principal wishes to appoint another manufacturer—does it have to change the manufacturing process?
- how to deal with the technical file before the competent authorities; and
- what happens if the CDMO cannot ensure continuity in its services but does not wish to disclose or transfer its knowhow to another CDMO?, etc.

Tips For The Principal

Anticipate An Increase In The Goods' Prices

Due to the recent pandemic and the geopolitical situation, the prices of raw materials and energy have significantly increased. Therefore, it is more important than ever to clearly specify whether the CDMO may increase its fee and, if so, which modalities it has to comply with (unilaterally or not, only once during a contractual year or at any time during a contractual year, subject or not to the demonstration of a correspondent increase in manufacturing costs, subject to a certain cap or not).

Usually, a fair compromise for both parties is to consider an annual review of the CDMO fees, where an increase reflects the actual increase of manufacturing cost and is subject to a cap. In the absence of such a clause, some national laws might recognize the concept of hardship.

Indicate What Happens In Case Of Defects And Recal

In principle, the manufacturer is liable for manufacturing defects. However, there are situations where a product that is not defective (meaning it has been manufactured in compliance with its technical specification) may still be subject to a recall from the market. This may occur when a product is found to be dangerous to human health after its use on a larger scale of people (compared to the population involved in the relevant clinical trials). It is therefore recommended to specify:

- who is responsible to decide about a recall (when this has not been ordered by the competent authority)
- who should bear the costs for the recall; and

- which party should be liable for the damages caused by the recall and, more generally, by the product (including, for example, claims from third parties) and the extent of this liability (loss of profits, consequential losses, etc.), taking into account that certain exclusions/limitations of liability are prohibited under national law.

Regarding the last aspect (i.e., responsibility for damages), it is often useful to ascertain the actual cause of the recall and possibly of the damage. To that end, it is important to ensure that the principal has adequate inspection and access rights to the technical documentation pertaining to the product. In cases where the service agreement is silent on this respect and the relevant information is held by a public administration (as it would be for technical information submitted before a competent authority for the purpose of authorization/certification/registration of a product), the principal could rely on the applicable laws on access to documents (also called freedom of information laws), which may differ from one country to another.

Specify What Happens At The Termination Of The Service Agreement

The agreement should clearly indicate the effects of its termination. If these aspects are not clearly defined, there might be uncertainties, for example, about the following issues:

- whether the principal has the necessary IPRs to continue manufacturing the products with another manufacturer
- whether the CDMO is obliged to facilitate the transfer of the relevant technology (if this belongs to the principal) to another manufacturer; and
- whether, after the termination of the service agreement, a transitional period applies, during which the CDMO will still be responsible for manufacturing the product (and therefore for the business continuity) pending the technology transfer and completion of the relevant regulatory procedures.

Tips For The CDMO

Principal Minimum Obligations

When the final formulation of the product has not yet been defined (and, consequently, the product has not yet been authorized), it is recommended to provide in the service agreement that at the achievement of a certain result (normally the production of a certain number of batches of the product compliant with the applicable technical specifications), the principal shall be obliged to request the authorization/ certification/registration of the product, as the case may be, and that when the product is eventually placed on the market, the principal shall be obliged to purchase the product exclusively from the CDMO and possibly in a certain minimum amount per contractual year. This is meant to enable the CDMO to get a return on investment and avoid a scenario where the principal changes its business strategies (deciding to no longer market the product or adequately invest in the project).

Limitation Of Liability Clauses

It is always in the CDMO's interest to limit/exclude its liabilities insofar as allowed under the applicable law.

Timeline

While the principal has a clear interest in imposing fixed dates for the manufacture (and development) of the products, the CDMO's interest is to gain some flexibility in the process, to avoid penalties caused by delays.

Source

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