Making the Right Moves

A Practical Guide to Scientific Management for Postdocs and New Faculty

Burroughs Wellcome Fund
Howard Hughes Medical Institute

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Chapter 11

UNDERSTANDING TECHNOLOGY TRANSFER

Two decades of explosive growth in biomedical science have quietly revolutionized the role of academic investigators in the commercialization of research results. Patent applications for promising discoveries, once the near-exclusive domain of industry, are now filed routinely by research universities. Through the process known as technology transfer, these patents are licensed to companies for development into marketable products or services.

The technology transfer guidelines at your institution will be based, at least in part, on federal and state laws, regulations, and guidance. This chapter provides an overview of the technology transfer information most important to academic scientists. The information should be viewed as a supplement to the information in your institution's faculty handbook and its intellectual property policies.

The chapter reviews the role of the university's technology transfer office (TTO) and covers the ways in which a university's intellectual property (IP) is protected, the process for bringing an invention to market, and diverse types of legal agreements. Conflicts of commitment and interest are also discussed.

UNIVERSITY TECHNOLOGY TRANSFER OFFICES

In 1980, the U.S. Congress passed the Bayh-Dole Act to jump-start the transfer of inventions from federally funded academic laboratories to the public. As a result, today most academic research institutions have TTOs that, with the help of the inventor, evaluate an invention for potential use and marketability and handle the forms, filings, negotiations, and follow-up of technology transfer. Most universities' TTOs follow the provisions of the Bayh-Dole Act, regardless of whether the research is federally funded. This means that if you make a discovery with potential commercial value, your university will own and control the IP, but you will get a percentage of any resulting licensing income, including royalties.

Soon after taking your post at your new institution, you should meet with the TTO staff. They can tell you about what they do and how they can help you.

THE TECHNOLOGY TRANSFER PROCESS

It Starts with an Invention

For a scientist, most technology transfer begins with an invention: a new and useful process, a machine, an article of manufacture, composition of matter, or any related improvement to these. The invention itself has two steps: conception and reduction to practice. Reduction to practice is further subclassified into two types:

- Constructive reduction to practice involves filing a patent application even though an invention isn't yet physically reduced to practice or "made." The information in the application should make it possible for a person of ordinary skill in the art to make and use the invention without undue research or experimentation.
- Actual reduction to practice requires a working model demonstrating that the invention will work as intended.

Moving from Invention to License

The journey from invention to license can be frustratingly long and very expensive. The following are typical steps:

- *Discussion:* The inventor informally discusses the invention with the institution's TTO. These discussions may help the inventor decide whether to proceed with filing an invention disclosure. In some cases, further work on the invention may be advisable before proceeding.
- *Disclosure:* The inventor reports the invention to the TTO using the institution's standard disclosure form.
- *Evaluation:* The TTO assesses the invention for patentability and commercial potential.
- *Filing and commercialization decisions:* The TTO may ask the inventor to do further work on the invention before proceeding, may file a patent application if the invention has commercial potential and appears to be patentable, or may decide to market the invention without filing for patent protection. If the TTO is not excited by commercialization prospects, it may "waive title," in which case ownership rights may be released to the inventor. Some universities waive title only on certain conditions—for example, an inventor may be asked to reimburse patent costs or pay a percentage of any income from the invention or both.
- *Marketing:* The TTO will contact potential licensees.
- *Licensing:* The TTO will negotiate and manage licenses to companies.

At the end of this process, approximately 30 percent of inventions reported to the TTO (disclosure) will be licensed.

Should I File an Invention Disclosure?

Deciding whether to file a disclosure with the TTO to report a discovery made in your lab may not be a clear-cut matter. You may wish to discuss it with TTO staff before making a decision. Some of the factors that might encourage you to file include the following:

- The invention could lead to a useful diagnostic or pharmaceutical, and patent protection would be necessary to convince a company to incur the costs of development and clinical trials.
- You and your university, department, and colleagues could profit from a patent both financially and in terms of enhanced reputation.
- If you pass on the opportunity to file a disclosure, and go ahead with public disclosure of your work, it may not be possible to obtain patent protection later on.

Before filing a disclosure, you should also be aware of the following considerations:

- Dealing with the TTO, patent attorneys, and eventually, licensees, can be very time-consuming.
- Filing for patent protection can delay publication; you will want assurances from the TTO that the delay will be minimal (often 30–60 days is reasonable).
- If you can't identify a specific use and potential licensees, it may be unrealistic to expect that the TTO will be able to solve this problem.
- Be careful with patents on research tools; you will want your invention to be made broadly available, not restricted for the use of a few.

THE LEGAL TERMS AND AGREEMENTS

This discussion is an overview of some of the common terms and legal agreements used in connection with technology transfer. For more information and project-specific assistance, consult your institution's TTO.

Patents

The U.S. Patent and Trademark Office (USPTO) grants three types of patents:

- Utility patents (20 years) may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, composition of matter, or any new and useful improvement to these.
- Design patents (14 years) may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture.
- Plant patents (17 years) may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.

Most patents produced by academic researchers fall into the utility category.

> *Educate yourself about what constitutes public disclosure. Talking to a grad student doesn't, a faculty lecture comes close, and a presentation in a public forum may cost you the patent rights.*
>
> —Martha Connolly, Maryland Technology Enterprise Institute

What does a patent do? A patent gives the owner or an exclusive licensee the right to exclude others from making, using, or selling the patented invention for a specific period that begins with issuance of the patent. The patent provides protection within the country where the patent is granted. For U.S. patent protection, an application may be filed up to one year after public disclosure of the invention, but patent rights outside the United States can't be obtained if public disclosure occurs before a patent application is filed.

Question: Are the public disclosure rules the same for foreign patent rights?

Answer: No. If your invention is publicly disclosed before you file a patent application, you lose foreign rights. If you file a U.S. application before the first public disclosure, you have one year from that filing date to file foreign patent applications. A Patent Cooperation Treaty application preserves the right to file in selected foreign countries for 18 months after the one-year period.

Researchers must have a clear understanding of what constitutes public disclosure. If something you say or write allows someone else to practice your invention before a patent application is filed, you may have created a bar to filing patents on your invention outside of the United States. Before discussing your discovery in any forum that could be considered public, you may wish to consult your TTO about the proposed disclosure.

What is—and is not—patentable? To be patentable, an invention must be useful, novel, and "nonobvious" to someone of ordinary skill in the art. If you think you have a discovery that meets these criteria, the best approach may be to go directly to your TTO and let the experts take charge from there.

You may want to conduct a "patentability search" of key words at *http://www.uspto.gov* to screen for similar inventions in the files of patent applications. You can do this yourself, without the aid of a patent professional.

Certain forms of unpatented IP may be licensed to companies by the TTO for commercial use. These kinds of IP include the following:

- *Tangible property:* This can be licensed for compensation but without patent protection; others are not precluded from independently developing the same materials. Examples are cloned DNA, viral vectors, cell lines, seeds, tissues, and organisms.

- *Know-how:* This can be licensed in some circumstances, usually nonexclusively in conjunction with a patent license. Examples are techniques, experimental systems, and special knowledge.
- *Copyrighted works:* Although copyright in scholarly works normally rests with the authors, copyright in other written works may be claimed by the university. Examples are formulas, algorithms, and software, including source code.

In contrast to industry, universities almost never maintain trade secrets, which are antithetical to the knowledge-expanding culture of an educational institution.

Who Owns Inventions at a University?

As a condition of employment, U.S. universities require faculty and staff to assign invention rights to the university. A common key phrase in university IP policies is "use of university funds or facilities" in conception or reduction to practice of inventions or development of materials, which extends the institution's ownership to IP of graduate students and guest researchers. In other words, the university owns inventions made by university personnel and may have rights in inventions made by others using university funds or resources.

The patent application. When the TTO is confident that your invention meets the criteria for being patented and has commercial potential, it's time to prepare a patent application. Like most legal documents, a patent application is best prepared by a specialist—a patent attorney or agent. Universities normally hire patent law firms to prosecute patent applications.

The patent attorney is likely to need input both from the inventor(s) and the TTO in order to prepare a patent application. You can expect to speak with the patent attorney several times over the course of the patent process. You will probably also be asked to review draft documents. The major elements of a patent application are the abstract, background/introduction, specification (how to practice), and claims.

In preparing the patent application, the patent attorney will need to make a determination of who should be named as inventors. It is important that this determination be accurate, because a patent may be invalid if the named inventors are not correct (either because an individual who did not make an inventive contribution is named or because an individual who made an inventive contribution is not named). The inventors may differ from the authors of the paper that describes the invention. For example, a postdoc who joined the project after the inventive steps had occurred and then provided supporting data might be a coauthor but not an inventor. Normally, only the named inventors share royalties under institutional policies.

Question: How much does it cost to get a patent?

Answer: Costs vary widely depending on factors such as the patent attorney's time spent and hourly rate, what is being patented, the number of claims in the application, the number of (and reasons for) USPTO rejections, and whether foreign filings are pursued. Preparation costs can run between $5,000 and $20,000 and up, and filing fees and possible prosecution cost between $3,000 and $5,000 and up (sometimes much more). The university pays the fees, but in almost all cases, the first income from the invention is earmarked for reimbursement of these costs. Only then does the income-sharing formula for the inventors kick in.

What happens to the patent application? From the time the application is filed, the USPTO usually takes 12 to 18 months to complete its examination and issue an "Office Action."

The first Office Action is generally a rejection. The applicant is then required to narrow patent claims and justify the novelty or nonobviousness of the invention in the light of prior art identified by the USPTO. Subsequent Office Actions often result in issuance of a patent, but this process takes an average of about three years.

An alternative is a provisional patent application, a streamlined version that can be filed without some of the time-consuming formalities of the standard form. The USPTO doesn't examine this type of application, a patent can't be issued directly from it, and it expires automatically one year after its filing. During that year, the university can file a regular patent application. So what's the point? This option has at least three benefits:

- Temporary filing protection can be secured for your invention for less money (less time for an attorney and a filing fee of only $100 for a small entity or a university).
- If filed before a public disclosure, a provisional application preserves the right to file for foreign patent protection.
- The one-year term of a provisional application doesn't count toward the 20-year (or other) patent term.

Many applications filed by universities are provisional, even if the application is extremely thorough. The reason: This option buys valuable time. The technology is usually at an early stage of development. A year later, the TTO can file a regular application that includes not only the invention described in the provisional patent application but additional results developed in the interim, which may result in approval of broader claims.

Technology Transfer and Faculty Recruitment

Increasingly, TTO staff are part of the university recruiting team. When faculty candidates compare employment offers, many often consider the university's commercialization record and policies regarding income sharing.

Commercialization record. Licensing and commercialization success can be strong selling points, along with the TTO's track record in crafting advantageous terms.

Income sharing. Formulas differ for distributing IP-related royalty and equity income, but a common distribution is 40 percent as taxable income to the inventors (split if there are multiple inventors), 40 percent to the inventors' departments for education and research, and 20 percent to the university for management of the invention and support of technology transfer efforts. However, some universities give the inventors as much as 50 percent of net licensing income, and others give the inventors as little as 20 percent.

Despite its conditional nature, a provisional application shouldn't be a sloppy filing that the TTO plans to fix during the following year. It should be prepared by a patent attorney or agent and held to the same standards as the work that led you to this point. In addition, be aware that in some cases in which a provisional patent is filed, TTO staff may not yet have done a thorough search for competing or similar patents. You should find out whether such searches have been conducted and make sure a patent attorney examines the results.

Licensing Agreements

In technology transfer terms, a license is a legal contract that allows a company to make, use, and/or sell a university's invention. Through a licensing agreement, someone agrees to pay for the use of IP that someone else (in this case, the university) owns—under strictly defined terms and conditions that are specific to each license—but the university maintains its ownership rights to the IP. In other words, a license allows people (or entities) to make, use, or sell something they don't own without being prosecuted. If special know-how developed by the inventors is needed to "practice" the invention, it's often included as part of the licensing agreement.

Licenses can be exclusive or nonexclusive. An exclusive license grants the right to use the invention to only one licensee. Exclusive licenses usually allow the license holder to sublicense the invention to others for a fee. These sublicenses generate "pass-through royalties" as an additional source of income to the university. A license also can be granted exclusively to one licensee for a specific application, or "field of use," maintaining the university's option to issue licenses for other fields of use.

A nonexclusive license can be granted to multiple companies. The TTO, with the inventor, will decide whether an invention is best licensed exclusively or nonexclusively. Know-how is usually licensed nonexclusively in order to preserve the inventor's right to share the know-how with other scientists informally.

Question: Do I have any say in where my invention is licensed?

Answer: Although your university has ultimate authority regarding the choice of licensee and the license terms, you will probably have some control over where your invention goes. In the licensing process, a full faculty member's preferences will likely carry more weight than a postdoc's. In some cases, a company will already have licensing rights because it provided research funding or materials. If it exercises those rights, the university may not be able to license the invention to any other company, regardless of the university's or inventor's preferences.

Your TTO will probably handle licensing arrangements for your institution, but keep in mind one point: Many companies often want all future improvements to an invention to be licensed to them. However, universities generally do not license inventions or improvements (unless very narrowly defined) that have not been made. This policy serves as a protection to you, the inventor, to keep from encumbering your future research results. You need to be aware of the tension between the interests of the university and the companies to whom inventions may be licensed.

Negotiating the Agreement

The TTO has responsibility for protecting the university's and the inventor's interests. If the inventor insists on unreasonable terms, some TTOs may be obliged to present them, damaging the negotiating process and the relationship in which all of you will be tied. So, try to refrain from inserting yourself into the negotiating process in this way. During the negotiation, however, it is necessary for you to understand what restrictions an exclusive license may impose on your ability to share data or materials with others.

Option Agreements

An option agreement is a right to negotiate a license—a document that says, "I want to and I hope I can, but I'm not ready yet." It's less complex than a license, relatively easy to negotiate, and may or may not include the financial terms of the expected future license.

Because it's of limited duration (usually 6 to 12 months), an option agreement is a useful mechanism in dealing with start-up companies and their inherent uncertainties. It gives the hopeful licensee an opportunity to secure funds and attract other resources needed for commercial development, and it gives all parties time to evaluate the technology and what each brings to the table and to establish trust.

Material Transfer Agreements

Often as a result of a publication or presentation, other researchers may request materials from your lab—generally a cell line, animal model, research reagent, genetic construct such as a plasmid or phage, or purified proteins. Some institutions require that a material transfer agreement (MTA) be signed and returned before material is sent out. Some send the MTA form with the shipment and consider delivery of the material to be implied consent, whether or not a signed MTA is ever returned. Others may be unconcerned about keeping records for outgoing material (at least when the recipient is another nonprofit institution).

Almost all MTAs for incoming materials require the signature of an authorized representative from the university. Even if an institutional signature is not required by the materials provider, university policy may call for institutional review of the terms anyway. Check with your university's TTO about who needs to approve the terms for and signs MTAs for incoming materials for your lab.

MTAs have distinct uses and caveats according to the entities involved. The following lists address three MTA scenarios: transfer of materials between academic labs, from academia to industry, and from industry to academia.

MTAs covering transfers between academic labs. These MTAs usually have relatively benign provisions. An exception is when the materials have been exclusively licensed to a company that successfully negotiated for restrictions on distribution. Work to avoid this situation because it puts your responsibilities as an author to share reagents at odds with your contractual responsibilities to a licensee. MTAs used for transfers to an academic lab typically and reasonably require that recipients of the materials do the following:

- Use the materials for noncommercial research purposes only.
- Acknowledge the providing scientist in publications.

- Not send materials to third parties without the provider's consent.
- Assume responsibility for damages caused by use of the materials by the recipient.
- Not use the materials in human subjects.

MTAs used for transfers from academia to industry. These MTAs usually do not permit use of the materials commercially (e.g., for sale or to make a commercial product) or in human subjects but allow use for defined internal research purposes. They may also require that recipients do the following:

- Share manuscripts before publication, in addition to providing proper acknowledgment in publications.
- Indemnify the provider for damages caused by use of the materials by the recipient.
- Not send the materials to third parties.
- Pay a fee.

MTAs used for transfers from industry to academia. These MTAs tend to be the most restrictive and difficult to negotiate. They may include the following terms:

- *Ownership:* Beware if the definition of materials specifies that the company will own all derivatives and modifications made by the recipient or if the MTA requires assignment of inventions to the company or provides the company with an automatic nonexclusive license to all inventions. Many institutions try to avoid granting broad "reach-through" rights in new materials or inventions developed by their faculty.
- *Publications:* Beware if the MTA reserves to the company the right to approve or deny publications. More reasonably, the company may require review of manuscripts 60 days or more before submission for publication, and delay of publications for 60 days or more after manuscript submission. At a minimum, most companies want a 30-day prepublication review to protect confidentiality and their investment and to consider filing for patent protection.
- *Reporting:* The MTA may require extensive reporting and sharing of data from the recipient.

The university's TTO will scrutinize the language of an MTA for incoming materials for restrictions like these and weigh the costs and benefits. If negotiations can't alter unacceptable MTA terms, the university may refuse to proceed. Under these circumstances, the requesting university scientist will not be able to get the materials from that provider.

SPONSORSHIP AND CONSULTATION

Through publications, presentations, and personal contacts, the work of an academic investigator might pique the interest of industry. If there's a good fit between the avenue of research and the company's strategic interests, the company may want to buy an option to commercialize the lab's research results or support some of the investigator's research. Or the company may invite the investigator to become an adviser or consultant. The typical mechanisms for doing so are described next.

Sponsored Research Agreements

When a company funds a university laboratory's research, the terms are spelled out in yet another form of legal agreement, called a sponsored research agreement, negotiated by the TTO or the university's grants and contracts office. Most sponsored research agreements will take into account the following guidelines:

- *Project control:* The work should be entirely under the control of the university, not directed in any way by the sponsor.
- *Technical representatives:* A person from the institution and the sponsoring company should be identified to serve in this capacity, establishing a researcher-to-researcher relationship. These are usually the scientists leading the research at both places.
- *Reporting:* Reporting requirements should be limited, and oral reporting allowed as much as possible, to minimize what can otherwise be a time-consuming burden. Sponsors usually require quarterly or semiannual reports or meetings for periodic updates on the research.
- *Publishing rights:* The university should ensure that the laboratory has the right to publish and present all findings. The sponsor may have the right of advance review but not the power to veto proposed publications and not the right of editorial control.
- *Invention rights:* The university owns inventions that arise from the sponsored research but will tell the sponsor about the inventions in confidence.
- *Licensing rights:* The sponsor is usually given a time-limited right to negotiate for an exclusive or nonexclusive license to inventions that arise from the research.
- *Discussion and collaboration:* The university researchers should have the right to discuss their work on the sponsored project with other academic scientists and to collaborate with them (as long as the other scientists are not funded by a different company).

Question: How do I find the right sponsor for my research?

Answer: Look for a strategic as well as a scientific fit, an alignment of business objectives, and a supportive alliance with management. Heed your instincts: If it doesn't feel right, chances are that it's not right.

Consulting Agreements

Faculty members are usually allowed to spend a limited amount of time on consulting outside their institutions. If you have a manual that outlines the university's consulting policies, make sure you read it and understand the policies.

Review the agreement. If your institution chooses to review consulting agreements involving employees, the appropriate office will examine your proposed agreements for conflicts of interest and other problems. If your institution does not review these agreements, consider hiring a qualified person (e.g., a contract law specialist) at your own expense to conduct a contract review because consulting may subject you to personal liability. The TTO can probably give you a referral for this purpose.

Best practices. Consulting agreements vary widely to suit the particulars of a given situation, but they should abide by some general best practices as outlined below.

Companies should engage consultants for the exchange of ideas only, not to direct or conduct research on behalf of the company. They should not use the name of a consultant or university in promotional materials unless they have written consent.

Consultants should have a limited and reasonable time commitment (e.g., a maximum number of days per year for a specific number of years). There should be a provision allowing the consultant to terminate the agreement by giving reasonable notice, and it is fair for the company to have the same right. Consultants should

Protecting the Rights of Graduate Students

Typically, industry-funded research agreements provide the industrial partner with an interest (normally licensing rights) in intellectual property that results from the funded research and include confidentiality obligations restricting the dissemination of the results.

Such provisions may raise issues when students are involved in the research. For example, a graduate student has to be able to communicate his or her thesis work in order to graduate. It is important that students are fully informed by their existing or potential supervisors of any existing or potential contractual agreements between an industry sponsor and the university or academic center that may affect their projects. It is also important that university policies relating to student participation in industry-funded projects are followed. The supervisor should have a clear understanding of what the agreements entail and how they might affect a student's ability to communicate his or her work as well as inform students of any restrictions that may affect them. During the course of the industry-funded project, graduate students working on the project must be free to present and discuss their research in university forums, such as lab meetings or graduate student seminars, and meetings of the thesis advisory committee. This may be directly in conflict with confidentiality obligations in the agreement. In some cases, it may be possible to arrange for confidentiality agreements to be signed (e.g., by the thesis advisory committee); in other cases, it may be neither possible nor consistent with university policy. As to final publication, many universities have guidelines stipulating that publication of thesis-related research may be delayed no longer than 90 days from the time a manuscript is submitted to the sponsor for review. This delay should be sufficient for the filing of a patent application and allow the industry sponsor an opportunity to request deletion of any of its proprietary information from the manuscript.

not disclose information about their laboratory research that they wouldn't normally disclose to members of the scientific community. In addition, they may assign to the company rights in inventions arising from consulting activities if such rights haven't arisen from their own research undertaken as a university employee.

Consulting agreements should acknowledge that the consultant is an employee of the university and is subject to all of its policies, including those related to IP and conflict of interest (COI). If the company requires a noncompetition clause, the consulting agreement should state that this provision doesn't apply to the consultant's relationship with the university.

CONFLICTS OF COMMITMENT AND INTEREST

Whether the lure is simply scientific inquiry or economic rewards, a career can easily run aground on conflict of commitment or interest.

Conflict of Commitment

Is your time really your own? Yes and no. As an employee, your first professional obligation is to fulfill your agreed-upon duties to your employer—the university or research institution. Faculty members should give priority to their time and goals accordingly. The "20 percent rule" is a good guideline (if consistent with your university's policies): You may take up to 20 percent of your time for outside activities that are in the interest of you and the university.

Conflict of Interest

When dealing with technology transfer, a COI can lurk anywhere from the sponsorship of research to the nature and timing of published research results. One of the most common scenarios for COI is when the content or timing of published research findings affects license income, funding, or stock value for the financial gain of the investigator or the institution. The following definition, from Francis Meyer of A. M. Pappas & Associates, can help you recognize a potential COI:

> *"A conflict of interest is a situation in which financial or other personal and institutional considerations may directly or significantly affect, or have the appearance of directly and significantly affecting, a faculty or staff member's professional judgment in exercising any university duty or responsibility or in conducting or reporting of research."*

Here are some tips to help you avoid COIs:

- Remember that industry is interested in science to increase sales and profits. Altruism and enlightenment are not corporate incentives.
- Be careful about your involvement with start-up companies. With a start-up, you're more likely to have significant equity in the company, and if the company was founded on your technology, the possibility of a COI increases.

- Be careful of what you say during press interviews. It may be better to let the university do the public speaking about your research. Off-the-cuff remarks can present an opportunity for a COI to be perceived where none exists, and the perception can be as damaging to a scientist's credibility and career as the reality.

At some point in your research career you may make a discovery in your lab that has potential commercial application. By having a better understanding of the concepts, processes, and potential pitfalls of technology transfer, you will be better prepared to work with your university's TTO and with industry to bring your discovery to market.

RESOURCES

Association of American Medical Colleges. Reports from Task Force on Financial Conflicts of Interest in Clinical Research, *http://www.aamc.org/research/coi/start.htm*.

Association of American Universities. Information on intellectual property issues, *http://www.aau.edu/intellect/ipissues.cfm*

Association of University Technology Managers. *http://www.autm.net/index_ie.html*.

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