**Academic Entrepreneurship for Medical and Health Scientists •
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Working with the University Technology Transfer Office

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Topic Relevance by Timeline

Summary

- Academic technology transfer is a rigorous process that involves many different constituencies within the university with different perspectives and interests. Aligning those interests is crucial to a successful transfer of inventions that ultimately result in commercialization of value-added products and services.
- Individuals within universities should leverage the technology transfer office's (TTO) resources and advice as early as when the idea was originally conceived. TTOs can help move the innovation process forward and keep track of progress to guide the next point of inflection.
- In building relationships throughout the technology transfer process, inventor(s) must understand the terms and policies involved. Starting with the TTO, they must pay careful attention to the university's intellectual property (IP) policies.
- When dealing with outside companies, investors must negotiate the terms carefully to make sure that every party has their interests aligned. The TTO would be of valuable help in conducting negotiations to achieve this. In addition, they can be a link to other internal and external resources, including investment capital and mentoring that can help the academic entrepreneur commercialize their innovation.

Introduction

Universities and public research institutes (PRIs) are the major recipients of federal funding in research and development. In the United States, since the passage of the Bayh-Dole Act by Congress in 1980, which is codified in 37 CFR 401, institutions developing an invention have the opportunity to take ownership of the intellectual property ([U.S. Government Accountability Office](#)). The act also requires any profit made from the commercialization of government-funded research by companies to be shared with the inventors. This incentivized inventors and institutions to translate their inventions into commercialized products. This process of transferring discoveries from research done by universities and other PRIs into the commercial sector is commonly

known as technology transfer. The transfer involves multiple parties: the researchers or inventors themselves, the institution under which they do their research, outside companies, and investors.

The transformation of research findings and inventions into useful products, processes, and services can have a major impact on improving life and economic development by providing job opportunities ([Zuniga and Correa](#)). This is where the TTO comes in. After disclosing their invention to the TTO, academic entrepreneurs are provided with guidance and resources valuable to the tech-transfer process. TTOs play a significant role in advancing research and development into commercial products.

To show how technology transfer is benefiting society and the economy, the Association of University Technology Managers (AUTM) released statistics of the 2016 technology transfer life cycle in the U.S. It shows that in 2016, there were 25,825 invention disclosures and 16,487 new U.S. patent applications filed, of which 7,021 were issued. In the same year, 7,730 licenses and options were executed, 1,024 startup companies were formed, and 800 new products were created ([Association of University Technology Managers \(AUTM\)](#)).

There are four common types of intellectual property: trademarks, patents, copyrights, and trade secrets. These are briefly reviewed here and discussed in detail in other chapters. Trademark, according to the U.S. Patent and Trademark Office (USPTO) website, is a brand name. It can be a name, a symbol, a color, or a combination of those, and serves to indicate the source and the uniform quality attributed to a product.

Patents, on the other hand, are the tools that the holder of the patent can use to exclude others from making, using, offering for sale, or selling the invention ([Van Norman, Gail A., and Roï Eisenkot. "Technology Transfer: From the Research Bench to Commercialization: Part 1: Intellectual Property Rights-Basics of Patents and Copyrights"](#)). To qualify for a patent filing, an invention must be useful, novel, and nonobvious. The USPTO issues three types of patents: utility patents for processes, machines, articles of manufacture, or composition of matter; design patents; and plant patents. Before considering filing a patent application, an inventor should make sure that there is no similar "prior art" that would disqualify the invention from the novel requirement, along with considering other requirements, such as nonobviousness. A provisional application can be filed as a placeholder (first to file) before the full, non-provisional patent is filed within a year. The 1-year period does not count against the 20-year patent life. Inventors often choose to file a provisional application to buy time while they are developing the invention.

Under the law, copyright protection extends to original works of authorship fixed in any tangible medium of expression, which includes literature, musical works, drama, choreography and pantomime, pictorial or graphic work, sculpture, motion pictures and other audiovisual works, sound recordings, architectural works, and certain computer programs ([Van Norman, Gail A., and Roï Eisenkot. “Technology Transfer: From the Research Bench to Commercialization: Part 1: Intellectual Property Rights- Basics of Patents and Copyrights”](#)).

Finally, trade secrets are information, innovation, or processes an owner keeps confidential. According to article 39, paragraph 2, of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), member nations (United States included) are obligated to provide means of protecting “information that is secret, commercially valuable because it is secret, and subject to reasonable steps to keep it secret.” Therefore, to be eligible for protection, a trade secret must give the business a competitive advantage in the marketplace, and the owner must treat the information in a way that can prevent others from learning about it, except with improper acquisition or theft.

Licensing Agreements

Licensing is the most common partnership pursued by academic institutions to take their researchers’ inventions to the commercial stage. A licensing agreement is a partnership between an intellectual property owner (licensor) and another party authorized to use the said intellectual property (licensee) in exchange for a fee. Licensing terms are the issues addressed in a license agreement. There are many key issues that need to be covered in a technology licensing agreement, and, to make it more complicated, each key issue can be resolved in many different ways. [Figure 1](#) shows a non-exhaustive list of several key points commonly found in a university license agreement.

In addition to the key terms shown in [Figure 1](#), the inventors/researchers should try to minimize automatic rights to future or follow-up developments or future improvements. Licensees oftentimes ask for a guaranteed access to such developments, which may constrain the researcher’s group to award the company the licensing of the first invention. The rights licensed should be limited to existing patents and only to claims in any follow-up patents that are fully supported by the current

patents and entitled to the priority date of that patent ([Association of University Technology Managers \(AUTM\)](#)).

Terms	Explanation
Definitions	The technology being licensed or licensed products or processes
Grant of License	Exclusive vs. Non-Exclusive (all commercial rights to a certain technology are granted to one party exclusively vs commercial rights to a certain technology are granted to a party and the same rights can be granted to others)
	Field of use (use of the technology to develop therapeutic vs diagnostic or human vs animal health, etc.)
	Territory (where the license grants the right to practice the licensed technology; for example, worldwide vs. US only, etc.)
	Sublicense rights (e.g., can the licensee sublicense the technology to other parties)
	Reservation to the university that it can use the technology for research or academic purpose
	Reservation of rights to government
Financial Considerations	License fee and maintenance fees
	Equity (if licensee is a start-up)
	Royalties and sublicensing provisions
	Milestone/diligence payments
Patent prosecution and payment	University usually controls the patent prosecution and provides licensee the opportunity to make comments, prosecution strategy, which countries to file, etc.
	Licensee reimburses the university for patent prosecution costs
Diligence requirements – performance milestones	Certain diligence milestones set by the university to ensure the technology is being diligently developed and commercialized (developed in collaboration with the company to be mutually agreeable and reasonable)
	Products diligence terms: first product prototype, product available for sale, first commercial sale
Infringement	Identifies who will have the first right to enforce the licensed patents
	Indicates which party pays the expenses
	Distribution of damages between licensee and university after enforcement expenses
Representation and warranties	Licensee assumes all risk associated with the licensed technology and products developed from it
Indemnification and insurance	Licensee will indemnify university against all claims, proceedings, liabilities of any kind whatsoever arising out of its use of the patent rights and commercialization of products
	Licensee is required to obtain certain amounts of product liability insurance prior to commercial sale of a product
Termination	Duration of licensed patent rights
	Licensee can terminate at will upon advance notice of termination to university
	University can terminate for breach
	Terms of sublicenses after termination
	Dispute resolution between both parties

Figure 1. Key Terms in a University License Agreement.

([Bastani et al.](#)); ([Van Norman, Gail A., and Roï Eisenkot. "Technology Transfer: From the Research Bench to Commercialization: Part 2: The Commercialization Process"](#)); ([World Intellectual Property Organization \(WIPO\). Successful Technology Licensing](#))

Technology Transfer

Technology transfer may be defined as the process of getting early-stage technology in the hands of the public, usually in the context of commercialization from research institutions to outside companies (see the chapter "[Intellectual Property: Commercializing in a University Setting](#)"). The technology transfer process varies widely between institutions. However, there are several common elements, which are shown in [Figure 2](#).

Inventions often come from observations made during research activities. Thus, research is fundamental for innovating; it feeds the pipeline of innovation. As such, the overall research and development climate of the industry also ultimately determines whether or not the invention would be translated into valuable products. For example, if the level of demand for innovative ideas in the industry is low, universities are less likely to develop and transfer new technologies into the commercial space ([Apax Partners](#)).

Figure 2. Common Pathway from Disclosure to Licensing Between Academia and Industry.

Invention Disclosure

The technology transfer begins when the inventors disclose the technology/inventions to the university's TTO through a formal invention disclosure process. In some cases, the TTO will then assign an invention disclosure or docket number to the material to help track it; the inventors can use this docket number in correspondence with the TTO, on nondisclosure agreements, and other legal documents. The TTO will then usually conduct a preliminary evaluation to determine what the product is, whether the invention is patentable, its commercial potential, and the amount of funding needed for the invention. This also provides a crucial opportunity for the university to

identify relevant co-inventors to help mitigate the risk of patent nullification due to failure to include all co-inventors. The university TTO will ultimately play a key role in resolving disputes regarding ownership amongst co-inventors affiliated with the university. Finally, another determining factor is whether there are already prospective commercial partners who are interested in the technology ([Van Norman, Gail A., and Roï Eisenkot. "Technology Transfer: From the Research Bench to Commercialization: Part 2: The Commercialization Process".](#)).

Evaluation/Assessment

During this time, the TTO reviews the disclosed technology and further analyzes the market readiness and potential for the invention. The evaluation will further guide which commercialization path the inventors (and TTO) should pursue: licensing agreement or creating a startup company. At the same time, the TTO also does a more thorough patent search for “prior art.”

IP Protection

Even though not all companies require universities to patent their inventions prior to partnering with them, doing so would certainly be advantageous in striking licensing deals because it creates a clear understanding of the scope of the technology being licensed. Patent protection begins with the filing of a patent application to the USPTO and to foreign patent offices if needed ([Massachusetts Institute of Technology—Technology Licensing Office \(MIT TLO\)](#)) (see the chapter “[Intellectual Property: Ownership and Protection in a University Setting](#)”).

Finding (or Forming) a Licensee

Depending on the nature of the invention, market trends, funding availability, and interest from outside companies, there are two paths of commercialization to bring the technology to the market: partnering with an existing company (through a licensing agreement or other collaborations) or forming a startup company (see the chapter “[Startup Company Formation and Management](#)”). In the former case, the TTO or researcher will find the potential licensees/collaborators to work with. However, if creating a startup spun from the university is deemed to be the better path, the TTO may help plan and find the funding instead.

Negotiation

There are several factors that the TTO will consider when negotiating the deal with outside companies:

- the perceived risk of the technology brought by the inventors;
- the current stage of development;
- the estimated cost of further development and commercialization;
- potential market size and profit margin;
- strength of patent claims (and whether the patent has been issued);
- estimated cost of R&D spent on the invention;
- scope of the licensing agreement (see [Figure 1](#)).

In addition, according to section 401.7 of the Bayh-Dole Act, the university should make some effort to give licensing preferences to smaller businesses if they are equally likely to bring the invention to the market as compared to a larger company ([Van Norman, Gail A., and Roï Eisenkot. "Technology Transfer: From the Research Bench to Commercialization: Part 2: The Commercialization Process"](#)).

Licensing

A license agreement is a binding contract between a university and a company (be it an established company or a startup) in which the university's right to an invention is licensed. The common key terms addressed are shown in [Figure 1](#). It is standard for many initial IP concepts to develop multiple subsequent follow-on patents that emerge over the subsequent years in partnership with the company; developing a strategy for handling these can be an important aspect of successful licensing as well.

Product Development

After the technology is licensed, the company now has the rights to further develop the invention into a commercialized product. The university's rights to continue the development in-house (usually for research purposes) are retained upon agreement. Also, the government, which funded the research in the first place, must be granted a nonexclusive, nontransferable, irrevocable royalty-free license to practice the invention. This excludes federal government commercialization or assistance to competitors of the licensees ([Van Norman, Gail A., and Roï Eisenkot. "Technology Transfer: From the Research Bench to Commercialization: Part 2: The Commercialization Process"](#)). However, in practice, this is very rarely executed by the government. In addition, in cases where the research was funded by a foundation or other entity, it is increasingly common for these groups to request to review the licensing agreement thoroughly for due diligence, and they may impose a timeline by which commercialization by the university must have been realized. Furthermore,

foundations may request ownership of the intellectual property if the university decides not to pursue filing.

Commercialization

The company continues to advance the technology and invest (or find investors) in product development, and is hopefully successful in bringing the product to the market. Universities are increasingly implementing commercialization and acceleration programs that provide funding, mentoring, and opportunities to connect with external investors and customers (see the chapter “[Resources at Academic Entrepreneurship Centers](#)”). The TTO can refer the inventor to these programs and to entrepreneurial and innovation centers (covered in other chapters), as well as to external resources.

Different Perspectives, Different Incentives

Universities

The major impetus for academic technology transfer started when the Bayh-Dole Act was passed in 1980. Giving universities the opportunity to obtain title to any inventions made with taxpayer money clearly spurred a new era of product commercialization. The act also induced universities to invest in building their own dedicated technology transfer offices and hiring licensing professionals to facilitate the process. Similar models might not work in other countries, however, the success of the Bayh-Dole Act in changing the landscape of IP ownership—and ultimately in bringing innovations from universities to the market—has provided universal lessons and has disrupted international industrial policy, namely in Germany, the U.K., and France ([Apax Partners](#)).

Academics/Researchers

By nature, academics pursue careers in academia for research. Encouraging academics to pursue technology transfer and commercialization of their research can be a hard sell. However, to an increasing extent, academicians are becoming entrepreneurial and wish to pursue dual tracks of academic research and entrepreneurship. Universities can try to motivate researchers to actively participate in the technology transfer and commercialization space by providing support and enabling the researchers to take leaves of absence without having to worry about losing their faculty position ([Apax Partners](#)) (see the chapter “[Careers in Academia and](#)

[Industry: Transitions and Challenges](#)"). Furthermore, for many inventors, being able to see their discoveries move forward and impact society may be the strongest inducement. Many institutions now offer assistance in the form of capital, facilities, and mentorship in moving startups and the associated technologies forward, and this support provides additional incentive to those inventors.

Companies

The entrepreneurial climate for companies, or the industry in general, should be supportive for them to be able to successfully profit from commercial activity. This largely depends upon economic factors, which would strongly influence access to capital, and overall industry trends. The government can also incentivize companies to work with universities—for example, by providing tax incentives for collaboration.

Investors

Many startup companies begin as research projects in universities. Most investors, such as venture capital (VC) firms, realize the power of incentivizing universities and researchers in advancing new technologies that can lead to commercial products. The growing trend of new VC firms, angel funds, and internal investment groups in large, established companies (e.g., big pharma) speaks volumes about how much investors are interested in funding these innovations ([Bhambra](#)) (see the chapter "[Seeking Venture Capital Investment](#)").

In addition to those investors, a number of universities now have their own seed funds, investment, and venture arms. For example, in 2009, the University of Arizona Office of Technology Transfer announced that they had signed a memorandum of understanding (MoU) with the University Fund to accelerate the commercialization process of the university's inventions ([Harrison](#)).

University IP Policy

A growing incentive for some publicly funded institutions to conduct research is the potential ownership of IP and the possibility of developing it into the commercial stage (see the chapters "[Intellectual Property: Ownership and Protection in a University Setting](#)" and "[Intellectual Property: Commercializing in a University Setting](#)"). In this case, having an institutional IP policy is required to further ensure a successful transfer of technology between academia and commercial partners in the industry. Without a formal, legally binding policy regulating ownership of the IP, all parties

involved in the tech transfer process (inventors, outside companies, foundations, government agencies) would have no legal certainty in making decisions regarding IP. In addition, having an IP policy facilitates compliance with relevant laws and regulations, and it also balances the conflicts of interest between the university, industry, and society ([World Intellectual Property Organization \(WIPO\). Intellectual Property Policies for Universities](#)).

In the U.S., after the Bayh-Dole Act was passed, universities started to build and continually revise their IP policy. After the act went into effect in 1981, universities replaced invention equity with ownership claims. Some universities also extended the definition of “inventions” to include “inventions that are not patentable,” while others combined inventions, copyrights, and data under “intellectual property” ([American Association of University Professors](#)).

As an example, the University of Pennsylvania, through its tech transfer office—the Penn Center of Innovation (PCI)—has a patent policy that covers participation agreements, disclosure and reviews, inventions outside the policy, student inventions, and return of inventions ([Patent and Tangible Research Property Policies and Procedures of the University of Pennsylvania](#)). In terms of technology transfer, the policy also regulates the requirements for licensing deals and the distribution of future revenue from inventions, as well as the allocation of the equity pool. Finally, in order to avoid conflicts of interest, PCI has also established rules governing the inventors’ research activity and the use of tangible research property within the university (see the chapter “[Understanding Conflict of Interest for Academic Entrepreneurs](#)”).

Challenges

As expected, academic technology transfer is not an easy process to navigate. There are several challenges in transferring universities’ inventions into commercial stages. First of all, it is sometimes difficult to encourage the academic inventors to disclose their inventions to the TTO. Despite the Bayh-Dole Act mandating that researchers must file for invention disclosure, universities sometimes have to create an incentive, such as a certain amount of royalty, to encourage researchers to disclose ([Siegel et al.](#)). Furthermore, since university-related inventions often involve participation of multiple faculty members, trainees, and students, determining co-inventor status can be complex.

There are several challenges related to the commercialization of early-stage technologies. If the technologies are being transferred to an external company, the first concern is often around how developed the technologies are and where they fit in the product development/commercialization pathway of the company (see the chapter [“Conducting Insightful Market Research”](#)). The reality of university research is that sometimes it is still in its very early stages, which often leads to incompatibility with the company’s portfolio or timeline ([Bastani et al.](#)). Most cutting-edge innovations only have a few potential commercial partners because of the high-risk nature of such innovations. In addition, there is a tendency toward prompt academic publication from the university, which is sometimes contrary to the licensee’s preference toward maintaining the secrecy of the invention in order to avoid compromising patentability ([Bastani et al.](#)). Furthermore, there is a dilemma in whether to choose a larger or a smaller firm. While smaller, early-stage firms are usually more focused and have a stronger desire to make the invention work, they often have a weaker financial position and less experience. Generally, outside companies may also be eager to move a licensing agreement forward quickly, while resource-constrained TTOs may need to take longer to evaluate the agreement—although exceptions certainly exist, and large companies can be slow to make decisions. Finally, different beliefs surrounding the value of the invention may cause problems. Outside companies sometimes have a hard time determining the economic value of academic discoveries. Similarly, researchers often do not have enough information about the commercial value of their inventions and may have unrealistic expectations ([Siegel et al.](#)).

On the other hand, if the inventors decide to build a startup company, having faculty members on the board of directors or as executive leaders may complicate matters on several levels (see the chapter [“Building a Successful Startup Team”](#)). First, there could be a conflict of commitment for these faculty members because their commitment (in terms of time given) to the new company takes away from their commitment to their full-time academic position. In addition, as they are connected to their academic institution’s reputation, being too involved with commercialization activities may raise questions from the public about their—and ultimately the institution’s—integrity ([Van Norman, Gail A., and Roï Eisenkot. “Technology Transfer: From the Research Bench to Commercialization: Part 2: The Commercialization Process”](#)). Similarly, financial conflict of interest (FCOI) is a key consideration that may require developing a careful conflict-of-interest management plan in partnership with the university.

Obtaining Expert Counsel

Not all ideas born from academic research have commercial value. TTOs can help with screening and continuing to follow the maturation of new inventions. If inventors maintain regular communication with the TTO after disclosure, the TTO will help further with evaluation and assessment of the ideas. In addition, the TTO helps inventors to gain the IP protection they need through the process of filing patent applications (see the chapter “[Intellectual Property: Ownership and Protection in a University Setting](#)”). Finally, the TTO can facilitate inventors in securing a contract with a potential licensee/collaborator. The key is for the inventors to stay in touch and keep track of the timeline and deadlines while engaging with the TTO.

Beyond IP, a TTO will have access to information about obtaining valuable assistance from different entities within the university. Free-of-charge consultations on legal and marketing strategies offered by the law school and business school organizations/clubs, respectively, are two examples.

Costs

Throughout the tech transfer process, there are several expenses that will be incurred. The research that would later become the source of the invention needs considerable financial support. More often than not, ideas disclosed to the TTOs come from research that is already being funded through government or foundation grants. Other costs are patent application filing and prosecution fees, as well as legal fees incurred during negotiation with the prospective licensee/collaborator.

Once the commercialization path has been chosen, either by building a startup spun from the university or through a licensing agreement, and a deal has been made, funding opportunities toward commercialization of the invention can be pursued more intensively. Depending on the stage of development, VC funds and Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) grants are some of the common funding sources for academic startups; these are reviewed in other chapters ([Van Norman, Gail A., and Roï Eisenkot. “Technology Transfer: From the Research Bench to Commercialization: Part 2: The Commercialization Process”](#)).

Conclusion

Commercializing research discoveries is a complex process. In the past few decades, the trend has changed due to the incentivization of researchers and universities in terms of IP ownership. Technology transfer offices provide guidance and valuable resources for the inventors to advance their discoveries into commercial stages through collaborating with existing companies or creating startups. Given the number of entities with different interests involved in the technology transfer process, there are several major challenges that inventors and TTOs face. However, the overall climate for academic technology transfer is increasingly positive, as the various parties are getting better at aligning their interests and providing the right incentives.

Resources

Intellectual Property Policies for Universities ([World Intellectual Property Organization \(WIPO\). Intellectual Property Policies for Universities](#))

- This document provides guidance and examples of how a good IP policy within universities and other public research organizations should be.

Successful Technology Licensing ([World Intellectual Property Organization \(WIPO\). Successful Technology Licensing](#))

- This document provides a comprehensive guide on license agreement negotiations.

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