Scientist's Guide to Business Development & Technology Transfer at Cold Spring Harbor Laboratory

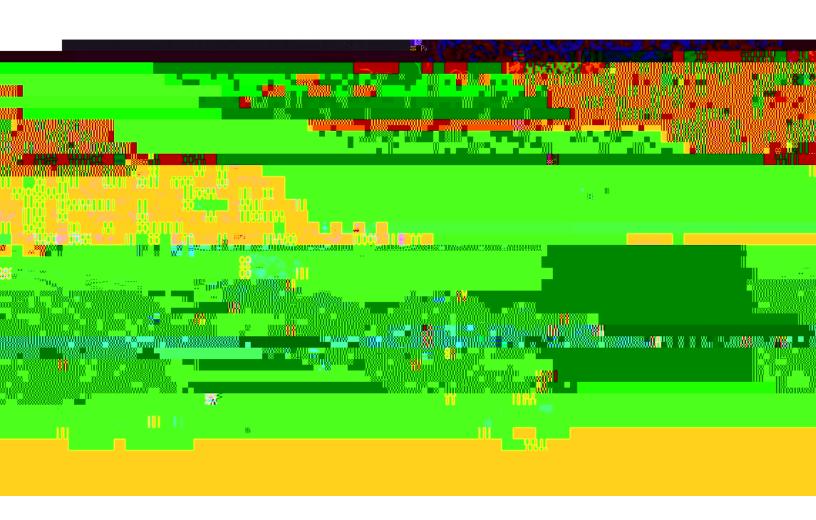




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OVERVIEW

What is business development and technology transfer?

Business Development is the process of establishing and managing relationships with external companies and organizations to drived

The tasks of the office include, but are not limited to, fostering access to funding for financing early stage ideas, technology disclosure assessments, patent preparation and prosecution, commercial market analysis, contract negotiations for licensing, alliance management, and post deal management.

How does the Office of Technology Transfer foster relationships with industrial partners?

The Office of Technology Transfer seeks to increase industrial relationships through four broad categories of activity:

Why would a researcher want to participate in the technology transfer process?

The reasons are unique to each researcher and may include:

Introducing new ideas and products that enhance science and medicine; Making a positive impact on society;

relationships (preferably before they begin) to understand the implications for any subsequent inventions or other intellectual property.

Can a student contribute to intellectual property?

Yes, students, research technicians and other staff may work on research leading to intellectual property at CSHL. CSHL owns inventions made or created by the faculty, students, staff, visitors, employees, volunteers, and others participating in CSHL programs while acting within the scope of their employment or using CSHL funds, facilities, or other CSHL resources.

What is knowhow?

In the context of intellectual property, knowhow is a component in the transfer of a technology and can be defined as information in the form of unpatented inventions, formulae, designs, drawings, procedures and methods, together with accumulated skills and experience in the hands of a CSHL personnel which could assist a licensee. It can be further supported with expert knowledge on the operation, maintenance, use, and application of a product and of its sale, usage or disposition.

LEGAL PROTECTIONS

Legal protection for technology

There are 2 main and interconnected means of protecting technology:

- 1. Legal agreements
- 2. Filing of patents

Certain inventions can also benefit from copyrights protection, particularly in software development.

Legal Agreements or Contracts

Protection for commercial ideas and technology come in the form of legal agreements or contracts that define the relationship between CSHL and a commercializing entity the rights to the technology in exchange for current and future financial consideration. CSHL is typically very active in developing relationships with commercial companies, often well in advancet8(s)]TETlopinments

Patents

It is highly desirable where possible for CSHL to file strong patents to protect breakthrough inventions made by CSHL scientists. The rules of patenting are stringent and have changed in recent years in a way that has changed what intellectual property and technology, and the extent that intellectual property and technology can be protected by patenting.

What is a patent?

In the United States, patents are granted by the United States Patent and Trademark Office

written description of the claimed invention telling what the invention is, how it works, how to make it, and how to use it. The specification concludes with one or more numbered sentences called patent claims, which define the boundaries of the legally protected inventions.

Although rights may vary from country to country, in general, a patent gives the holder the right to exclude others from making, using, selling, offering to sell, and importing the patented invention

de the holder any affirmative right to practice a technology; that practice may fall under a broader patent(s) owned by others. A

invention and how to practice it); protectable invention).

What type of subject matter can be patented?

Things that are patentable include new, non-obvious and useful processes, machines, compositions of matter, manufactured items, articles, and methods such as methods for manufacturing items and materials.

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). The type of inventions that are patentable vary from country to country.

There are a number of explicit exclusions on patentable matter that are determined by case law and the patent office. In the context of work done at CSHL, these would include any naturally occurring compositions, even if they have not been described before, including genes and gene products. The emphasis in patents is not on the function of an invention, rather on the physical components of an invention.

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

The USPTO is the federal agency, organized under the Department of Commerce, which administers patents on behalf of the government. The USPTO employs patent examiners skilled in all technical fields in order to appraise patent applications. The USPTO also 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 any invention

What's different about foreign patent protection?

A patent is enforceable only in the country in which it issues. U.S. patents, for example, are not enforceable outside the U.S.

Why does CSHL protect intellectual property through patenting?	
Patent protection is can be a requirement of a potential commercialization partner	
(required to bring the technology to market. It is now also common that agreements are	

patent rights in all the major world markets will therefore commonly require between \$250,000 and \$500,000. Once a patent is issued in the United States or in foreign countries, maintenance fees are required to keep the patent in force.

What if I created the invention with someone from another institution or company?

If you created the invention under a sponsored research or consulting agreement with a company, the Office of Technology Transfer staff will need to review the 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 Office of Technology Transfer staff will usually enter into an

protecting and licensing the invention, sharing of expenses associated with the patenting process, and allocating any licensing revenue. If the technology is jointly owned with a company, the Office of Technology Transfer staff will work with the company to determine the appropriate patenting and licensing strategy.

Will CSHL initiate or continue patenting activity without an identified licensee?

Often CSHL accepts the risk of filing a patent application before a licensee has been identified.

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, or if it is determined that we cannot obtain reasonable claims from the USPTO.

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

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, public performance, and making derivative 0.01 [TE1 72.024 258.26 Tme75.1 25uia0 / .1 25uia0

How do I represent a proper CSHL copyright notice?

Although copyrightable works do not require a copyright notice, we recommend that you use one. The following notice is to be applied on CSHL owned works to protect the copyright:

Copyright © 20XX Cold Spring Harbor Laboratory. All rights reserved.

The date in the notice should be the year in which the work is first embodied or published. No notice other than the foregoing is to be used for CSHL owned works.

For additional copyright protection, certain works should be registered with the United States Copyright Office using its official forms.

If you have any questions about copyright notices and registration, please contact the Office of Technology Transfer or the Office of the General Counsel.

What is a trademark or service mark,

registration, the registrant is presumed to be entitled to use the trademark throughout the United States for the goods or services for which the trademark is registered.

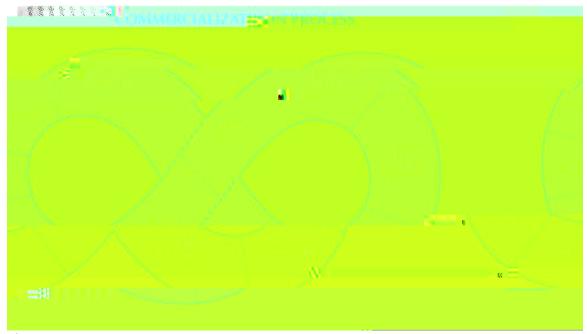
THE TECHNOLOGY TRANSFER PROCESS

How do I work with the Office of Technology Transfer?

We encourage you to contact the Office of Technology Transfer during your early research activities to be aware of the options that will best leverage the commercial potential of your research. The Office of Technology Transfer staff are ready to assist you with questions related to marketability, funding sources, commercial partners, patenting and other protection methods, new business start-up considerations, CSHL policies and procedures, and much more.

What are the typical steps in the process?

The process of technology transfer is summarized in the steps and diagram 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 or technologies. An invention is any new and useful process, machine, composition of matter, or any new or useful improvement of these. Often, multiple researchers may have contributed to the invention.

2) Pre-Disclosure:

An early contact with the Office of Technology Transfer staff to discuss you0.1 h0 de

Ideas emerging from academic work seldom provide a final solution or product for commercialization. During the Assessment phase, consideration will be given to gaining support for the initial work by consultation with external experts in the field, which could include venture capitalists, business leaders and or companies. In this period, careful protection of the ideas will be completed, usually under the protection of a Non-Disclosure Agreement between the parties. Many times, the relationships developed from these early disclosures of potentially valuable ideas, can lead to sourcing of new funds to advance the validation of the inventions, such as Sponsored Research in the lab of the inventor. CSHL has institutional agreements in place for this type of work, and can provide introductions to expert groups to evaluate inventions.

6) Protection and Marketing:

The process in which intellectual property protection for an idea is pursued, Patent protection, a common legal protection method, begins with the filing of a patent application with the U.S. Patent and Trademark Office (USPTO) and, when appropriate, for eign patent offices. Once a patent application has been filed, it typically will require several years and hundreds of thousands of dollars to obtain issued U.S. and for eign patents. Other protection methods include copyright, trademark, trade secrets, and contractual use restrictions (e.g., for databases and materials).

With your active involvement, the Office of Technology Transfer staff identifies candidate companies that have the expertise, resources, and business networks to bring the technology to market. This may involve partnering with an existing company through a research collaboration or license, or forming a start-up. Your active involvement can dramatically shorten and enhance this process.

7a) Existing Business:

If a suitable and interested existing company, or companies, are selected as a potential collaborator or licensee, the Office of Technology Transfer will work with those potential licensees to develop the appropriate financial and diligence terms to commercialize the technology.

7b) Form a Start-up:

If creation of a new business start-up has been chosen as the optimal commercialization path, the Office of Technology Transfer will work on connecting you to business formation consultants or others as needed to assist in planning, forming, and funding the start-up.

8) Licensing:

A license agreement is a contrac rights to a technology are licensed, without relinquishing ownership, for financial and other benefits. A license agreement is used with both an established company as well as

Talk to the Office of Technology Transfer if you have questions before you start

consistent with policies, including those related to employment responsibilities as well as use and ownership of intellectual property.

The Office of Technology Transfer is available to provide informal advice on how your consulting agreement relates to your CSHL Intellectual Property; and Counsel reviews all faculty consulting agreements to ensure that they are consistent with institutional policies and have followed the proper CSHL review and approval process. A sample consulting template is available from the Office of Technology Transfer or the General Counsel.

TECHNOLOGY DISCLOSURES

What is a Technology Disclosure?

A Technology Disclosure is a written description of your invention or development that is provided to the Office of Technology Transfer. The first step in pursuing potential commercialization of a Technology generated at CSHL is for the Investigator to complete a Technology Form (https://www.cshl.edu/wp-content/uploads/2020/11/Technology Evaluation Form.pdf) for early review of the Technology with the Office of Technology Transfer. If a commercial application is identified, a Technology Form (https://www.cshl.edu/wp-wcontent/uploads/2020/11/Technology Disclosure Form.pdf) will be completed to assist in compiling information necessary for any patent filings and/or government or foundation reporting and disclosure obligations. The Technology Evaluation/ Disclosure forms should list all collaborators, the contributions of each, and sources of support; ideally, it shoul3(r)4 contl3(r)4 contl3(

First, complete a Technology Form. If you have any questions, call the Office of Technology Transfer at 516-367-8301 or e-mail us at technology Transfer at 516-367-8301 or e-mail us at technology Disclosure Form to be completed.

ASSESSMENT OF A TECHNOLOGY DISCLOSURE

How does CSHL assess new technologies?

Office of Technology Transfer staff examine each newly reported technology to consider a wide range of issues relevant to commercialization, including whether, or the extent to which it can be protected by patent or other legal protection, 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 technology, and potential competition from other products/ technologies. This assessment may also include consideration of whether the technology can be the basis for a new business startup.

Each technology disclosure will be reviewed by Office of Technology Transfer staff with input from the inventor(s) and external resources considering obligations to research sponsors, commercial interest from potential licensees, research collaborators or investors, and scope of intellectual property protection relevant to commercial use.

If the inventors believe that their invention (all IP) should be licensed non-exclusively to all potential users for the public good, will CSHL honor our request?

The Office of Technology Transfer will work with you to develop the appropriate commercialization strategy for the invention. Some technologies lend themselves to non-exclusive licensing (licensing to multiple third parties), while others will only reach the commercial marketplace, and therefore the public, if they are licensed on an exclusive

the final decision should be determined by which strategy will produce the most benefits for the public, consistent with governmental or institutional policies and other obligations.

How do we decide whether to commercialize with a traditional or an "open source" license for software?

Generally, the Office of Technology Transfer supports CSHL software developers who choose to distribute their programs through open-source mechanisms at no charge, provided that CSHL retains the right to distribute the program as well, that open sourcing

the decision.

Is an invention ever assigned to an Inventor?

If the Office of Technology Transfer decides not to pursue patent protection and/or chooses not to actively market the technology, CSHL may transfer ownership to the scientist(s) making the Technology Disclosure. Reassignment of inventions funded from U.S. government sources requires the inventor to petition the funding agency and obtain approval for reassignment, based on agency guidelines.

TRANSFERRING MATERIALS

The transfer of materials and research tools is an essential part of scientific research. When a paper is published, the scientist must often provide the material to fellow researchers in order for others to repeat the experiment and verify the results. A Material Transfer Agreement (MTA) is the legal contract between CSHL and the party to receive or that will provide the materials, used to define the terms and conditions for the exchange of materials.

Why are MTAs essential?

MTAs are essential to protect:

Publication rights Intellectual property rights Against liability to other parties.

When the material is of a unique or proprietary nature, the provider may wish to control how the material is used and limit its further distribution.

An MTA typically sets forth rights to use the materials and may control rights to the results of their use. Often MTAs address such issues as publication, limitations on the use of the materials, and the intellectual property rights of the provider and the recipient parties in inventions arising from the use of the material.

Given that money is rarely associated with these transfers, MTAs may be perceived by some to be inconsequential transactions. However, they are binding legal agreements that

MTAs are processed through the Office of Technology Transfer. In order for us to process MTAs in a timely manner, please alert our office to the need for one as early as possible, well before the materials are required, as MTAs may require time to negotiate.

Types of MTAs for requesting or providing materials:

- 1) Academic/Non-profit
- 2) Company/ For-profit (usually requires more time to negotiate than an MTA with an academic/ non-profit)

Under what circumstances are MTAs needed?

MTAs are needed in most circumstances whenever a material is traveling out from CSHL to another party, or traveling in from another party to CSHL.

What MTA terms and conditions frequently pose problems for acceptance by CSHL?

CSHL will typically not accept terms that:

Restrict academic freedom, such as restrictions on publication

Technology Transfer 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 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 start-up company is a better option. It is rare for CSHL to have multiple potential licensees bidding on a technology (invention).

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

Per CSHL policy, a share of any financial return from a license is provided to the contributors list on the Technology Disclosure. Most inventors enjoy the satisfaction of knowing their technology is being deployed for the benefit of the public. New and enhanced

research, and consulting. In some cases, additional sponsored research may result from the licensee.

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

Many licensees require the active assistance of the scientist 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 start-up can require substantially more time, depending on your role in or with the company and your continuing role within CSHL. Your participation with a start-up or any consulting agreement with a licensee is governed by CSHL conflict-of-interest policies, the approval of your supervisor, and the approval of the CSHL President.

What other types of agreements and considerations apply to technology transfer and are administered by the Office of Technology Transfer?

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

Material Transfer Agreements (MTAs), used for incoming and outgoing materials at CSHL, are administered by the Office of Technology Transfer. These agreements describe the terms under which CSHL 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.

result, most licenses do not yield substantial revenues and most investment in patent protection is not recovered.

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 often go beyond financial considerations alone.

What will happen to my invention if the start-up 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. While licensees usually can terminate at will, generally CSHL is only able to terminate if the licensee is not performing under the agreement.

REVENUE AND EQUITY DISTRIBUTIONS

How are license revenues distributed?

The Office of Technology Transfer is responsible for managing the expenses and revenues associated with technology agreements. Per the CSHL Commercial Relations Policy, revenues from license fees, royalties, and equity minus any unreimbursed patenting and related expenses are shared with inventors.

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

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

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

Revenues waived by inventors are distributed to CSHL for research and educational purposes. To avoid potential tax liability, revenues waived by you to your department/institute must not be under your control.

How are inventor revenues distributed if there are multiple inventors and/or multiple inventions in a license?

In the case where a license involves a technology with multiple inventors, authors

Transfer, stating their agreement and providing the specific income distribution scheme. This distribution will be recommended to the President, who will make the final decision on distribution. In the event that such agreement cannot be achieved, the President will make the determination.

What is equity?

Equity is defined as an ownership interest in a company, including but not limited to: shares of stocks, warrants, options, convertible instruments, and participation as a partner in a partnership.

What if I receive equity (stock) from a company?

Under CSHL Policy, scientists who receive equity from a licensee or other company doing business with CSHL are required to report this as described in the conflict of interest policy.

How is equity from a license distributed?

When equity is part of the payment for a technology license, it is shared with the inventors or contributors the same way as other license revenue. It can be shared as equity (issued to the relevant individuals at the time it is issued more broadly) or distributed as cash when the equity is realized and becomes cash. If CSHL acquires the equity through investment of cash or as a founder, distribution will be at the discretion of the CSHL President.

CONSIDERATIONS FOR A START-UP COMPANY

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

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

Availability of start-up management and investment (is there management and investors willing to go at risk with the company);

development risk (often companies in established industries are unwilling to take the risk);

development costs versus investment return (can investors obtain their needed rates of return);

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.

CSHL scientists typically serve as technology consultants, advisors or in some other technical developmental capacity. CSHL does not allow faculty to serve as employees of the company as it is seen as an unmanageable conflict. In many cases, the faculty role is suggested by the start-up investors and management team, who identify the best role

change. Faculty involvement of any kind in a start-

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.

NAVIGATING CONFLICT OF INTEREST

How does CSHL define a conflict of interest?

A conflict of interest can occur when a CSHL employee, through a relationship with an outside organization, is in a positi , or other interests that may lead to direct or indirect personal financial gain, 2) adversely impact or influence research or teaching responsibilities, or 3) provide improper advantage to others, to the disadvantage of CSHL.

When should I seek guidance on conflict of interest?

The best approach is to fully disclose your proposed arrangement to your supervisor and discuss the implications for your job responsibilities.

How does CSHL manage possible conflicts of interest associated with research and technology transfer transactions?

Office of Technology Transfer staff can advise you on conflict-of-interest issues or direct you to the Conflict of Interest and Compliance Coordinator within CSHL. It is the responsibility of the scientist to disclose and document any outside arrangements as described in CSHL's Investigator Conflict of Interest Policy (https://www.cshl.edu/wp-content/uploads/ 2020/ 11/ Investigator_Conflict-of-Interest_Policy.pdf).

REINVESTMENT AND RELATIONSHIPS

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Common Acronyms

CDA: Confidential Disclosure Agreement

COI: Conflicts of Interest

CSHL: Cold Spring Harbor Laboratory

IIA: Inter-Institutional Agreement

IP: Intellectual Property

MTA: Material Transfer Agreement

NDA: Non-Disclosure Agreement

PCT: Patent Cooperation Treaty

SRA: Sponsored Research Agreement

USPTO: United States Patent aAc2TFat(cam)ac3(soffice12 Tq0.00000912 0o73 Tm0 g27A3(erics*nl60).

Important CSHL Contact Information

Office of Technology Transfer

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