

Survival Guide to Structuring Life Sciences Partnering and M+A Agreements

The life sciences space is ever-growing and dynamic as the industry witnesses more companies and, therefore, more collaboration, licensing and M&A agreements, come into the spotlight. While these deals are exciting opportunities for life sciences companies at all stages, they can also be daunting when it comes to their legal structure. In order to best leverage assets, align incentives, allocate risk and draft agreements to position your partnership for success, Goodwin recommends considering the following business, legal and litigation perspectives as you navigate these type of agreements.

1. Consider your diligence obligations

Diligence obligations are intended to ensure that the party taking the asset forward is appropriately proceeding with the development and commercialization of the asset. Typically, a party is required to use its "Commercially Reasonable Efforts" (CRE) to develop and commercialize the asset. The definition of CRE is a typical term to be negotiated and breach of diligence obligations may be the basis for a potential dispute. Therefore, the definition should be specific and measurable enough to benchmark the level of effort required from the performing party.

2. Evaluate alternative diligence criteria

In addition to requiring the performing party use CRE, consider whether heightened diligence obligations are warranted depending on the situation. Heightened diligence requirements may include minimum obligations for activities, an absolute obligation to achieve a particular goal by a specified date, economic solutions and incentives, cue periods for diligence breaches, and country-by-country and product-by-product terminations based on failures to meet specific diligence goals.

3. Review and draft detailed governance provisions

Most partnering agreements involving a joint research or development component contain governance provisions, which often provide for a joint steering committee responsible for oversight, communication, coordination, approval of research and development plans, and decision-making in relation to the agreement. Governance provisions ultimately create an arena in which information can be shared and disagreements can be discussed and, hopefully resolved, without arbitration or litigation. If a dispute does arise, governance provisions can include escalation procedures that help the committee evaluate circumstances and severity surrounding the dispute before taking any specific action.

4. Mitigate risk by establishing clear economic terms

If partnering and M&A agreements do not contain clear economic terms, there is a greater risk that a dispute will arise relating to royalties, sublicensing revenue, allocations and more. Including appropriately drafted and clear language that reflects the parties' understanding of the consideration to be paid under the agreement may help avoid a potential dispute early in its tracks; but when a dispute cannot be resolved, litigation counsel should become involved as soon as possible.

5. Prepare for the possibility of agreement termination

It is important to include appropriate clauses permitting each party the ability to terminate the agreement in certain scenarios. Early termination could occur by a licensee for convenience, by either party for material breach from or upon bankruptcy of the other party, or by a licensor for the patent challenge by the licensee. Additionally, partnering or M&A agreements may include provisions to return the asset to the licensor following termination of the agreement in some cases, which means the it should specifically address compensation and allocate responsibilities to ensure an orderly transition of the asset to the licensor to carry the program forward in the future.

6. Determine whether litigation or arbitration will resolve a dispute

It is crucial to partner with legal counsel to determine whether litigation or arbitration is the best course of action when resolving a dispute. While arbitration may be favored in some cases as a less public process than litigation, it lacks some of the benefits of a court proceeding. Other considerations include the domiciles of the parties and applicable arbitral rules, governing law and forum.

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