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Pharma Licensing

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Open Innovation in Pharma Licensing

In recent years, companies operating in the Life Sciences and Healthcare (LSHC) market are engaging more often in open innovation to overcome various R&D and/or commercial challenges.[1] The concept of open innovation involves sourcing new technologies, skills, and knowledge from third parties, in contrast to adopting more traditional or closed models which heavily rely on innovation stemming from in-house developments.[2] According to Deloitte's analysis, biopharma assets sourced via open innovation approaches demonstrate a higher probability of later-phase clinical success than those from closed model product development.[3] For big pharma companies, in-licensing innovative technologies offers many benefits, such as providing a more cost- and time-effective route to bring products to market[4]—therefore, shortening the time for market entry and gaining first-mover advantage over competitors—as well as providing access to talent, new technologies, broader geographies, and different therapeutic areas. Conversely, for smaller pharma/biotech or spin-out companies which may not have the commercial infrastructure to get innovative products to market, partnering with big pharma by out-licensing the technology offers a solution to this problem.

However, for smaller companies in the LSHC market, planning and executing a successful licence campaign with a big pharma company presents multiple challenges. Below we've identified four key factors for consideration to help you navigate the out-licensing process.

1 https://journals.sagepub.com/doi/abs/10.1177/000812560304500301?journalCode=cmra; https://books.google.co.uk/books?hl=en&lr=&id=RdcSDAAAQBAJ&oi=fnd&pg=PR9&ots=kRT94_LeB4&sig=5PijUT2gadXkTTM8mHzgCn4XLX4&redir_esc=y#v=onepage&q&f=false
2 https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-open-innovation.pdf
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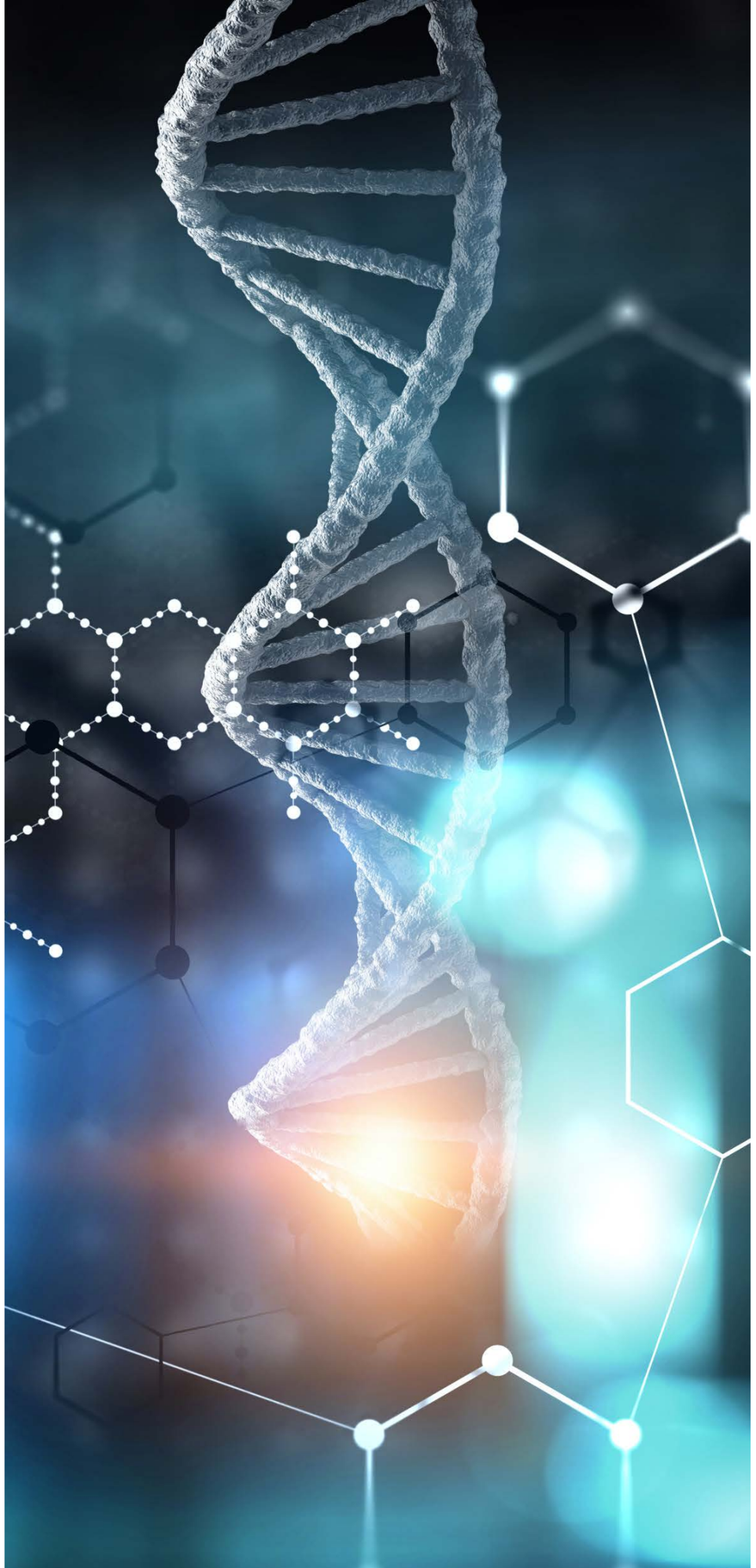
4 https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-open-innovation.pdf



4 Key Factors to Consider

01. Deciding when to seek a partner

Deciding when to seek a partner to out-license your product is largely dependent on the development phase. For example, you may wish to realise value from products still in the earlier phases of development, products which have been deprioritised or are not receiving sufficient commercial support, or even existing products but for new indications, combinations, geographical regions, etc.

For products still in development, partnering early is an appealing option for reducing in-house development costs and development risk. However, it's important to be aware of the potential pitfalls associated with this approach. In particular, partnering early may create premature expectations from investors and big pharma may be less likely to partner for riskier, undefined technologies with limited preclinical and clinical data. The uncertainty surrounding the product during early development is typically reflected in a lower upfront payment[1], and may also increase the risk of a licence deal being terminated early if the product is unsuccessful in later development phases.

On the other hand, if your product is out-licensed at a later development phase, promising clinical results lower the risk for the partner and the product is likely to attract a higher upfront payment.[2] In waiting longer, however, you bear the continued development costs and potential risk of the product not being viable.

In addition to your product's development status, choosing the optimal time to partner may also be affected by market trends or demand for a certain product at a particular time. While high demand for your technology may increase your likelihood of finding a suitable partner, achieving a successful deal could be impacted by greater competition from other licensors.

Early consideration of the value realisation strategy is key to on-going plans. Our dedicated team of IP experts with extensive experience in advising on commercial IP matters can support you through the development of your IP and transaction strategy options and help you develop your IP story.

1 https://www2.deloitte.com/us/en/insights/industry/health-care/biopharma-companies-deals-research-development.html
2 https://www2.deloitte.com/us/en/insights/industry/health-care/biopharma-companies-deals-research-development.html

02. Identifying the right partner

A factor with strong ties to deciding when to partner is identifying the right partner. Gaining an understanding of what technologies, indications, phases of development, etc. the big pharma company is interested in is a crucial step in prioritising companies who may be better suited to your requirements. This process also prompts you to analyse the potential partner's strategy and the fit of your product within the potential partner's existing portfolio.

In addition, business/operational considerations such as a potential partner's geographical coverage, markets, regulatory knowledge, manufacturing facilities, finances, culture, and organisational fit can also help to eliminate less relevant companies. Consider conducting research into potential partners' past partnerships with other companies (ideally with similar products to yours) to provide insight into the abilities of the potential partner to execute a successful commercialisation programme.

Being aware of differences or nuances in corporate culture between your company and a potential partner plays a crucial role in influencing the management of the partnership. In general, the larger the company is, the longer it takes to make decisions. This has a knock-on effect, potentially slowing product development progression, gaining regulatory approvals, time to market, cash flows, and so on. Therefore, it's important to gain an early understanding of cultural fit to build trust and transparency, and manage expectations.

In terms of geographical coverage, it's important to think about your IP portfolio. Notably, what jurisdiction(s) is your product protected in and is your product protected in countries where you seek to commercialise it? Our IP experts can help you to develop an IP strategy and operating plan, ensuring your IP strategy is aligned with your business strategy, and with your internal targets and budgets, enabling you to achieve a strong IP footprint which protects your company's differentiators.

A variety of sources can be used to gather the relevant background information on potential partners. Company websites typically include a dedicated page for partnering or business development and are a good place to start, in addition to industry publications and databases. You may also wish to consider attending and presenting at events or conferences big pharma are likely to attend to garner interest in your research and product.

Finally, having good access to a potential partner's decision makers is highly advantageous, so utilise any existing connections between your key executives and those in the potential partner company. Once discussions start gaining traction with a potential partner, ensure you keep up the momentum in communications.

Our IP team has extensive experience in helping clients maximise the value generated from their IP portfolio. We can support you throughout the partner identification process, from leveraging our connections in the LSHC market to help you to develop a comprehensive list of target licensees, to creating a target pre-qualification and market plan including background research, key angles, and final target prioritisation.

03. Prepare comprehensive offering materials

A successful patent licensing deal involves the preparation of compelling marketing materials that will persuade potential licensees to enter into further discussions, and will also provide them with sufficient information to proceed with the submission of realistic indicative offers.

There are several data points that can be pertinent to include in your marketing materials, including:

- An overview of your product and its current development stage.
- Clear articulation of the value proposition of your product over existing products, for example if it meets an unmet medical need or alternatively provides some cost, efficacy, safety, route of administration, etc. benefits.
- Clear rationale for what you're seeking from the out-licensing opportunity, any requirements around licensing terms and expectations in regards to the commercialisation route.
- Commentary on the market opportunity including the target therapeutic area, addressable market size, patient population, competitors, etc., with an indication of the projected potential market share.
- Summary of clinical data and any approvals that have been received.
- The IP that is available for licensing and how it relates to the product. In addition to patents, this can include other forms in IP such as R&D data, manufacturing know-how, technical materials, statistical data, etc.
- Any points that a potential licensee should take into consideration such as encumbrances or freedom-to-operate (FTO) issues.
- A roadmap including the level of further investment required as well as development timelines for the product to go to market.
- Company and management information that positions the strengths of your company.

Effective marketing material covering the above data points in an insightful and engaging manner—without overestimating the addressable market size or underestimating the development timelines—will drive fruitful discussions with potential licensees. Our IP team can provide IP transaction support to help execute outreach through the preparation of marketing material which could comprise, inter alia, a teaser and information memorandum, as well as an assessment of IP of relevance, which will contain objective views on value indicators, robustness and market attractiveness of your product and associated IP.

04. Deal negotiation skills

There are a number of factors to consider in negotiating a licensing deal, and the skills to execute it successfully can play an important part influencing the value of the deal. In the LSHC market, there are a number of specific risks in product development that can affect the likelihood of a product reaching the market, such as drug induced adverse side effects in safety trials. These specific risks need to be taken into consideration when structuring a deal.

A key part of the deal is negotiating the financial terms, these may include:

- Upfront payments that are one-off payments due at the execution of the agreement and sometimes at the receipt of data. Where significant risk exists for early-stage products, small upfront payments are favoured in exchange for a share of the profits.
- Milestone payments that are triggered by specific stage gates, such as points where important data is generated, or achievement of points in the development process (e.g. a payment contingent on successful completion of phase IIb clinical trials). It's important to set realistic milestones and clearly agree definitions, as terms such as "successful" can be nebulous. There may also be unforeseen issues in the development process, and the agreement should be negotiated such that there are not negative financial consequences as a result of these, particularly if milestone payments come with specific timelines.
- Royalty payments are payments typically determined by the net sales of a product. This is common in pharma licensing where there can be a number of risks in the development process. It's important to ensure that if a product targets a specific indication, separate payment terms are considered for other indications.

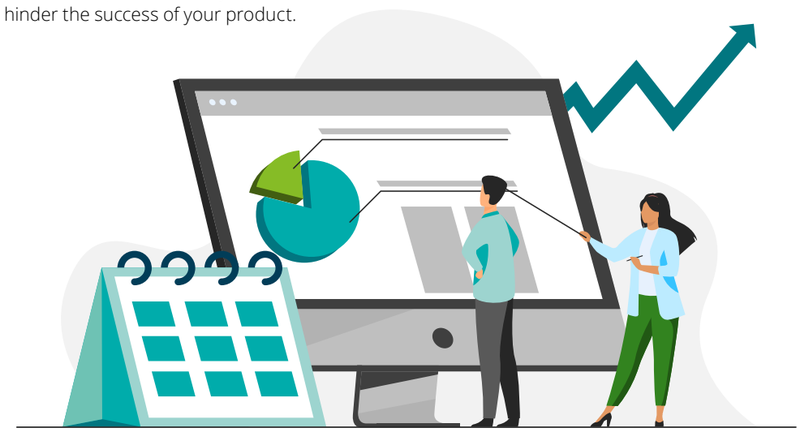
We typically see a combination of these financial terms in licensing deals. In addition to these payment terms, licensors may also request other terms, for example royalty reductions to cater for issues further down the line, such as FTO. Our IP team can help you to de-risk market entry by identifying IP risks through competitive intelligence and performing FTO analyses.

When structuring a deal, it's also important to clarify and define the responsibilities of each party, particularly if the deal involves the co-development of a product. You may want to partner with a large pharma company to take advantage of their expertise and capabilities. This can, however, give rise to a level of complexity, particularly in terms of decision-making and operations. In addition, there may be a requirement for you to provide assistance and support to a licensee for the development of the product. As such, the responsibilities of each party should be clearly defined in the agreement.

Structuring a deal should also include considerations of background IP (IP created prior to deal execution) and foreground IP (IP created after the deal is executed). Background and foreground IP should be clearly defined particularly in terms of its ownership, usage, field of use and jurisdictional coverage. Complexities can arise when deciding how to handle the ownership of data, know-how and trade secrets generated during the development process, particularly around IP that is not directly related to the product in development. It's crucial to negotiate provisions around the handling of IP so that you are compensated fairly, and do not hinder the success of your product.

Other factors that should be considered during negotiations include defining the goals, indications, doses, licensing territories, future preclinical/clinical development, manufacture and commercialisation routes.

Effective deal negotiation involves being cognisant of the underlying interests of the potential licensee in order to come to an agreement that benefits both parties. To maintain a strong bargaining position, it's useful to have a clear understanding of your dealbreakers and be able to walk away when they're not met. It's also key to understand the terms on which you are open to compromising. An effective deal negotiation should have scientific experts with deal expertise to understand the specific risks around your product development as well as the relevant market. Our IP team is multidisciplinary and experienced in successfully closing IP transactions in a range of technical areas; we can advise you in negotiating a deal to achieve a win-win scenario.



Overview of the end-to-end IP services Deloitte's IP team can offer to help you execute a successful licensing campaign

Conclusion

Closing a LSHC deal successfully is an art and there are multiple factors and risks to consider. Choosing the right time to partner is essential for realising value at the optimal stage of the development process, and choosing the correct partner that aligns with your business strategy and culture is important to the long-term success of the deal. Once you've identified a suitable partner, obtaining partner interest and engagement requires the development of comprehensive marketing materials articulating the value of your product and any associated IP. When negotiating the licence, ensure that you're equipped with the necessary skills to ensure a favourable outcome for both parties, as signing a deal is the beginning of a long-term collaboration.

Our IP team's suite of end-to-end IP services can support you through each stage of the licensing process, including the full spectrum of post-transaction activities, notably: the comprehensive capture and transfer of know-how, ongoing royalty monitoring, and optimisation of your portfolio.

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