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INSIGHTS

Partner with your Legal Team for Successful R&D Collaborations

If innovation teams partner with legal up-front, "legal" can be a force for success in R&D collaborations rather than the stereotypical obstacle to closing partnership deals quickly and effectively.

Pharmaceutical companies are increasingly entering into R&D collaborations with external parties that create Intellectual Property (IP) and competition law considerations. The pharma companies' legal teams have a critical and important role for the success of such collaborations. They are the "risk gatekeepers" between the internal and external worlds, ensuring success through a balanced approach to risk mitigation. An excessively risk-averse approach can hinder the potential outcomes of a collaboration or at worst terminate it before an agreement can be reached. On the contrary, limited effective risk assessment and mitigation can endanger the company's unique advantages. To explore good practice in this area we have explored the "voice of legal" based on a set of targeted interviews with internal and external lawyers and our experience. Our conclusion shows that if innovation teams partner with legal up-front, "legal" can be a force for success in R&D collaborations rather than the stereotypical obstacle to closing partnership deals quickly and effectively.

In this paper, we cover the important legal considerations that R&D teams must consider as they engage with external parties such as industry consortia, academic institutions and other pharma/biotech companies. First we review how best to manage and own the Intellectual Property (IP). Then we explore how to deal with contamination and spillovers, and finally we will look at compliance and jurisdiction laws that can have an impact

on R&D collaborations. We have based our paper on a set of interviews with lawyers at pharmaceutical companies and external lawyers who work across industries including pharma/biotech.

Clarify IP ownership and licence arrangements early on

In the Pharma industry, the management and ownership of Intellectual Property (IP) can be highly complex and challenging issues for companies and their partners when embarking on R&D collaborations. Pharma companies tend to hold on to their IP very tightly as it is considered to be its main value creator and an entry barrier to other competitors. In that respect, Pharma companies can be quite traditional when it comes to IP: they are very IP rich, aware of it and are not willing to share it or open it easily. To address this frame of mind, companies need to look at their IP with fresh eyes and draw the line between sharing and giving access to what is not critical while retaining a competitive advantage by protecting what is considered their own and should therefore remain a black box to the partners. This can require a change of mindset with regards to what is important IP and what is not.

> **"Who is responsible of filing the patent? Who is going to pay for the costs? Who is protecting it? Will it be used in different fields of activity between the partners?"**

When initiating a partnership it is critical to start with the difficult discussion first and agree with all parties how new created IP will be managed and who will own it. Questions to answer include: who is responsible of filing the patent? Who is going to pay for the costs? Who is protecting it? Will it be used in different fields of activity between the partners? What happens when it is licensed to others? What are the rules and royalty payments? What happens when it is sold? The innovation team needs to think about all aspects of the collaboration and have a discussion with the partner upfront about such matters.

It is also important to note that IP ownership is not always necessary, especially if a broad and strong license is negotiated. A licence can be good enough and in some cases may be better than ownership, as it carries lower risks. This is often the case when partnering with academia: pharmaceutical companies can prefer to access IP through licensing or options from the academic scientists to build trust. Academics are motivated by doing cutting edge research, publishing papers, filling patents and accessing funds, while sharing the risks and rewards, which should be considered when negotiating the partnership. The fear over IP is increased if the partnership involves parties of different sizes: it is important to be transparent to nurture a trusted relationship with the partners of all types.

In the special case of co-ownership of IP all details from the logistics of the filling to the split of the potential reward should be defined, clarified and settled early on.

Some companies prefer to work with the same partner once the trust and ways of working are agreed, as it makes the following collaborations easier. In the case of multiple parties partnering with an academic institution or centre, it is important that the industry partners have a common approach to simplify the complexity from having multiple parties involved.

For IP, pharma companies should therefore ensure alignment across the organisation regarding IP considerations as follows:

1. Involve the legal and patent team early on in partnership discussions
2. Develop a clear risk mitigation plan and share it with the senior management and the partnership team to make sure that the IP risks are clearly understood and accepted
3. Ensure that good internal governance is in place to address IP risks

Manage contamination risks proactively

A commonly mentioned risk when working with external partners is contamination. In the excitement of research and motivation to solve problems, won't scientists divulge more than what it is in scope for the collaboration?

For this specific risk, the legal team has the opportunity to play an important role in helping the company to protect its critical secret sauce, its value creation engine and its technological differentiation. Education of the innovation team and the scientists working directly with the partners on the legal risks associated with the specific project is indeed the first safeguard to be put in place against spill-overs and contamination.

Scientists need to be on top of what is specifically in scope for the partnered project and what is not. The awareness should cover all workforce and not be restricted to senior staff. In the case of technology transfers, the confidentiality agreement needs to define and clarify the remit and set up good working practices. The Stevenage Labs is a good example of successful collaborative research between GSK scientists and external scientists that can come and use the lab. One of the reasons for its success is the dedication of space to the specific scope of planned collaborations to avoid contamination. A data repository related to each collaborative project can also be separated and ring-fenced from other proprietary data.

To avoid contamination and negative spill-overs:

1. The legal team should be very proactive, drafting policies, frameworks and procedures
2. The organisation should be clear from the start of the collaboration about what information data, methodologies, processes, capabilities and technologies are to be shared and how
3. Scientists should record and track their work to ensure traceability in the case of future litigation

Stay on top of competition law changes and jurisdiction variability

Competition laws are designed to ensure competition between companies, so R&D collaboration agreements between pharmaceutical companies can raise compliance issues. This is therefore a dimension that needs to be considered carefully when entering into an R&D collaboration. Even if EU competition law and US antitrust law are similar, it is important to understand national competition law subtleties when partnering outside of those geographical areas.

Competition law will always be modernised as new creative partnership agreements are signed, and innovation teams need to work closely with their legal teams to ensure that the agreements are compliant with the latest competition laws in place.

As an example, the European Commission document “Intellectual property and legal issues in open innovation in services” raises a number of questions in connection with Open Innovation and competition law. The use of intense networking between companies to develop the creative commons and positive spill-over effects implies a concentrated market structure, and significant cooperation between companies. This prompts legitimate antitrust concern and can result in calls for a competition analysis. The document does also recognise the complexity of Open Innovation projects and generally does not have a problem with research and specialisation agreements, and in fact positively encourages them in the framework of research programmes (e.g. Horizon 2020). Competition law will always be modernised as new creative partnership agreements are signed, and innovation teams need to work closely with their legal teams to ensure that the agreements are compliant with the latest competition laws in place. For example one such modernisation of competition law occurred with the European Community Merger Regulation adopted in 2004.

There is a perception from some pharmaceutical companies that the UK politically has always pushed for innovation, and promoted partnership and collaboration with academia. This is probably a reflection of the UK succeeding in creating a ripe environment to bring academia and industry together by facilitating access to funding from non-governmental organisations (such as Cancer Research UK and Medical Research Council, as well as the European Commission. On the other hand, US regulation is typically perceived to be less favourable, though this may change in the future. The Leahy–Smith America Invents Act (AIA) was implemented in 2013 and it switches the US patent system from 'First to invent' to 'First inventor to file'. This aims to reduce the patent protection but potentially reduce the number of IP litigations.

In summary, the innovation teams of Pharma companies should work closely with their legal and patent teams to understand and keep up to date of the regulation of the territories in which their R&D collaborations will be active, be it for competition laws or patent regulations or both.

Conclusion

Many Pharma companies are now seeing the benefits of R&D collaborations, and those that have not yet done so are typically looking for ways to do more. Pharma companies tend to be more comfortable with taking higher risks as they have more funding and money than their smaller biotech counterparts. Smaller biotechs tend to be less well funded and are therefore more protective, using R&D collaborations and consortiums to plug their funding gaps. In this context he biggest challenge for Pharma companies is to accept that in R&D collaborations some control may be lost, and to put in place mechanisms to mitigate the risks.

Pharma companies' innovation teams therefore need to collaborate with their legal teams early on. If teams are not able to collaborate internally with each other effectively, external collaborations become even more challenging. Nurturing a collaborative mindset across functions and departments is critical: with this mindset, the legal team can be a force for good in delivering successful R&D collaborations through:

- Clarifying IP ownership and licence arrangements early on
- Managing contamination risks proactively
- Staying on top of competition law changes and jurisdiction variability