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Exclusive Licensing May Offer Biotechs a Financial Lifeline

WRITTEN BY

LuAnne Morrow

With volatile market conditions and recent FDA shakeups, biotech companies are increasingly focused on bolstering cash runways and accelerating R&D efforts. But fierce competition for financing has some biotechs turning to exclusive licensing arrangements as an alternative strategy to manage cash burn and secure funds for their most critical projects.

While out-licensing technology can provide biotechs with an alternative source of cash, it's not a one-size-fits-all solution. Licensing arrangements for funding purposes are best suited for non-core assets, including those that fall outside the biotech's immediate commercial focus or demand substantial resources for R&D.

For biotech companies considering this alternative capitalization strategy, the following are some key considerations to ensure the arrangement aligns with the company's business objectives.

Scope of the License Grant

Just because the license is exclusive, it does not mean the licensee should have unfettered use of the IP asset. It's essential to tailor the scope of the license grant to protect the biotech's commercial interests.

In particular, the license should specify limitations on fields of use, geographical territories, right to sub-license, and the duration of the license, in addition to clearly identifying what assets are being licensed (patents, pending patents, trade secrets, trademarks). Licensors typically want to assign fields of use and geographic territories that are different from ones they are already using the technology in, have licensed the technology to a third party in, or plan to cultivate or expand commercialization efforts to in the future. For example, if the biotech has an existing third-party licensee or plans to develop its own use of the technology in one therapeutic area of use, it may want to limit the license grant to a different therapeutic area or limit the grant to specific jurisdictions and markets the biotech cannot easily access.

Defining a set term, often tied to the life of the licensed patents, is typical. If the term is shorter than the term of the last patent to expire, or can be terminated prior to the end of the term, robust post-termination/expiration provisions should be included in the license, and the agreement should contemplate the sell-off of commercial products in the market, transfer of data and research back to the biotech, and destruction of confidential information.

By addressing these factors in the licensing arrangement, a biotech can ensure that the licensee's use of the

asset aligns with the biotech's strategic objectives now and down the road.

IP Ownership

The key question for any licensing transaction is what happens when a licensee completes development of the licensed technology or uses it to create a new product.

Absent a contractual agreement, generally the inventor of the new technology holds IP ownership in the new IP, even if the new technology is comprised of a component that is licensed by another company. While there may be circumstances where a biotech's contribution of its licensed asset to the new technology could give rise to certain ownership rights, it is ultimately an area where there can be legal uncertainty if the parties did not contractually allocate ownership rights at the outset.

At first blush, contracting for joint IP ownership of the end technology may seem like the obvious solution. However, joint IP ownership can become a complicated endeavor — even when there are agreements in place on how the IP will be used, managed, and commercialized by each party. Issues such as decision-making authority, profit sharing, and responsibility for legal liabilities can become points of contention and need to be explicitly addressed to avoid disputes and ensure effective IP management.

In the exclusive license scenario where the licensee will make significant investments to develop and commercialize the IP, most licensees will expect to own the IP they develop. Biotech licensors, however, should exercise caution before giving up their rights to new IP that is based on their underlying IP. A common solution is for the biotech to seek a royalty-free cross-license to the new IP.

Biotech licensors may also want access to research data and reports, as well as the right to participate in patent filing decisions to the extent that they impact their underlying IP. Some biotechs may have the leverage to negotiate for ownership of the new IP — with such an arrangement typically including an automatic license to the new IP to the licensee as part of the existing license grant, and would require the licensor to take on all costs to protect and defend the new IP (with input from the licensee). If the licensee is contributing or combining their own existing IP with the licensed IP, that will add a layer of complexity to the ownership and cross-licensing options.

Payment Structures

Exclusive licenses typically involve payment structures designed to balance risk and reward between the biotech company and licensee. However, before entering a licensing arrangement, it is critical that the biotech company evaluate the licensee's intention and ability to develop and/or commercialize the licensed technology. If the licensee can't perform or abandons the project during R&D, not only will the biotech potentially lose out financially, but it may also render the licensed technology inaccessible for other uses for the remainder of the license term.

Upfront payments are a common feature, and have the benefit of providing immediate capital to a biotech in need. These payments also signal the licensee's commitment to commercialize the licensed technology — which is particularly important for payment packages that also include milestone, profit-sharing, or royalty payments.

Milestone payments are generally triggered once the licensee achieves specific objectives such as progress in product development, clinical trials, or regulatory approvals. By spreading payment over the life cycle of development, the licensee can mitigate risk if the product doesn't make it to commercialization, and the biotech licensor gets a regular cash infusion through periodic payments. The biotech can also negotiate for royalties or profit-sharing at the commercialization stage, resulting in a continuous revenue stream.

To mitigate the risk of the licensed product going cold on the R&D pipeline and the biotech losing out on future payments, it is customary to require the licensee to engage in commercially reasonable efforts to bring an end product to market. Given potential challenges such as regulatory changes and extended approval timelines, it is crucial for parties to anticipate pinch points and clearly delineate what constitutes commercially reasonable efforts to ensure alignment and minimize disputes. This often includes specific benchmarks and measurable criteria and rights to terminate if milestones are not met.

Biotechs may also add value to the exclusive licensing relationship by offering consulting services to a licensee in addition to the technology licensed. This may be a short-term consulting agreement to transfer knowledge or ongoing subcontracting of certain services, both of which could be another option for generating income for the biotech.

Regulatory Challenges

There are several regulatory considerations that can impact a licensing arrangement.

For example, the Hart-Scott-Rodino Act (HSR) can significantly impact exclusive licensing arrangements, particularly in biotech. If implicated, filing obligations have the potential to create serious delays for biotech companies that are relying on a licensee's initial lump sum payment to stay afloat. While HSR requirements are generally associated with large acquisition transactions, certain licensing arrangements can also qualify as an "acquisition" subject to HSR, including exclusive licenses transferring "all commercially significant rights" related to certain pharmaceutical preparations, medical and botanical products, biological products, and in-vitro diagnostic substances.

If an exclusive licensing arrangement meets financial thresholds and triggers HSR, not only must the parties notify the Federal Trade Commission and the Department of Justice, but they must also observe a 30-day waiting period, which could be extended if additional information is requested. We specifically discuss the impact of HSR on licensing arrangements in more detail here.

The Bayh-Dole Act is another regulatory consideration. Under the act, technology that was developed using federal funds is subject to certain requirements and restrictions. Failure to comply with the act's requirements can result in the government exercising its "march-in rights," and potentially taking control or title of the invention. In an exclusive licensing scenario,

Bayh-Dole concerns arise from a situation where the biotech is licensing technology funded by the government and the end licensee is violating the act's requirements, such as outsourcing manufacturing abroad. While historically the act has not been heavily enforced, the current administration's push for domestic manufacturing in the pharma industry could potentially have an impact on the government's Bayh-Dole enforcement efforts. To

address these risks, the biotech licensor may consider placing certain restrictions on the licensee and seek the right to audit for compliance with any regulatory requirements that apply.

Other Considerations

Some other key considerations for biotech companies exploring the option of exclusive licensing include: data sharing, confidentiality provisions that extend beyond the licensee to any sub-licensees, contractors and employees, post termination and expiration provisions, restrictions on assignment and sub-licensing, regulatory reporting and audit provisions, audit provisions for any milestones and royalty payments, and mechanisms to report suspected infringements and claims of infringement concerning the biotech's IP, including who will be responsible for defending claims, managing settlement and costs, allocation of liability, and any limitations.

Conclusion

Exclusive licensing can be a strategic financial lifeline for biotech companies. However, these transactions require careful consideration, and biotech companies must tailor these arrangements to fit their specific needs and strategic goals and protect their interests.

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