IP issues in outsourcing R&D

Life sciences companies are increasingly outsourcing R&D to keep pace with scientific and technological advancements and tougher regulatory demands. In selecting the optimal approach, they must take care to assess the opportunities and potential pitfalls

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Research and development (R&D), the lifeblood of the pharmaceuticals and life sciences industries, has become increasingly complex as a result of rapid advances in molecular biology and bioinformatics, coupled with the rising demands of clinical trials and regulatory submissions. Companies in the life sciences industries are turning to alternative solutions such as outsourcing R&D to keep pace with such rapid changes. Whether the chosen solution will succeed depends in large part on the scope of intellectual property protection, since success in the pharmaceuticals and life sciences industries is highly dependent on strong protection of IP rights.

In particular, proper allocation of IP rights between contracting parties is a key concern. Potential problems can be avoided by making sure that each relationship has well-defined IP provisions that clearly define the scope of ownership and use rights. This article provides an overview of different approaches to outsourcing R&D, together with the opportunities and potential pitfalls.

Internal R&D

Typically, companies that frequently engage in extensive R&D consider using their own internal resources and facilities before outsourcing some portion of their R&D function. On the one hand, internally conducted R&D raises fewer questions with respect to the ownership of IP rights that may result from execution of the R&D project. Research conducted internally can also significantly lower the risk that important confidential know-how might be disclosed to the public, and to competitors in particular.

However, other decisive factors may hinder independent research. For example, a company needs human resources with both the capacity and the right capability for research projects. Companies must consider whether their human resources can be used in a more productive way. Could others do the research work more efficiently due to their specialised experience? In some cases a company may be required to look elsewhere for R&D capabilities. Another aspect is that specific funds granted by national governments and the EU research framework programmes such as the Seventh Framework Programme require the participation of a number of entities with different obligations. Such programmes can also drive the need to look to external resources.

Conventional outsourcing to third parties

One alternative to performing internal R&D is to outsource the R&D work to a third party. Outsourcing tools have expanded in scope to provide strategic and business advantages for pharmaceuticals and life sciences companies. In particular, outsourcing can provide a number of financial advantages such as cost reduction and broader access to new expertise and technology, while improving process quality. Significantly, outsourcing can help to

shorten the time to market. Companies not only outsource non-core functions such as clinical trials and manufacturing, but are increasingly seeking to improve productivity and efficiencies throughout the entire development and marketing value chain, including drug discovery and other critical R&D.

In a conventional sense, outsourcing involves a relationship between a company seeking to transfer some R&D function externally and its contracting partner, which is obligated to conduct the specific R&D as defined by the company. In exchange, the contract partner is compensated according to an agreed scheme for services rendered. This raises one of several potential pitfalls for R&D outsourcing arrangements, since the outcome of any R&D project — particularly in the life sciences industries — cannot be predicted with a high degree of certainty. Specifically, an external contract party generally will not provide a warranty that the services will produce a specific result, but rather will tie its obligations to some performance standard. In this respect, the company seeking outsourcing services cedes control of the project and may wish to negotiate for the appropriate performance standard that it would expend on the project were the R&D conducted internally.

Another potential drawback can be the degree of difficulty required to transfer any new technology from the outsourcing partner back to the paying company, in addition to the risk that some know-how may be lost in the process. On the positive side, however, in addition to gaining access to high-quality R&D capabilities, the paying company should secure sole ownership of, or at least exclusive licence rights to, any IP rights developed pursuant to the research project.

Outsourcing to universities

In the case of outsourcing involving university scientists, specific issues must also be taken into consideration. For example, the contractual participation of both the university and the scientists is recommended in some jurisdictions (eg, under German law). As a result of the abolition of the professors' privilege in the German Employee Inventions Act, universities have the right to claim inventions from their scientists and return of payment of 30% of any proceeds received through commercialisation of the invention, on condition that the invention was made in the context of performing a service on behalf of another party. Thus, a company seeking to outsource an R&D project in this context should seek a waiver from the university to claim the rights to the inventions made by the scientist. Alternatively, the company should negotiate an obligation on the part of the university to claim all such inventions under the R&D project, together with a direct transfer of all such rights to the paying company.

Additionally, the scientists actually undertaking the research should be contracting parties to the definitive agreement, to ensure that they are also obliged not only to undertake the research. The company should also seek a waiver from the scientists concerning their so-called "negative publication rights", which the university cannot require them to waive in advance. Such negotiations with universities on R&D projects sometimes prove time consuming. Additionally, companies should keep in mind that universities tend to desire to retain ownership of any so-called "foreground IP rights" which are developed under the R&D project and are willing only to grant (exclusive) licences.

R&D collaborations

Collaboration arrangements are another mechanism for performance of high-quality R&D through external resources. They are most common between parties with different strengths. For example, in the medical devices industry, one partner may be specialised in software-related technologies, while the other provides the relevant device know-how and corresponding clinical experience. The advantage of such a collaboration is clear, as each party contributes its own specific know-how, resulting in a competitive time and cost-saving advantage with respect to third parties.

In the case of collaborations between direct competitors, the parties may seek to reduce or eliminate competition. Collaboration in any R&D project works best when the parties minimise the possibility of disputes by integrating carefully circumscribed IP clauses into their agreement that reflect their business and strategic needs. Typically, any background IP owned, developed or otherwise controlled by one of the parties before starting the R&D project remains the sole property of the original owner. The other party, however, may require a non-exclusive licence under market conditions to use such background IP after the successful termination of the R&D project, if necessary for use of the results of the R&D project.

The parties also need to account for the right to use any foreground IP rights. A

practical patent/know-how protection strategy is necessary for the protection of such new IP rights. Should the inventions just be kept confidential as trade secrets or do the parties wish to file patent applications? If so, where should any patent application(s) be filed? If not, how can know-how be kept secret and is the scope of protection adequate to protect the business needs of the parties? Additionally, both parties need to ensure that they adequately protect their employees' inventions, such as by using appropriate invention assignment provisions in their employment agreements. Also, they should properly claim the rights to their employees' inventions in accordance with the applicable law in those jurisdictions where they are required to do so in order to perfect their rights.

Furthermore, foreground IP rights should be allocated to the parties according to their intellectual, financial and actual contributions, as well as under consideration of their core business objectives and future intentions. The field of use must also be determined, while at the same time managing potential antitrust issues. Other significant problems may arise in connection with the principle of exhaustion if both parties are free to use the new IP without restriction and if they are entitled to grant licences to third parties. The potential insolvency of one of the collaboration partners must also be addressed in the R&D agreement.

In sum, collaboration arrangements provide a valuable tool for improving R&D functions, but can also raise significant legal questions which must be specifically addressed in the R&D agreement.

Joint ventures

Parties occasionally enter into even more complex relationships where they form new legal entities to control their combined interests separately from their core businesses. For example, they may enter into a separate joint venture agreement with the goal of growing a new business focused on a specific R&D function, and perhaps later on manufacturing and production of products resulting from the R&D projects. Joint ventures can operate to create a formal structure requiring each party to make specifically defined financial and other capital contributions, as well as contributions of know-how and human resources. However, formation of the joint venture typically foresees the exit of one of the partners at a later date.

Problems can arise in relation to loss of know-how and confidential information, in addition to other questions of IP ownership — in particular, when one of the parties eventually leaves. IP clauses in a joint venture arrangement must therefore take into account the consequences of an exit by one or both parties. In particular, the contractual treatment of any dual-use rights used by the joint venture is challenging and requires an in-depth analysis of all parties' needs. Furthermore, the formation of a joint venture requires sound antitrust advice.

IP acquisitions

Another commonly considered option is the simple acquisition of an IP portfolio covering a strategically important product, process tools and/or corresponding methods for treating relevant diseases or conditions. Such acquisitions can require extensive scientific and legal due diligence. As a practical matter, the scope of the IP rights and legal ownership must be confirmed. Consideration should also be given to the impact of local laws on the presumed scope of the rights. For example, in the United States patent owners are perceived to find it more difficult to obtain an injunction against infringers in some cases; although the conventional justification that the decision should block patent trolls with no commercial products does not apply in the same way to the life sciences industries, where companies frequently perform research but do not bring commercial products to market.

Since much or all of the difficult R&D work is usually already completed in IP acquisition transactions and some degree of certainty has already been established, the acquisition of developed IP rights can be expensive. Further, opportunities to acquire patents protecting pharmaceuticals which have already received regulatory marketing approval from the relevant agencies are rare. Even where such opportunities exist, the potential purchaser should consider that scientists, and specifically research institutes, often wish to retain some ownership interest in the patent portfolio in order to use it for further projects. In such cases, the parties must be sure to define carefully their respective IP rights in order to assure that they can achieve their individual business objectives.

In-licensing

Frequently, patent portfolios or other relevant IP rights will already have been developed by a third party that may be unwilling to transfer fully the rights. Alternatively, the rights holder may desire to share its technology and rights with

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multiple partners through non-exclusive relationships. In such cases the parties commonly enter into licensing arrangements. As in the other scenarios presented here, the scope and limitations of the rights granted must be carefully considered and described in the documentation.

One problem feared by IP rights owners – particularly in the case of exclusive licence agreements – is that the licensee will not fully exploit the IP in an attempt to hinder competition with one of its existing products (and thus the licensor may not receive what it perceives to be adequate compensation for granting the licence). The licensor thus commonly requires the licensee to pay minimum royalties. The licensor may also ask for an affirmative obligation to exploit the IP rights for the manufacture and distribution of the licensed products pursuant to some defined performance standards, as a way to incentivise exploitation of the IP rights.

Another factor that should be taken into consideration and addressed in the agreement is whether and to what extent the licensee may challenge the validity of the underlying licensed IP rights. In the United States, for example, a licensee in good standing is permitted to seek to invalidate licensed patents. Licensors that are interested in foreclosing the opportunity for potential licensees to seek invalidation should consider which options might be permitted without raising antitrust concerns in the relevant jurisdiction.

Another significant issue from the licensee's perspective– at least under German law – is the licensor's insolvency. In the event of the bankruptcy or insolvency of the licensor, the insolvency administrator has discretion to terminate the licence agreement, despite significant investment in the project by the licensee. Thus, the licensee must consider potential alternatives in advance.

Recommendation

The optimal strategy for enhancing R&D opportunities must be assessed and selected on a case-by-case basis, with careful consideration of the potential advantages and pitfalls. The primary considerations must always include the specific business requirements and objectives of the relative parties, which should be clearly defined from the outset of the project. Companies should use a robust selection process to identify appropriate partners. The relevant factors should include adequate consideration of the scope of IP protection afforded by the legal regime of the partner's jurisdiction, since industrial espionage and poor IP protection can severely undermine outsourcing objectives. By paying careful attention to these details, a company will be more likely to optimise the financial advantages of pursuing value-added, high-end research and increase its chances of commercial success. *iam*

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