TECHNOLOGY TRANSFER OVERVIEW

What is technology transfer?
Technology transfer refers to the formal licensing of technology to third parties, under the guidance of professionals employed by universities, research foundations and businesses, in departments focused on these activities.

Who does Tech Transfer?
Tech Transfer at Yale University is done by The Office of Cooperative Research, which is composed of specialists in licensing, business development and intellectual property matters, whom are widely experienced in developing and commercializing technologies from the life sciences, physical sciences, and engineering.

Why would a researcher want to participate in the technology transfer process?
The reasons are unique to each researcher and may include:
- Achieving financial and recognition reward
- Generating additional lab/departmental funding
- Attracting research sponsors
- Making a positive impact on society
- Feeling a sense of personal fulfillment
- Meeting the obligations of a research or contract employment
- Creating educational opportunities for students
- Linking students to future job opportunities

How is technology transferred?
Technology is typically transferred through a license agreement in which Yale grants its rights in the defined technology to a third party for a period of years, and sometimes for 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 start-up. Licenses include terms that require the licensee to meet certain performance requirements and to make financial payments to Yale. These payments are shared with the inventors, Yale and other institutions in the case of jointly owned inventions, to provide support for further research, education and participation in the tech transfer process.

What is the Bayh-Dole Act?
The U.S. Bayh-Dole Act of 1980 allows universities and other non-profit institutions to elect 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, and sharing any resulting revenues with the inventors. The Bayh-Dole Act is credited with stimulating interest in tech transfer activities and generating increasing research, commercialization, educational opportunities and economic development.

This information is based on University of Michigan's "Inventor's Guide to Technology Transfer", with adaptations for Yale University and Yale's Office of Cooperative Research. We are grateful to the staff of UM Office of Technology for their kind permission to use their material and to the University of Michigan for permission to use its copyright.

THE TECH TRANSFER PROCESS

How do I work with Office of Cooperative Research?

We encourage you to contact the Office of Cooperative Research during your discovery process to ensure you are aware of the options that will help maximize the commercial potential of your research. The Office of Cooperative Research staff members will assist you with questions related to marketability, funding sources, commercial partners, patenting and other protection methods, new business start-up considerations, Yale policies and procedures, and much more.

What are the typical steps in the process?

The process of technology transfer is summarized in the steps that follow. Note that these steps can vary in sequence and often occur simultaneously.

1. Research:

Observations and experiments during research activities often lead to discoveries and inventions. An invention is any useful process, machine, composition of matter, or any new or useful improvement of the same. Often, multiple researchers may have contributed to the invention.

2. Pre-Disclosure:

An early contact with OCR personnel to discuss your invention and to provide guidance with respect to the disclosure, evaluation, and protection processes described below.

3. Invention Disclosure: http://www.yale.edu/ocr/disclose.html

The written notice of invention to OCR that begins the formal technology transfer process. An invention disclosure remains a confidential document, and should fully document your invention so that the options for commercialization can be evaluated and pursued. An invention disclosure should be ideally be submitted before any disclosure of your technology outside of the Yale community.

4. Assessment:

The period in which you and your OCR representative review the invention disclosure, conduct patent searches (if applicable), and analyze the market and competitive landscape to determine the invention's commercialization potential. The evaluation process, which may lead to a broadening or refinement of the invention, will guide our strategy on whether to focus on licensing to an existing company or creating a new business start-up.

5. Protection:

The process in which protection for an invention is pursued to encourage third party interest in commercialization. Patent protection, a common legal protection method, begins with the filing of a patent application with the U.S. Patent Office and, when appropriate, foreign patent offices. Once a patent application has been filed, it will require several years and many thousands of dollars to obtain issued U.S. and foreign patents.

Other protection options include copyright and trademark protection.

6. Marketing:
With your active involvement, OCR staff will identify candidate companies that have the expertise, resources, and business networks to bring the technology to market. This may involve partnering with an existing company or forming a start-up. Your active involvement can dramatically shorten this process.

7. a. Form a Start-Up:
If creation of a new business start-up has been chosen as the optimal commercialization path, OCR's Director of New Ventures will assist in planning, creating and funding the start-up.

7. b. Existing Business Relationship:
If an appropriate and interested existing business is identified as a potential licensee, OCR licensing specialists identify mutual interests, goals and plans to fully commercialize this technology through a license agreement.

8. Licensing:
A license agreement is a contract between Yale and a third party in which Yale's rights to a technology are licensed (without relinquishing ownership) for financial and other benefits. A license agreement is used with both a new start-up business or with an established company. An option agreement is sometimes used to enable a third party to evaluate the technology for a limited time before licensing.

9. Commercialization:
The licensee company continues the advancement of the technology, and makes other business investments to develop the product or service. This step may entail further development, regulatory approvals, sales and marketing, support, training, and other activities.

10. Revenue:
Set portions of the revenues received by Yale from licensees are distributed to the inventors, Yale and other institutions (in the case of jointly owned inventions) to fund additional research and education and to encourage further participation in the tech transfer process.

How long does the tech 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?

• Call the Office of Cooperative Research at 203.436.8096 or submit your invention **disclosure online** (http://www.yale.edu/ocr/disclose.html) when you believe you have a scientific or technical observation with potential commercial or research value.

• Complete and submit the Invention Disclosure before publicly disclosing your technology or submitting a manuscript for publication.

• To avoid risking your patent rights and possibly hindering the opportunity to market your invention, contact OCR before holding any discussions with people outside the Yale community. In general, discussions with third parties often should be done under a Confidential Disclosure Agreement which an OCR Licensing Specialist can put in place for you.

• On the Yale Disclosure Form, include companies and contacts you believe might be interested in your intellectual property (IP) or who may have already contacted you about your invention. Studies have shown that over 65% of all licenses are executed with commercial entities known by the inventor, so your contacts can be extremely useful.

• Respond to OCR and outside patent counsel requests. While some aspects of the patent and licensing process will require significant participation on your part, we will strive to make efficient use of your valuable time.

• Keep OCR informed of upcoming publications or interactions with companies related to your intellectual property.

RESEARCH CONSIDERATIONS

Q: Will I be able to publish the results of my research and still protect the commercial value of my intellectual property?

A: Yes, but since patent rights are affected by these activities, it is best to submit an Invention Disclosure (discussed in next section) well before any public communication or disclosure of the invention. This will maximize the intellectual property options for your potential invention.

There are significant differences between the U.S. and other countries as to how early publication affects a potential patent. Once publicly disclosed (published or presented in some form), you have only 12 months to file a U. S. patent application. Additionally an invention is publicly disclosed without patent protection may have restricted or minimal potential for patent protection outside of the United States. Be sure to inform OCR of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, dissertation/masters thesis, publication, or other public presentation of the invention.

Q: May I use material or intellectual property from other academic institutions or companies in my research?

A: Yes, though there may be restrictions on the use or the rights to inventions if the intellectual property is being provided under a Material Transfer Agreement (MTA). It is important to document carefully the date and conditions of use so that we can determine if this use may influence the ownership rights of your subsequent research results. If you wish to obtain materials from outside collaborators, an incoming MTA should be completed. In some cases, there may be restrictions placed on the use of materials provided by companies, even if the materials are purchased.

Q: Will I be able to share material, research tools or intellectual property with others to further their research?

A: Yes. However, you must be sure that you have the right to do so if the materials have been provided under an MTA or a license. 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 outgoingMaterial Transfer Agreement (MTA) should be completed for this purpose. It also may be necessary to have a Confidentiality Agreement completed to protect your research results or intellectual property. Please contact OCR for assistance completing outgoing and incoming MTAs.

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

A: The Sponsored Research Agreement should specify the intellectual property (IP) rights of the sponsor. Yale 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 defined and expected outcomes of 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. Therefore, it is important to define the scope of work within a research agreement.

Sponsored research projects may be handled by OCR, but they are more typically negotiated by Grants and Contracts. OCR works with Grants and Contracts to clarify IP issues in sponsored research agreements.

Q: What about consulting?

A: When researchers enter into consulting agreements, they are deemed to be acting outside of the scope of their employment. Therefore consulting arrangements are not negotiated by Yale. Researchers who enter into consulting agreements should familiarize themselves with Yale Policies on consulting (http://www.yale.edu/ocr/pfg/policies/consulting.html) and make sure that they are first in compliance with the terms of the consulting agreement. The researcher is expected to ensure that the terms of the consulting arrangement are consistent with Yale policies, including those related to IP ownership, employment responsibilities and use of Intellectual Property. OCR is available to provide informal advice on how your consulting agreement relates to your intellectual property.

INVENTION DISCLOSURES

What is an Invention Disclosure?

An Invention Disclosure (ID) is a description of your invention or development that is provided to OCR. The ID lists all collaborating sources of support and includes information necessary to begin pursuing protection and commercialization activities. To initiate the process, please disclose your invention online or email, fax or hand deliver the fully signed Invention Disclosure to OCR. This document will be treated as "confidential." Using the Disclosure, OCR can then generate a non-confidential description of your invention to assist in marketing the technology and creating confidentiality agreements with outsiders to allow more detailed exchanges of information with potential partners.

Why should I submit an Invention Disclosure?

When you disclose your invention to OCR, it starts a process that could lead to the commercialization of your technology. On the part of OCR, this may involve beginning the legal protection process and working to identify outside development partners. If government funds were used for your research, you are required to file a prompt disclosure. 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?

You are encouraged to submit an Invention Disclosure for all inventions and developments that you feel may solve a significant problem and/or have significant value. If you are in doubt, contact OCR to discuss the invention. We can also advise on alternatives to licensing.

When should I complete an Invention Disclosure?

You should complete an Invention Disclosure 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. Once publicly disclosed (i.e., published or presented in some form), an invention may have restricted or minimal potential for patent protection outside of the United States. Differences exist between the U.S. and other countries on the impact of early publication on a potential patent. For example, once you have presented the information publicly or the abstract has been made available publicly, your invention is not patentable in many countries. Be sure to inform OCR of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal, dissertation/masters thesis, publication, or other public presentation 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. Research tools do not necessarily need to be protected by patents in order to be licensed to commercial third parties and generate revenue for your laboratory. If you have research tools that you believe to be valuable, or wish to provide to others (including research collaborators),

OCR will work with you to develop the appropriate protection, licensing and distribution strategy.

How do I submit an Invention Disclosure?
You can submit an Invention Disclosure by going to www.yale.edu/ocr and clicking "Disclose an Invention." You must be at a computer on the Yale system to fill out the online Disclosure Form.

A sample Invention Disclosure Form is provided there for your reference as help in filling out the form. The Disclosure Form asks for descriptions, applications, stage of development and advantages of your new invention. You should also have on hand the names and departments of all inventors, information about any funding used for the invention and any publications.

After clicking the "Disclose an Invention" button and signing in using your Yale netID, our website will ask you to create a separate user name and password for the OCR database. You are free to use your Yale netID or any other username for this process.

Once you have signed in, you can move through the online disclosure fields. Please be as detailed as possible and try not to skip any questions.

If you have any questions about the disclosure form, or have any problems using it, please contact Tina Muzzy, Tiny.Muzzy@yale.edu , 436.8097

OWNERSHIP OF INTELLECTUAL PROPERTY

What is "intellectual property"?
Intellectual property is material that may be protected under the patent, trademark and/or copyright laws.

Who owns what I create?
Ownership depends upon the employment status of the creators of the invention and their use of Yale resources or facilities. Considerations include:
• What is the source of the funds or resources used to produce the invention?
• What was the employment status of the creators at the time the intellectual property was made?
• What are the terms of any agreement related to the creation of the intellectual property?
As a general rule, the Yale owns inventions made by its employees while acting within the scope of their employment or using Yale resources. In some cases, the terms of a Sponsored Research Agreement or Materials Transfer Agreement may impact ownership. When in doubt, it is best to call OCR for advice.

Who owns rights to discoveries made while I am consulting?
The ownership of inventions made while consulting for an outside company depends on the terms of your consulting contract which should indicate that inventions typically are owned by your primary employer. It is important to clearly define the scope of work within consulting contracts to minimize any issues with inventions from Yale research. If you have questions, OCR is available for informal advice.

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

Can a student contribute to an invention?
Yes, a student can even be the sole contributor or inventor. The ownership of an invention developed with or by a student depends on 1) whether the invention was created by a student in a capacity as a Yale employee and 2) whether the invention was created using Yale resources. The Yale owns, at least in part, any invention created by a student employee with Yale resources.

ASSESSMENT OF AN INVENTION DISCLOSURE

How does OCR assess Invention Disclosures?

OCR examines each invention disclosure to review the novelty of the invention, patentability and marketability of potential products or services, 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 (IP), 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 start-up.

Is an invention ever reassigned to an Inventor?

If Yale decides that it does not wish, and has no legal obligation, to participate in the patenting or licensing of an invention, Yale may release its interest in the invention to the inventor(s) in exchange for a share of any future income and the right to practice the invention for Yale's research and educational purposes. Such a release will require the agreement of all inventors. Reassignment of inventions funded by the U.S. government may also require the government's prior approval.

PATENTS AND OTHER LEGAL PROTECTION

What is a patent?

In the U.S., a patent gives the patent holder has the right to exclude others from making, using, selling, offering to sell, and importing any patented invention. Thus, a patent does not necessarily provide the holder any affirmative right to practice a technology. Instead, it provides the right to exclude others from practicing it. Patent claims are the legal definition (often called the "metes and bounds") of an inventor's protectable invention.

What type of subject matter can be patented?

Patentable subject matter includes any new and useful processes, machines, compositions of matter, 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?

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 advantages of using the variant.

What is the United States Patent and Trademark Office (PTO)?

The PTO is the federal agency, organized under the Department of Commerce, that administers patents and trademarks on behalf of the government. The PTO employs patent examiners skilled in all technical fields in order to appraise patent applications. The PTO also issues federal trademark registrations.

What is the definition of an inventor on a patent, and who determines this?

An inventor is someone who has made an intellectual contribution to the claimed invention. 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 furnishes money to build or practice an invention is not an inventor. Inventorship is not something that can be negotiated. Inventorship may require an intricate legal determination by the patent attorney prosecuting the application. Inventorship is often more restricted than authorship, thus it is important to note that authorship on an academic publication does not necessarily equate to inventorship on a patent application.

Who is responsible for patenting?

OCR contracts with outside counsel for IP protection, thus assuring access to patent specialists in diverse technology areas. Inventors work with the patent counsel in drafting the patent applications and responses to worldwide patent offices. OCR will help with the selection and oversight of the outside patent counsel.

What is the patenting process?

Patent applications are generally drafted by a patent attorney or a patent agent (a non-attorney with a science education licensed to practice by the PTO). 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 an Inventor's Declaration and an Assignment, which memorializes the inventor's pre-existing duty to assign the patent to Yale. In about one year, depending on the technology, the patent attorney will receive written notice from the PTO as to whether the application and its claims have been accepted in the form as filed. More often than not, the PTO rejects the application because either 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). The letter sent by the PTO is referred to as an Office Action or Official Action. 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 and/or point out why the PTO's position is incorrect. This procedure is referred to as patent prosecution. Often it will take two PTO Official Actions and two responses by the patent attorney—and sometimes more—before the application is resolved. The resolution can take the form of a PTO notice that the application is allowable; in other words, the PTO agrees to issue a patent. During this process, input from the inventor(s) is often needed to confirm the patent attorney's understanding of the technical aspects of the invention and/or the prior art cited against the application. The PTO holds patent applications confidential until published by the PTO, which occurs 18 months after initial filing.

Is there such a thing as a provisional patent?
No. However, there is a provisional application for a patent, which is described below.

What is the difference between a provisional application and a regular (or "utility") patent application?
In certain circumstances, U.S. provisional 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 form in order to receive its early filing date. However, an applicant only receives the benefit of the earlier filing date for material that is 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 United States. In foreign countries, however, an inventor will lose any patent rights if he or she publicly discloses the invention prior to filing the patent application. In contrast, the United States 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 regular) 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.
A PCT application 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. However, pursuant to this treaty, these so-called "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 PTO-mandated maintenance fees are paid.

Why does Yale 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 their expense, patent applications are not possible for all intellectual property. We carefully review the commercial potential for an invention before investing 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 protection for as many promising inventions as possible.

Who decides what gets protected?
OCR and the inventor(s) consider relevant factors in making recommendations about filing patent applications. Ultimately, the Director of Licensing?? makes the final decision as to whether to file a patent application or seek another form of protection.

What does it cost to file for and obtain a patent?
Filing a regular U.S. patent application may cost between $5,000 and $10,000. Obtaining an issued patent may require an additional $5,000 to $15,000 for patent prosecution, or more depending on the amount and nature of prior art in the field. 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 or annuity fees are required to keep the patent alive.

What if I created the invention with someone from another institution or company?
If you created the invention under a contract or consulting agreement with a company, the OCR licensing manager 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, OCR will work with other organizations under "inter-institutional" agreements that provide for one of the institutions to take the lead in protecting and licensing the invention, sharing of expenses associated with the patenting process, and allocating any licensing revenues.

Will Yale initiate or continue patenting activity without an identified licensee?
Often Yale accepts the risk of filing a patent application before a licensee has been identified. After Yale's rights have been licensed to a licensee, the licensee generally assumes 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.

What is a copyright and how is it useful?
Copyright is a form of protection provided by the laws of the United States to the authors of "original works of authorship." This includes literary, dramatic, musical, artistic, and certain 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 copyright the exclusive right to conduct and authorize various acts, including reproduction, display, distribution, public performance and making derivative works. Copyright protection is automatically secured when a work is fixed into a tangible medium such as a book, software code, video, etc.

CONSIDERATION FOR A START-UP COMPANY

What is a start-up and why choose to create one?

A start-up is a new business entity formed to commercialize one or more related intellectual properties. Forming a start-up business is an alternative to licensing the IP to an established business. A few key factors when considering a start-up company are:

• Development risk (often large companies in established industries are unwilling to take the risk)
• Development costs versus investment return (can the investors realize an attractive return on their investment?)
• Potential for multiple products or services from the same technology (few companies survive on one product alone)
• Sufficiently large competitive advantage and target market
• Potential revenues sufficient to sustain and grow a company

OCR can help evaluate these and other factors.

Who decides whether to form a start-up?

The choice to establish a new company for commercializing IP is a joint decision made by OCR and the inventors. If a new business start-up appears to be an preferred commercialization path, OCR's Director of New Ventures will assist you in planning and executing the process. The Director of New Ventures serves as business formation consultant, providing hands-on assistance and access to Yale and outside resources.

What assistance and resources are available to the inventor?

The Director of New Ventures serves as a coach, advisor, resource locator and project planner to help fill the gap between the technology and the formation of a start-up. The Director of New Ventures' responsibilities may include locating prospective management talent, developing a funding strategy, making introductions to probable investors, reviewing business plans, and hiring experts to work on key gating issues. The Director of New Ventures can also draw upon an appropriate network of resources and experience to assist you.

What role does an inventor usually play in a company?

Yale University's faculty typically serve as technology consultant, advisor or in some other technical developmental capacity. Some university faculty choose to play founding roles in the formation and financing of companies. Rarely does Yale's faculty choose to leave Yale and join the start-up. In many cases, the faculty role is suggested by the start-up investors and 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. Yale University's faculty involvement of any kind in a start-up is also reviewed by Yale's Conflict of Interest Committee. Student inventors and post-docs may choose to join the start-up upon graduation but typically will partner with more experienced business executives to manage the new company.

How much of my time and effort will it take?

Starting a company requires a considerable amount of time and effort. Until the start-up team is identified and engaged, the 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 Yale processes such as conflict of interest reviews.

Does Yale share equity in the company?
Yale often co-founds companies with faculty and/or outside business partners, and, like other founders, will receive founders stock in a company that is separate from any license consideration. The decision to enter into such a partnership and the determination of relative ownership stakes are made only when by mutual agreement of all parties involved.

Will the Yale pay for incorporating a start-up company?
No. As a separate entity, the start-up pays for its own legal matters, including all business incorporation matters and licensing expenses.

What legal assistance is needed in creating a start-up?
In addition to corporate counsel, the start-up may have its own intellectual property counsel to assist with corporate patent strategy, especially if the company will be involved in a patent-rich area. The start-up's counsel must be separate from Yale counsel, though it is advisable and recommended that the corporate IP Counsel and the Patent Counsel coordinates activities. Also, it is wise for inventors to have agreements regarding their roles with the start-up reviewed by their own counsel to ensure that all personal ramifications—including taxation and liabilities—are clearly understood.

LICENSE AGREEMENTS

What is a license?

A license is a permission that the owner or controller of intellectual property grants to another party, usually under a 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 Yale. Yale license agreements usually stipulate that the licensee will diligently seek to bring the intellectual property into commercial use for the public good and provide a reasonable return to Yale.

How is a business 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 business with experience in similar technologies and markets is the best choice. In other cases, the focus and intensity of a start-up company is a better option.

What can I expect to gain if my IP is licensed?

Per Yale's policies on intellectual property, a set share ranging from 30% to 50% of any net financial return from a license is provided to the inventor(s). For more information on Yale's policies, please visit http://www.yale.edu/ocr/pfg/policies/index.html. Most inventors enjoy the satisfaction of knowing their inventions are being commercialized and deployed for the benefit of the general public. New or enhanced relationships with businesses is another outcome that can augment one's teaching, research and consulting.

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

Most licensees require the active assistance of the inventor to facilitate their commercialization efforts. This can range from infrequent, informal contacts to a more formal consulting relationship. Working with a new business start-up can require substantially more time, depending on your role in or with the company and your continuing role within Yale. Your participation with a start-up is governed by Yale's conflict of interest policies and the approval of your supervisor. For more information on Yale's policies on conflict of interest, please visit http://www.yale.edu/provost/html/coi.html.

What other types of agreements and considerations are handled by OCR?

• Non-Disclosure Agreements (NDAs), also known as Confidential Disclosure Agreements (CDAs), are often used to protect the confidentiality of an invention during evaluation by potential licensees. NDAs/CDAs also protect proprietary information of third parties that Yale researchers need to review in order to conduct research, or evaluate research opportunities. OCR enters into NDAs/CDAs for Yale proprietary information shared with someone outside of Yale.

• Inter-Institutional Agreements describe the terms under which two or more institutions (e.g., 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 Yale 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 at Yale, or are entered into with third parties wishing to evaluate the technology prior to entering into a full license agreement.

• Material Transfer Agreements (MTAs), used for incoming and outgoing materials at Yale, are administered by OCR when the other party is a for-profit entity. These agreements describe the terms under which Yale researchers and outside researchers may share materials, typically for research or evaluation purposes. Intellectual property rights can be jeopardized if materials are transferred and used without a proper MTA.

• Sponsored Research Agreements (SRAs) or Collaboration Research Agreements (CRAs) with for-profit organizations are also negotiated by OCR. These agreements include provisions that address how intellectual property, which may arise out of the research, will be handled.

MARKETING TO FIND A LICENSEE

How does OCR market my inventions?

The licensing team at OCR uses many sources and strategies to identify potential licensees and market inventions. Sometimes existing relationships of the inventors, the OCR staff, and other researchers are useful in marketing an invention. Market research using subscription-based database tools can also assist in identifying prospective licensees. In addition, we also examine other complementary technologies and agreements to assist our efforts. We use various websites to reference inventions, leverage conferences and industry events, and make direct contacts. Faculty publications and presentations are often excellent marketing tools as well.

How are most licensees found?

Studies have shown that 70% of licensees were known to the inventors. Thus research and consulting relationships are often a valuable source for licensees. Licensees are also identified through existing relationships of the OCR staff. 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, and the size and intensity of the market. Most Yale inventions tend to be in the early stage in the development cycle and thus require substantial commercialization investment, making it more 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 both 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 tech 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 only for a unique field-of-use (application) or geography.

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 requirements for adoption by customers. This can involve additional testing, prototyping for manufacturability, durability and integrity, 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 related to the license or any personal agreements.

What revenues are generated for Yale if commercialization is successful? If unsuccessful?

Most licenses have licensing fees that can be very modest (for start-ups or situations in which the value of the license is deemed to warrant a modest license fee) or can reach hundreds of thousands of dollars. Royalties on the eventual sales of the licensed products can generate similar revenues, although this can take years to occur. Equity, if included in a license, can yield similar 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% 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 start-up Company or licensee is unsuccessful? Can the invention be licensed to another entity?

Licenses typically include performance milestones that, if unmet, can result in termination. This allows for subsequent licensing to another business. However, time delays and other considerations can hinder this effort.

NAVIGATING CONFLICT OF INTEREST

How does the Yale define a conflict of interest?

A conflict of interest can occur when a Yale employee, through a relationship with an outside organization, is in a position to: 1) influence Yale's business, research or other areas that may lead to direct or indirect financial gain, 2) adversely impact or influence one's research or teaching responsibilities, or 3) provide improper advantage to others, to the disadvantage of the Yale.

What kinds of issues concern conflict of interest reviewers?

Examples include the appropriate and objective use of research, the treatment and roles of students, supervision of individuals working at both Yale and a licensee company, and conflict of commitment (i.e., your ability to meet your Yale obligations).

What are examples of a conflict of commitment?

A conflict of commitment may exist if duties, assignments or responsibilities associated with a technology license or outside business arrangement have a negative impact on your ability to meet commitments associated with your Yale employment or exceed the amount of time available to you for these activities. The best approach is to fully disclose your situation to your supervisor and discuss the implications for your job responsibilities.

How does Yale manage conflict?

OCR representatives can advise you on conflict of interest issues. It is the responsibility of the researcher or faculty member to disclose and document any outside arrangements that constitute disclosable situations or interests as described in Yale conflict of interest policies. To view Yale's policy and guidelines regarding Conflict of Interest, click on <link>

REVENUE DISTRIBUTIONS

How are license revenues distributed?

OCR is responsible for managing the expenses and revenues associated with technology agreements. Per OCR Intellectual Patent Policy, revenues from license fees, royalties and equity—minus any un-reimbursed patenting and filing expenses—are shared with the inventors, laboratory(ies), department(s) and sponsors such as HHMI.

What are the tax implications of any revenues I receive from the Yale?

License revenues are typically taxed as Form 1099 income. Consult a tax advisor for specific advice.

What happens to my share of the revenue if I waive rights to it?

Revenues waived by inventors are distributed to the associated department/laboratory. To avoid potential tax liability, revenues waived by you to your department/unit must not be under your control. See OCR for additional information.

How is equity from a license distributed?

When Yale equity is liquidated by the Yale's OCR, the resulting funds are distributed in accordance with Yale's royalty distribution plan. Shares of publicly traded businesses may be distributed to inventors before liquidation.