Dealing with Spinout Companies

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ABSTRACT

This chapter provides a practical guide for organizations seeking to transfer their intellectual property (IP) rights to a spinout company (normally through a licensing agreement) so that the company can convert the IP into products or services that benefit the public. Based on experiences at Stanford University over the past three decades, key issues have been identified for negotiating transfer to a spinout, and guidance on best practices for reaching a successful agreement is provided. The chapter briefly reviews potential conflict-of-interest and conflict-of-commitment issues that inevitability arise when employees of public research organizations become involved in spinout companies.

1. INTRODUCTION

Public Research Organizations (PROs) often create spinout companies to commercially develop and market the PRO's inventions. The new company may be formed by PRO faculty, staff, and/or students, by entrepreneurs not affiliated with the PRO, or by a combination of these parties. In almost all cases, investors in the new company desire a relationship with the inventors of the licensed technology. The investors recognize that the know-how, "show-how," and detailed knowledge of the technology possessed by the inventors will be important to the company's success.

The technology transfer office (TTO) has an important role to play in this process, one that can take many forms. The TTO must be clear about what roles it will or will not play in the formation of new companies that utilize PRO technology and/or PRO employees. The most common model for U.S. TTOs is passive involvement. Referrals are provided to resources that can assist in the spinout process, but the TTO itself is not actively involved. Active involvement does occur when the TTO engages in some, or all, of the following activities: writing or help in writing the business plan, assisting with incorporation of the company, finding initial seed funding, recruiting a management team, and securing the first-round venture funding. Such active involvement can be very time consuming and normally requires people with special skills and experience.

Spinout companies are frequently formed because spinouts are the only alternative available for converting a technology into useful products or services. Of course, it is the *products and services* stemming from new technology that improve our health and standard of living—*not* the technology itself. Often, however, inventions are undeveloped and unproven, and established companies are unwilling to commit resources to license and develop the technologies. The inventors, on the other hand, may believe strongly in the social value of the inventions, and so will assume risk and make deep commitments to foster an invention's further development into products. The inventors often do so by getting involved in spinout companies.

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The AUTM (Association of University Technology Managers) surveys show that in recent years, 5% to 10% of licenses annually granted by U.S. universities are granted to spinout companies. In 2003, U.S. universities reported 374 licenses to spinout companies, or about 7.5% of the total licenses granted. Sold equity totaled US$39 million, which was about 3% of total royalty income in 2003.

Over the past 15 years, Stanford University has taken equity as part of its licensing agreements with 140 spinout companies. As of 2005, Stanford holds equity in 85 companies. Fourteen percent of the companies in which Stanford has taken equity have failed, making the equity worthless. For 18% of the companies, equity has been sold. Two companies generated more than 80% of the total amount of cashed-in equity (US$22.5 million). Spinout companies have paid earned royalty income and annual minimum payments, but no data exists for these categories. As is true for licensing in general, when licensing and supporting spinouts, the focus should *not* be on how much income can be generated, but on the value flowing from a new partnering relationship (for example, consulting opportunities for professors, sponsorship of research, hiring of graduating students, and donations and gifts of equipment) and on the public benefits from the products and services the spinout may produce. Spinout companies can be a significant source of new jobs and of local, state, and federal taxes. They can produce exports. A few spinouts (for example, Hewlett-Packard in Silicon Valley) have grown into major corporations that are regional anchors, attracting entrepreneurs and other companies.

2. EVALUATING THE ENVIRONMENT

The role the TTO plays with spinout companies will be strongly influenced by the general attitude of the PRO's senior administration and members of the governing board toward spinouts. These individuals can be encouraging, supporting, merely tolerating, or discouraging. One can see why in some cases their views may be less than positive. The involvement of PRO personnel with spinouts can create conflicts of interest, and valued faculty members who take a leave of absence to work in a spinout may not return. Moreover, leaves of absence require changes in teaching assignments and graduate-student supervising. If leaves are not taken, the commitment of faculty members to spinouts may lead faculty members to neglect teaching or research responsibilities (such conflict issues are covered in detail later in this chapter). Clearly, concerns of senior administration and board members about spinouts, involving PRO personnel, can be legitimate.

Almost all PROs in the United States at least tolerate spinouts, and the trend in recent years is toward greater acceptance of spinouts. Most faculty who are actively involved with spinouts speak positively about their experiences. If these individuals obtain significant wealth, usually through stock options, they serve as role models for others. Experience working with a spinout can also *enhance* faculty performance at the university. John Hennessy, the president of Stanford University, took a one-year leave of absence in the 1980s to be involved with a spinout named MIPS. He openly reports that the experience with MIPS was extremely valuable and useful for managing his teaching and research activities after returning to Stanford.

3. NEGOTIATING A LICENSE AGREEMENT

The TTO's first involvement with a spinout is usually to provide a license to the technology that the company plans to convert into commercial products or services. In most cases, the licensed technology will be the company's fundamental technology, and so the company will request an exclusive license. Investors want to be assured that their investments will be protected by patents or other intellectual property. In the license agreement itself, investors will normally focus on:

- the length of the exclusive period
- field-of-use limitations
- improvement inventions
- agreement assignment provisions
- financial terms

Investors almost always request a life-of-patent exclusive period. This is to be expected. In the

United States, because a large percentage of inventions is generated through research supported by the federal government, the policy is to limit the exclusive period. In the initial Bayh-Dole Act, the U.S. government specified that the exclusive period would end either at five years from first product sale or eight years from the effective date of the license agreement, whichever came first. Although this requirement was later eliminated, it is still used as a guideline by many U.S. TTOs. In the United States, government guidelines are that the term of the exclusive period should be the shorter of eight years from the effective date of the license agreement or five years from the date of the first sale of the licensed product. Experience has shown that in most cases, a period of five years from the first licensed product sale allows a fair return. However, if the company can provide convincing evidence that a longer period would be needed in the company's situation, such evidence would be evaluated and considered. If such evidence were not available at the time of licensing, but might appear at a later time, the new evidence could eventually justify extending the exclusive term.

Investors almost always prefer no limitations in the license. And if the TTO insists on a defined field of use, the investors will want a limitation as small as possible. Sometimes a compromise allows a grant of exclusive right for a specific field of use but permits access to other fields of use. Such an arrangement could be made by granting a nonexclusive right to other fields of use, or by specifying a right to add other fields at a later time, but with a requirement for a business plan, added payments, and appropriate diligence terms for licensed product development in the added fields.

Investors will also prefer to be automatically added to license-improvement patents that may emerge from continuing research in the area of the licensed technology. If the improvement has been described in the specification of the licensed patent, and the original invention and the improvement have common inventors, then the improvement could be filed as a continuation-in-part (CIP) application. In such cases CIPs would normally be part of the definition of licensed patent(s). During the exclusive period, no one else could practice the improvement patent without rights to the dominant licensed patent, so the improvement patent has no value to the PRO. To add improvement patents that are not CIPs under the license agreement, the recommended policy is to do this only with the express written consent of the potential inventors.

Experience has shown that the most common exit pathway for PRO-based spinout companies is merger and acquisition. Very few reach an initial public offering (IPO). Thus, the ability to assign the license rights to the merging or acquiring party can be very important. The options for the TTO are: (1) no assignment without the written permission of the TTO, (2) automatic assignment to a party, of all of the assets of the licensee, without an added fee, or (3) automatic assignment to a party, of all of the assets of the licensee, *with* an added fee. The typical approach is to combine (1) and (3), so an assignment that is not part of a merger or acquisition requires written approval, and an assignment that *is* part of a merger or acquisition is automatic but requires payment of a negotiated amount.

Spinouts must carefully manage their available cash; for license fees, the spinout will prefer to trade equity for cash. Although fully paid licenses for equity are sometimes written, they are rare, and usually normal financial terms apply. The cash license fee is kept low (but usually not to zero), with equity taken as a substitute. The annual fee may start low and then increase over time. The earned royalty is targeted at what would be normal for the technology; however, in some circumstances, the spinout must also license from others to have all the rights needed to create a licensed product. In such circumstances, each of the licensing parties is asked for a reduction, so that the total earned royalty rate is reasonable. And with patent cost reimbursement, the payments are sometimes delayed until a certain funding level for the spinout is reached.

How much equity should the PRO receive for the technology license? This is a challenging question. Certainly the amount of equity to the PRO should not be so great that insufficient equity remains for successfully developing the business. Equity will be needed to secure fund-

ing and to attract the best available people. Some entrepreneurs have proposed that the amount of founding equity for the technology should range from 1% to 10%. If the technology is an unproven idea, then 1% would apply. If the technology is essentially ready for market, then 10% would apply. Following this rule, most PRO technology, which is in the earliest stage of development, would fall within the 2% to 4% range. However, the specific situation may include other factors that affect how much equity is reasonable.

Another issue is whether the percentage ownership of the PRO should remain the same through subsequent funding rounds by antidilution clauses. Investors will not want the PRO to get an increasing number of shares at no cost at each funding round. This is reasonable. However, most will agree to some antidilution provision, such as nondilution through the initial venture round (usually called funding round A), or antidilution until the company reaches a certain valuation.

Investors will also be concerned about diligence terms, which require the spinout company to reach certain milestones or face the TTO's termination of the agreement. Any clause that permits the TTO to terminate the agreement is cause for investor concern, but such diligence terms for the spinout are important because they ensure that the company does not become what John Preston (former director of the TTO of the Massachusetts Institute of Technology) refers to as the "living dead." In such cases, the spinout company never grows beyond a few employees and never progresses beyond the product development phase, or only manages to sell small quantities of licensed product, mostly for evaluation purposes. The intent of the diligence terms (reaching specified funding levels, having production facilities, and reaching certain sales volumes by agreed-to dates) is to ensure that the spinout doesn't lose its viability.

Other sections of a license agreement that are typically discussed during negotiation are:

- *Definitions*, in which key words are defined
- *Infringement provisions*, in which the respective responsibilities of the parties are defined in the event that infringement by a third party of licensed patents is detected
- *Sublicensing*, in which the parameters for sublicensing (including sharing of sublicensing income) are defined
- *Warranties and indemnities*, in which the provisions for protection of the university are defined.

Definitions will normally be the first section of a license agreement. In this section, key words used in the agreement are defined. What is meant by "Licensed Products," "Licensed Patents," and "Licensed Field of Use" is extremely important. A definition should be clearly written so both parties fully understand the meaning; any possible future dispute over the meaning of a key term should be avoided utterly. It is therefore worth investing time to ensure that definitions are clear and unambiguous. Sometimes giving an example will make a definition more understandable. As is true with any of the agreement terms, if a person is presented with a definition that he or she does not fully understand (for example, it contains unfamiliar, legal wording), then the person can either rewrite it to reflect his or her understanding or ask the potential licensee to reword it so that it is understandable.

The *Infringement provisions* section describes what actions will be taken if infringement of the licensed patent(s) by a third party is detected. In the United States, infringement litigation is very expensive; if carried through to trial it can amount to many millions of dollars. Thus, the license agreement should not require the university licensor to pursue litigation for any reason, and certainly not for an infringement. The most common approach to settling accusations of infringement is for the parties to review the evidence of infringement and then decide how to proceed. The most desired outcome is a solution that does not involve litigation. The university may be able to use its influence to find such a solution—most companies wish to maintain good relationships with universities, so they will usually also seek a satisfactory solution. However, if it appears that litigation is the only possible course of action, then the licensee and the university can

agree to pursue the litigation jointly (and share both costs and awards), or if one party does not wish to join, the other party can pursue the litigation. The nonjoining party will provide reasonable support as requested, but the litigating party would pay all costs and retain any awards that might result.

The Sublicensing section describes how the licensee may grant another party the right to make and sell licensed products under the third party's brand name. Sublicensing does not apply to situations where the licensee is having components for a licensed product manufactured by others or where the licensee is using a distributor or other party to sell licensed products. A sublicensing provision is only included in an exclusive license. For a nonexclusive situation, the TTO will grant further licenses to the licensed patent(s). The main issue in the sublicensing provision is how the sublicensing income will be shared. At the time the license is signed, the most common approach is to share sublicensing income equally. In practice, sublicensing is very rare, but if it does occur, it will occur well after the licensee has been selling licensed products. Typically many years will have passed since the license was signed and the 50/50 sharing will probably have been renegotiated. The sublicense, at the time of issue, would almost certainly include patents, know-how, and perhaps even training from the company issuing the sublicense. To be fair, the TTO should agree to compare the relative value of the original licensed patent(s) to what the company is adding under the sublicense to determine a fair distribution of sublicensing income.

Warranties and *indemnities* are provisions that protect the university. This is one area in which attorneys are necessary and legal terminology may be required. If any significant changes to these provisions in the template agreement are requested during negotiations, the technology transfer officer should stress that making any changes is very difficult and will need to be approved by the university's attorneys. In most cases, university attorneys will not approve significant changes. Companies will usually complain that these provisions are too one-sided in favor of the university, but without such provisions, the risks to the university would be so great that licensing would not be possible. Given that the parties are partners and not competitors, and that both have strong motivations to maintain a good relationship, disputes can often be resolved through discussion. Thus, the provisions in the warranties and indemnities section of the agreement are very rarely, if ever, invoked.

4. CONFLICT OF INTEREST AND COMMITMENT

Conflict of interest and conflict of commitment are serious concerns for the PRO. The presidents and members of the governing boards of PROs are charged with maintaining and protecting the reputations of their institutions. These individuals worry about any type of activity or situation that could reflect badly on the integrity of the PRO, because a loss of public trust would have serious negative consequences, including lost gifts, donations, and funding from potential research sponsors. So it is not surprising that considerable attention is given to identifying and managing COI (a conflict resulting from a financial interest held by a person employed by the PRO) and COC (a conflict whereby the commitments of the PRO employee to the institution are adversely affected).

Conflicts can result in:

- loss of public trust in both the PRO and/or an individual connected to the PRO
- unfulfilled commitments to research sponsors, students, and/or to general PRO responsibilities
- bias, when reporting research results or not reporting research findings at all
- exploiting the work of graduate students
- adverse and embarrassing reports in the media

Some potential outcomes due to conflict situations include:

- research directions and priorities moving toward company interests
- restrictions on the distribution of research results

- pipelining of research results and related IP to a particular company
- inappropriate access by a company or individual to PRO facilities

Most PROs recognize that conflict situations are unavoidable in the current environment. If the PRO is to contribute to the public good, the PRO must enter into relationships in which conflicts can arise. Governments worldwide are looking more and more to PROs to contribute to economic development and growth, and legislation similar to Bayh-Dole is appearing all over the world. PROs therefore are creating "early warning systems" to identify when a potential conflict situation is developing. Attention can then be directed to the situation to ensure it does not evolve into an actual conflict with negative results. A conflict situation in itself may not be bad, and in fact it may allow important benefits to flow to the individual and/or the PRO. But the conflict-management system of the PRO must review and monitor conflict situations to avoid negative outcomes.

To manage conflict situations, many PROs implement an annual survey of all faculty members. The faculty person lists all outside interests of himself or herself and his or her spouse (if any) that could create conflicts. The information is reviewed by the PRO administration, and any areas of concern are discussed with the faculty member.

Most PROs have developed COI and COC policy statements that identify specific situations requiring an ad hoc conflict review. At Stanford University, if an employee (for example, a professor) is to be involved with a spinout company that has applied for or been granted a license from the PRO, then an ad hoc conflict review would be required.[1, 2]

Box 1 sets out examples, involving conflicts of interest and commitment, that may clarify some of the issues PROs may confront.

5. CONCLUSIONS

A spinout company may be the best, or perhaps the only, alternative by which newly discovered technology is converted into products or services for public benefit. Governments everywhere have, or are creating, policies and laws to encourage spinouts based on IP rights from PROs. Successful spinouts create new jobs and contribute to economic development, and they have the potential to grow into large multinational corporations. Thus, creating an environment that nurtures and encourages the formation of spinout companies is a reasonable goal of all regional economies. The role of the TTO in such an environment can take many forms. The TTO must evaluate the environment in which it exists and determine what role it will play in the formation of the spinout company. One fundamental role is to provide the licensing agreement that will allow the spinout to seek funding from potential investors. In doing so, the TTO must balance the interests of the PRO it represents with those of the spinout, as well as with the interests of society. The TTO also must recognize potential damaging conflict situations and participate in developing and implementing policies and procedures to avoid or minimize them. ■

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1 See Stanford University's policies on faculty conflicts of commitment and interest at www.stanford.edu/dept/DoR/rph/4-1.html.

2 Other sources of COI guidelines include: (1) the October 2001 *Report on Individual and Institutional Financial Conflict of Interest* published by the Association of American Universities (AAU), (2) the June 2003 *Recommendation of the Council on Guidelines for Managing Conflict of Interest in the Public Service* published by the Organisation for Economic Co-operation and Development (OECD), and (3) the 2004 *Approaches to Developing an Institutional Conflict of Interest Policy* published by the Council on Government Relations (COGR).

Box 1: Examples Involving Conflict of Interest and Conflict of Commitment

Example 1:
This example is from the first of a series of symposia held at Stanford University in 1982 titled Universities, Industries, and Graduate Education (reported by Lee Randolph Bean in the October 1982 *Hastings Center Report*). Stanford's then-president, Donald Kennedy, presented this example to illustrate the problems that arise as faculty members move from the role of teacher/investigator to that of entrepreneur. Although more than 20 years old, the example is as relevant today as it was then.

Dr. X and his graduate students work on a basic molecular biology project. Dr. X is a consultant and shareholder in Clotech, Inc., which has built a scaled-up facility for producing and testing a useful protein that is the primary gene product from a plasmid Dr. X first got from bacteria cells. Stanford, which has an assignment to the patent on the product, is now considering offers to invest in Clotech, and plans to offer an exclusive license to Clotech for a related process for which Stanford holds patent rights. Meanwhile, Mr. Y, a graduate student who is good at purifying the protein, has complained to the university ombudsman that Dr. X is using every means at his disposal to induce Mr. Y to accept outside employment with Clotech.

The issues Kennedy wished to bring forward for discussion at the symposia were:

Conflict of interest. Is Professor X devoting undue time and effort to Clotech because of his profitable consulting and equity arrangements, to the neglect of his teaching responsibilities? Do his outside ties create competing loyalties between Stanford and Clotech?

Secrecy. Has Dr. X kept past research results to himself, because his colleague, Dr. Z, works for a competitor company? Did Clotech ask Dr. X to delay publication of his work in order to secure an exclusive license from Stanford? [Author's comment: Should Stanford have marketed the license to the patent(s) to others to determine if another party, perhaps one better qualified, would develop licensed products? Or should Stanford seriously consider offering nonexclusive licenses to all interested parties?]

Patents. Should scientific knowledge be owned and traded for profit? Should the university share in that ownership?

Research priorities. Does Dr. X's involvement in a commercial production facility indicate a shift in his focus from basic to applied research? Will the future direction of scientific research be skewed to respond to the needs of private industry?

Graduate students. Have Mr. Y's time and talents been exploited for the gain of his advisor's company?

Public perception. Will extensive ties to the private sector erode public confidence in the detachment and trustworthiness of university research?

Scientific norms. The open and free sharing of information and a disinterested approach to research that puts the advancement of science first are norms that have traditionally governed science, according to sociologist Robert Merton. Are those norms disintegrating as the pull for commercial application of research and consequent profits intensifies?

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Box 1 (continued)

Example 2:
This illustration and the following one were created by the author and are based on experiences at Stanford University.

Clotech has expanded and upgraded the scale-up facility to the point that it will now permit Mr. Y to run experiments in pursuit of his Ph.D.-, qualifying research work that he cannot do with the facilities in Dr. X's lab. Mr. Y's research is fully funded under a U.S. government grant. Clotech is willing to make its facilities available for the research project of Mr. Y, as the company realizes such work will be very relevant to their product plans. Clotech has requested a right to help guide the research work of Mr. Y and also requested a document signed by the university stating that any IP created by Mr. Y resulting from the use of their facilities will be owned by Clotech. Dr. X is encouraging Mr. Y to utilize Clotech's facilities in his research, and is urging the university to accept the requests of Clotech. Clotech has indicated that it would be willing to hire Mr. Y as a paid consultant, as long as he follows the guidance of Clotech in his research, and that any IP created from the research would be owned by Clotech. Dr. X is supportive of Mr. Y being a paid consultant for Clotech under these terms.

Ms. Z in the Office of the Dean of Research has been asked to review the situation and inform Dr. X and Clotech as to what the university's policies will allow in this case. After a careful review, including discussions with Dr. X and Mr. Y, her response is as follows:

- Any IP created by Mr. Y that is related to his research program for his Ph.D. degree, as specified under the work statement in the government grant that is funding Mr. Y's research, will be owned by the university. This is regardless of where and with what facilities Mr. Y conducts such research.
- Mr. Y cannot be a paid consultant for research work that is also funded by the government.
- A designated professor in the department of Dr. X will become a co-advisor for Mr. Y and will be charged with ensuring the research work of Mr. Y is in full compliance with progress toward his Ph.D. degree.
- A collaboration agreement will be negotiated between the university and Clotech that will spell out clearly the terms of the proposed collaboration, including university ownership of IP created by Mr. Y and the right of Mr. Y to freely publish, at any time, the results of his research.
- A meeting will be held with Dr. X and the dean of research to discuss the situation and to ensure Dr. X understands that the university would not allow, under any circumstances, an outside company to direct the research of a graduate student and that ownership of any IP created by a graduate student, as part of his funded research work will be owned by the university.

Example 3:
Professor A in the university's ophthalmology department, a renowned eye surgeon, disclosed an invention four years ago to the technology licensing office. This invention holds great promise for eye surgery. A patent, assigned to the university, has issued. The patent is exclusively licensed to the spinout company EyeCare, Inc., to which Professor A is both a consultant and the chair of the Scientific Advisory Board. Professor A has been given 100,000 shares of the company stock for her services. The university received 200,000 shares of stock as partial compensation for the exclusive license. In addition, EyeCare has sponsored research in Professor A's lab for the past three years (ever since the company was formed). When EyeCare first proposed supporting the research of Professor A, the university established an oversight panel to review research proposals and results, as well as the involvement of graduate students with the company, and to advise Professor A of potential conflict situations.

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Box 1 (continued)

Because of this sponsorship, EyeCare has exercised its right to exclusively license three improvement patents resulting from the research. A separate conflict review was required before the exclusive license could be granted. The university licensing office submitted a report on its marketing the invention to other parties, and a statement that EyeCare is the best alternative for commercialization of the invention, in a timely manner. This conflict review very carefully evaluated how the relationship with EyeCare might impact the graduate students conducting research in Professor A's lab, as the potential for altering the work of students to benefit the company was a major concern.

The invention licensed to EyeCare has now reached the stage where clinical studies, with human subjects, will be required to obtain government approval to sell the medical device in the United States. The lab of Professor A is clearly the best source for coordinating such trails, with Professor A and her colleagues performing the procedures. However, the relationship of Professor A with EyeCare, through which she could profit handsomely if the clinical trails are successful, is a cause of great concern. The university must therefore carefully review the situation in order to determine if it will conduct the trails or not, and if it will permit conducting the trials, what level of oversight and controls will it exercise.

The university, following a review, decides to conduct the trials with the following oversight conditions:

- Professor A must sell all her shares in EyeCare and agree not to acquire any shares in the future, including options to acquire shares.
- The university will sell all its shares in EyeCare and agree not to acquire any shares in the future, including options to acquire shares.
- Professor A will participate in the clinical trails, but will not be the principal investigator for the trials.
- An oversight committee will be formed that will review the results from the trials and any publications related to the trials. The committee will include Professor B, a respected eye surgeon from another university medical center.
- Professor A will fully disclose her relationship with EyeCare in any publications or presentations related to any research connected to EyeCare.
- Professor A's relationship to EyeCare must be fully disclosed and explained on the "informed consent" agreement signed by every human subject participating in the trials.