**Portfolio Media. Inc.** | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

# In-License Agreements With Nonprofits: 5 Considerations

Law360, New York (May 15, 2012, 1:01 PM ET) -- Many of the most successful and profitable technologies being developed and commercialized by technology-based companies, particularly in the areas of life sciences and clean technology, were initially developed by universities and other nonprofit institutions. Since these technologies are frequently out-licensed by the nonprofit institutions at early stages of development, most of the responsibility for developing and commercializing these technologies will be assumed by commercial entities.

In most cases, the ability of a company to succeed in producing a commercial product based on licensed technology will largely depend on how successful the company is in obtaining funding from the investment community. The process of obtaining such funding will involve the conduct of a significant amount of diligence by the entity's existing and/or potential investors and will include, among other things, a review of the terms of all in-license agreements.

Any such in-license agreement that fails to include certain critical provisions or includes provisions that are viewed by existing or potential investors as overly burdensome or unreasonable can severely inhibit the company's ability to raise funding from investors.

These provisions that may be subject to heightened scrutiny include monetary terms — such as up-front fees, sublicense fees, and milestone and royalty payments — as well as other provisions that relate to the rights to technology improvements and diligence obligations. Set forth below are five issues that will typically attract the interest of potential investors and should be considered by a company when negotiating an in-license agreement with respect to technology from a nonprofit institution.

## 1) Rights to Improvements

The inclusion in the in-license of a precise definition of the technology being licensed, the scope of the license grant, and any limitations upon the scope of the license is, of course, of great significance to the company and its potential investors. However, in addition to the rights granted to the company on the date of execution of the license agreement, attention should be paid to the rights of the company to any future improvements that may be developed by the nonprofit entity.

Most nonprofit entities are reluctant — either as a matter of policy or due to the restrictions of the Bayh-Dole Act — to grant rights to new technologies that are developed by the nonprofit entity after the effective date of the license agreement. On the other hand, the company (and its investors) has an interest in securing rights to any future improvements to the licensed technology that the nonprofit entity develops after the effective date of the license agreement to avoid both the need to negotiate new terms each time an improvement is identified and the risk of having a competitor gain access to the improved technology.

In most cases, the company should be able to negotiate an understanding in its in-license agreement that the license grant covers improvements that are "dominated" by the original licensed patent rights. In addition, if the nonprofit entity is reluctant to grant an automatic license to future improvements, the company should consider attempting to obtain an option or a right of first refusal to license future improvements on terms to be negotiated in good faith at the time the improvement is identified.

The company may also consider including other limitations that may make it easier for it to obtain rights to such improvements, including limiting its rights to only those improvements that arise from the laboratory of the inventor(s) of the licensed technology and/or to limit its rights to improvements made during a definitive period following the effective date of the in-license agreement.

## 2) Right to Sublicense

The company will typically try to avoid the imposition of any restrictions upon its ability to sublicense the licensed technology to a third party in order to enhance the likelihood that such technology will be successfully commercialized. This issue has become even more important in the current market as companies increasingly turn to nondilutive sources of funding — such as strategic partnerships and collaborations — which usually will require the company to grant a sublicense to its collaborative partner.

Nonprofit entities may attempt to include limitations on the company's right to grant sublicenses through a variety of mechanisms including by requiring notice to the nonprofit entity in advance of a sublicense and/or prior consent of the nonprofit entity. The company should resist the inclusion of any limitations on its right to grant sublicenses to the licensed technology. Further, the company should consider clarifying the effect that termination of its in-license agreement with the nonprofit entity will have on any outstanding sublicenses.

At a minimum, the company should attempt to negotiate an obligation of the nonprofit entity to negotiate in good faith a direct license with the sublicensee in the event of termination of its in-license agreement. In order to avoid the potential for future disputes over such terms, the in-license agreement should provide that, in the event of such termination, the nonprofit entity will automatically enter into a license agreement directly with the sublicensee on substantially similar terms as those contained in the in-license agreement between the company and the nonprofit entity. Such provisions are crucial since any sublicensee will invariably require assurances as to the survivability of its rights to the licensed technology whether through a sublicense with the company or a direct license with the nonprofit entity.

## 3) Diligence Obligations

Most nonprofit institutions will insist upon a right to terminate the license agreement in the event that the company fails to meet certain performance or diligence obligations. These diligence obligations may include a general requirement to use commercially reasonable efforts in developing the licensed technology or specific requirements to achieve certain financial, development, or regulatory goals by certain dates (including raising a certain amount of external funding, making certain filings with the U.S. Food and Drug Administration or other applicable regulatory authorities, and/or making the first sale of a product incorporating the licensed technology).

Given that a failure to meet a diligence obligation may result in termination of the license agreement, the company should take care to negotiate reasonable diligence obligations that include some flexibility, including rights to cure failures to meet specific diligence milestones and/or automatic extensions of diligence dates (which are sometimes granted in exchange for an additional payment) if the company is otherwise using commercially reasonable efforts to develop the licensed technology.

## 4) Control Over Patent Prosecution

In many cases, the nonprofit entity, as the owner of the technology, will negotiate to retain control over the prosecution of licensed patents. Most nonprofit entities are, however, willing to grant the company the right to review and comment upon patent prosecution strategy and filings applicable to the licensed patents. Further, even if the nonprofit entity seeks to retain control over patent prosecution, it will typically require the company to assume the costs related to future patent prosecution and, in many cases, all or a portion of the costs related to the filing and prosecution of the licensed patents conducted prior to the effective date of the license agreement.

Since control over patent prosecution is viewed favorably by the investment community, the company should attempt to retain as much influence over the process as possible, including its right to choose counsel of its own to assist with patent prosecution and/or the right to participate in the choice of the nonprofit entity’s counsel who will manage the patent prosecution process.

Further, in some cases, the nonprofit entity will agree to permit the company, as the exclusive licensee of the licensed patents, to control the prosecution, albeit with the inclusion of certain controls, including covenants to diligently prosecute patents in certain jurisdictions and to reasonably consider all comments and suggestions made by the nonprofit entity or its patent counsel with respect to the prosecution of the patents.

## 5) Change in Control Transactions

A change of control transaction involving the company will frequently highlight the delicate balance between the interest of the investors of the company in realizing a gain on its investment and the interest of the nonprofit entity in being able to control the entity that is developing and commercializing its licensed technology. In most cases, the company should resist granting any right to the nonprofit entity to directly or indirectly influence its ability to consummate a change of control whether through a requirement that the nonprofit entity consent in advance to any such change of control transaction or otherwise.

The company may consider offering to provide the nonprofit entity with prior written notice of a sale transaction or even the payment of a fee to the nonprofit entity upon consummation of the sale transaction, the amount of which may be dependent upon the period of time between the execution of the license agreement and the consummation of the change of control transaction and the importance of the licensed technology to the value of the company.

The five issues described above are not the only issues that require attention by companies during in-license negotiations; however, these issues are often overlooked. Companies should not be hesitant to raise these issues during negotiations as these provisions can be structured in a variety of ways to address the concerns of the company (including its existing and potential investors) and the nonprofit entity.

--By Tania Rodrigues Cleary and John J. Cheney, Mintz Levin Cohn Ferris Glovsky and Popeo PC

*Tania Rodrigues Cleary and John Cheney are members in Mintz Levin's Boston office.*

*The opinions expressed are those of the authors and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.*