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Licensing From Universities: Identifying And Managing Unique Issues

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The most important asset of a life sciences company is its intellectual property portfolio. In order to adequately develop and grow the company and its product pipeline, management must first properly develop and grow its portfolio. In light of the fact that many novel medical inventions originate in the laboratories of university-based scientists, management often attempts to achieve its goal, at least in part, through the in-licensing of patent and other intellectual property rights from universities. The resulting licensing arrangement between the life science company and the university, however, includes a unique set of issues and concerns. Management must analyze these issues carefully in order to properly negotiate and document the transaction.

The Scientific Inventor May Have Certain Rights

In the absence of a proper agreement between the university and its scientific inventor and depending on when and where the inventions originated, partial ownership of the underlying patent and other intellectual property rights may reside with the scientist. Typically, in connection with the

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employment or other agreement between the scientist and the university, the scientist will assign all of his or her ownership rights to the university. This assignment of inventions agreement is a critical foundation to the license agreement between the life sciences company and the university. As a practical matter, company management should conduct thorough due diligence regarding the identity and role of the various inventors. This due diligence should also include a review of the university's patent and other intellectual property policies to make sure that no obligations or potential issues arise by virtue of those policies, which often contain intellectual property ownership provisions. The license agreement should include a representation and warranty by the university that it owns the intellectual property free and clear and has the full legal power and authority to enter into the license agreement and to grant the underlying licenses, including a representation and warranty to the effect that all necessary assignments of inventions are in place.

Other Institutions May Also Have Certain Rights

Often, because scientists sometimes transfer their laboratories from institution to institution over a period of time or because two or more universities sometimes collaborate with respect to specific areas of research, more than one university may have ownership rights with respect to



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particular inventions. Under U.S. patent law, unless the parties otherwise agree, co-inventors (in this case, the separate universities) each generally have the separate independent right to commercialize jointly owned inventions. Therefore, each university may enter into its own license agreement with a third party with respect to the subject invention. However, by virtue of the fact that both universities may enter into such an agreement with different third parties, unless the universities otherwise agree, neither license may be in the form of an exclusive license.

In order to obtain the ability to grant an exclusive (more lucrative) license with respect to the subject inventions, universities with co-ownership rights often enter into an inter-institutional agreement (IIA). Pursuant to an IIA, the universities agree to work together to seek and contract with appropriate licensees of the inventions. The IIA will also typically contain provisions regarding sharing of revenue and expenses and delineation of patent prosecution and defense rights and responsibilities. By agreeing to work together *vis a vis* the licensee, the universities are better able to enter into a more favorable (to the universities) overall licensing arrangement.

In reviewing an underlying IIA, management of the life sciences company should be particularly aware of the rights and powers of each university in relation to the other (*e.g.*, whether one university has the right to negotiate and/or execute the license agreement on behalf of both institutions). Also, management should be mindful of termination provisions contained in the IIA and be sensitive to any other provisions that may

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negatively impact the company, especially if there is a demise in the relationship between the universities. In certain instances, the license agreement may even need to include or require one or more amendments to the IIA in order to provide management with sufficient comfort that the company's license will not be jeopardized by any conflicts or other problems between the universities, most of which are beyond the control of the company.

Use Of Grant Money Or Other Government Funds Is Significant

The development of university-based inventions is sometimes funded, in whole or in part, through the use of government funds. For instance, the university may receive a research grant from the National Institutes of Health or receive funds pursuant to the Orphan Drug Program. With respect to inventions developed with U.S. government funding, prior to 1980 the U.S. government retained an ownership right in such inventions. As a result, universities faced many obstacles in their attempts to license such inventions to third parties. For example, because of the U.S. government's rights, it was often difficult or impossible for the universities to grant exclusive licenses with respect to such inventions.

Pursuant to the ground-breaking federal Bayh-Dole Act of 1980, as amended, ownership of university inventions that result from federal government-funded research vests, at the election of the university, with the university. Therefore, notwithstanding the use of federal funds, the university is able to maintain ownership and grant a license (even an exclusive license) to the life sciences company. Under the Bayh-Dole Act, however, the U.S. government does retain certain limited non-commercial rights with respect to the subject inventions, including a non-exclusive, non-transferable, royalty-free right to use the inventions in its government laboratories for non-commercial purposes. Although such non-commercial governmental use is usually not problematic to the company, careful consideration should be given to any potential problems related to the company's commercialization plan as a result of the government's permitted uses. Additionally, in extreme circumstances (for example, where there is a danger to public health or the inventions are not properly exploited for the public good), the government may exercise its Bayh-Dole "march-in rights" and, among other things, force the university to grant a license with respect to the subject inventions to another third party. It should be noted, however, that the government very rarely, if ever, exercises these march-in rights.

The University Has A Desire To Exercise Academic Freedom

The university and the life sciences company often have competing interests with respect to the publication of results of academic research activities related to the patent and other intellectual property rights licensed to the company. The university inevitably desires to publicize (for example, by publishing a report in an academic journal or presenting a report orally in a conference setting) explicit results of the research and specific details regarding the underlying laboratory testing, data and intellectual property. Such publication may further two fundamental objectives of the university. First, it may advance the university's mission to serve the public good and educate the public. Second, it may improve or sustain the university's reputation and prestige in the academic and medical communities as a center of knowledge.

The company, by contrast, inevitably desires to preserve the confidentiality of such research activities in order to maintain a competitive advantage. A common compromise in the license agreement is inclusion of a provision pursuant to which the university is required to provide the company with an advanced copy of any proposed publication and the ability to require the removal of any of the company's confidential or proprietary information. Also, the license agreement should require that the publication or presentation be delayed for some period of time (often two to three months) in order to provide the company with the opportunity to obtain appropriate patent or other intellectual property protection.

The University May Want To Control Patent Prosecution And Infringement Matters

Patent prosecution is a very technical matter and it is crucial that a patent portfolio is handled with extreme diligence and care. Poor prosecution can result in the loss or diminishment of proper claim protection. Likewise, in the event of an actual or possible claim of infringement of the patent portfolio or that the manufacture, use or sale of the subject invention infringes the intellectual property rights of a third party, it is important that these claims are handled in a manner that adequately protects the interest of the company and the university.

In the context of an exclusive license, both the university and life sciences company often desire to control patent prosecution and defense. The university, as the owner, has a strong vested interest in pro-

tecting its ownership rights. The company, as an exclusive licensee with a substantial financial investment in the patent portfolio, has the same desire to control the prosecution and defense. Often a compromise can be reached pursuant to which one party (often the university) retains control of prosecution and defense, but must provide the other party (often the company) with opportunities to receive all material correspondence and documents (including advance copies of drafts thereof by such party) and provide significant, though often non-binding, comments and input. Further provisions may allow for one party (often the university) to have first right to prosecute or defend with an option to opt out and allow the other party (often the company) to obtain control. Also, the parties may agree to retain patent counsel mutually agreeable to both parties or selected by one party (often the university) and reasonably acceptable to the other party (often the company).

The University Requires The Life Sciences Company To Conduct And Rely On Its Own Due Diligence

In a non-university license agreement, the licensor will often provide the licensee with certain assurances regarding the validity of the licensed intellectual property rights. This typically includes, for instance, representations and warranties (which may be subject to a "knowledge" qualifier) to the effect that the licensed patent and other intellectual property rights do not infringe or misappropriate any rights of any third party. Universities, however, often strongly resist inclusion in the license agreement of any representations or warranties regarding infringement or misappropriation. Rather, it is a common university position to insist that the company conduct and rely solely on its own due diligence review. To this point, company management should request all of the usual representations and warranties, including relating to infringement or misappropriation, to the extent consistent with university policy.

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Universities can be a significant resource for the life sciences company. A successful licensing transaction between a university and the company is beneficial to both parties. By understanding the unique issues and concerns that arise when analyzing and negotiating a license agreement with a university, management is better able to advocate on behalf of the company and achieve its ultimate goal of maximizing shareholder value.