

Current Issues in University and Research Institution Licensing Agreements

Bob Licht, Partner in Choate's Life Sciences Group, moderated the panel "Current Issues in University and Research Institution Licensing Agreements" at the 2018 Boston Bar Association Life Sciences Conference. Below are key take-aways from the discussion:

Considerations other than cash

- Licensors are increasingly asking for and receiving a range of equity and other consideration from Licensees
 - Common or preferred stock, phantom equity (cash payments based on Licensee market capitalization) and change of control consideration
- Aligns interest of both sides in progressing research and development by preserving Licensee cash for that purpose

Aggregation of IP from multiple institutions

- Important for counsel to understand client strategy of building a drug development program around IP sourced from multiple Licensors
 - Increasing in importance given multi-component products and more complex therapeutics
- Distinguished from typical anti-stacking situation, where need for additional third party IP is discovered later in the timeline
 - Always need to consider rights to technology that might be developed if Principal Investigator moves to a different research organization
- Adjustment of different royalty structures
- Revise allocation of percentages of Sublicensing Income shared across multiple Licensors?
 - Conceptually similar to the combination product adjustment in calculating Net Sales
 - Licensee can get some mileage from Licensor desire to see the technology commercialized, which may make Licensors more willing to share its' percentage of Sublicensing Income with other Licensors
 - Holistic negotiation – important to understand the strategy and objectives of both parties as well as the economics

Option structures and de-risking

- Important that Licensee perform diligence on science, IP and commercial opportunity (unmet need) before entering into a License Agreement which entails a long term commitment
- Sometimes the science part cannot be done without either a License Agreement or an exclusive Option Agreement
 - Term of Option
 - Until patent claims issue
 - Until science is validated sufficiently to attract additional investment
 - What does Licensee pay for during Option Period? Past patent expenses? Ongoing patent expenses?

Performance obligations

- Often referred to as "diligence" but here it is Licensee's obligation to be diligent in moving the licensed technology forward, rather than the Licensee's diligence in validating the science and the drug candidate
- Commercially reasonable efforts is a subjective term and hard to prove
- Licensor wants to avoid the technology being "shelved"
- Licensor will therefore ask for specific and measurable objectives, but may be willing to modify or extend if circumstances change
 - "Science happens" and may require a different schedule than originally planned
 - To merit extension or modification of diligence requirements, Licensee should be utilizing resources consistent with agreed FTE/\$ budgets
 - Contract mechanism can be a period to cure default before termination and/or that Licensor and Licensee sit down to discuss objectives and timelines that are realistic

Effects of termination

- If collaboration/development fails, does IP get returned to Licensor for further development?
 - If yes, does Licensee ALSO give to Licensor material, data, results, and IP generated during research and development?
 - If yes, should Licensee then get a royalty if Licensor, or more likely Licensee 2, is successful in developing a product?
- Alternative is mutual abandonment of the drug development project and the related IP
- Does Sponsored Research/laboratory funding arrangement continue if License Agreement is terminated
- Importance of anticipating terms of a “pre-nuptial” agreement embodied in the Effects of Termination provision before entering into the Licensor/Licensee relationship

FOR MORE INFORMATION

To learn more about compliance considerations for nurse educator programs, please contact:

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