BASICS OF LICENSING TECHNOLOGY FROM UNIVERSITIES AND RESEARCH INSTITUTIONS

*By Daniel M. Mahoney**

Universities are wellsprings of creation. The importance of university research at a time when our knowledge and dependence upon technology and the life sciences is growing exponentially is paramount. The Bayh-Dole Act of 1980 gave universities the right to patent discoveries made with federal research funding, but also obligated them to license or transition the new knowledge to practical use. As a result, over 238 institutions in the United States have started technology transfer offices to manage these efforts.

In Arizona for example, all three of the State's universities have created technology transfer offices, with Arizona State University moving a step further through the creation of a separate "for profit" arm of the Arizona State University Foundation called Arizona Technology Enterprises (AZTE). AZTE is tasked with the role of transforming ideas and inventions into commercial products and services. Similarly, Translational Genomics Research Institute, also known as TGen, was established in Phoenix, Arizona in June 2002. TGen's mission is to make and translate genomic discoveries into advances in human health. To accomplish this, TGen has assembled a large team of laboratory scientists, computer experts, biomedical engineers and clinical partners who take the knowledge gained from the Human Genome Project and create practical discoveries that will ultimately help diagnose and treat many diseases. TGen has begun spinning out its technologies to private entities for commercialization.

Turning to universities or research institutions, such as TGen, for new developments in technology provides recipients early access to these innovations, often without incurring the attendant research and development costs. Typically, the technologies that reside in the universities or research institutions are extracted and exploited by third parties through a license. The license will usually involve a patent or a patentable technology. In short, a license ensures that the university cannot sue you for infringement of the technology that is the subject of the license. However, there are many nuances to obtaining the license.

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Be aware of the Process and Timeframe

The process can be labor intensive and will often require more time than anticipated. The process will begin with the due diligence phase, in which the viability and value of the technology is assessed. If satisfied, the licensee works with the university or research institution and, possibly, the inventing professor on the general terms of the license, which will usually be captured in a term sheet. Next, a final set of definitive documents will be prepared; usually using the university's or research institute's standard forms. However, if the deal contains enough nuances it may be necessary to craft a custom set of documents. Additional terms that were not identified in the term sheet may be the subject of further negotiation. Depending upon the complexity of the license arrangement, the depth of negotiation and the extent of ancillary issues, this entire process could take from one month to over a year.

Key Inventors

The licensed technology may be incomplete or may lend itself to further development. It may be critical to secure the cooperation of the professor in answering questions, providing consultation and facilitating further development. Moreover, the inventing professor may create future developments that will be important to the ultimate commercialization of the licensed technology. In the absence of explicit agreement, those future developments belong to the university and/or the professor. Accordingly, the license should address all future developments and improvements that may be critical to commercializing the technology. Additionally, records should be kept of all developments and who was responsible for those developments. This is important in the event the originating professor continues to develop the technology or makes improvements, or, alternatively, if the licensee's company has ties to the university (*i.e.*, uses university graduate students).

Avoiding Conflict Problems

Universities and Research Institutions will generally have policies prohibiting or impeding the involvement of a faculty member or employee in the negotiation process. This can often be burdensome if the faculty member is the founder of a spin out that will be licensing the technology or is otherwise a significant player. The institution will usually refuse to negotiate with the employee or faculty member and will simply instruct them to come back when a third party with whom the institution can negotiate (*i.e.*, a financial investor or outside manager) becomes involved. To this end, it is important for the team that will be licensing the technology to anticipate this issue and identify a lead negotiator that is otherwise unaffiliated with the institution.

Exclusivity vs. Non-exclusivity

Aside from cost, exclusivity is generally considered the most significant issue in licensing arrangements. Absolute exclusivity provides the licensee the ability to exclude all other parties or people from using or exploiting the technology and the university is prohibited from granting a license for the same technology to any other party. A non-exclusive license merely allows the licensee to use and exploit the technology without fear of being sued for infringement; however, the university can extend the same rights for the same technology to as many parties as it wishes, including competitors. There is a broad spectrum between these two extremes where much of the negotiation occurs.

Generally, the licensee will want to secure an exclusive license granting an unfettered right to exploit the technology and all future developments. However, this often is accompanied by a steep price. For example, the university is more likely to extract higher up-front costs, royalty payments, equity participation or strict and aggressive milestone developments.

Payment Structures

Payment structures can take many different forms. For example, the university may or may not require a one-time, up-front payment that may or may not be in addition to ongoing royalty payments. The royalty payments could be based on gross revenue or net earnings. It could be a more simplistic per-unit royalty or a more complicated structure that scales according to the commercial success of the technology. If the right to sublicense is granted, universities will generally require a royalty for a sublicensee's exploitation of the technology. A one to five percent royalty structure is typical depending upon the facts. If the institution also receives equity in the entity that is receiving the license the royalty and up-front payments may be reduced or discarded altogether.

Equity

The institution granting the license may require or request equity in the entity or venture that is licensing the technology. This is more typical in an early-stage or start-up environment and may even be preferential to the licensee as the grant of equity may serve as the quid pro quo for reducing or removing royalty, milestone or up-front payments. If the licensee is a well established enterprise this arrangement is unlikely. The grant of equity, however, raises the specter of dilution and the institution may want comfort that it will not be diluted by future rounds of financing. The rejoinder to this is that they should be treated no differently than any other stakeholder in the enterprise. Preferably, the institution would receive common stock, if a corporation, or simple interest, if a partnership or limited liability company, and such equity rights would not have anti-dilution protection or any of the other bells and whistles that

one might expect of a preferred equity security. If necessary to consummate the arrangement, however, the licensee can provide a non-dilutable security, a convertible preferred stock with anti-dilution rights or some floor on the institution's total dilution through the next round of financing but then none thereafter.

Right of First Refusal

The party that is licensing the technology should request the right to obtain licenses on future technology or intellectual property that exists within the same or similar realm on the same terms as the initial license. This can sometimes pose problems if the institution is a not for profit entity, in which case tax professionals will need to be involved to properly structure the arrangement. This type of provision may also be tied to an anti-dilution right. For example, the institution may be entitled to anti-dilution rights so long as the licensee receives a right of first refusal on all similar technology produced in the future on the same license terms as the initial license. If the right of first refusal expires so do the institution's anti-dilution rights.

Milestones

Universities will often grant a license subject to the licensee achieving or maintaining certain milestones. If the milestones are not achieved in a timely fashion, the university may terminate the license or convert it to a non-exclusive license. Some common milestone examples are the hiring of a key advisor or CEO; raising a certain amount of money either through grant funding or equity or debt investment; and creation of a business plan. In bioscience, milestones will generally include achievements with respect to clinical trials, FDA authorization and filing of 510(k)'s or PMA's.

Allowing Sufficient Runway

Aside from abbreviated or insufficient due diligence, licensees of biotechnology often make mistakes during negotiations with universities concerning milestones and payment structures. Generally, a licensee should use practical foresight when agreeing to these concepts. For example, drug development or invasive device development are difficult processes to predict with respect to clinical trials and FDA approval. Perhaps the most common miscalculation is the length of time that it will take to successfully raise money for a fledgling venture. Inexperienced entrepreneurs tend not to appreciate the extent of the chasm between receiving a rock solid commitment to invest and having that party actually write a check. Likewise, it is rare for a start up venture to hit its initial revenue projections.

A dose of practical reality at the outset of negotiations goes a long way in preventing renegotiation later on. The licensee should give itself

as much runway as possible. This can be accomplished by backloading or deferring license payments or royalties until a specified date or more appropriately, until the exploitation of the technology proves successful. Similarly, the university could be convinced to take equity or phantom equity in the venture in lieu of payment. It is harder to elicit these concessions from the universities if the license provides for absolute exclusivity. If the university is willing to place all of its eggs in one basket with respect to the technology in question, it will certainly want to maintain a tight grip and a short leash.

Sublicense and Assignment

A critical but often overlooked aspect of license negotiation involves the licensee's ability to sublicense or assign the licensed technology to a third party. It is a strategic advantage to a licensee if they retain the right to freely assign or sublicense the license to another party without the need to obtain the consent of the university, the professor or any third party. This is particularly valuable, if not essential, in an exit or liquidity event involving the sale of the venture. Even if an ultimate sale is not part of the initial strategy, the lack of such rights severely restricts the venture's flexibility in the long term. For example, the licensee may wish to reorganize or enter into a joint venture utilizing a drug or medical device for which they have procured a license. If they are unable to sublicense or transfer the license, they may be unable to achieve their strategic goal without renegotiating with the university, which in turn is likely to result in increased costs to the venture.

There are many other issues involved in the negotiation of a license for technology from universities (*i.e.*, length of the license; the right and process of termination; impact of termination on sublicenses; the university's rights to future developments or retained rights for educational purposes; and obligations to indemnify the university for any costs incurred by the university for claims arising out of the license). All parties planning on entering into negotiations with a university for the license of technology should seek proper counsel from a party experienced in the process.