

Intellectual Property: Ownership and Protection in a University Setting

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Topic Relevance by Timeline

Summary

- Ownership of inventions created in a university setting is fact-based and may be tricky to deduce. Most inventions created in a university lab, or that result from using university resources, belong to the university because of terms included in the academic entrepreneur's employment contract and because of the university's intellectual property policy. However, there are other possible owners of the technology as a result of collaboration and funding relationships.
- The entrepreneur may also claim ownership rights themselves and secure a waiver of the university's intellectual property policy if the inventing took place outside of the entrepreneur's employment, or if there is an agreement in place from a funding source other than the federal government.
- The university's technology transfer office will decide whether and how to protect any inventions owned by the university with formal intellectual property tools, usually using patent or copyright. This is a strategic decision that considers many factors.
- Even if the university controls the protection process, the academic entrepreneur has an important role to play in establishing strong protection, because they know the invention, the market, and the competitors better than anyone else.

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Introduction

Once an academic entrepreneur creates an invention with potential commercial application, they face some threshold questions: Who owns the invention? Is it eligible for protection using formal IP tools? If so, what steps do they need to take, either to protect it themselves or to help their university secure the strongest protection? This chapter will address such questions, focusing on the distinctive situation and needs of an inventor working within the structure of a university.

The Basics of Intellectual Property

Intellectual property (IP) rights permit an inventor to prevent others from exploiting their invention without their approval. The IP rights available to an inventor vary based upon the invention. For example: machines, processes, and formulas may be protected by patents or trade secrets; software code and publications may be protected through copyright; and names and slogans may be protected through trademark (“What Is Intellectual Property?”). In many cases, IP rights can be formalized through government-approved filings, including patent, copyright, and trademark applications, which grant the inventor specific, strong, statutory rights.¹ Patent and copyright are the IP tools most immediately relevant to university entrepreneurs since, given the importance of publication, most inventions from university labs can be best protected through patent rather than trade secret.² Copyright becomes relevant for publications, and sometimes for inventions involving software. Issues related to trademarks will not typically arise until the invention is well along the path toward commercialization. Therefore, the remainder of this chapter will focus primarily on protecting IP through patent and copyright.

Innovation in a university setting presents unique circumstances that make IP protection challenging (Figure 1). First, academic researchers may invent for different reasons and be incentivized differently than their counterparts in the for-profit world. An emphasis on discovery for discovery’s sake can downplay the importance of patenting, which may impact the inventors’ willingness to approach and work with the university technology transfer office (TTO) (see the chapter “Working with the University Technology Transfer Office”).³ Second, because the threshold for publishable achievements is high, university inventors may not immediately comprehend that an invention that is not publishable might have great value, and therefore they may not recognize the need to seek a patent. However, an invention does not need to be worthy of publishing in an academic paper to nonetheless be a useful product that fills a niche in the marketplace.

Third, even if the inventor realizes they should disclose the invention to the TTO, since university inventions are often very early stage, figuring out the patentable concept can be difficult and the long-term value of the invention is sometimes less clear than it would be at a for-profit company. Finally, IP protection questions are more challenging in a university setting because of the likelihood that many players might claim rights in the invention, including multiple inventors, the

university, the federal government or other grantors, third party companies, and even other universities. These circumstances make it critical that a potential academic entrepreneur be knowledgeable and proactive to troubleshoot questions of IP ownership and IP protection. This chapter will address the issues of ownership and protection in turn.

Figure 1. Challenges of IP Protection.



Ascertaining Ownership to Inventions

An academic entrepreneur cannot commercialize their invention until they first clarify who owns the underlying rights. The default in the United States is that an inventor owns the rights to what they invent, but they may assign their rights away through contract.

Does the inventor or the university own the invention?

Most academic inventors, by virtue of their employment contracts with their universities, have assigned away their rights to any inventions to their employer university. University IP policy statements⁴ guide the circumstances surrounding this assignment of rights, addressing: 1) who is subject to assignment; 2) what is assigned; 3) the circumstances surrounding when invention rights are transferred and when they are not; 4) how rights may be granted back to the inventor if the university opts not to patent the invention; and 5) how much the inventor, their department, and school may earn from the university's successful attempt to commercialize the invention ("Patent

and Tangible Research Property Policies and Procedures of the University of Pennsylvania”). Although an academic entrepreneur may request a waiver from the university IP policy if the invention was created outside of their employment, in most cases where the invention was created at the university, using university resources, the invention belongs to the university. For students, who pay tuition and are not employed by the university, the IP may belong to the student, unless it was created using university resources. It is prudent for students to read the guidelines for their particular university. In addition, before starting their work, students should carefully consider what university resources they plan to utilize, and whether faculty/staff partners with whom they meet have a duty to assign IP to the university, in order to mitigate the likelihood of university ownership of their invention.

Did others contribute to the invention through ideas or funding?

The academic entrepreneur may also have co-inventors, including other researchers, consultants, or service providers, among others. When the university owns the intellectual property, dealing with co-inventors within the university can be easier to navigate. Should the invention get licensed to a third party, the TTO will ensure that all co-inventors share the benefits by distributing shares of the license fees. The TTO can also help when co-inventors are outside of the university, for example, when inventors collaborate across universities, when the inventor uses consultants or service providers, or when the inventor incorporates substances, tools, or materials from a third party (with or without a valid Material Transfer Agreement). The TTO can create an agreement between parties or institutions that addresses how the invention will be patented, how the invention will be commercialized, and how the revenue will be shared.

Besides third party ownership arising because of shared ideas, ownership may also be bestowed by virtue of the terms of the funding that supported the invention. Although the TTO will help guide an academic entrepreneur through the funding process and negotiate all of the terms of the arrangements, the academic entrepreneur must ascertain if there are ownership implications if they accept money from a third party source.⁵ If their research was funded at least in part by a third-party company or foundation, or by the federal or a state government, these other parties, in certain circumstances, might also be able to claim ownership, or at least some rights to the inventions that resulted from the funded research. The extent of the rights is prescribed differently depending on the type of funding. It may be guided by contract in the case of third party company and foundation grants, by law in the case of federal government funding, and either by law or by contract in the case of state funding.

In the case of third party companies, the contract is usually referred to as a sponsored research agreement (SRA). Although SRA terms vary, the default is often that the university will own the rights to inventions resulting from the grant. The sponsoring company, however, may have an option for a license, or in rare cases may negotiate to own the invention completely, especially if the inventions are jointly developed with the company’s own employees. In that case, where the sponsoring company is the owner of the invention, the university may reserve a “license-back,” so

the university and its researchers may continue to use the invention for internal research purposes. But this means that should the academic entrepreneur need to use or commercialize research that stems from sponsored research, they should be careful and very knowledgeable about the terms of the SRA from the beginning. They must ensure that they will be able to license the rights they need, and that their intended uses would not conflict with the rights granted to any party under the contract, whether the rights to operate in a certain market, rights to a revenue share that might impact commercialization, or rights to publish resulting from further development of the invention that might conflict with the entrepreneur's own desire to publish.

Receiving funds through a state funding agency is also usually guided by contract, although in some cases it can be controlled by statute. When controlled by statute, there are generally similar requirements as under the federal granting statute, the Bayh-Dole Act (more below). Under such state statutes, the university maintains ownership of the inventions unless the university fails to meet certain requirements.

The scenario involving federal agency research is much simpler because all such funding is guided by the Bayh-Dole Act ("Bayh-Dole").⁶ Generally, as described in Bayh-Dole, the federal agency granting funding only has ownership rights in limited circumstances, and the legislation is designed to promote university efforts to commercialize the invention. In most instances, provided the university alerts the government in a timely fashion that it wishes to own and patent the invention, the agency retains no more than a nonexclusive license to use the technology it funded and a fail-safe "march-in" right to demand licensing if the invention is not being commercialized. Not only are the federal agency rights very narrow, but the academic entrepreneur and their university have every opportunity to prevent the federal agency from developing or exercising any rights that would interfere with commercialization plans (Reingand) (Figure 2).

First, federal agencies will claim no rights whatsoever in inventions resulting from their funding in at least two instances. Bayh-Dole only allows federal agencies to claim rights over new inventions (so-called "subject inventions"),⁷ not further developments of existing technologies. For example, if a federal agency funds an inventor's research to improve a prior technology to make it more commercially viable, the federal agency would not claim rights over that improvement or the prior technology. Therefore, an inventor could avoid all questions of assigning rights by choosing which projects are funded by the federal grant at what times. Second, federal agencies will not claim rights over inventions resulting from *educational* rather than *research* grants. For certain inventors, their federal funding may not even be an issue. Finally, a federal agency will only exercise its "march-in" rights, which permit it to force an inventor or their university to license, when the inventor fails to meet four specified conditions.⁸ Although these four conditions are somewhat open to interpretation, in summary, the inventor and their university can avoid all possibility of the federal agency "marching in" if they take reasonable efforts to commercialize the invention without violating federal regulations or health and safety needs, and without using

an exclusive licensee that does not substantially manufacture in the U.S. Federal government funding agencies have, to date, never once exercised their “march in” rights.⁹

Figure 2. Cases Where Federal Agencies Claim No Rights.

| | |
|---------------------------|---|
| EXISTING | Federal agencies could only claim rights over new inventions instead of further developments of existing technologies |
| EDUCATION | Federal agencies will not claim rights over inventions resulting from educational rather than research grants |
| MARCH-IN AVOIDANCE | Federal agencies will only exercise "march-in" rights when inventor fails to meet four specified conditions |

Protecting Intellectual Property

Once the academic entrepreneur has ascertained who owns the rights to their invention, as between themselves, their co-inventors, the university, third-party companies, and federal agencies or other grantors, the next questions revolve around protecting the intellectual property in the invention.

To patent or not to patent?

Assuming the invention is owned by the university, the TTO will make the IP protection decisions, including whether to protect the invention through patent. If a patent is filed, the TTO will also decide whether to file a provisional or non-provisional patent (the difference between the two options is explained below in the section entitled “The Inventor’s Role in the Patenting Process”) and in which countries to file (patent protection is accomplished on a country-by-country basis, with coverage in each country incurring additional fees). The TTO might also decide to rely, in part, on copyright, or occasionally on trade secret, if applicable. Although the TTO will make the final decision, the inventor does have power to influence the decision.¹⁰

The TTO's first step is to determine whether pursuing a patent would be a wise business decision. Not all inventions can, or should, be patented. The invention must hold the promise of future value, and a patent should be important to the commercialization plan. In a university setting, the future value of an invention is especially difficult to determine because it is still at an early stage of development. On the other hand, since the university's goal is usually to license rather than to productize the invention, securing a patent may be more important for the commercialization plan than it would be in a commercial setting (see the chapter "Intellectual Property: Commercializing in a University Setting"). Licensing technology is difficult without an asset in hand. Nonetheless, a TTO might consider several factors to determine whether or not to patent, including: whether the field of the invention turns over quickly; whether the invention is a seminal or an incremental development; whether the patent would complement or drive up the value of an existing portfolio; the potential markets for the invention; any potential licensees; and whether the invention is easily reverse engineered, among other factors.¹¹ Filing a patent might not be worthwhile if the invention is incremental, likely to change, not easily reverse engineered, or in a quick-moving field where parties do not patent their inventions. The invention may also not be worth patenting if the markets and licensees are uncertain.

Even if filing a patent remains a good business decision, there is still the question of whether a patent will actually issue. Patents can only protect so-called patentable subject matter, which does not include laws of nature, natural phenomena, and abstract ideas—three categories that encompass many university inventions.¹² Courts have tried to clarify the rules around patentable subject matter, but the rules remain somewhat inconsistent and difficult to interpret (Sheridan). In particular, patents in biotechnology, organic chemistry, and software have recently suffered from very low issuance rates (Underhill). In addition, the invention must be new, nonobvious, and useful.¹³ Especially in a crowded field, a patent applicant may be forced to explain why the invention is new and not anticipated by other inventions. Even if these arguments are successful, the United States Patent and Trademark Office (USPTO) might still argue to narrow the patent claims to avoid prior art.¹⁴ The TTO (or the inventor) must take the time-intensive, expensive, and complicated patent prosecution process into account when determining if filing a patent is worth the cost.

The academic entrepreneur can influence the TTO's decision to file a patent on the invention by providing information that makes a more compelling valuation argument. Often the academic entrepreneur knows more about the potential uses, market, and licensors for the invention than anyone else. The academic entrepreneur also likely knows about competitors in the field and potential prior art. Proactively sharing this information with the TTO will better build the case for formally protecting the invention through patent, as well as ultimately increasing the patent quality (see the chapter "Working with the University Technology Transfer Office").

The inventor's role in the patenting process

Assuming the invention can and should be patented, the academic entrepreneur should play a role. They must first alert the university to the invention by filling out an invention disclosure form

(IDF).¹⁵ The IDF will ask them to describe their invention and plans for further development, list any co-contributors,¹⁶ and describe the prospective market, along with any competitors/potential licensors in the space, if known. Typically, the IDF will also ask about any potential disclosures (past or future) of the invention.

Filing an IDF as soon as possible after invention is important in order to preserve the right to patent. Because the U.S. is newly a “first to file” jurisdiction,¹⁷ the first party to file a patent application, not necessarily the first to invent, secures the coverage. Any delay in filing an application might mean that another person files the patent first. Not only is it important to file quickly after invention, but it is also critical to file a patent before disclosure. Disclosure negates an inventor’s ability to file a patent *at all* in most jurisdictions overseas and starts a one-year clock to file a patent in the U.S.. Disclosure is a fact-based determination, but disclosure constitutes any activity through which the inventor makes the invention public, including, but not limited to, publishing an abstract or a paper, giving a talk, presenting a poster, blogging, submitting a grant proposal that will be publicly published, or potentially even discussing the idea with a potential investor (“Overview of Public Disclosure”). Preventing disclosure is possible through the use of non-disclosure agreements, but the inventor should at least consult with the TTO, if not also submit an IDF, before any potential disclosure to make sure they do not jeopardize any rights. The academic entrepreneur should file the IDF with plenty of time for the TTO to act and file a patent if necessary.

Is it ever too early to submit the IDF, since doing so will start the patenting process? When should the inventor consider the invention ready for patenting? The short answer is that the inventor should file the IDF to start the patenting process as soon as possible after their invention is “conceived.” When an inventor “conceives” an invention, they do not necessarily have to be sure that the invention will work exactly as they envision, but the invention must be developed and permanent enough that their description of it would permit a “person having ordinary skill in the art” to recreate the invention (“UNIVERSITY OF PITTSBURGH OF CMWLTH. v. Hedrick”). The TTO is accustomed to working with early stage technologies and can make the judgment call on whether to wait to file a patent if the invention is too speculative. It is better to fill out an IDF too early, which gives the TTO the option to file, rather than too late.

There are strategies for gaining protection over early stage technology while still maintaining flexibility and keeping costs under control. For example, often the TTO will first file a provisional patent application, which is a cheaper and less complete alternative to a non-provisional patent application. A provisional patent preserves the date of filing, yet gives the inventor twelve months to further perfect the invention, and the TTO time to find a potential licensor, before the TTO must file a non-provisional application. Even if the invention is further developed between the filing of the provisional and non-provisional applications, the inventor gets the earlier priority date on everything disclosed in the original provisional application. The TTO can also take advantage of filing an application under the Patent Cooperation Treaty (PCT) to reserve the right to file the

patent internationally, yet delay paying some foreign fees for up to 30-months (Pressman and Tuytschaevers). If it is in the interest of the inventor to speed up instead of slow down the prosecution process, the TTO can pay an extra fee to give the patent “Track One” prioritized examination, which will ensure a final disposition on the application in about 12-months (“USPTO’s Prioritized Patent Examination Program”).

After filing the IDF and starting the patent process, the inventor continues to play at least two critical roles in the prosecution of the patent. The first role involves supporting the attorney who is drafting the patent (the patent prosecutor). The inventor can provide a critical head start in researching prior art because of their deep knowledge of the technology and unique relationships within the field where they likely know most of the companies and researchers. They can quickly help the prosecutor search through citations and build a more comprehensive and potentially relevant prior art collection, thus helping to craft stronger patent claims that would more likely avoid problems during prosecution and defeat later litigation challenges. Because they understand the market, potential competitors and licensors, the inventor can also help the prosecutor to draft the patent with those third parties in mind. For example, they might recommend that the prosecutor include claims aimed at a competitors’ future product, or might recommend drafting a broader specification that describes additional uses for the invention, which might open a new market. Finally, since the inventor knows the invention better than anyone else, they can direct the prosecutor to emphasize certain elements of the invention in the claims and help to maintain those critical elements throughout the prosecution as much as possible.

The inventor’s second role is ethical: they have an obligation throughout the entire prosecution process to disclose to the USPTO any prior art they discover that they believe would impact the issuance of the patent. This obligation survives through the patent issue date, regardless of how involved the inventor is in the prosecution of the patent.¹⁸

Protecting invention through copyright

A discussion of options to protect IP invented in a university setting would not be complete without considering the role of copyright. The academic entrepreneur may encounter copyright in at least two distinct contexts. First, if there is a software component to their invention, besides potential patent coverage, the code itself might also be copyrightable. Second, their publications are also subject to copyright.

Software code is copyrightable since, as with books, screenplays, or other works, code is written expression fixed in a tangible medium. However, copyright coverage for software only covers the written expression of the specific coding and does not extend to the ideas behind the expression, meaning that another version of the code that is written slightly differently yet nonetheless has the same functionality as the copyrighted code, does NOT infringe the copyright. Given the current climate for software patents, copyright is an alternative to consider, however it is, at best, a cumulative rather than a primary protection strategy. More likely, an inventor will encounter

copyright when they are publishing papers, articles, or the results of their research. As in the patent realm, the default is that a creator owns rights to their work, although they can assign or license away some or all of their rights through contract. Unlike with patentable subject matter, not all University IP Policies mandate that academic employees of the university assign their rights in copyrightable works as a condition of employment. More often than not, academic entrepreneurs do not assign away their copyrights through their employment contracts.¹⁹

However, danger may lurk in author agreements with journals or publishing houses. When an inventor wants to publish their papers, articles, or results, they must be sure that: 1) the author agreement does not transfer ownership of the copyright over to the publisher; and 2) the rights the inventor licenses to the publisher do not unduly limit their own use of the work or their ability to license it to others for use. For example, if their employment contract requires the inventor to permit the university to publish their work through a university online repository, the inventor cannot grant a publishing company an exclusive right to publish their work or they will be in breach of both contracts. If the inventor wants to publish the article in another journal after the first version prints, they must limit the duration of the first publishing company's rights or make the rights nonexclusive. They must also remember if they are subject to any publishing requirements through the terms of grants that funded their research. For example, sometimes a federal agency deems publication a necessary condition of accepting a federal grant. In other cases, especially if the research concerns a classified technology, the federal agency might prohibit publication. The inventor must not license any publishing rights that would conflict with the terms of their grants. It is critical that the inventor consider what rights they need to retain, either for their own purposes or because of pre-existing contracts, like the University IP Policy or a grant document, and be sure to safeguard those rights by reading and negotiating their author agreements carefully.

Conclusion

An academic entrepreneur faces important IP considerations over their invention. They must first clarify issues of ownership and rights to use, in order to ascertain who controls the rights to their invention as between themselves, the university, any collaborator, and any funding source. Assuming university ownership, the academic entrepreneur can help to execute the protection strategy, whether or not that involves a formal patent application. They can, and should, play an active role as a partner with the TTO in deciding which elements of the invention to protect and how to create a holistic protection strategy that best positions the invention to be commercialized.

Endnotes

1. Some basic rights and remedies of copyright and trademark attach simply through creation or use, but filing for registrations increases the remedies available for infringement. In

contrast, enforceable patent rights do not attach until the government-endorsed patent is issued.

2. Trade secret is an option for protecting formulas, data, knowhow and other information with business value, but it can be difficult to use in a university setting for a variety of reasons, including that once a trade secret is disclosed, it loses all protection. This is not practical in a setting where publication is important.
3. A university technology transfer office is the arm of the university charged with protecting (usually through patent) and commercializing (usually through licensing to a for-profit venture) university-owned inventions.
4. These IP policy statements have various titles, such as Patent and Tangible Research Property Policies and Procedures of the University of Pennsylvania, and Guide to the Ownership, Distribution and Commercial Development of MIT Technology, etc. For simplicity's sake, I will refer to them all by the general term "University IP Policy." Sometimes there are separate policies for patentable inventions and copyrightable works, sometimes the policies are combined.
5. At some universities, research funding from some outside sources might be handled through a different university department instead of the TTO. At the University of Pennsylvania, for example, federal and non-profit funding is handled through a separate office called the Office of Research Services.
6. The Bayh-Dole Act's formal name is the University and Small Business Patent Procedures Act, and is set forth as Title 35 U.S.C. §§200-212; 37 C.F.R. 401.
7. 37 C.F.R. §401.14(a)(2).
8. 37 C.F.R. §401.14(j).
9. Several petitions have been filed, but as of May 27, 2018, all thus far are either pending or have been denied. Much of the consideration has been on using march-in rights to address high-priced pharmaceutical drugs resulting from federally-funded research.
10. Of course, if the university is not the owner of the invention, as is the case either if i) the invention falls outside of the University IP Policy; or ii) the inventor secures a waiver of rights from the university, the academic entrepreneur can and must make their own decisions about protection.
11. Factors that a for-profit (as opposed to university) venture might consider are different, and may include whether there are any potential competitors in the field and whether they have patented, whether a patent might be used defensively to guard against a competitor's gain, whether the patent could be used as a bargaining device with another party, and how likely the for-profit venture would be to enforce the patent against infringement.
12. These categories come from recent court cases interpreting patent law.
13. 35 U.S.C. §§101, 102, 103.
14. "Prior art" describes any information or invention that existed before a patent was filed that renders the patented invention not "new" or "non-obvious."

15. This standard university form goes by different names, for example Invention Disclosure Form at Georgia Institute of Technology, the Technology Disclosure Form at Penn State University, and a Report of Innovation at Harvard University. For simplicity's sake, I will refer to it as an invention disclosure form (IDF). For an example, see <http://www.research.psu.edu/sites/default/files/invention-disclosure-form.pdf>
16. The inventor should always keep detailed lab notebooks, especially in the case of collaboration. It is important to know who contributed what detail to the invention and when so that only people that contribute to the invention as described in the patent claims end up being listed on the patent. To prove when certain elements of the invention were invented, it is a good idea for the inventor to periodically have a third party verify and certify the lab notebook on every page and enclose the entire notebook in an envelope signed across the seal.
17. The law changed in March, 2013 with the passage of the America Invents Act, so the U.S. is now a "first to file" rather than "first to invent" jurisdiction, similar to most of the rest of the world.
18. 37 CFR §1.56(a)
19. Although the academic entrepreneur retains ownership, the employment contract may require a limited license for specific uses that benefit the university, for example a royalty-free license to publish the article in an online repository of works of university professors.

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