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Strategic Considerations for Life Sciences Partnering

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December 7, 2022

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Agenda

1. Recent trends in life sciences transactions
2. Transactions with universities and other research institutions
3. Addressing the effect of a change of control on licensing partnerships
4. Mitigating counterparty bankruptcy risk
5. Approaches to exclusivity

Recent Trends in Life Sciences Transactions

- Notwithstanding the macro environment affecting corporate transactions generally, a variety of life sciences transactions are continuing to occur as life sciences companies need to fill their pipelines, develop areas of importance and find new ways to monetize their existing pipelines.
- The trends in life sciences transactions that we are seeing in our practice include:
  - Interest in territory-specific deals, most notably involving China and Japan;
  - Increased number of companies with platform-based technologies to license, especially in areas such as gene therapy;
  - Transactions that provide for creating optionality in pipelines; and
  - We continue to see both early-stage (*i.e.*, involving pre-clinical assets or technologies) and late-stage (*i.e.*, clinical-stage assets or technologies) partnerships.
- For companies seeking to license platform-based technologies, it is essential to map out the distinct ways in which rights will be allocated among potential partners to ensure there is no overlap or conflict among transactions (*e.g.*, scope of targets, scope of compounds, data sharing, control over intellectual property prosecution and enforcement, etc.).
- In-licensing agreements need to be accounted for when structuring a licensing program that will involve a sublicense of rights.
- Companies should take a long-term approach and consider how a partnering strategy and related transactions will be viewed by potential acquirers or in connection with an IPO.

Issue #1 – Transactions with Academic Institutions

Agreements with academic institutions, be it a sponsored research or collaboration agreement or foundational license, present their own set of issues for life sciences companies, particularly those that have close ties to academic institutions.

- **Material Transfer Agreements**.
  - Risk: Material transfer agreements, or MTAs, with academic institutions are common, but frequently do not sufficiently address ownership of intellectual property rights arising from the use of the transferred materials.
  - Strategy: To ensure they acquire exclusive rights to intellectual property developed using transferred materials and to prevent freedom to operate issues, companies should expressly address ownership of arising intellectual property in any MTA.
- **Options**. It is common for sponsored research or collaboration agreements with academic institutions to include options for the company to negotiate for a license to certain intellectual property rights.
  - While this can be advantageous at an early stage by allowing the company to defer the expense of obtaining an exclusive license, it can leave the company without exclusivity or present freedom to operate issues for the company's product candidates.
  - Concern: The company may be required to go back to the academic institution to obtain the license, which can leave the company open to protracted negotiations and the possibility of being required to accept unfavorable license terms or failing to agree upon license terms at all.
  - Solution: If a license is not secured upfront, consider self-executing options based on pre-agreed terms.

Issue #1 – Transactions with Academic Institutions (cont.)

- **Dual Hats**. If a university employee will also be a company employee or consultant, it is possible that the individual's employment agreements with the university and the company contain conflicting invention assignment obligations.
  - The company should diligence the individual's employment agreement with the university (including the university's employee handbook).
    - If there is a conflict, obtain an assignment from the university of its rights to inventions relating to the company's product candidates or platform.
  - Watch out for agreements to assign which do not contain self-executing present assignments given that self-executing present assignments take priority over a mere promise to assign.
- **Inter-Institutional Agreements**. If the company is in-licensing patents that were jointly developed by inventors at multiple academic institutions, the company should diligence any inter-institutional agreement to ensure the licensing agent holds all necessary rights to the licensed patents.
  - The company should (i) require that the licensing agent obtain an exclusive license to each joint owner's interest in the licensed intellectual property so that such intellectual property can be exclusively sublicensed to the company or (ii) obtain a direct exclusive license from each joint owner.
    - If neither option is practicable, then, at a minimum, consider requiring each joint owner to acknowledge and agree that the company's license from the licensing agent encumbers each joint owner's interest.

Issue #2 – Effect of a Change of Control

The extent of a party's right to undergo a change of control will be transaction-specific and dependent on the context of the arrangement.

- It may be more likely for the licensor, as the smaller company in the partnership, to undergo a change of control, but even large companies can be an acquisition target.
- While some parties may generally be averse to change of control situations (regardless of the nature of the acquirer), parties are most often concerned about the prospect of their partners undergoing a change of control to a competitor or the divestiture of a party's rights to a less creditworthy or capable partner.
  - In negotiations, parties must balance their competing interests. For example, a licensee may not want a competitor to acquire rights to its licensed intellectual property, especially where the licensor is playing an active role in development or commercialization of the licensed products, and therefore may seek to place significant restrictions on the licensor. At the same time, a licensor may want to preserve business flexibility to be acquired as part of its long-term strategy.

Issue #2 – Effect of a Change of Control (cont.)

- Typically, parties are able to get comfortable with the possibility that their partner will undergo a change of control by including conditions that are appropriately tailored for the collaboration.
  - **Information Walls**. The imposition of informational walls can provide flexibility to undergo a change of control while providing the counterparty with the protection it requires. Information walls, however, can present operational obstacles and prevent synergies that would be appealing to prospective acquirers.
  - **Control of Operations**. Where parties are involved in any joint development or commercialization activities, the party not undergoing the change of control can be given the right to assume control of all such activities and the joint steering committee can be disbanded.
  - **Other Provisions**. Besides the change of control provision, the parties may, for example, agree for the scope of intellectual property included in the license grant to exclude intellectual property acquired as the result of a change of control or for a change of control to trigger a termination right.
  - **Divestitures**. Given parties are deliberate in selecting their licensing or collaboration partners, parties are less willing to permit a divestiture of rights that are subject to the agreement without their consent. This applies to certain sublicenses as well, especially if they are tantamount to a divestiture of some or all of the licensed rights.

Issue #3 – Mitigating Counterparty Bankruptcy Risk

- Parties entering into licensing or collaboration agreements historically have not focused on counterparty bankruptcy risk.
- **Intellectual Property and Bankruptcy Overview**:
  - Courts have generally defined executory contracts as those where obligations of both parties are "so far unperformed that the failure of either to complete performance would constitute a material breach excusing the performance of the other." Vern Countryman, Executory Contracts in Bankruptcy: Part I, 57 Minn. L. Rev. 439, 460 (1973).
  - Courts have generally found intellectual property licenses to be executory, because at their essence they are ongoing covenants not to sue.
  - In bankruptcy, the trustee may assume, assign or reject a debtor's executory contracts pursuant to § 365(a) of the Bankruptcy Code. Where the *licensor* is in bankruptcy, rejection by the trustee can be used as an attempt to unlock value that is encumbered by an existing license.

Issue #3 – Mitigating Counterparty Bankruptcy Risk (cont.)

- **Effect of Rejection – Patents, Copyrights and Know-How**: In 1988, Congress enacted 11 U.S.C. § 365(n) to protect the rights of intellectual property licensees (other than trademark licensees). Under § 365(n), if an intellectual property license is rejected by the debtor-licensor under § 365(a), the licensee may:
  - Treat the license as terminated, in which case the licensor's breach may give rise to a claim for money damages under § 365(g); or
  - Elect to retain certain of its rights under the license:
    - Trustee must comply with confidentiality and exclusivity provisions, and continue to provide access to the intellectual property, but the licensee has no other right to specific performance.
    - The licensee is required to "make all royalty payments due" under the agreement for the duration of the contract and waive any setoff rights it may have.

Issue #3 – Mitigating Counterparty Bankruptcy Risk (cont.)

- **Effect of Rejection – Trademarks**:
  - In May 2019, the Supreme Court held in *Mission Product Holdings, Inc. v. Tempnology, LLC* that the rejection of a trademark license by a debtor-licensor operates not as a rescission of the license but as a breach of the agreement, leaving the licensee able to continue to use the licensed trademarks.
  - The Court concluded that while § 365(n) does not apply to trademark licenses, such agreements are still executory contracts that fall within the general rule of § 365(g), which provides that rejection of an executory contract by a debtor-licensor constitutes a breach of such contract.
  - Given that the Court purported to extend its reasoning to executory contracts generally, licensees should consider the extent to which the decision will have applicability beyond trademark and other forms of intellectual property licenses in bankruptcy.

Issue #3 – Mitigating Counterparty Bankruptcy Risk (cont.)

- **Scenario #1:** A company is negotiating an exclusive option from a counterparty that is at risk of insolvency.
  - **Risk**: If the grantor of the option enters bankruptcy, it may have the right under § 365(a) to reject the agreement under which the option is granted. Because the option is not a license of intellectual property rights, the option holder may not be protected under § 365(n).
  - **Mitigation Strategy**:
    - Security Interests: The option holder can seek a security interest in the optioned intellectual property rights so it would be a secured creditor and could seek to foreclose on the optioned intellectual property rights.
    - Broader Service Agreements: The option holder can additionally seek to include the option grant in an agreement in which other rights or services are being provided by the option holder to incentivize the option grantor not to reject the agreement.

Issue #3 – Mitigating Counterparty Bankruptcy Risk (cont.)

- **Scenario #2:** A licensor is in financial distress and has offered its licensee the opportunity to expand the scope of its license and to reduce remaining contingent payment obligations in return for a one-time upfront payment. The licensee views the proposal as a favorable opportunity to expand its rights at a discounted cost.
  - **Risk**: The licensee's rights under the initially licensed intellectual property rights are protected under § 365(n). If the licensee accepts the licensor's offer, it is at risk that creditors of the licensor's estate could allege that the license of the additional intellectual property rights is a fraudulent transfer under § § 544 and 548 of the U.S. Bankruptcy Code and seek to claw back the additional intellectual property rights. In such a scenario the licensee would likely not be able to recover the full amount of the lump sum payment.
  - **Mitigation Strategy**:
    - Given that the licensee already has a sufficient license for its development and commercialization activities that can be quarantined under § 365(n) in the event of the licensor's bankruptcy, the licensee should consider rejecting the offer unless it can get comfortable that the licensor is solvent. However, the lookback period for a fraudulent transfer claim can be as long as six years depending on the state, and therefore if the licensor enters bankruptcy within that period, the arrangement could be vulnerable to a claim given its discounted nature.
    - The amended economic structure of the license not only puts the additional lump sum consideration at risk, but it may result in an increased likelihood of rejection under § 365(a) given most of the consideration would have been paid upfront instead of being deferred.

Issue #4 – Approaches to Exclusivity

Non-Compete Covenants

- It is common to see non-compete covenants that either bind one or both parties.
  - From the licensor's perspective, the non-compete covenant helps to provide comfort that the licensee is not going to commercialize a competing product while sitting on the exclusive rights to the licensor's products or technology.
  - From the licensee's perspective, the non-compete covenant helps to provide comfort that the licensor will not compete with the licensee with respect to the licensed products or license a competing product to a third party.
- There are many ways to tailor a non-compete covenant; however, in order to be enforceable and not violate antitrust law, non-competes and exclusivity restrictions must be appropriately tailored in scope and ancillary to a legitimate business purpose.
  - In addition, antitrust authorities under the Biden administration are applying heightened scrutiny of non-compete and exclusivity provisions.
- <u>Takeaway</u>: Parties should consider whether non-compete or exclusivity covenants are necessary or whether their relevant commercial concerns can be addressed through other approaches. Non-compete and exclusivity covenants should not be considered in a vacuum given that other provisions in the agreement may work in tandem with or obviate the need for non-compete covenants.

Issue #4 – Approaches to Exclusivity (cont.)

Non-Compete Covenants

- For example, diligence obligations require the licensee to use a certain level of efforts to develop and/or commercialize the licensed product or technology. If a licensee is subject to robust diligence obligations to develop and commercialize a licensed product, such commitment, in addition to the licensee's economic investment in the licensed product and transaction, may mitigate or obviate the need for additional protections through a non-compete.
- From the licensee's perspective, if there is a concern that the licensor could commercialize or license to a third party a competing product, the licensee could consider seeking preferential rights to such product for a period of time.
- There are also ways to address certain aspects to these risks through the use of exclusive intellectual property licenses.
- Takeaway: One should assume that any non-compete or exclusivity restriction will potentially be subject to enhanced scrutiny (and possibly challenge) by antitrust authorities and therefore antitrust counsel should be consulted to ascertain the limits on what is permissible in the context of a particular arrangement. In any event, alternative approaches that are not anticompetitive but still address the commercial concerns of the parties should be considered.