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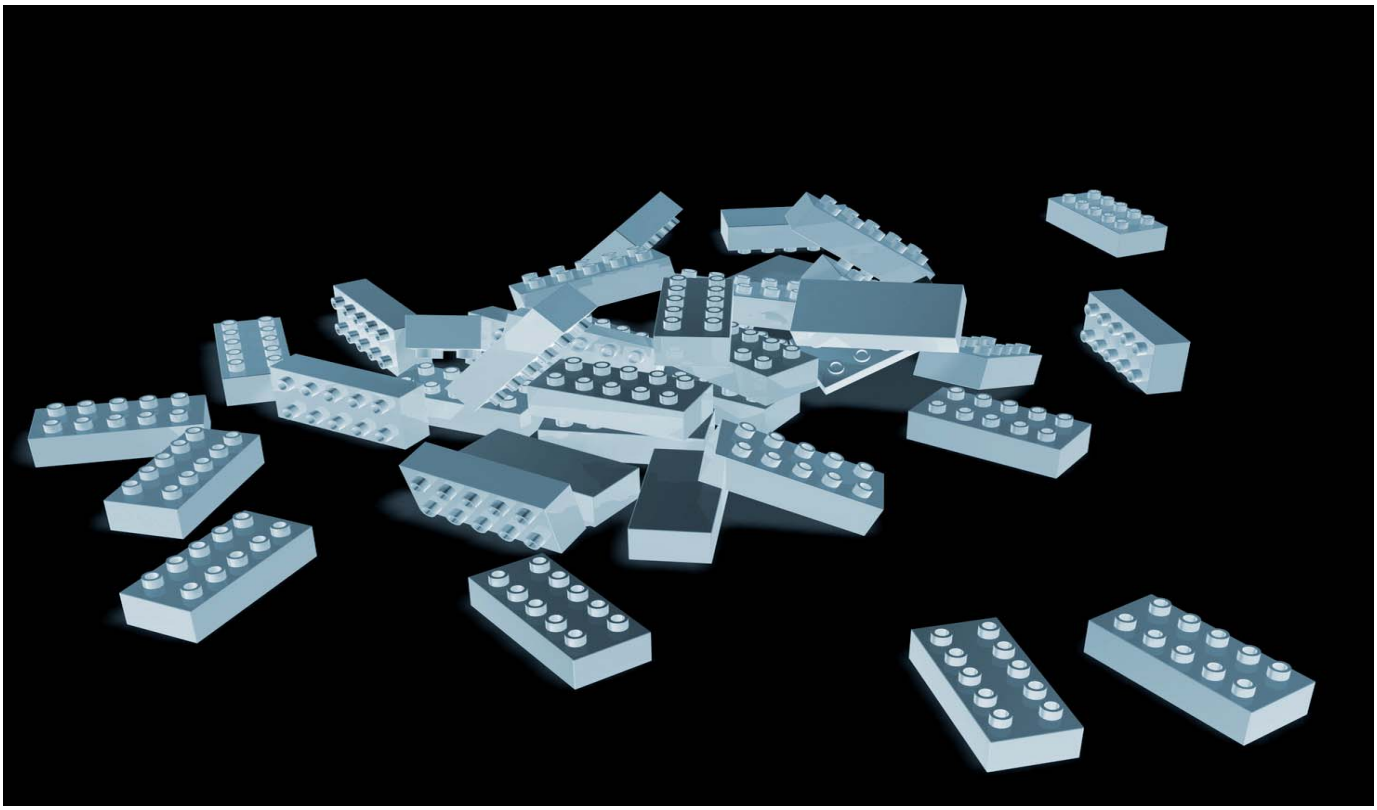

Technology Transfer Management At Smaller Institutions

by
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The »WHY« Question

Your institution may be a smaller academic institution with a modest but highly productive research program, a free-standing independent not-for-profit research institute, or a research institute affiliated with a health care institution. For the purposes of this article, "small" is defined as a research program with an annual expenditure level of $40 million or less.

You and your leadership have realized that good technology management is indeed a sine qua non of a well-balanced sponsored research program. There are many reasons for this which will be discussed below. However, like all modestly-sized institutions, you are doing a broad range of administrative management functions with a limited staff, and technology management is a complex and somewhat esoteric set of functions in itself. What do you do if you want to start a technology transfer program?

»A good technology leadership is a sine qua non of a well-balanced research program«

Before we address the issues of "what to do" and "how to do it," let us consider the answers to the question, "Why?"

First, research is becoming much more results-related. Even public programs expect grantees to pay attention to the application of research results to the solution of problems and the advancement of the state of technology, as well as the state of knowledge.

Second, the pathways from early-stage discovery to commercial application have dramatically shortened in all fields of science, but especially biotechnology, electronics and computer science, although barriers to application in the field of therapeutics and diagnostics continue to be considerable due to FDA regulations in the U.S. and similar clearance requirements elsewhere in the world. The application of new discoveries as process technology in incremental improvement technologies applies to the biomedical and life sciences areas. The highly competitive nature of electronic and computing industries makes the adoption of new technology an absolute survival necessity for companies in these industries.

Third, external sponsors, both public and private, expect a high degree of institutional stewardship of intellectual property. U.S. government agencies in support of the Bayh-Dole Act of 1980 expect grantee institutions to appropriately manage their technology. State agencies interested in technology development in support of economic development are just as insistent; and for-profit research sponsors, with specific goals and objectives in mind related to their business development, are especially concerned that their rights and investments are protected by their sponsors.

Public and private sponsors both expect a high degree of stewardship of intellectual property.

In the times of global economy, research institutions are hubs for regional economic growth. One of the most successful examples is Research Triangle Park in North Carolina.

Fourth, an increasing number of the most productive scientists now expect their institutions to assume an obligation to protect and promote their inventions and discoveries. Many of these scientists have learned their profession in environments where effective technology management has been practiced. Research groups at the leading research universities have become attuned to protecting and promoting inventions, and are aware of the benefits of successful commercialization. Increasingly, the people trained in those groups want to be in institutions where they can see the results of their research used to solve significant problems of health and disease, industrial competitiveness, and quality of life. There is also growing evidence that those investigators deeply involved in industry-sponsored research and technology transfer are among the elite in their fields in terms of more traditional indices of scholarship.

Fifth, in an era of flattened or declining levels of federal research support, universities and other research institutions are realizing the monetary value of inventions through increased royalty payments from technology licensing deals, as well as from increased sponsored research support by licensees. In some institutions, these revenues have reached millions of dollars per year, as institutions become more "entrepreneurial."

Finally, in a now-global economy which is knowledge-intensive, entrepreneurial, and linked by advanced communications systems, the research institutions become "hubs" for regional economic growth and development. Examples such as Research Triangle Park in North Carolina, Route 128 in the Boston area, Silicon Valley in California, and the Salt Lake-Provo technology corridor all attest to the power of university-industry partnerships to create new enterprises and high-quality jobs. For all these reasons and more, it is important that a research institution which intends to be competitive in any field in the coming years, be properly equipped to protect and manage technology.

The »WHAT« Question

Let us next consider "what to do." An organization's technology transfer program consists of a number of elements and functions which are interrelated. Let's consider the foundational elements of a program:

Intellectual Property Policies

An organization should have in place a set of intellectual property policies, covering patentable inventions, copyrights, and other potentially valuable intellectual property such as trademarks and know-how. These policies usually specify policies for the ownership of intellectual property, set out the institution's goals and objectives with regard to the development of intellectual property, delineate responsibilities, and establish the policy for division of proceeds from successful transfers. For academic and non-profit organizations, patent policies have become fairly standard. Even starting with model policies, institutional leadership must make a series of important decisions concerning their reasons for adopting a policy, program priorities, and their approach to the division of royalty proceeds between the organization, its various sub-elements and the inventor or inventors. A customized policy reflecting the priorities and unique characteristics of the organization usually emerges.

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Policies for copyrights, trademarks, and other intellectual property can often be as complex and important as patent policies, but have different aspects due to the legal status of copyrights, as opposed to patents and the cost involved in obtaining proper protection.

The other important element in institutional policies is establishment of the responsibility for implementing the activity and administering the continuing program. Therefore, an organization needs to make key decisions regarding staff responsibilities and operating principles as a policy is being developed.

Model patent and intellectual property policies are available from the Association of University Technology Managers (AUTM), the Council of Government Relations (COGR), and other educational organizations.

A sound set of intellectual property policies, however, is only the necessary foundation for any continuing effort to promote technology development.

Staff Patent Agreements

Once an organization has developed an intellectual property policy it is important that staff, especially those already employed at the time the policy is adopted, sign an institutional patent agreement which in effect obligates them to disclose inventions and to accept an understanding that intellectual property will be assigned to the institution at the time inventions occur (or works are created in the case of copyrights). At the same time, these institutional agreements assure the staff member that the institution is prepared to meet its obligations with regard to the evaluation, development or disposition of inventions or other intellectual property. In many states, attorneys will suggest that patent agreements are not necessary because

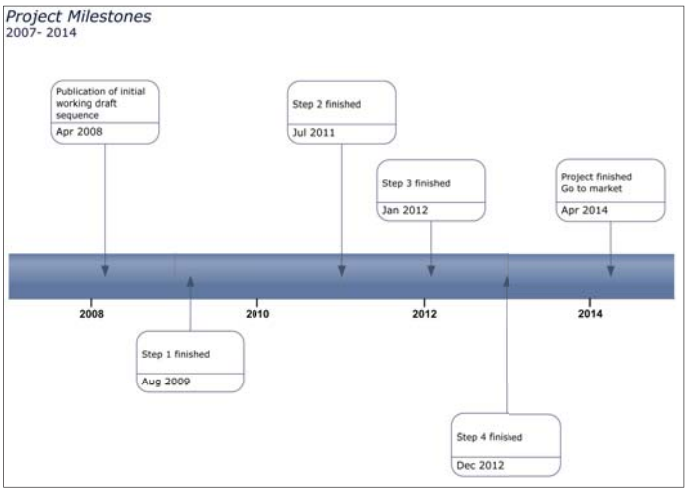
administrative policies become a "condition of employment." However the most prudent course (which may prevent serious conflicts at a later point when a lot of money is at stake) is to adopt a simple patent agreement and include it in employment contracts.

Internal Procedures

Faculty and staff inventors should have a readily accessible road map to guide them when they believe they have made an invention. This road map should be embodied in a set of internal guidelines for inventors or a similar document which explains the institutional policy and operating procedures in sufficient clarity. Procedures should also include the institutional invention disclosure form, and procedures for obtaining appropriate departmental and intermediate level management review and concurrence with the disclosure. Review and concurrence is not a management approval step, but serves as a technical review, and as a means for department chairmen, deans, and research leaders to buy in to the invention, and to stay informed. The internal procedures should look professional and made widely available to faculty, staff and graduate students, both in printed form and if possible, on an organization's electronic intranet. If the system permits, and is secure from external tapping, an organization might consider allowing disclosures to be prepared and submitted electronically. Disclosures, however have importance as a legal document, and should be secure and available in their original form.

Faculty Orientation and Familiarization

Once institutional policies are in place and procedural documents prepared, it is time to provide an orientation to faculty and staff of the new program. There are a range of options and choices for doing this kind of orientation. One successful model is to hand pick promising investigators and schedule a block of time (minimum of four hours) for a technology innovation and commercialization workshop involving outside experts, local or nearby academic success models and representatives of the nearby entrepreneurial community to provide role models for venture development.



Faculty and staff inventors should have a readily accessible road map to guide them.

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A second option would be to have a similar developmental experience for key managers and leaders of the institution (science department chairmen, deans, corporate level administrators, etc.) The focus of this leadership academy would be on the institutional potentials and leadership requirements of such technology innovation and commercialization. Plans should be made to continue faculty orientation and development on a

Even the most cost-effective plan will need some available cash to function. Therefore an important element of a program is having the financial resources.

regular schedule with particular emphasis on including new faculty active in research as quickly as possible after they join the organization.

A policy has been adopted, faculty have been oriented, the leadership has been familiarized, and procedures have been developed. The following operational elements are necessary to have a functional program. We will assume that your organization is approaching this program with the intent of being cost-effective and prudent, and that an already overworked management staff will have to deal with a new and complex set of responsibilities and activities when invention disclosures begin to surface.

Financial Preparation

Even the most cost-effective program, or one highly dependent on outsourcing as described below, will need some available cash to function. An important element of the commitment to a technology transfer program is having the financial resources available to perform a minimal array of tasks which cannot, or should not, be done by in-house staff. External patentability opinions and market analyses which are essential to the proper consideration of options will cost money. In-house staff time requirements to manage the process, keep proper records, and submit necessary reports to public and other sponsors has its cost as well, even though such cost may have indirect impacts on other functions. It is wise in the planning stages of a new program to estimate the potential cost and to plan for it in the organizational budget. In many situations, creative new sources of funding can be sought to fund the initial start-up period of a technology transfer program. For example, community economic development or investment banking interests may be interested in helping to support a technology transfer effort in return for an early look at inventions which may become new business opportunities.

Staff Preparation

Just as a reserve of funds is necessary to launch a technology transfer program, the in-house staff will have to be prepared to handle questions from managers and inventors, and to manage the process of review and disposition of invention disclosures when they are submitted. When a faculty member submits an invention disclosure, it will have to be reviewed.

The initial review can be conducted by the appropriate full-time staff administrator using a relatively simple series of questions. If the invention then passes that hurdle, the institution should be prepared to quickly establish (1) is the invention patentable or protectable? and (2) is there sufficient market potential in the invention to warrant an expenditure of an investment in protecting the invention and seeking a commercial development partner?

Technology Transfer Functions

As individual cases proceed, the responsible staff member, even with external help, will have to manage the process, review progress, help make decisions, and maintain institutional records. The next step is to consider the functions which are involved in a technology transfer program, and then how to accomplish them. The following functions are time-consuming and require professional skill and experience. A new or small program can augment staff effort through outsourcing.

Preliminary Patentability Opinion

A common practice is to ask a patent attorney to review the invention, interview the inventor, and possibly interview a sample of the relevant scientific literature provided by the inventor, and to assess the invention with a view toward the prior art of patent literature. This effort should determine whether or not the invention is likely to attain patent protection. The patentability opinion should identify closely related inventions or patents and may even identify, in the opinion of the reviewing attorney, the scope of claims which can be made based on the invention.

The patentability opinion is not comparable to preparing a patent application. However, it is the first step in the process of preparing a patent application. The attorney should be given a specific task and a dollar limitation. Patent searches can go on indefinitely, and the attorney should be constrained by a specific dollar and time limitation. Most patent attorneys familiar with working with academic or non-profit clients can prepare a reasonable patentability opinion at a cost not exceeding $1,000. The patentability opinion also adds value to the inventor's research work in addition to helping to evaluate an invention. Even if the opinion is negative, it can give the inventor clues and direction for future research and discovery. A word of caution is appropriate. Since U.S. patent applications are not public information until the patent issues, there is always the possibility that an application not yet issued might contain prior art which a patentability search may miss. Therefore, prudent attorneys will never give an assurance of an invention's patentability based on a preliminary search.

»It is wise in the planning stages of a new program to estimate the potential cost of external opinions and to plan for it in the organizational budget.«

Preliminary Marketability Analysis

A patent, copyright, or any intellectual property is only valuable if the property owner has an opportunity to make money using the property. Understanding an invention's technical and market potential at an early stage is an essential element of decision-making regarding the future investments in developing the invention. This process takes a degree of time and attention and knowledge and data information sources. Understanding the market potential of an invention is essential to making a reasonable decision on future investment or attention. In the best of all circumstances, the patentability and market appraisals should be done in sequence rather than concurrently.

If an invention is not patentable or otherwise protectable, its market value will certainly be limited, and information developed by the patentability review will facilitate the market analysis. The marketability analysis should consider the potential commercial applications, the size of the existing market, its growth potential, competing technologies, and the effort needed to commercialize the invention. Upon completion of the patentability and marketability evaluations, the institution should have enough information to decide either to continue to pursue commercialization in some way or to return the invention to the inventor, with or without advice.

»Business advice is highly desired and legal advice is absolutely necessary.«

If the invention is returned, the institution is in effect, relinquishing its rights to further development, unless the inventor is advised to continue his research and to resubmit a disclosure at a later time when research activities can further develop the concept or move the invention in a more commercially appropriate direction.

The alternative is for the institution to determine to proceed with the following steps of protection and development.

Protection

Protection strategy would be, in the case of a patentable invention, the preparation and submission of a patent application. Generally, a U.S. patent application will cost $15,000 to $20,000 and will require two to three years from date of submission until issuance of a patent. Up-front costs can be limited by the practice of submitting a provisional application which allows the applicant a period of nine to twelve months to further perfect the patent application, avoid investment in the major cost of a patent application, or decide to abandon the invention and the patent application. The protective value of provisional applications for academic or non-profit institutions is, at this time, unclear as the practice is quite new and case law and precedent is non-existent. The use of provisional patents should be considered quite carefully.

Marketing

Concurrent with a decision to file for patent or other protection, the institution should be prepared to initiate a marketing effort – appropriate to find the licensee or licensees. This involves evaluating the outcome of the marketability analysis, screening a broad range of potential licensees or development partners, determining the most appropriate development strategy, and finding the most appropriate partner. This is an invol-

ved process which takes considerable time and attention. It is a function that is most often accomplished at larger institutions by a technology transfer staff of marketing and licensing specialists providing day to day effort and oversight of a number of marketing campaigns simultaneously. This becomes difficult in a multi-function research administration setting. It is often times impossible to do the necessary follow-up on time and to deal with problems as they arise.

The desired end-point to a marketing effort is a license to an established company or even perhaps a new start-up or spin-off company. Negotiating a license can be involved, and take considerable time and attention to assure that the interests of all parties (the research organization, the inventor, and the licensee) are protected, and commercialization can proceed.

Business advice is desired, and legal advice is necessary. When a license is in place, the real work is just beginning. Managing a license project can be as daunting as getting the license set up and you soon will find out that help by experienced professionals is needed.

The »HOW« Question

Finally, we should consider "how to do it," particularly when an institution is compelled to limit its overhead costs and to deal with a broad range of additional management responsibilities which are more directly germane to the organization's day to day survival as a research organization. These responsibilities include seeking research support sources, preparation and organizational review of proposals, negotiations of awards and management of research projects once awarded, including both financial management and compliance with an array of sponsor-imposed conduct requirements and standards. In these circumstances, your organization may not be able or willing to add a full-time technology transfer professional.

In small research organizations, invention disclosures are sometimes few and far between. However, the dilemma is that each must be dealt with promptly and professionally in order to protect the invention and realize its full commercial potential. A research organization could expect at best approximately one invention disclosure a year for each $1.5 million in research expenditures. This ratio will be more like one per $2 million or $2.5 million in organizations which have not emphasized the potential of technological innovation and commercialization to their research staff, or have demonstrated

Researchers often don't find the time to care for the commercialization of their products ...

... so they hire Professionals to protect their invention and realize its full commercial potential.

an inability to promptly deal with staff inventions. Those institutions which actively support participation in technology development and have shown an organizational attitude which rewards and supports inventors may see more than one disclosure for each $1.5 million.

In any event, there are elements to a technology transfer program which can work in small institutions with a staff spread thin. A suitable patent attorney can be engaged to do patentability opinions, and to follow up with patent applications. Selecting the right attorney is critical. The attorney or firm should have experience and educational preparation in the scientific field where your inventions are most likely to occur. If your institution is a medical research institute, an attorney with experience in mechanical devices and processes will not be helpful. If your engineering and physical science schools are the most likely source of inventions, a biotechnology specialist would not be appropriate. Continuity is important. If the attorney who prepares a patentability opinion knows that he will also get the patent application case, he is likely to be more diligent and complete. He will also do the application more quickly.

»In the patent business continuity is among the most important issues.«

The best attorney will have also had experience working with non-profit or academic clients, which have different needs than businesses have; and he will have suitable contacts for filing international applications as necessary. Another benefit of continuity is having access to a patent attorney to help with staff training and advice to management on general issues. In a few large institutions with large numbers of inventions, technology transfer offices may have

specialists on their staffs who can do patent searches quickly and accurately. This skill will be rare and will probably not be cost-effective for the small or start-up program to have in-house. Outsourcing patentability opinions and searches to a competent attorney is recommended.

A new or small program can also outsource the market analysis and marketing functions as well. In some cases, this will require the investment of cash by the institution in paying the consultant or consultant firm for the analysis and marketing efforts. This investment should be recovered rapidly if an invention is successfully licensed. There are other options. Organizations such as University Innovations and Research Corporation Technologies will perform an initial evaluation of an invention, and if they are interested, will generally provide modest compensation to the institution in return for an assignment or conveyance of the property rights and full autonomy in further licensing and development efforts.

These organizations generally retain a significant portion of royalty proceeds (35% to 45%). In the case of a highly successful invention this "delayed cost" will often far exceed the initial cost and significantly limit the total return of the invention's value. The institution and the inventor also lose the ability to participate in decision-making regarding the licensing process or outcome. This may or may not be problematic.

Outsourcing the most specialized and professionally complex technology transfer functions is an appropriate and valid alternative to developing and maintaining in-house staff capability to meet relatively infrequent needs. Even when outsourcing is used, the institution still needs a solid infrastructure of policies and procedures and in-house management staff who understand the technology transfer process and relate on a day-to-day basis with inventors and other researchers. Until the number of invention disclosures exceeds 18 per year, outsourcing the evaluation and marketing functions may be an appropriate alternative to developing in-house capability. The options open to an institution to pay for evaluation and marketing services, and to receive benefit from successful licensing and commercialization efforts, should be carefully considered and evaluated as choices are made.

»Outsourcing patentability opinions is recommended. A small program can outsource marketing functions too.«

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If you would like to share your experience in these issues, send an email to

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