Unlocking Germany's Potential

In the face of mounting pressure on the pharmaceutical and biotech sector to hit punishing targets, outsourcing has increasingly been touted as the panacea to an industry's ills. Henning Mennenoeh and Wolfgang Kircher of Hogan & Hartson ponder whether Germany will embrace this movement.

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In contrast to more mature markets like the US or UK, the German market for outsourcing services to pharmaceutical and biotech companies is less developed. The potential for growth in this area over the next few years is particularly strong. This update outlines typical deal structures and important legal issues relating to service agreements and the transfer of assets in connection with life sciences outsourcing deals in Germany.

The international pharmaceutical and biotechnology industry has felt increasing pressure to achieve more efficient cost structures. The reasons for the need to reduce costs include: losses of sales as a result of expirations of patents; lack of new potential blockbusters; increasing costs for research, development and manufacturing of drugs resulting from stricter regulatory requirements; and new price restrictions in many markets. A growing number of companies have responded to this pressure by outsourcing research, development, manufacturing, sales or other functions to specialised external service providers.

The number of suppliers in the market for services to pharmaceutical and biotech companies is increasing quickly. These focus on a specific segment of the value chain and offer special expertise, flexibility and cost benefits. They also enable their customers to concentrate on their own core competencies. The most important areas of outsourcing in the life sciences sector are contract research, contract manufacturing and contract sales – all with high annual growth rates. Other areas of outsourcing in the sector include logistics, IT, HR, procurement, facility management and security.

TYPICAL DEAL STRUCTURES

Traditional Structures

The traditional outsourcing structure is a contractual relationship between the customer and the supplier with respect to the outsourced services, which may also involve the transfer of certain relevant assets and employment relationships from the customer to the supplier. The service agreement is either exclusive (in which case the supplier may or may not be entitled to use sub-contractors) or non-exclusive, allowing the customer to use other suppliers too. The customer will usually agree to the use of sub-contractors only, provided that the supplier remains fully liable under the outsourcing agreement. If the customer prefers non-exclusivity, it will often have to agree to minimum revenue commitments in favour of the supplier. The customer should be aware that integration of services may become an issue if it uses several suppliers.

Joint Venture Structures

In multi-party outsourcing transactions, a joint venture structure, involving a new company rendering the outsourced services to the customer on the basis of a service agreement, is often preferable to a traditional structure. The parties to the joint venture should ensure compliance with all applicable anti-trust laws. There are several ways to implement a joint venture structure. For example:

- Multiple suppliers can form a joint venture company that services either one customer exclusively or several customers
- Multiple customers form a joint venture company that combines their market power for particular areas of demand such as logistics
- Customer(s) and supplier(s) can form a joint venture company that provides services to the customer(s) and potentially also to new customers outside the joint venture

Although this last option enables the customer to exercise a great degree of control, doing so is costly in terms of time and money. In view of the fact that concerns regarding control may be sufficiently addressed by a service agreement within the traditional structure, such added expenses may not be

justifiable. All structures may entail the transfer of certain relevant assets and employment relationships from the customer and/or supplier to the joint venture company.

TYPICAL RISKS

Risks must be properly managed and controlled in order for the decision to outsource to pay off. These should be addressed and allocated in the outsourcing agreements – in particular the performance risk (in relation to the delivery of the service), the costs risk (regarding the realisation of costs savings) and the reputational risk (in relation to the overall impact of the service on the customer's business and goodwill). The customer needs to retain key controls to manage the risks it faces as a result of the transfer to the supplier of part of its business operations, while the supplier should be given sufficient operational control to generate value and to control its own performance risk.

SERVICES AGREEMENT

The principal agreement governing the contractual relationship between the supplier and the customer is the services agreement containing the commercial terms applicable to the provision of services. Most services agreements have numerous detailed schedules setting out, for example, specifications and details as to the service levels, relationship management, security and audit.

In multi-jurisdictional transactions, a master services agreement and, if necessary, master transfer agreement set out the principal commercial terms of the contractual relationship. They are usually complemented by local services agreements and, if necessary, local transfer agreements which take into account the local law particularities relevant in connection with the implementation and execution of the outsourcing services.

General Issues

There are five key issues in any services agreement on which the parties should focus throughout the negotiations: the scope of services and service fees; customer protections; supplier protections; termination; and liability.

A key issue of the negotiations is the exact scope of services and the calculation of the service fees, which are in many cases linked to service levels. It is in the customer's interest to negotiate contractual provisions on a change control process, and thus maintain flexibility regarding the volume and the type of services required.

Where the scope of services cannot be set by reference to existing service levels or a standard market practice, the parties may agree on a post-contract verification process pursuant to which the service level baseline is agreed in a transitional period after the signing of the agreement. In such cases, it is very important to agree on objective criteria for the post-contract verification process. The parties can appoint an independent expert to apply such criteria. Inflation risks are often balanced by linking the fees to a price index. Given some restrictions under German law in this respect, indexation clauses should be very carefully drafted.

Another important part of the negotiations of a typical outsourcing services agreement is customer protections, which usually include provisions with regard to audit rights, benchmarking, business continuity, regulatory compliance, disaster recovery, intellectual property rights, reporting and governance, security, service levels and service credits, step-in rights and representations and warranties. The customer should be aware that a very broad range of customer protections is not always advantageous, as it is likely to increase the service fees and the scope of the customer's management obligations. Consequently, a balanced approach is recommended, focusing on the protections that are most important to the customer.

On the other hand, a balanced outsourcing services agreement also provides for supplier protections, such as a minimum revenue commitment by the customer, service debits if the supplier exceeds the contractual standards and certainty as to the scope of services (which must be weighed against the customer's flexibility needs). The scope of the supplier's remedies in the event that the customer fails to perform its obligations is often a negotiating issue. The customer can argue that in most cases, relief of the supplier's obligation to render the contractual services will be a sufficient means of protection.

A further key issue of negotiations is termination rights and consequences. In order to avoid disputes at a later stage, the outsourcing agreement should be as specific as possible with respect to circumstances that trigger termination rights and their consequences. The parties should be aware that, pursuant to German case law, they cannot validly exclude the extraordinary termination of the outsourcing agreement for cause – but they can, and should, define instances constituting such cause (for example failure to meet a specific service level or change of control).

The parties should also agree on an exit plan for post termination issues. For instance, the scope of, and fees for, transition support and training, the customer's access to know-how, the ownership – and possibly licensing – of intellectual property rights, in particular with regard to new inventions and bespoke intellectual property rights first reduced to practice by the supplier during the term of the outsourcing agreement should all be discussed. Further, employee issues likely to arise in connection with the termination should be addressed, for example by way of a non-solicitation obligation with respect to employees of the other party.

Another focus of the negotiations is allocation of liability and risk apportionment. Damages in cases of *force majeure* and for indirect and consequential loss, as well as for loss of profits, are often excluded in the services agreement. To avoid any misunderstanding it is advisable to look carefully at the meaning of terms like indirect or consequential loss. There are also certain kinds of liability which cannot be excluded or limited under German law: liability for intentional acts or omissions (wilful misconduct) can never be excluded or limited, and liability for gross negligence and death or personal injury can only be excluded or limited to a certain extent.

SPECIAL ISSUES IN THE PHARMACEUTICAL/BIOTECHNOLOGY BUSINESS

Typically, there are at least two major areas in services agreements relating to pharmaceutical and biotechnology activities that require particular attention, namely:

- Conformity and compliance
- Allocation of responsibilities

With respect to conformity and compliance, the agreements governing the outsourcing relationship should specify all relevant laws, rules, regulations and standards which are applicable to the services outsourced to the supplier. References should be made; for example, to the current GMP of all relevant countries, the European Pharmacopoeia and its international equivalents, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, and the WHO standards. Further details of conformity requirements are often set out in a quality agreement that is attached to the services agreement as an exhibit, and in additional exhibits which contain, for example, specifications, the customer's technical information and instructions on manufacturing and testing. The agreement should contain a provision to the effect that the supplier is responsible for the compliance with all regulatory changes.

It is in the interest of the customer to retain audit rights in order to verify the supplier's compliance with the contractual conformity requirements. The customer will also wish to have product recalls and withdrawals under his control and to impose a co-operation duty on the supplier. Additionally, the service agreement should provide for an obligation of the supplier to notify the customer without delay if any specifications are not achieved, any other compliance issues arise and if any regulatory inspections are announced. A mechanism to implement changes to specifications, manufacturing procedures or other applicable contractual standards should be set out in an exhibit regarding change and deviation management.

The supplier usually warrants the conformity with the agreed standards as described above, in most cases in the form of a non-fault guarantee German law. In addition, the services agreement often includes guarantees by the supplier to the effect that: it has sufficient resources and capacity; no conflicting agreements exist; there is no violation of third-parties' intellectual property rights; and the supplier has all required public authorisations in place.

As far as allocation of responsibilities is concerned, it is important that no doubt remains as to which party is responsible for the various elements of the outsourced pharmaceutical activities. The often very complex nature of outsourcing in the pharmaceutical and biotechnology sector usually necessitates extensive schedules to the services agreement that precisely allocate the responsibilities. In contract manufacturing agreements, for instance, these include product and process validation, the individual production steps, in-process controls and batch protocols, selection of samples and analysis thereof, the determination of product conformity if the parties disagree, record keeping and obtaining and maintaining required approvals and licenses.

In light of certain German law requirements, it is occasionally insufficient to allocate responsibility to either of the parties, but certain responsible persons also have to be determined – for example the Production Manager (Herstellungsleiter), Control Manager (Kontrollleiter) and Sales Manager (Vertriebsleiter) (1).

TRANSFER OF ASSETS

If the outsourcing deal provides for the transfer of certain assets and employment relationships from the customer to the supplier or the joint venture company, the following options exist for such transfer under German law: asset deal; share deal; contribution in kind; and spin-off (Ausgliederung or Abspaltung). The decision for any of these options should be based on the careful analysis of all relevant factors, for instance tax implications, timing, costs and liability risks.

The transfer by way of asset deal is often complex, as German law requires the identification of the assets in the agreement or annexes thereto, for example by detailed asset lists. The assignment of contracts and of liabilities requires the third-party's consent.

A transfer by way of share deal is generally straightforward and includes the rights and obligations of the transferred entity without any third-party consent requirements (third-parties may, however, in some cases exercise contractual termination rights based on a change of control). As there is usually no separate legal entity holding just the assets and contracts that are relevant to the outsourcing transaction, an asset transfer, with the implications described above, will in most cases have to precede the share transfer.

By way of a contribution in kind, listed assets and liabilities can be transferred (as described under 'asset deal' above) from the customer to a joint venture company against issuance of a shareholding in the joint venture company to the customer. Depending on the legal form of the joint venture company, different German corporate law requirements, for example registration in the commercial register and/or notarisation of the corporate documents, must be satisfied.

A spin-off pursuant to the German Business Transformation Act results in the automatic transfer by way of law of listed assets, contracts and liabilities from the customer to a joint venture company against issuance of a shareholding in the joint venture company to the customer. Except in cases where the assignment is excluded by contract, no third-party consent is required for the transfer to become effective. There are various notarisation and registration requirements under German in connection with such spin-offs.

The co-ordination of the various agreements and schedules necessary to implement an outsourcing deal is a challenging task, especially if assets and employment relationships are transferred. Diligent planning and co-ordination of the separate steps is very important to properly protect each of the parties against possible risks and to avoid disputes at a later stage. ◆

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Reference

1. cf. sections 14 and 15 of the German Drug Act – AMG