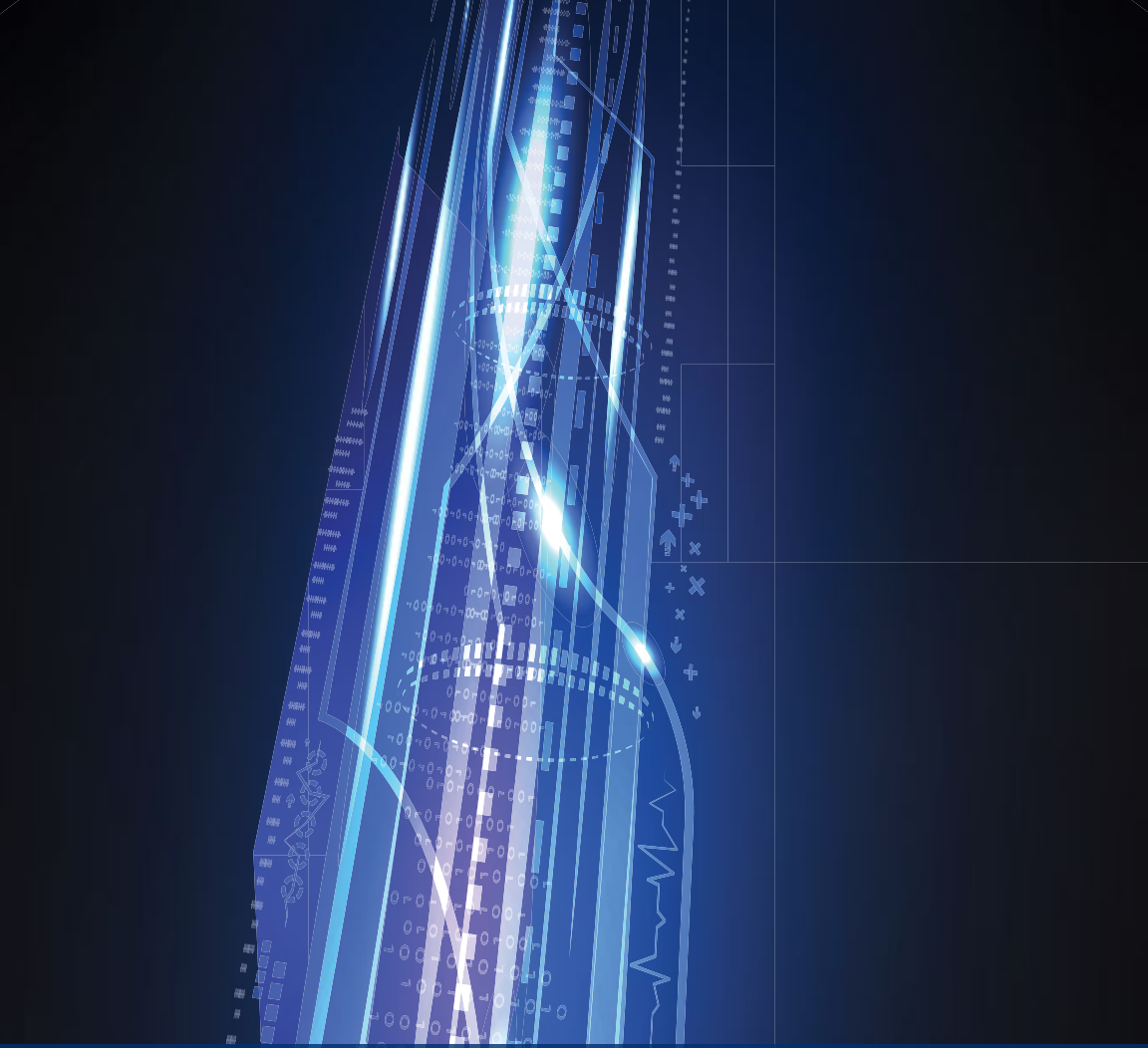
THE TECHNOLOGY TRANSFER OFFICE:

Inventor's Guidebook

CASE WESTERN RESERVE UNIVERSITY



The Inventor's Guide to Technology Transfer outlines essential elements of technology transfer at Case Western Reserve University.

This guide, organized to answer the most common questions we typically receive from our research community, provides a broad overview of the technology transfer process and services available for researchers.

For more information, visit the Office of Research and Technology Management's website or email the CWRU Technology Transfer Office at techtransfer@case.edu.

Please note: This booklet is based on the University of Michigan's "Inventor's Guide to Technology Transfer," with adaptations for CWRU and the CWRU Technology Transfer Office. We are very grateful to Ken Nisbet and the staff of the UM Office of Technology Transfer for their kind permission to use their excellent material and to the University of Michigan for permission to use its copyright.

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TECHNOLOGY TRANSFER OVERVIEW

What is technology transfer?
Technology transfer is the transfer of knowledge and discoveries to the public. It often occurs through publications, educated students entering the workforce, exchanges at conferences, and relationships with industry, among other things. For the purposes of this guide, technology transfer refers to the process of transferring scientific findings and/or technology from one organization to another for further development and commercialization under the guidance of professionals employed by universities, research foundations and businesses.

What is the CWRU Technology Transfer Office?
The CWRU Technology Transfer Office (TTO) is an office committed to serving our innovators with full-spectrum intellectual property services and leading the successful commercialization of innovations created at CWRU. As steward of the intellectual property assets of CWRU, TTO has resources to protect the rights of the inventor and the university and to assess the commercial potential of new discoveries. TTO also seeks to educate university faculty, staff and students, as well as the regional community on issues such as intellectual property, standard licensing practices and the formation of new ventures. The office consists of professional staff members who possess a mix of business, technical, scientific, legal and venture capital experience. They are also experienced in transferring technologies from the life, physical, information and computer sciences.

Why would a researcher want to participate in the technology transfer process?
Reasons for participating in the technology transfer process are unique to each researcher and may include:

- Making a positive impact on society
- Feeling a sense of personal fulfillment
- Achieving recognition and financial rewards
- Generating school and departmental funding
- Meeting the obligations of a research contract
- Attracting research sponsors
- Creating educational opportunities for students
- Linking students to future job opportunities
- Applying research to real world problems

How is technology transferred?
Technology is typically transferred through a license agreement in which CWRU grants to a third party a license to use CWRU's intellectual property rights in the defined technology for a specific amount of time, often limited to a particular field of use and/or region of the world. The licensee (the third party licensing the technology) may be an established company or a new business startup, and such a license grant may be exclusive or non-exclusive. License agreements include terms that require the licensee to meet certain performance requirements to ensure advancement of the technology and to make financial payments to CWRU. These payments are shared with inventors with a portion reinvested back into the university to provide support for further research, education and participation in the technology transfer process.

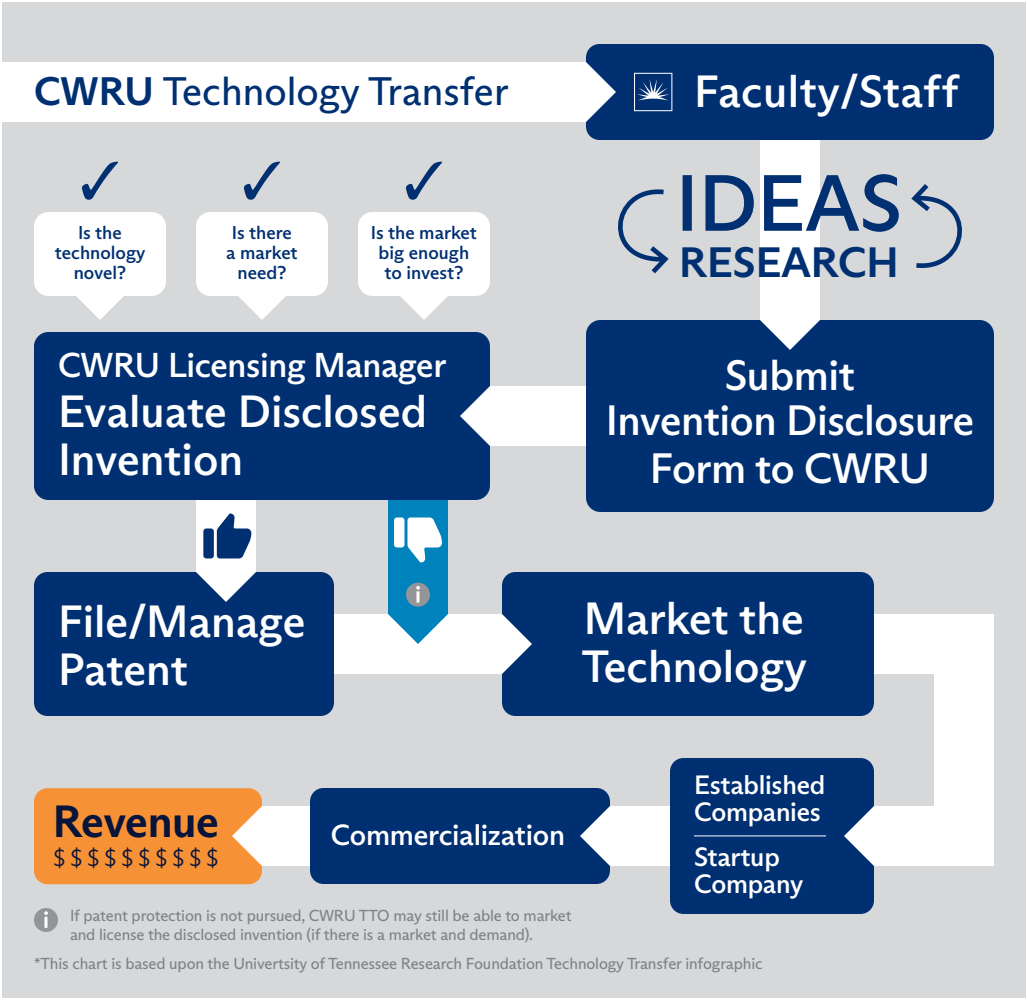
What is the Bayh-Dole Act?
The U.S. Bayh-Dole Act of 1980 allows universities and other nonprofit institutions to have ownership rights to discoveries resulting from federally funded research, provided certain obligations are met. These obligations include:

- Making efforts to protect (when appropriate) and commercialize the discoveries
- Submitting progress reports to the funding agency
- Giving preference to small businesses that demonstrate sufficient capability
- Sharing any resulting revenues with the inventors

The Bayh-Dole Act is credited with stimulating interest in technology transfer activities and generating increased research, commercialization, educational opportunities and economic development in the United States.

THE TECHNOLOGY TRANSFER PROCESS

How do I work with the CWRU Technology Transfer Office?
We encourage you to contact the Technology Transfer Office (TTO) early during your research and discovery activities to be aware of the options that will best leverage the commercial potential of your research. TTO staff are trained to assist you with questions related to marketability, funding opportunities, commercial partners, patenting and other intellectual property protection methods, new business startup considerations, university policies and procedures, and much more.



*This chart is based upon the Univertsity of Tennessee Research Foundation Technology Transfer infographic

How long does the technology transfer process take?
The process of protecting the technology and finding the right licensing partner may take months—or even years—to complete. The amount of time will depend on the development stage of the technology, the market for the technology, competing technologies, the amount of work needed to bring a new concept to market-ready status and the resources and willingness of the licensees and the inventors.

How can I help in this process?

- Contact TTO to discuss when you believe you have created or discovered something unique with potential commercial or research value.
- Complete the CWRU Invention Disclosure Form and submit it to TTO before publicly disclosing your technology or submitting a manuscript for review and publication. You will be assigned a licensing professional who will guide you through the technology transfer process.
- To avoid risking your patent rights and possibly hindering the opportunity to market your invention, contact TTO before holding any discussions with people outside the CWRU community. If a patent application has not yet been filed, we will give you a Non-Disclosure Agreement for the outside party to sign before you describe your invention to them.
- On the CWRU Invention Disclosure Form, include companies and contacts you believe might be interested in your invention or who may have already contacted you about it. Studies indicate that over 70% of all licenses are executed with commercial entities known by the inventor, so your contacts can be extremely useful.
- Respond to TTO and outside patent counsel requests. While some aspects of the patent and licensing process may require significant participation on your part, we will strive to make efficient use of your valuable time.
- Keep TTO informed of upcoming publications or interactions with companies related to your intellectual property.

RESEARCH CONSIDERATIONS and MATERIAL TRANSFER AGREEMENTS

Will I be able to publish the results of my research and still protect the commercial value of my intellectual property?
Yes, but since patent rights are affected by these activities, it is best to submit an Invention Disclosure Form well before any public communication or disclosure of your invention. There are significant differences between the United States and other countries as to how early publication affects a potential patent. Once publicly disclosed (published or presented in some form), an invention may have restricted or minimal potential for patent protection outside of the U.S. Be sure to inform your assigned licensing professional of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, dissertation/master's thesis, publication or other public presentation of the invention.

May I use material or intellectual property from others in my research?
Yes, but it is important to carefully document the date and conditions of use so that we can determine if this use may influence the ownership and license rights of your subsequent research results. If you wish to obtain materials from outside collaborators, an incoming Material Transfer Agreement (MTA) should be considered. Visit the MTA webpage or contact the Office of Pre-Award Services and Agreements (PASA) at cwru-mta@case.edu for more information on incoming MTAs.

Will I be able to share materials, research tools or intellectual property with others to further their research?
Yes; however, it is imperative to document items that are to be shared with others and the conditions of use. If you wish to send materials to an outside collaborator, an outgoing MTA should be completed for this purpose. It may also be necessary to have a Non-Disclosure Agreement (NDA) executed to protect your research results or intellectual property. If you need assistance completing an outgoing MTA, contact PASA or contact the Technology Transfer Office (TTO) if you need help completing a NDA.

What rights does a research sponsor have to any discoveries associated with my research?

The Sponsored Research Agreement should specify the intellectual property (IP) rights of the sponsor. CWRU generally retains ownership of the patent rights and other intellectual property resulting from sponsored research; however, the sponsor may have rights to obtain a license to the intellectual property arising from the research. Often, sponsored research contracts allow the sponsor a limited time to negotiate a license for any patent or intellectual property rights developed as the result of the research. Even so, the sponsor generally will not have contractual rights to discoveries that are clearly outside of the scope of the research (and which do not use funds from the research agreement). Therefore, it is important to define the scope of work within a research agreement.

Sponsored Research Agreements are handled by the Office of Pre-Award Services and Agreements (contact resadm@case.edu), which works closely with TTO on IP issues in Sponsored Research Agreements.

What about consulting?

When researchers enter consulting agreements for work to be done without use of CWRU facilities, they are deemed to be acting outside of the scope of their employment. Therefore, consulting arrangements are not negotiated by the university nor formally reviewed by TTO. If you enter into consulting agreements, you should familiarize yourself with CWRU policies relevant to consulting activities including those in the Conflict of Interest (COI) Policy. Researchers are expected to ensure that the terms of the consulting arrangement are consistent with CWRU policies, including those related to intellectual property ownership, employment responsibilities and use of intellectual property. Consulting agreements will need to be disclosed. For additional information, view the "Conflicts of Interest" section of this guidebook.

INVENTION DISCLOSURES

What is an Invention Disclosure?
An Invention Disclosure, also known as an Invention Disclosure Form (IDF), is a written description of your invention or development that is provided to the Technology Transfer Office (TTO). The IDF should list all inventors (i.e., anyone who contributed to the claims of a patentable invention), provide all sponsors of the research and include all of the information necessary to begin pursuing protection, marketing and commercialization activities. This document will be treated as confidential and you will be contacted by your assigned licensing professional shortly after your submission to discuss the invention and its potential commercial applications. Based on the IDF, your licensing professional may generate a non-confidential description of your invention to assist in marketing the technology. As an inventor, you may be asked to review the non-confidential description prior to marketing. Once potential partners have been identified and confidentiality agreements have been signed, more detailed exchanges of information can be made.

Why should I submit an Invention Disclosure?
When you disclose your invention to the TTO, it starts a process that could lead to the commercialization of your technology. This may involve beginning the legal protection process and working to identify outside development partners. If government foundations or sponsored research funds were used for your research, you are required to file a prompt disclosure, which will be reported to the sponsoring agency. Similar requirements may exist for other sponsored projects.

How do I know if my discovery is an invention? Should I be submitting an Invention Disclosure Form?
You are encouraged to submit an IDF for all inventions and developments that you feel may solve a significant problem and/or have significant value. If you are in doubt, contact TTO to discuss the potential invention. We can also advise on alternatives to licensing.

When should I complete an Invention Disclosure?
You should complete an IDF whenever you feel you have discovered something unique with possible commercial value. This should be done well before presenting the discovery through publications, poster sessions, conferences, press releases or other communications. In the United States, patents must be filed within one year of public disclosure of the invention. In the majority of other countries, patents must be filed before public disclosure of the invention.

Should I disclose research tools?
Typically, research tools are materials such as antibodies, vectors, plasmids, cell lines, mice and other materials used as "tools" in the research process. Most research tools do not necessarily need to be protected by patents in order to be licensed to commercial third parties and/or generate revenue for your laboratory. If you have research tools you believe are valuable or wish to provide to others (including research collaborators), TTO will work with you to develop the appropriate protection, licensing and distribution strategy.

How do I submit an Invention Disclosure?
You can download an Invention Disclosure Form and simple instructions from the Commercialization Forms webpage. Invention Disclosures are assigned to a licensing professional within the office. If you have any questions, call 216.368.0362.

OWNERSHIP OF INTELLECTUAL PROPERTY

What is "intellectual property"?
Intellectual property (IP) includes inventions (e.g. materials, concepts, software) that may be protected under patent, trademark and/or copyright laws and sometimes by contract.

Who owns what I create?
Ownership depends upon the employment status of the creators of the invention and their use of university facilities. Considerations include:

- What is the source of the funds or resources used to produce the invention?
- What was the employment status of the creator(s) at the time the IP was made?
- What are the terms of any agreement related to the creation of the IP?

As a general rule, CWRU owns inventions made by its employees while acting within the scope of their employment or using CWRU resources. CWRU's IP Policy describes the applicable guidelines for allocation of the rights to inventions and discoveries produced by research conducted at CWRU. In some cases, the terms of a Sponsored Research Agreement or Material Transfer Agreement may impact ownership. When in doubt, it is best to contact the Technology Transfer Office (TTO) for advice.

Does the university ever release intellectual property to inventor(s)?
This is a rare occurrence. When IP is offered for release to the inventor(s), they must inform the Vice President for Research and Technology Management, in writing, if they wish to pursue commercialization of the IP on their own. For more details about the university's IP Policy, visit the Office of Research and Technology Management's website.

Who owns rights to discoveries made while on sabbatical?
Generally, if you are on a sabbatical paid by the university, CWRU still retains rights to any discoveries connected to your scope of employment. Contact the TTO or your department chair before your sabbatical to ensure that ownership considerations are documented.

Should I list visiting scientists or scientists at other institutions on my Invention Disclosure?
All contributors to the ideas leading to a discovery should be mentioned in your disclosure, even if they are not CWRU employees. TTO, along with legal counsel, will determine the rights of such persons and institutions. It is prudent to discuss with TTO all working relationships (preferably before they begin) to understand the implications for any subsequent inventions.

Can a student contribute to an invention?
Yes, many students work on inventions at CWRU under a wide variety of circumstances. CWRU promotes student entrepreneurism, and students can be named as inventors or creators under the CWRU IP Policy. Typically, a student will own their rights to an invention unless it was created by a student working on a project or program financed in whole or in part by a grant or contract, or if CWRU funding, equipment, staff or physical facilities were employed in the process of developing the invention.
View the CWRU IP Policy for more details.

ASSESSMENT OF AN INVENTION DISCLOSURE

How does the Technology Transfer Office assess Invention Disclosures?
Licensing professionals in the Technology Transfer Office (TTO) examine each invention disclosure to review a wide range of factors, which include the:

- Novelty of the invention,
- Protectability and marketability of potential products or services,
- Maturity of technology and its stage of development,
- Relationship to related intellectual property,
- Size and growth potential of the relevant market,
- Amount of time and money required for further development,
- Pre-existing rights associated with the intellectual property, and
- Potential competition from other products/technologies.

This assessment may also include consideration of whether the intellectual property can be the basis for a new business startup.

Is an invention ever assigned to an inventor?
If TTO decides not to pursue patent protection or chooses not to actively market the invention, Case Western Reserve University may transfer ownership to the inventor(s) if specifically requested, in writing. However, the inventor should consider this carefully and is advised to discuss such transfer thoroughly with TTO. For example, the process of releasing an invention requires buy-in and approvals from several sectors of the CWRU administration, in addition to our office.

There may be complicating factors because of rights owned by external funders. Reassignment of inventions funded from U.S. government sources requires the government's prior approval. Additionally, continued development may be hampered if the invention is released because that also precludes any further use of CWRU funds, facilities or resources to develop the technology. Among the key factors in deciding to reassign are whether additional university resources or private resources could best improve marketability. For more information on this topic, visit our website.

Startups | Marketing | COI | Agreements | Commercialization | Royalties | Cycle of Innovation

PATENTS AND OTHER LEGAL PROTECTION

What is a patent?
In the U.S., a patent gives the holder the right to exclude others from making, using, selling, offering to sell and importing the patented invention. It is important to note that a patent does not necessarily provide the holder any affirmative right to practice a technology since it may fall under a broader patent owned by others. Instead, it provides the right to exclude others from practicing the invention. Patent claims are the legal definition of an inventor's protectable invention.

What type of subject matter can be patented?
Patentable subject matter includes processes, machines, compositions of matter, articles, some computer programs and methods (including methods of making compositions, methods of making articles and even methods of performing business).

Can someone patent a naturally occurring substance?
Generally, no. A natural substance that has never before been isolated or known may be patentable in some instances, but only in its isolated form (since the isolated form had never been known before). A variation of a naturally occurring substance may be patentable if an inventor is able to demonstrate substantial non-obvious modifications that offer advantages of using the variant.

What is the United States Patent and Trademark Office?
The United States Patent and Trademark Office (USPTO) is the federal agency, organized under the Department of Commerce, that administers patents on behalf of the government. The USPTO also employs patent examiners skilled in all technical fields in order to appraise patent applications and issues federal trademark registrations.

What is the definition of an inventor on a patent and who determines this?
Under U.S. law, an inventor is a person who takes part in the conception of the ideas in the patent claims of a patent application. Thus, inventorship of a patent application may change as the patent claims are changed during prosecution of the application. An employer or person who only furnishes money to build or practice an invention is not an inventor. Inventorship is a legal issue and may require an intricate legal determination by the patent attorney prosecuting the application. A helpful rule of thumb is that *inventorship is not the same as authorship*.

Who is responsible for patenting?
TTO contracts with outside patent attorneys for IP protection, thus assuring access to patent specialists in diverse technology areas. Working with inventors, TTO facilitates drafting of the patent applications and responding to communications issued by worldwide patent offices.

What is the patenting process?
Patent applications are generally drafted by a patent attorney or a patent agent (a nonattorney with a science education licensed to practice by USPTO). As the inventor, the patent attorney generally will ask you to review an application before it is filed and will also ask you questions about inventorship of the application claims.

At the time an application is filed, the patent attorney will ask the inventor(s) to sign inventor declaration and assignment forms, which evidences the inventor's duty to assign the patent to the university. TTO routinely assists patent counsel with completing these documents and appreciates your attention to such requests. If you have questions about the execution of any of these documents, which are sometimes referred to as "formal papers," please contact your licensing professional.

In about a year, depending on the technology, the patent attorney will receive written notice—referred to as an office action or official action— from USPTO as to whether the application and its claims have been accepted in the form as filed. More often than not, the USPTO rejects an application because certain formalities need to be cleared up, or the claims are not patentable over the prior art—anything that workers in the field have made or publicly disclosed in the past.

If the application is rejected, the patent attorney must file a written response, usually within three to six months. Generally, the attorney may amend the claims or point out why USPTO's position is incorrect; this procedure is referred to as patent prosecution. Often it will take two USPTO Official Actions and two responses by the patent attorney before the application is resolved.

The resolution can take the form of a notice that the application is allowable; in other words, USPTO agrees to issue a patent. During this process, input from the inventor(s) is often needed to confirm the patent attorney's understanding of technical aspects of the invention and/or the prior art cited against the application. USPTO holds patent applications confidential until published, which occurs 18 months after initial filing.

Is there such a thing as a provisional patent?
No. However, there is a provisional patent application, which is described later in this section.

For more information, view the "General Information Concerning Patents," section on the USPTO website.

What is the difference between a provisional patent application and a regular, non-provisional (or "utility") patent application?
In certain circumstances, U.S. provisional patent applications can provide a tool for preserving patent rights while temporarily reducing costs. This occurs because the application is not examined during the year in which it is pending and claims are not required. A regular U.S. application and related foreign applications must be filed within one year of the provisional application in order to receive the benefit of its early filing date or "priority date." You can only receive the benefit of the earlier filing date for material that is adequately described and enabled in the provisional application. As a result, the patent attorney may need your assistance when an application is filed as a provisional.

What's different about foreign patent protection?
Foreign patent protection is subject to the laws of each individual country, although in a general sense the process works much the same as it does in the U.S. In foreign countries, an inventor will lose any patent rights if they publicly disclose the invention prior to filing the patent application; in contrast, the U.S. has a one-year grace period.

Is there such a thing as an international patent?
Although an international patent does not exist, an international agreement known as the Patent Cooperation Treaty (PCT) provides a streamlined filing procedure for most industrialized nations. For U.S. applicants, a PCT application is generally filed one year after the corresponding U.S. application (either provisional or non-provisional) has been submitted. The PCT application must later be filed in the national patent office of any country in which the applicant wishes to seek patent protection, generally within 30 months of the earliest claimed filing date.

The PCT provides two advantages. First, it delays the need to file costly foreign applications until the 30-month date, often after an applicant has the opportunity to further develop, evaluate and/or market the invention for licensing. Second, the international preliminary examination often allows an applicant to simplify the patent prosecution process by having a single examiner speak to the patentability of the claims, which can save significant costs in prosecuting foreign patent applications.

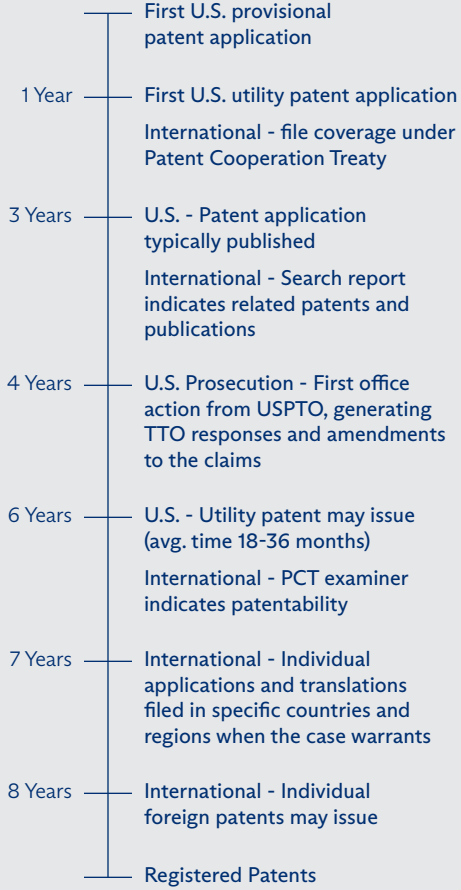
An important international treaty called the Paris Convention permits a patent application filed in a second country (or a PCT application) to claim the benefit of the filing date of an application filed in a first country. Pursuant to this treaty, these convention applications must be filed in foreign countries (or as a PCT) within one year of the first filing date of the U.S. application.

What is the timeline of the patenting process and resulting protection?
Currently, the average U.S. utility patent application is pending for about two years, though inventors in the biotech and computer fields should plan on a longer waiting period. Once a patent is issued, it is enforceable for 20 years from the initial filing of the application that resulted in the patent, assuming that USPTO-mandated maintenance fees are paid.

Why does CWRU protect some intellectual property through patenting?
Patent protection is often a requirement of a potential commercialization partner (licensee) because it can protect the commercial partner's often sizable investment required to bring the technology to market. Due to the expense and length of time required to obtain a patent, patent applications are not possible for all CWRU inventions. TTO carefully reviews each invention for its commercial potential before investing the university's resources in the patent process. However, because the need for commencing a patent filing usually precedes finding a licensee, we look for creative and cost-effective ways to seek early protections for as many promising inventions as possible.

Who decides what gets protected?
TTO and the inventor(s) consider relevant factors in making recommendations about filing patent applications. Based on a recommendation from the licensing professional, the Associate Vice President of Technology Transfer and Commercialization ultimately makes the final decision as to whether to file a patent application or seek another form of protection.

Patent Process Timeline



What does it cost to file for and obtain a patent?
Filing a non-provisional U.S. patent application may cost between $7,000 and $15,000. To obtain an issued patent may require an additional $10,000 to $15,000 or more for patent prosecution. Filing and obtaining issued patents in other countries may cost $20,000 or more per country. Also, once a patent is issued in the U.S or in foreign countries, certain maintenance fees are required to keep the patent alive.

What if I created the invention with someone from another institution or company?
If you created an invention under a sponsored research agreement or consulting agreement with a company, your TTO licensing professional will need to review that contract to determine ownership and other rights associated with the contract and to determine the appropriate next steps. Should the technology be jointly owned with another academic institution, the licensing professional will usually enter into an inter-institutional agreement that enables one of the institutions to take the lead in protecting and licensing the invention, sharing expenses associated with the patenting process, and allocating any licensing revenues. If the technology is jointly owned with another company, the licensing professional will work with the company to determine the appropriate patenting and licensing strategy.

Will the university initiate or continue patenting activity without an identified licensee?
Sometimes CWRU accepts the risk of filing a patent application before a licensee has been identified. After university rights have been licensed to a licensee, the licensee generally pays the patenting expenses. At times we must decline further patent prosecution after a reasonable period (often a year or two) of attempting to identify a licensee and one cannot be identified, or if it is determined that we cannot obtain reasonable claims from USPTO.

What is a copyright and how does it work?
Copyright is a form of protection provided by U.S. laws to the authors of original literary, dramatic, musical, artistic works and other intellectual works, as well as computer software. This protection is available to both published and unpublished works. The Copyright Act generally gives the owner of the copyright the exclusive right to conduct and authorize various acts, including reproduction, public performance and making modifications of the copyrighted material. Copyright protection is automatically secured when a work is fixed into a book, software code, video or other tangible medium. In some instances, CWRU registers copyrights, but generally not until a commercial product is ready for manufacture.

What is a trademark or service mark and how is it useful?
A trademark includes any word, name, symbol, device or combination that is used in commerce to identify and distinguish the goods of one manufacturer or seller from those manufactured or sold by others, and also to indicate the source of the goods. In short, a trademark is a brand name. A service mark is any word, name, symbol, device or combination that is used—or intended to be used—in commerce to identify and distinguish the services of one provider from those of others and to indicate the source of the services.

What is trademark registration?
Trademark registration is a procedure in which the United States Patent and Trademark Office provides a determination of rights based upon legitimate use of the mark. However, it is not necessary to register a trademark or service mark to prevent others from infringing upon the trademark. Trademarks generally become protected as soon as they are adopted by an organization and used in commerce, even before registration. With a federal trademark registration, the registrant is presumed to be entitled to use the trademark throughout the U.S. for the goods or services for which the trademark is registered.

How do we decide whether to commercialize with a traditional or an "open source" license for software?
Generally, the TTO supports CWRU developers who choose to provide free access to their software through open source mechanisms. It's also possible to provide open source licenses to the academic/non-profit community only or to follow a freemium model. In the event a developer wishes to make their software available without restriction, developers should seek authorization from an appropriate department chair or dean to ensure that they understand and agree with foregoing any possible income from the software. Any licensing scenario (traditional or open) will require that the university retain the right to use and create modifications of the software, and will also require that any pre-existing contractual obligations to third parties are satisfied.

CONSIDERATIONS FOR A STARTUP COMPANY

What is a startup company and why choose to create one?
A startup is a new business entity formed to commercialize one or more related inventions. Forming a startup company is an alternative to licensing the IP to an established business. A few key factors when considering a startup company are:

- Development risk (often companies in established industries are unwilling to take the risk);
- Development costs versus investment return (can the investors obtain their needed rates of return);
- Experience of a management team or level of a faculty member's entrepreneurial interest;
- Potential for multiple products or services from the same technology (few companies survive on one product alone);
- Sufficiently large competitive advantage and target market; and
- Potential revenues sufficient to sustain and grow a company.

Who decides whether to form a startup?
The choice to establish a new company for commercializing CWRU IP is a joint decision made by TTO and the inventors. If a new business startup is chosen as the preferred commercialization path, your licensing professional will assist you in the process. TTO staff members can connect you to CWRU and outside resources.

What role does an inventor usually play in a company?
CWRU faculty members typically serve as technology consultants, founders, scientific advisors or in some other technical developmental capacity—rarely do they choose to leave the university and join the startup. In many cases, the faculty member's role is suggested by startup investors and the management team, who identify the best role based on the inventor's expertise and interests. As the company matures and additional investment is required, the inventor's role may change. Faculty involvement of any kind in a startup is also reviewed by the CWRU Conflict of Interests (COI) committee. Student inventors and postdocs may choose to join the startup upon graduation but rarely have the experience or business skills to serve as the company's sole management.

How much of my time and effort will it take?
Starting a company requires a considerable amount of time and effort. Until the startup team is identified and engaged, a faculty member will need to champion the formation effort. After the team is in place, effort is required for investor discussions, formal responsibilities in or with the company and university processes, such as conflict of interests reviews.

Can CWRU accept equity in the company?
CWRU can accept equity as part of the financial terms of the license. Equity may be substituted for other cash considerations that are often difficult for startups. It is also a way for the university to share some of the risk associated with the startups. A decision to take equity must make sense for both the university and the company.

Will CWRU pay for incorporating a startup company?
No. As a separate entity, the startup should pay for its own legal matters, including all business incorporation matters and licensing expenses.

Business Plan Basics
Before licensing a technology to a startup company, TTO requires the startup to submit a business plan. This business plan will be used to determine if the startup company represents the best chance for the technology to make it to the marketplace and should include:

- Business problem technology solves and how it solves it
- Competitive advantage of the technology
- Management team
- Production/ Manufacturing plan
- Marketing plan
- Market/Opportunity size
- Intellectual Property plan
- Competition
- Fiscal projections

What legal assistance is needed in creating a startup?
In addition to corporate counsel, the startup may have its own IP attorney to assist with corporate patent strategy, especially if the company will be involved in a patent-rich area. The startup's counsel must be separate from CWRU counsel, though it is advised and recommended that the startup's IP attorney and the CWRU patent attorney coordinate activities. It is also wise for inventors to have agreements regarding their roles with the startup reviewed by their own counsel to ensure that all personal ramifications—including taxation and liabilities—are clearly understood.

MARKETING TO FIND A LICENSEE

How does the Technology Transfer Office market my inventions?
Licensing professionals use many sources and strategies to identify potential licensees and market inventions. Sometimes existing relationships of the inventors, TTO staff members and other researchers are useful in marketing an invention. Market research can assist in identifying prospective licensees. At TTO, we examine other complementary technologies and agreements to assist our efforts and use a marketing website to post inventions, leverage conferences and industry events and make direct contacts. Inventor publications and presentations are often excellent marketing tools as well.

How are most licensees found?
Studies have shown that 70 percent of licensees were already known to the inventors; thus, research and consulting relationships are often a valuable source for licensees. Licensees are also identified through existing staff relationships. We attempt to broaden these relationships through contacts obtained from website posting inquiries, market research, industry events and the cultivation of existing licensing relationships.

How long does it take to find a potential licensee?
It can take months and sometimes years to locate a potential licensee, depending on the attractiveness of the invention, its stage of development, competing technologies, and the size and intensity of the market. Most university inventions tend to be in the early stage in the development cycle and thus require substantial commercialization investment, making it difficult to attract a licensee.

How can I assist in marketing my invention?
Your active involvement can dramatically improve the chances of matching an invention to an outside company. Your research and consulting relationships are often helpful in identifying potential licensees and technology champions within companies. Once interested companies are identified, the inventor is the best person to describe the details of the invention and its technical advantages. The most successful technology transfer results are obtained when the inventor and the licensing professional work together as a team to market and sell the technology.

Can there be more than one licensee?
Yes, an invention can be licensed to multiple licensees, either non-exclusively to several companies or exclusively to several companies, each for a unique field-of-use (application) or geography.

NAVIGATING CONFLICT OF INTEREST

How does CWRU define a conflict of interests?
A conflict of interests (COI) can occur when there is a divergence—potential or actual—that can be perceived between an individual's personal interests and their professional obligations to CWRU such that an independent observer might reasonably question whether the individual's professional actions or decisions are influenced by considerations of commercial gain, financial or other considerations. To review the COI Policy and guidelines for managing COI, visit our website.

When should I seek guidance on conflict of interests?
Whenever a question or uncertainty arises, you should seek guidance from the Conflict of Interests committee. Two situations when guidance is required include:

- When research proposals using licensed technology are submitted to external sponsors, and
- When a license or option agreement is being considered with a company in which the faculty member, family member or any CWRU employee, has an equity, management interest or management (fiduciary) role.

What kinds of issues concern conflict of interests in research?
Examples include the appropriate and objective conduct of research, preservation of the integrity of the research and data, protection of the human and animal subjects involved in research, the treatment and roles of students and supervision of individuals working at CWRU.

How does CWRU manage conflict associated with research and technology transfer transactions?
It is the responsibility of the researcher or faculty member to disclose and document any arrangements that constitute outside interests as described in the CWRU Conflict of Interests (COI) policy. An update to your annual outside interest disclosure should be made within 30 days of a new relationship or outside interest. The COI committee will review your outside interest and determine if there is a conflict with your participation in related research. The committee will also work with you to develop a management plan to protect the objectivity of the research and ensure compliance with federal regulations and CWRU policy. If you need assistance, contact cwrucoi@case.edu.

LICENSES AND OTHER AGREEMENTS

What is a license?
A license is a legal permission granted by the owner of intellectual property that allows another party to act under all or some of the owner's rights in that invention, usually under a written license agreement.

What is a license agreement?
License agreements describe the rights and responsibilities related to the use and exploitation of intellectual property developed at the university. CWRU license agreements usually stipulate that the licensee should diligently seek to bring the intellectual property into commercial use for the public good and provide a reasonable return to the university.

How is a company chosen to be a licensee?
A licensee is chosen based on its ability to commercialize the technology for the benefit of the general public. Sometimes an established company with experience in similar technologies and markets is the best choice. In other cases, the focus and intensity of a startup company is a better option. Typically, a university does not have multiple potential licensees bidding on an invention.

What can I expect to gain if my intellectual property is licensed?
Most inventors enjoy the satisfaction of knowing their inventions are being deployed for the benefit of the public. New and enhanced relationships with businesses are another outcome that can augment one's teaching, research and consulting. Per CWRU policy, a share of any financial return from a license is provided to the inventor(s). In some cases, additional sponsored research may result from the licensee. For more information, review the CWRU IP Policy at the Office of Research and Technology Management website.

What is the relationship between an inventor and a licensee, and how much of my time will it require?

Many licensees require the active assistance of the inventor to facilitate their commercialization efforts, at least at the early stages of development. This can range from infrequent, informal contacts to a more formal consulting relationship. Working with a new business startup can require substantially more time, depending on your role in or with the company and your continuing role at CWRU. Your participation with a startup is governed by CWRU conflict of interest policies and the approval of your school and department.

What other types of agreements and considerations apply to technology transfer?

- **Non-Disclosure Agreements (NDAs)**, also known as **Confidentiality Agreements** or **CDAs**, are often used to protect the confidentiality of an invention during evaluation by potential licensees. NDAs also protect proprietary information of third parties that CWRU researchers need to review in order to conduct research or evaluate research opportunities. The TTO enters into NDAs for university proprietary information shared with someone outside of the university. The TTO also manages incoming NDAs related to research contracts.
- **Material Transfer Agreements (MTAs)**, used for incoming and outgoing materials at the university, are reviewed, negotiated, approved and officially signed by the Authorized Institutional Representative in ORTM (CWRU faculty/staff do not have authority to sign MTAs or NDAs). These agreements describe the terms under which university researchers and outside researchers may share materials, typically for research or evaluation purposes. Intellectual property rights can be endangered if materials are used without a proper MTA.
- **Inter-Institutional Agreements** describe the terms under which two or more institutions (generally two universities) will collaborate to assess, protect, market, license and share in the revenues received from licensing jointly owned intellectual property.
- **Option Agreements**, or option clauses within research agreements, describe the conditions under which the university preserves the opportunity for a third party to negotiate a license for intellectual property. Option clauses are often provided in a Sponsored Research Agreement to corporate research sponsors or Option Agreements are entered into with third parties wishing to evaluate the technology prior to entering into a full license agreement.
- **Sponsored Research Agreements** or **Sponsored Service Agreements** describe the terms sponsors provide for research support to the university. These are negotiated by the CWRU Office of Research Administration or the Office of Grants and Contracts in the School of Medicine. For more information about sponsored research, visit the ORTM website.

COMMERCIALIZATION

What activities occur during commercialization?
Most licensees continue to develop an invention to enhance the technology, reduce risk, prove reliability and satisfy the market and regulatory requirements for adoption by customers. This can involve additional testing, prototyping for manufacturability, durability and integrity, clinical trials and further development to improve performance and other characteristics. Documentation for training, installation and marketing is often created during this phase. Benchmarking tests are often required to demonstrate the product/service advantages and to position the product in the market.

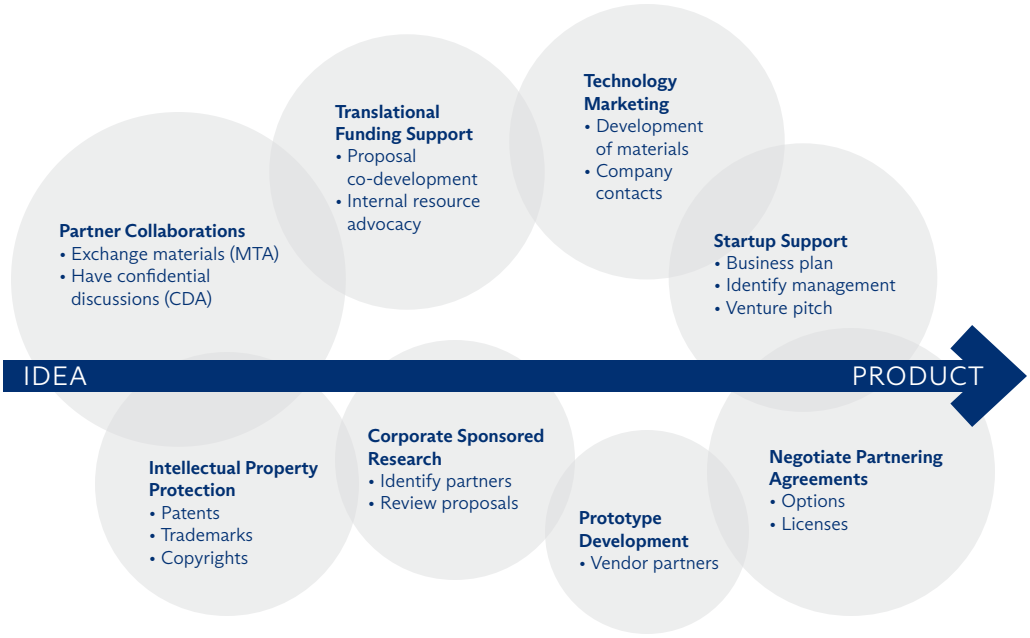
What is my role during commercialization?
Your role can vary depending on your interest and involvement, in the interest of the licensee in utilizing your services for various assignments and any contractual obligations or personal agreements related to the license.

What assistance and resources are available to the inventor?
The Technology Transfer Office (TTO) provides a unique translation process for its research assets through various advancement programs, each of which serves as a "diligence engine" to analyze and pressure-test promising inventions. Working with the inventor, each licensing professional provides help through mechanisms for advancing new products toward the market through funding and commercialization support offered by CWRU's translational research, validation and entrepreneurial venture programs.

What revenues are generated for the university if commercialization is successful?
Most licenses have licensing fees that can be very modest (for startups or situations in which the value of the license is deemed to warrant a modest license fee) or occasionally can reach hundreds of thousands of dollars. Royalties on the eventual sales of the licensed products can generate revenues, although this can take years to occur. Equity, if included in a license, can yield returns, but only if a successful equity liquidation event (public equity offering or a sale of the company) occurs. Most licenses do not yield substantial revenues.

A recent study of licenses at U.S. universities demonstrated that only 1 percent of all licenses yield over $1 million. However, the rewards of an invention reaching the market are often more significant than the financial considerations alone.

What will happen to my invention if the startup company or licensee is unsuccessful in commercializing the technology? Can the invention be licensed to another entity?
Licenses typically include performance milestones that, if unmet, can result in termination of the license. This termination allows for subsequent licensing to another business.



REVENUE DISTRIBUTIONS

How are license revenues distributed?
The Technology Transfer Office (TTO) is responsible for managing the patent expenses and licensing revenues associated with each technology. Per CWRU's Intellectual Property (IP) Policy, revenues from license fees, royalties and equity—minus any unreimbursed patenting, administrative and file expenses—are shared with inventors. The inventors receive 50% of this net revenue, and net revenue over $100,000 is subject to a 15% administrative fee.

How are inventor revenues distributed if there are multiple inventors and/or multiple inventions in a license?
While there may be some variation in the procedure, typically when a license agreement is developed, a royalty split agreement is drafted and signed to memorialize the distribution of any subsequent revenues to the inventors. The revenue split is based on the contributions listed in the Invention Disclosure Forms relating to the license. TTO asks one inventor within the group to serve as coordinator and to report the percentages determined by the inventors collectively. All inventors must sign the Royalty Split Agreement, signifying their approval. Should the inventors be unable to agree on a revenue distribution plan, TTO will make the final revenue allocation decision.

How is equity from a license distributed?
Inventors share of CWRU equity is held until liquidation by the CWRU Office of the Treasurer, then distributed like revenues under CWRU's IP Policy. Shares of publicly traded businesses may be distributed to inventors before liquidation.

How are revenues from co-owned inventions with affiliates and other universities handled?
It is not unusual that technologies are co-invented with investigators from other universities or affiliates of CWRU. Distributions for co-owned inventions are handled according to Inter-Institutional Agreements between CWRU and the other university for the particular technology or affiliation agreements govern the handling of revenues with affiliates.

What are the tax implications of any revenues I receive from the university?
License revenues are typically reported under "Other Income" in Box 3 of Form 1099-MISC. Consult a tax advisor for specific advice.

CYCLE OF INNOVATION

Every year, TTO works with our CWRU inventors and business partners to:

- Assist with over 150 invention disclosures,
- Negotiate over 60 option and license agreements, and
- Support the formation of four or more new business startups

This activity generates revenue, which is shared among CWRU schools, departments, inventors and affiliated institutions. These revenues are reinvested in additional research and education, which fosters the creation of the next generation of researchers and entrepreneurs. Additionally, after licensing relationships are established, licensees provide a yearly average of over $4 million dollars in revenue to CWRU.

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