

## IP ADVISOR

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2007 ISSUE**TOP 10 ISSUES IN LICENSING TECHNOLOGY FROM UNIVERSITIES***By Kingsley L. Taft and Laurie A. Burlingame*

Many successful products on the market today began as embryonic inventions in university research laboratories. Gene splicing, magnetic resonance imaging and atomic microscopy, for example, all had their beginnings in the university setting. Since the passage of the Bayh-Dole Act in 1980, universities have sought to license their core patents and technology to entrepreneurs and companies of all sizes, in the hopes of achieving commercial success. According to a 2007 report from the Association of University Technology Managers, member universities granted 4,932 new licenses in 2005, bringing the total number of current, active licenses to 28,349.

Obtaining a license to university patents and/or technology can benefit all parties involved. Below we offer a series of issues that companies (or individuals) should consider when reviewing and negotiating an exclusive university license. These matters are ones that universities and licensees can generally resolve in a manner that protects the university licensor's interests while also giving the company licensee ample room to develop and commercialize the licensed technology.

**1. Make sure the license grant contains all the university rights needed to commercialize the licensed technology.**

One of the most important aspects of the license is definition of the rights that the license confers upon the licensee. In this regard, a company should ensure that the definition of the "Licensed Patents," "Patent Rights" or other term used to describe the licensed rights, contains all of the patents and patent applications owned by the university needed to carry out the research and development plan. Moreover, companies should make sure to obtain a license or other right to use any other university technology or materials that are necessary for fully commercializing the licensed patents. For example, in the case of patents that cover inventions in the biotechnology industry, companies will often need to also obtain a license to the actual biological materials, such as cell lines or microbial strains, in order to be able fully exploit the licensed invention. In other areas, companies might need to obtain a license from the university to technology or know-how associated with the invention.

**2. Consider broadening the license grant to include improvement inventions.**

Companies may want to consider negotiating with university licensors for rights to future improvements. A company's success with this request often varies with the university involved, because universities have varying policies on whether a license or option to future improvements is possible.

Ideally, companies should try to obtain rights to any improvements that might be developed after the effective date of the license agreement so as to avoid having to

negotiate a new license when the situation arises. In contrast, universities often are concerned about licensing improvements on set terms before the actual improvements exist. Some negotiated outcomes include an improvements provision that covers inventions created in a particular university laboratory related to the licensed patents over a particular period of time, or that relate to any improvements that are dominated by the licensed patents. Regardless of how improvements are defined, the company typically will try to have the improvements automatically become part of the license grant. Alternatively, universities often prefer to offer an option to negotiate a license to the improvements, as opposed to an automatic license grant.

### **3. Consider the scope of the university's retained rights.**

In our experience, the university will ask to retain rights to practice and use, and allow other academic institutions and not-for-profit entities, to practice and use, the licensed rights. These clauses are typically limited to non-commercial research and educational purposes, and thus are generally acceptable to companies. One area of potential disagreement is whether such research could be funded by a for-profit commercial entity. Companies may have concerns that sponsored research by a competitor could allow a competitor to gain access to improvement inventions, whereas universities often insist on protecting their academic scientists' freedom to conduct research no matter the funding source. Resolution of this issue will vary with the technology involved and in our experience can often lead to the company not only taking a license but also sponsoring research at the university.

### **4. Obtain commercially useful sublicensing rights.**

To successfully commercialize products based upon the licensed patents, companies will often enter into collaborations with other parties who will need access to the licensed patents. Therefore, when negotiating a license agreement, companies should ensure that it grants them adequate sublicensing rights. Conversely, universities will be concerned with unfettered sublicensing rights and will want a variety of limitations on sublicensing activity. For example, companies will not want to be required to obtain the university's approval to enter into any specific sublicensing agreement, whereas universities may want to review the identity of the proposed sublicensee and ensure that the sublicensing terms are at least consistent with (if not the same as) those in the license agreement. In our experience these provisions are often heavily negotiated to take these different interests into account.

One additional issue that often arises when granting sublicenses is what happens to a sublicense upon termination of the license agreement. Sublicensees will likely want some assurance that they will have access to the licensed patents over their entire life. Therefore, companies often ask the university to assume the sublicensing agreements if the license agreement with the university terminates before the sublicense term has expired. Alternatively, universities often are more comfortable agreeing to negotiate a direct license with any sublicensee upon license termination as opposed to committing in advance to taking on a sublicensee as a direct licensee. This issue is often deferred until there is a sublicense agreement in the works, whereupon the company may approach the university for additional protections for the proposed sublicensee. At this point, the university is often willing to grant the additional protections, since the sublicensee's identity and proposed sublicense use are then known.

## **5. Structure reasonable royalty provisions given the proposed business.**

Companies should use royalty calculation methods that will allow them to make commercially reasonable payments possible given their proposed use of the licensed technology. Some typical methods used for calculating royalties include stream of fixed payments, per-unit royalty based upon fixed costs, or percentage of total sales of licensed products (often defined as net sales). Universities are typically open to different payment approaches, if those approaches match the proposed business and result in a reasonable return for the university. Companies and universities are often willing to combine these different methods in the same agreement, if justified by the company's commercial operations.

Companies often also want to consider including clauses that will help them lower their overall royalty burdens on licensed products. For example, companies often request a royalty stacking provision, whereby a company has the right to decrease the total amount of royalties paid to the university in a royalty period by a specified percentage, typically 50%, if the company needs to obtain licenses from third parties to practice the licensed technology or commercially develop the licensed product. As another example, if royalty payments are calculated based on a percentage of total sales, companies will often ask that the license specify a formula for calculating net sales of licensed products that contain more than one product, *i.e.* combination products, as the company would like to only pay royalties based upon the net sales on the portion of the product that is covered by the licensed patents. In our experience, if properly framed, universities are often willing to consider these company requests.

## **6. Review closely the payment obligations.**

Companies should carefully scrutinize all defined terms that relate to payments to be made to the university under the license. For example, if royalty income is to be paid based upon the percentage of sales method, the company should make sure that the definitions of "Net Sales" and "Sublicensing Income" are customary and do not contain any surprises. For example, the Net Sales definition typically excludes trade and cash discounts; amounts repaid or credited by reason of price adjustments, returns or rejections; and any sales taxes or government imposed charges paid for by the licensee. Moreover, companies may want to have set aside a certain portion of the licensed products for marketing and promotional purposes, which should not be used in calculating Net Sales. Finally, if a company is going to pay royalties on sales by its sublicensees, then sublicensing income shared with the university should specifically exclude Net Sales by sublicensees to make sure there is no double counting.

## **7. Develop commercially reasonable performance milestones.**

Companies should develop performance milestones that they feel meet with a reasonable amount of commercial diligence. In our experience, universities understand this need and are typically chiefly concerned with a licensee not using the licensed technology at all or only in a narrow field when the licensed technology has broader application. For early stage companies licensing nascent technologies, companies will often want the milestones to be fairly broad and open-ended as it is likely too early in time to determine the events that will occur over time. For example, a performance milestone can be linked to obtaining a certain level of financing over a specified period of time, or to setting aside a certain amount of money for research and development each year. When licensing a more advanced technology, the milestones are often more detailed. For example, in the case of a potential pharmaceutical product that has passed initial testing,

performance milestones may be linked to the outcome of clinical studies or selling a certain percentage of products over a specified period of time.

Attention should also be directed to defining the consequences of failing to achieve performance milestones. In our experience, universities are often willing to provide for reasonable cure periods, provided the company licensee is continuing to develop the licensed technology and working to cure any diligence failures.

### **8. Managing patent prosecution and dealing with regulatory agencies.**

Companies should give some thought to the role they would like to play in patent prosecution. University licenses typically grant this role to the university and provide for some sort of input right on the part of the licensee. If a company is uncomfortable with this situation, it should consider adding a provision whereby it will be able to designate patent counsel to assist in these filings or suggest that outside patent counsel, acceptable to both parties, be hired for patent prosecution and maintenance purposes. As an alternative, companies may request control over patent prosecution, a request that some universities will grant if there are sufficient protections in place to ensure that the licensed patents are prosecuted to the fullest extent possible (and if not, then returned to the university's control). In almost all cases, companies typically pay patent prosecution costs for the licensed patents.

In other regulatory areas, companies often take the lead. For example, typically university licenses grant the companies the right to control and assume responsibility for any regulatory filings for commercial approvals, such as filings with the FDA for medical devices or pharmaceuticals. This approach makes good sense, for universities are usually not in the business of commercializing products.

### **9. Make sure the termination provisions work for the business.**

License termination provisions vary based upon the technology and industry, however, companies typically have the right to terminate the license for convenience upon giving prior written notice. This allows a company licensee to return a license it is not using without penalty.

Companies should consider whether other termination provisions are appropriate. Clearly there are certain situations where the university should have the right to terminate the license, such as if a company fails to pay royalties when due after a reasonable cure period. However, there are other situations that are more debatable. For example, does the company wish to allow the university the right to terminate the agreement if the company does not meet certain performance milestones within a specified period of time? Such termination rights are often closely watched by both the university and the company, to make sure the university is adequately protected and the license cannot be revoked unfairly from the company.

Even in situations where termination is appropriate, it is important for both parties to make sure that the language used to describe the terminating event is clear because the stakes can be so high. For example, termination for bankruptcy is an occasion when disagreements can arise, such as whether the university should be able to immediately terminate the license if a petition in bankruptcy is filed against the licensee, or whether the university should only be able to terminate if a petition in bankruptcy has not been

removed within a specified period of time after filing. Clear, specific drafting will help to avoid disputes in the future.

**10. Carefully review all sections of the agreement, even the seemingly routine.**

Companies should also carefully review all other sections of the license agreement to see if there are any unacceptable or unusual provisions. For example, companies should make sure they are comfortable with dispute resolution causes, assignment provisions and publicity rights. Universities are typically open to modifying these seemingly routine clauses if there is a good business reason. One area in which universities generally show more caution is indemnification, because universities do not want to put any university assets (such as the endowment) at risk. Universities will often refuse to accept company proposed changes to indemnification and limitations on liability provisions.

One way to address specific company concerns is to draft around the particular circumstance. For example, university licenses typically state that the licensee cannot use the name of the university in any promotional material without the prior written approval of the university. Here, a company could seek an exception whereby it would not need university approval to disclose the fact that the university has exclusively licensed the company.

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