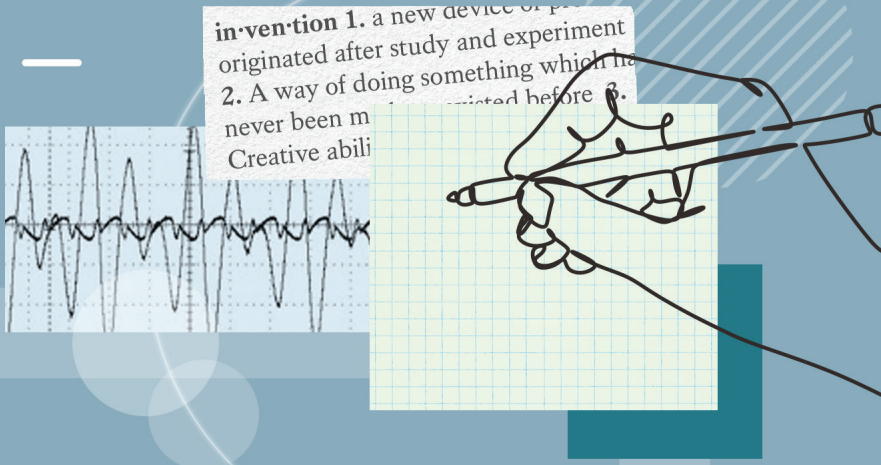
THE ROCKEFELLER UNIVERSITY



The Inventor's Guide to Technology Transfer

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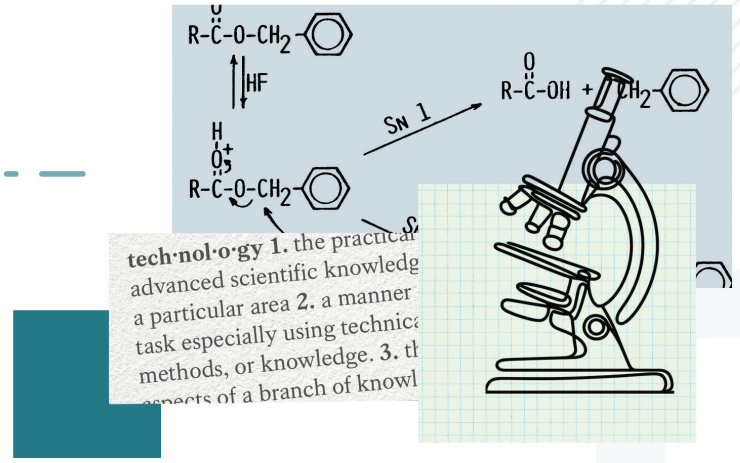
For more information:
Visit Rockefeller's Office of Technology Transfer at
www.rockefeller.edu/technology-transfer/

The Inventor's Guide to Technology Transfer

outlines the essential elements of technology transfer at The Rockefeller University. Created to provide helpful information about intellectual property for inventions, copyrightable works, and tangible property, this guide provides an overview of technology transfer, information about related processes and activities, and answers to common questions from the university's research community.



Overview

The Mission of The Office of Technology Transfer is to identify, protect, and strategically position potentially commercially relevant Rockefeller discoveries to best enable their transfer to partners capable of further advancing and bringing products to the public based on these discoveries.

What is technology transfer?

In its most basic form, “technology transfer” is the transfer of a new technology from the originator to a secondary user. In the academic setting, technology transfer has evolved to become much broader and more diverse than a simple transfer from one party to another, but the core function of transferring technology from the University to a commercial partner remains the central function of the technology transfer office.

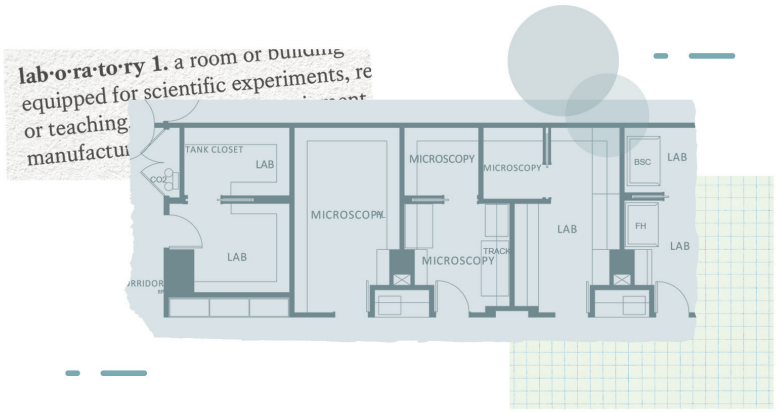
Technology transfer involves activities across the lifetime of discovery, from facilitating technology sharing for collaborations to executing commercial licenses. This form of technology management and commercialization is an intrinsic part of the creation of products stemming from the results of scientific and technological research in an academic setting.

What is the role of the Office of Technology Transfer?

The **enterprise role** of the Office of Technology Transfer (OTT) includes engaging with researchers and scouting of research, strategic positioning of commercially valuable innovation, marketing, negotiating license agreements, and managing post-transaction license compliance. OTT is the primary facilitator of interactions and activity for both internal and external stakeholders as it relates to academic innovation that may positively impact society through commercialization.

The **service role** of OTT includes negotiation of industry sponsored research and other enabling agreements, including material transfer agreements, confidential disclosure agreements, and other contracts with significant intellectual property components.

OTT also provides services to its research community through education about intellectual property, entrepreneurship and commercialization. OTT serves as a resource to the Rockefeller community, helping our scientists understand, and often participate in, the different processes and roles required for commercialization.



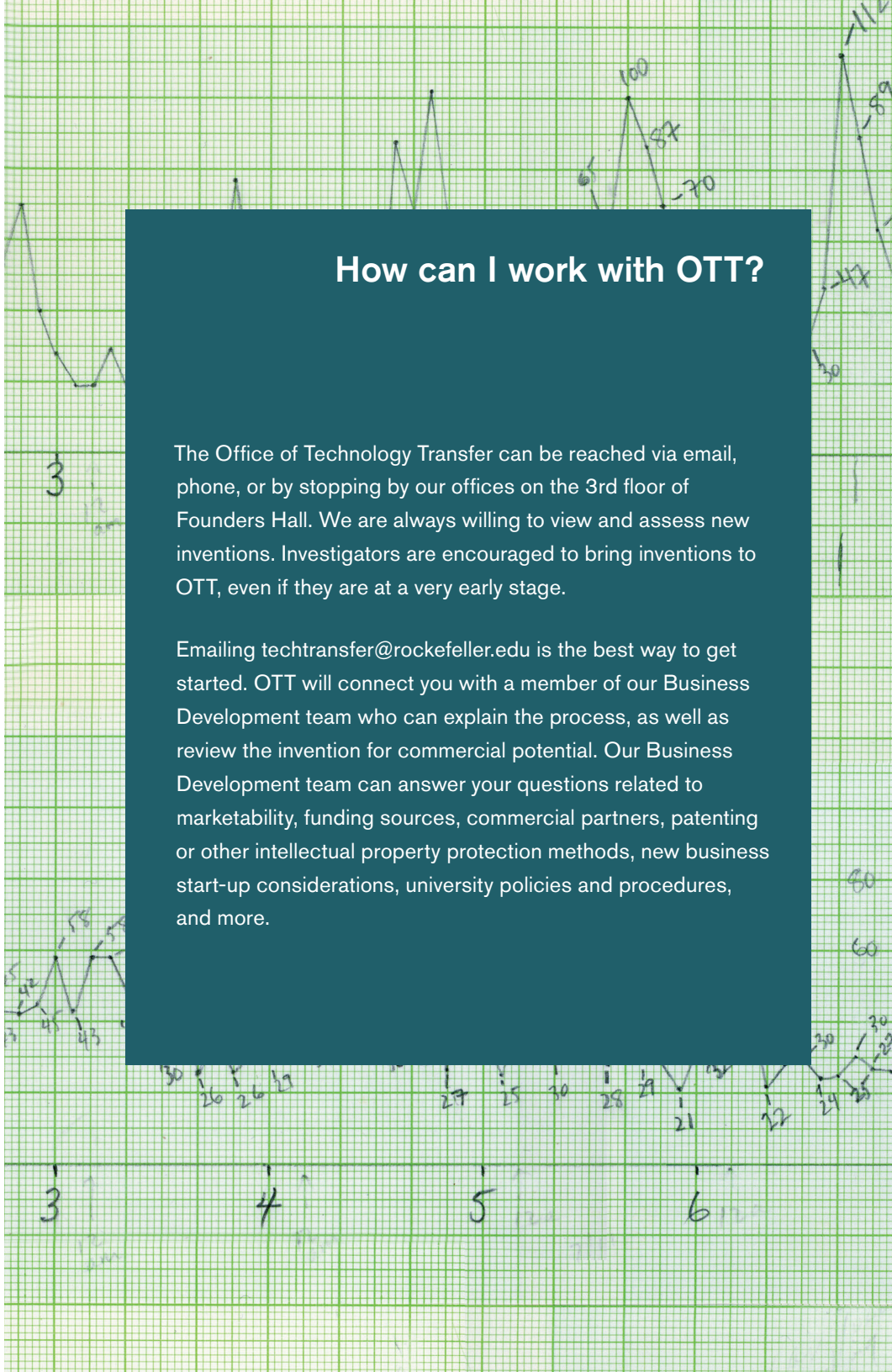
In furtherance of the Rockefeller mission, OTT is engaged in creating opportunities for academic discoveries to become new products to benefit society. OTT takes into consideration access, impact, and how to address unmet need. When OTT's activities include intellectual property protection and the granting of an exclusive license, which is often necessary for the development of new medicines, OTT endeavors to negotiate terms that seek to maximize the beneficial societal impact of the product. OTT believes that any positive role that it can play in influencing a licensee's practice to create or augment access to underserved communities, has the potential to be a seed of change. OTT cannot be so prescriptive in the use of specific terms as to create insurmountable obstacles that would deter a potential licensee from entering into a transaction to develop a product and considers each innovation in its own context. OTT further recognizes that in a changing and evolving landscape, it must be creative, proactive, flexible, and ambitious in working to bring together science, business, entrepreneurship, law, economic development, and common sense in how we enable the outputs of research being done at the University to be advanced through partnerships that move discoveries to products outside of the academic setting.

Both the enterprise and service roles of OTT are driven by Rockefeller's mission: *Science for the Benefit of Humanity.*

What role does an academic play in commercialization?

From time to time, the downstream effect of basic scientific research is the generation of useful technology that must be disseminated in order to benefit society. Sometimes this comes in the form of donating knowledge to the public, through publication of scientific findings that others can build on. Sometimes, it is through the distribution of research tools to further scientific understanding. Other times—through the pursuit of patent protection and the exclusivity that may accompany a patent—OTT incentivizes commercial entities to invest in the advancement of a scientific finding to create a commercial product based on that science. No matter the mechanism, the benefit can be seen in many ways. Medicines and diagnostics that save or improve lives are just two examples of the result of OTT's activities.

The reasons for participating in commercialization are unique for each scientist. One attractive reason is the ability to have a positive impact on society by enabling the translation of bench research to products that can reach and impact the public by a party capable of commercial development. Other reasons include the educational experiences about how products come to market, possible job creation for those individuals interested in industry and entrepreneurship, recognition from industry, and the potential for financial returns to both Rockefeller and the inventors.

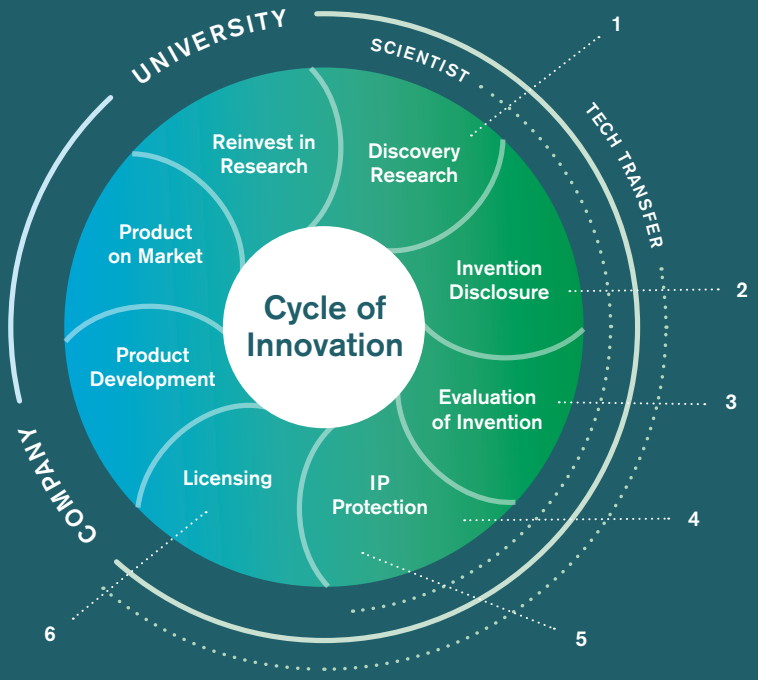


How can I work with OTT?

The Office of Technology Transfer can be reached via email, phone, or by stopping by our offices on the 3rd floor of Founders Hall. We are always willing to view and assess new inventions. Investigators are encouraged to bring inventions to OTT, even if they are at a very early stage.

Emailing techtransfer@rockefeller.edu is the best way to get started. OTT will connect you with a member of our Business Development team who can explain the process, as well as review the invention for commercial potential. Our Business Development team can answer your questions related to marketability, funding sources, commercial partners, patenting or other intellectual property protection methods, new business start-up considerations, university policies and procedures, and more.

The Technology Transfer Process



How long does the process from research to licensing take?

The technology transfer can take months or even years to go through the protection and licensing process for an invention. The length of time will depend on the technology's stage of development, the market for the technology, competing technologies, the amount of work needed to make a new concept market-ready, and the resources and willingness of the licensees and the inventors. Even though the entire process may sometimes be lengthy, many of the most important actions are taken at very early stages. For example, filing of a provisional patent prior to the initial publication or other public disclosure of the technology is critical for obtaining international patent rights which would not be available after publication of the invention.

Academic technology transfer is rarely predictable, and the resulting impact of a license depends on many factors. It is important to note that a very small percentage of licensed inventions ultimately result in a product on market or revenue returned to Rockefeller and the inventors. A lack of sufficient funding to keep continuing development by a startup company licensee, lack of efficacy of a medicine in clinical studies, rejection of patent claims that provide sufficient coverage, and countless other reasons result in failure to reach a marketed product.

Even though the entire process may sometimes be lengthy, many of the most important actions are taken at very early stages.

1. Research

The process begins with research. Rockefeller University is known for its cutting-edge scientific research. This environment is fertile ground for new and useful discoveries. Observations and experiments during research activities often lead to discoveries and inventions. An **invention**, as used herein, is any useful process, machine, composition of matter, software, or any new or useful improvement thereof. Though the word "invention," in legal context, refers more specifically to patentable inventions, in this guide we use "invention" to capture other useful technologies such as copyright protected software and tangible materials.

During the course of research activities, when an invention is still in nascent stages, it is a good time to get in touch with OTT. This could be before the invention is reduced to practice (demonstration that the invention works as intended), but the concept is identified by the researcher. In this **pre-invention** stage, OTT can start assessing the potential invention, taking into account the market, the potential impact, and potential avenues of intellectual property protection. Discussions with OTT at this stage also provide a good opportunity for researchers to engage with OTT about process and identification of potential commercial partners.

2. Technology Disclosure

Once the invention is reduced to practice, it is time to submit a **technology disclosure form** to OTT. Typically, this means that even if some additional experiments or development are required, the invention is well defined, and it is not anticipated to change significantly as a result of those additional experiments. The technology disclosure form will include important information about the invention that OTT will use both to obtain appropriate protection over the invention and to assess the invention for commercial potential. The technology disclosure form also includes information about the individuals who provided significant intellectual input to the invention and sources of funding used to generate the invention.

A disclosure made to OTT is and remains a confidential document and should describe in detail what has been made in order for OTT to begin the process of evaluation. Submitting a technology disclosure form allows OTT to create a record of the invention in our database and triggers any reporting obligations OTT may have to government, industry, or other sponsors or third parties who may have contributed. The federal government requires a completed technology disclosure form as part of its reporting requirements. A manuscript, grant application, or other written document will not suffice in the absence of completion of the technology disclosure form used by OTT. The invention receives a unique Technology ID, which will be used to monitor protection and commercialization of the invention.

A disclosure made to OTT is and remains a confidential document and should describe in detail what has been made in order for OTT to begin the process of evaluation.

3. Evaluation of Technology

Once the technology disclosure form is submitted, OTT will proceed with assessment of the invention. OTT will review the form, conduct a patentability review or assess suitability for other means of intellectual property protection, and analyze the market and competitive technologies to determine the invention's commercial potential. OTT will work collaboratively with the inventors to clearly define the invention and will take into consideration a number of factors that will enable OTT to make a decision about whether to accept the invention into Rockefeller's portfolio of technologies and how best to move forward with the invention. This evaluation process will guide the strategy on how to protect the invention and where to focus commercialization efforts. For example, the assessment may determine whether to focus on licensing to an existing company or a new business startup.

4. Intellectual Property Protection

When a determination has been made by OTT to proceed with intellectual property protection, the appropriate protection will be sought. Safeguarding IP through patents and copyrights is crucial to fostering innovation. Without the protection of ideas, universities and individuals generally cannot create sufficient economic incentive for a potential licensee to develop inventions to the point where they can be brought to market.

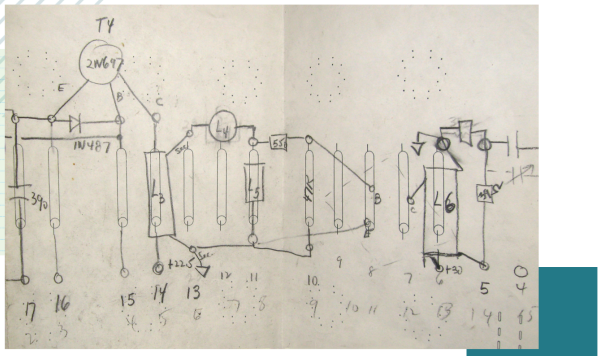
5. Patenting

Patent protection begins with the filing of a patent application with the U.S. Patent and Trademark Office (USPTO) and, when applicable, with foreign patent offices. Once a patent application has been filed, it typically will require several years and tens of thousands (in many cases hundreds of thousands) of dollars to obtain issued U.S. and foreign patents. Other intellectual property protections include copyright, trademark, and contractual use restrictions (e.g., for databases or tangible research property, such as biological material). Generally, the type of intellectual property protection Rockefeller can obtain over the invention depends on what type of invention it is (compositions of matter, useful methods, software, devices, etc.).

After a patent has been filed or other IP protection has been secured, OTT will proceed to the **marketing** of the invention to potential commercial partners. This may involve marketing to an existing company or entrepreneurs seeking opportunities for a startup company. The Business Development team at OTT identifies candidate companies or entrepreneurs that have the expertise, resources, and business networks to bring the technology to market. Active involvement of the inventors can dramatically influence the marketing process. Historically, inventors have been the best source for identifying potential licensees. In addition to identifying potential partners, the inventors' involvement in this process may include confidential conversations about the invention with one or more individuals from potential licensees. These representatives are typically scientists with relevant domain knowledge.

6. Licensing

When a potential commercial partner is interested in moving forward, it is time for licensing of the invention. In some cases, multiple potential commercial partners may be interested. In some of these cases, it may be appropriate to license an invention to multiple parties through non-exclusive licensing. However, in many cases a commercial partner will desire an exclusive license in order to establish a viable business model for commercialization. The Business Development team of OTT will select licensees that have the greatest potential to commercialize a technology and will work with those companies to develop the appropriate financial and diligence terms to fully commercialize a technology. If the potential licensee is a startup company, inventors can expect to work with OTT to help assess the management team and business plan, as well as to help incorporate relevant diligence terms in the license agreement.



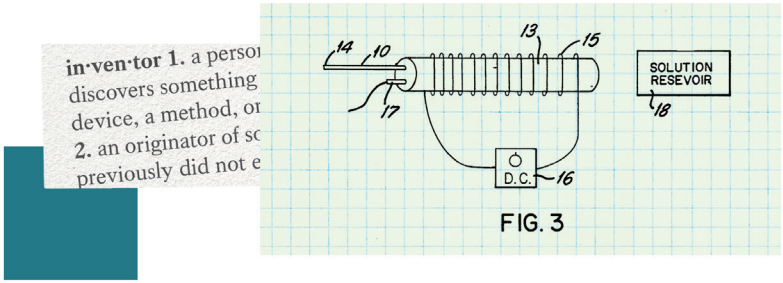
After a license has been put in place, the licensee takes the lead in **commercializing** the invention. This may include taking the invention through regulatory processes such as clinical trials and developing and marketing a product for sale based on the invention. OTT will monitor this commercialization to ensure that the licensee is advancing the invention towards a final product in accordance with the diligence terms of the license and is compliant in all other ways with the license, including fulfilling reporting obligations and any terms related to broad accessibility of a product.

When the licensee starts generating **revenue** from a product based on the invention, a typical arrangement requires the licensee to share a portion of the revenue with Rockefeller. In some cases, Rockefeller may receive licensing revenue from the licensee due to milestone payments or other fees prior to commercial sale of the product. For revenue received pursuant to licensing of a Rockefeller invention, Rockefeller has in place a distribution policy by which Rockefeller shares a portion of revenue it receives with the inventors.

What is the inventor's role in the process?

Inventor involvement can make the difference between an unlicensed technology and a blockbuster drug. During the process, inventors should expect to work closely with OTT. Often there are multiple inventors for any given invention. At Rockefeller, we require that all technology disclosures are approved by the Head of Laboratory (HOL). We also ask that the inventors indicate to OTT who should be the primary point of contact for the inventors. This is often the HOL. The first role that an inventor has in this process is to inform OTT about the invention. As mentioned earlier, this can happen before submission of the technology disclosure form.

In order to preserve potential patent rights, inventors must disclose inventions before publicly describing the invention in a presentation, lecture, poster, abstract, website description, research proposal, dissertation/master's thesis, publication, or other public forum. It is also very important that laboratory notebooks are well maintained in order to document the conception and reduction to practice of an invention.

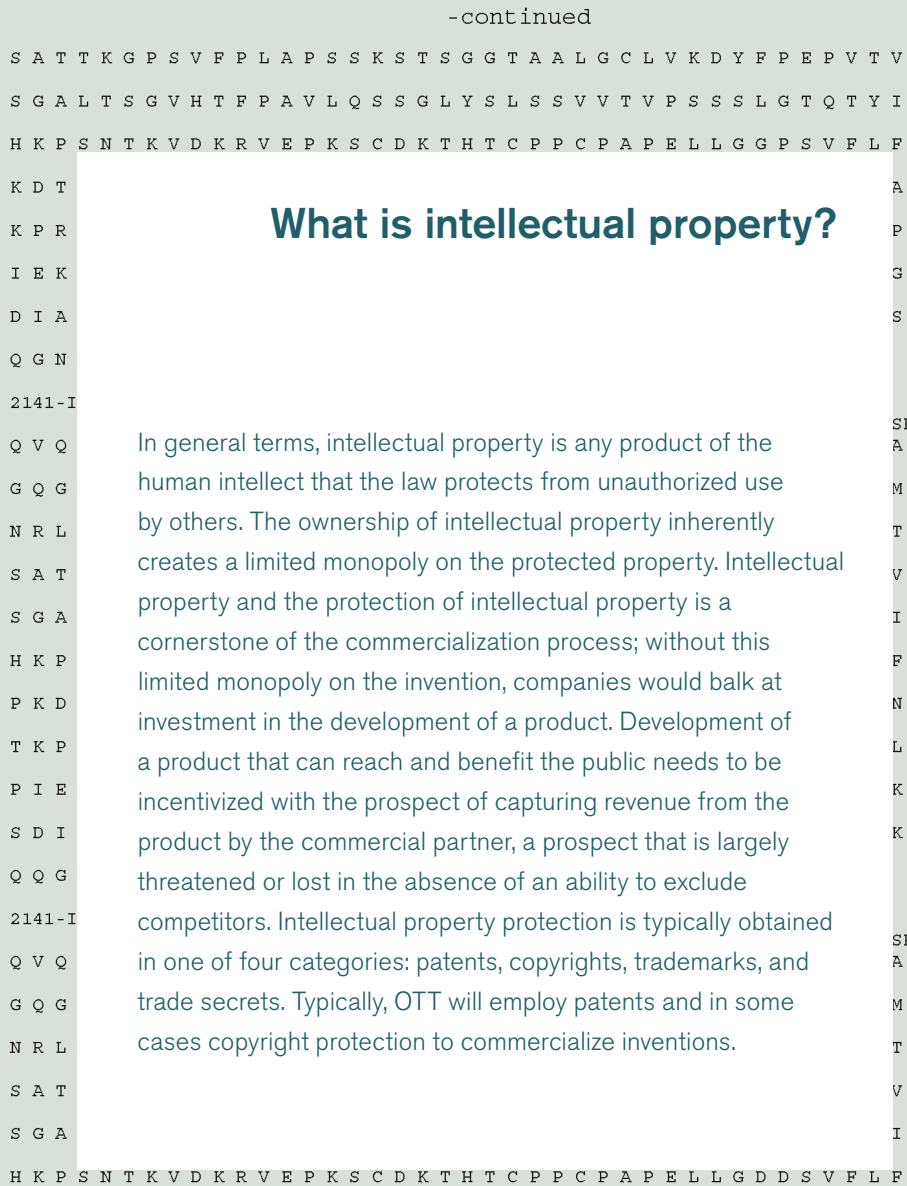


Inventors will also be involved in working with OTT and outside patent counsel to protect the invention. If OTT decides to pursue patent protection for the invention, the inventor will need to review the patent application for completeness and accuracy prior to filing. The patent counsel will also need input when responding to the relevant patent office as the patent prosecution progresses. Inventors should also keep OTT informed about significant technology developments, upcoming publications, and interactions with companies related to the invention. During the process of obtaining intellectual property protection of an invention, certain forms accompanying a patent application must be submitted to the government. From time to time, the inventors may be required to sign these documents. It can often be critical to submit these documents promptly to ensure appropriate protection of the invention.

A large portion of licenses are executed with commercial entities known by the inventor, so inventor contacts can be extremely useful. OTT will also ask for the inventor's input when creating non-confidential marketing materials to share with potential licensees.

Inventors may be involved in helping OTT prepare marketing materials and identify potential licensees. A large portion of licenses are executed with commercial entities known by the inventor, so inventor contacts can be extremely useful. OTT will also ask for the inventor's input when creating non-confidential marketing materials to share with potential licensees. In addition, OTT relies on inventors to help respond to technical questions from interested companies.

Intellectual Property Explained

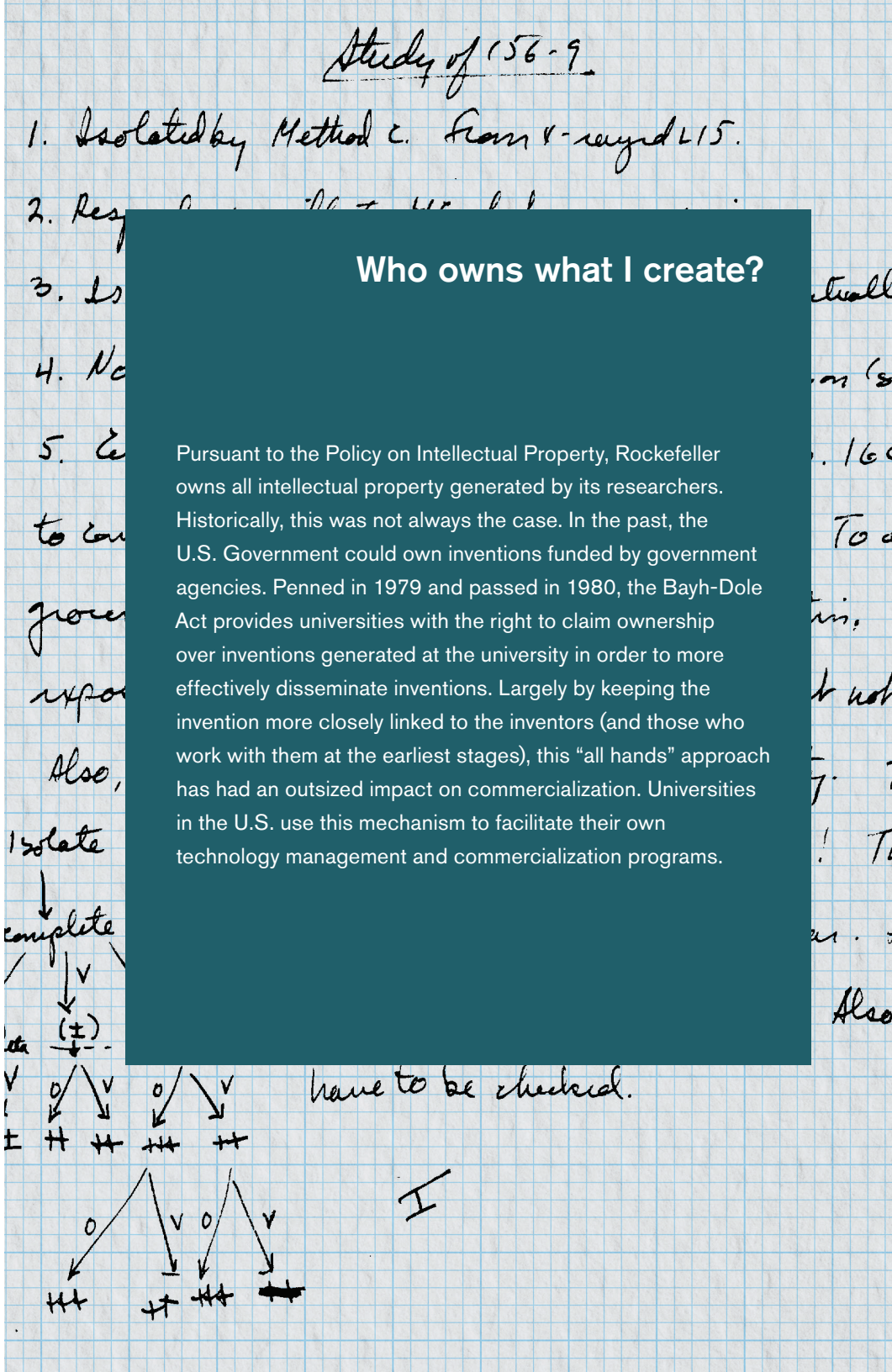


What is intellectual property?

In general terms, intellectual property is any product of the human intellect that the law protects from unauthorized use by others. The ownership of intellectual property inherently creates a limited monopoly on the protected property. Intellectual property and the protection of intellectual property is a cornerstone of the commercialization process; without this limited monopoly on the invention, companies would balk at investment in the development of a product. Development of a product that can reach and benefit the public needs to be incentivized with the prospect of capturing revenue from the product by the commercial partner, a prospect that is largely threatened or lost in the absence of an ability to exclude competitors. Intellectual property protection is typically obtained in one of four categories: patents, copyrights, trademarks, and trade secrets. Typically, OTT will employ patents and in some cases copyright protection to commercialize inventions.

Who is an inventor?

The definition of “inventor” is legal in nature. Generally, an inventor is someone who contributed to the conception of the invention or who participated in significant development of an important element of it. Inventorship is not the same as authorship, however. A “skilled set of hands” who carried out the instructions of another person is not an inventor, even though such a person may be considered a co-author or contributor in a scholarly sense. Most often, there is a good faith consensus about the individuals whose contributions rise to the level of inventorship, but with inventorship being a legal matter it may need to be assessed by OTT. For copyright protected materials, the term “author” may be used, although for the purposes of this guide the word “inventor” encompasses author. As opposed to an inventor according to patent law, an author of a copyright protected work is the person or people who actually wrote, recorded, performed or created the tangible form of the copyright protected work. An example is a person who wrote certain software.



Who owns what I create?

Pursuant to the Policy on Intellectual Property, Rockefeller owns all intellectual property generated by its researchers. Historically, this was not always the case. In the past, the U.S. Government could own inventions funded by government agencies. Penned in 1979 and passed in 1980, the Bayh-Dole Act provides universities with the right to claim ownership over inventions generated at the university in order to more effectively disseminate inventions. Largely by keeping the invention more closely linked to the inventors (and those who work with them at the earliest stages), this “all hands” approach has had an outsized impact on commercialization. Universities in the U.S. use this mechanism to facilitate their own technology management and commercialization programs.

What is the Bayh-Dole Act?

The U.S. Bayh-Dole Act of 1980 allows universities and other non-profit institutions to have ownership rights to discoveries resulting from federally funded research, provided certain obligations are met. Prior to the passage of the Bayh-Dole Act, inventions generated using federal funding were required to be assigned to the federal government. This resulted in a backlog of inventions held by the federal government, the dissemination and commercialization of which was bottlenecked by the resources and personnel that the government would require to appropriately manage all the inventions made using federal funding. In fact, fewer than 5 percent of the 28,000 patents being held by federal agencies had been licensed, compared with 25 to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention. To facilitate a more efficient means of mobilizing the inventions generated with federal funding, the Bayh-Dole Act was passed. Along with providing for ownership rights for universities and other non-profit institutions to inventions resulting from federally funded research, the act allows universities and non-profit institutions to manage the protection and dissemination of their own inventions, 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, and giving preference to small businesses that demonstrate sufficient capability to advance the discovery.

The Bayh-Dole Act is not the only basis for determining the ownership of inventions arising from research at universities. The terms of an inventor's employment and use of other funding sources can also affect ownership of inventions. At Rockefeller, the rights that the university holds in any invention made at the university or through the use of university funds, equipment, or facilities generally follow those established by the Bayh-Dole Act of 1980. Rockefeller owns all such inventions in accordance with the University's Policy on Intellectual Property, and OTT manages those inventions at Rockefeller.

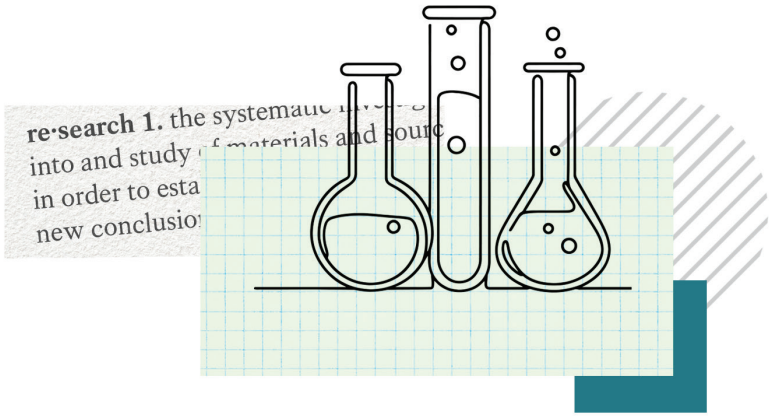
What's Rockefeller's policy on the sharing of revenue with inventors?

While the Bayh-Dole Act requires sharing of licensing revenue with inventors, it does not provide specific guidance, leaving universities to vary widely in how this sharing is applied. The Rockefeller University's policy on sharing of revenue with inventors is described in **Rockefeller's Policy on Intellectual Property**.

What rights does a research sponsor have to my research discoveries?

Although some sponsorship scenarios may vary from the typical arrangement, the most common obligation that the University will have to **private entities funding research** is that the private entity (most commonly a for-profit company) will have rights to use an invention for internal research purposes only and not for the sale of a commercial product. They may also have a time-limited option to negotiate an arms-length, revenue-bearing exclusive license with the University to inventions generated during the course and in performance of research that was funded by the private entity. This option does not give anything away for free and the private entity will need to negotiate a license on reasonable terms with Rockefeller to be able to commercially exploit the invention. In addition to these rights, sponsoring organizations will also typically have the opportunity to review proposed publications for the inadvertent inclusion of their confidential information. Other funding organizations will also have the ability to receive research results from the funded project to be used internally by the organization.

Of note is the ever-increasing trend of **nonprofit foundations** attaching terms to their sponsorship of research that include the foundation in patenting and commercialization decisions led by Rockefeller, as well as revenue sharing of the downstream commercialization. While Rockefeller does not currently have a policy explicitly rejecting such terms, there are guiding principles and limits OTT uses in reviewing and negotiating the terms of such sponsorships. Certain foundations have a “take it or leave it” approach and will not change their terms. Researchers seeking foundation funding are encouraged to review the terms of a funding agreement and discuss with OTT in advance of applying. Rockefeller has entered into arrangements with foundations to allow the foundation to pay for patent expenses on Rockefeller’s behalf in exchange for a grant of certain rights, such as revenue sharing, but will not grant outright ownership to a foundation. Rockefeller is also willing to consider granting a commercial license to a foundation for intellectual property that Rockefeller elects not to pursue or for which Rockefeller cannot find a licensee, but any such license would require a demonstrated commitment for further advancement.



Patent Protection

OB POLYPEPTIDES, MODIFIED FORMS AND COMPOSITIONS

Inventors: **Jeffrey M. Friedman**; **Yiying Zhang**, both of New York; **Ricardo Proenca**, Astoria, all of N.Y.

Assignee: The N.Y

Appl. No.: 08/

Filed: Aug

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What is a patent?

A patent is a form of intellectual property protection that gives its owner the legal right to exclude others from making, using, or selling an invention for a limited period of time. The rights afforded by a patent covering an invention are the most common rights to be granted by Rockefeller to a company by way of a license. Without a patent, anyone could make, use, or sell an invention without any obligations to the inventor or the owner.

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variations thereof, that demonstrate the ability co participate in the control of mammalian body weight and that have been postulated to play a critical role in the regulation of body weight and adiposity. The present invention further provides nucleic acid molecules for use as molecular probes or as primers for polymerase chain reaction (PCR) amplification. In further aspects, the present invention provides cloning vectors and mammalian expression vectors comprising the nucleic acid molecules of the invention. The invention further relates to host cells transfected or transformed with an appropriate expression vector and to their use in the preparation of the modulators of the invention. Also provided are antibodies to the OB polypeptide. Moreover, a method for modulating body weight of a mammal is provided.

What can be patented?

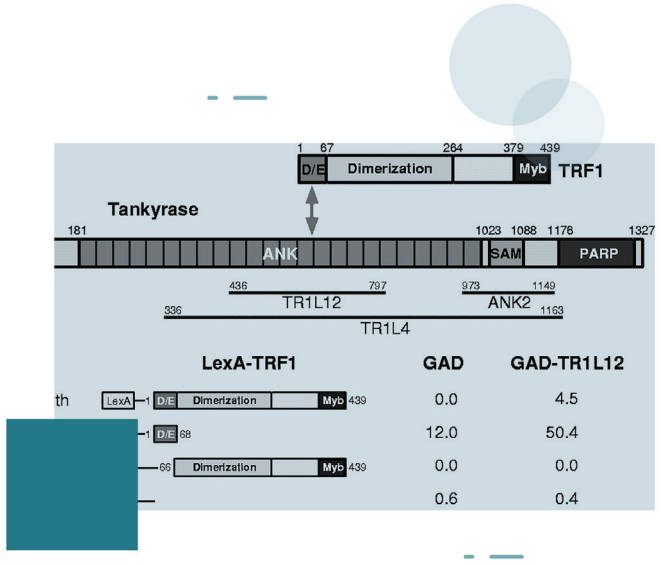
A patent can cover any useful method, machine, or composition of matter. Generally, there are types of discoveries that cannot be patented. Abstract ideas (including math) and natural phenomenon are types of discoveries that cannot be covered by a patent. However, there may be applications of those discoveries that can be covered by a patent. Additionally, patents can only cover novel inventions. If an invention has already been published, offered for sale, or patented by somebody else, a patent cannot be issued covering the invention because it is deemed to have been committed to the public via publication or has already been patented by another party. Patentability can entail nuanced and intricate analysis. OTT will help inventors understand whether there is a possibility of getting a patent issued and what the likely challenges may be.

What is the benefit of patenting?

As noted above, patent rights are the most common intellectual property rights for Rockefeller to license to commercial partners. Without some form of intellectual property protection, a license cannot be executed.

Who is responsible for patenting?

When an invention is assessed by OTT and approved for filing of a patent, OTT manages the engagement with outside counsel to draft, submit, and prosecute a patent. Outside counsel may have questions for the inventor during the patent preparation process. Inventor participation throughout the life of the patent can be critical in obtaining strong patent claims. OTT is responsible for deciding to file and maintain patent applications and issued patents, manages the arrangement with outside counsel, and pays the costs of patenting using Rockefeller funds unless a license is granted to a third party, at which time some of those activities may be shifted to the licensee under the license. An exclusive licensee of an invention will typically have the right to contribute to the patenting process and will pay patent related expenses.



What is the patent process?

Most often, a provisional patent application is filed prior to the publication of the invention in a paper by the inventor. A **provisional patent application** lasts one year and acts as a placeholder for a full patent application that must be submitted within that year. Generally, this full patent application is submitted in the form of a **Patent Cooperation Treaty** (PCT) that acts as a central international patent application and maintains the ability to pursue multiple patent applications in foreign jurisdictions in parallel. This process of moving from a provisional patent application to a full patent application is referred to as conversion of the patent. It is possible to add additional supporting data to the application upon conversion, but not later.

After 18 months from the submission of the PCT, territories must be selected in which the patent application will be examined, and issuance of patent rights will be sought. This process is called nationalization. A PCT may be nationalized in any number of countries, noting that the European Union is considered one territory for this purpose. Of course, every territory in which the patent is nationalized increases the total cost; the burden of expenses borne by Rockefeller is considered in the decision to nationalize a patent application, as is the licensing status in the selected territories. Once the patent is nationalized, the process of patent prosecution can begin. It is during this process that a patent examiner (within a specific territory, e.g. US examiner, European Patent Office examiner, Canadian examiner) accepts or rejects the claims in a filed patent application. This is done through written communications for which the applicant (Rockefeller University) has a limited time to respond. It is during this process that inventors are expected to work closely with OTT and outside counsel to prepare compelling responses to the patent examiners. Generally, one can expect at least one rejection in this process. Prosecution can often be the most lengthy and costly part of the patenting process. Prosecution can end in a few different ways:

- OTT may determine that pursuit of further patenting efforts is futile and that claims are unlikely to issue, in which case OTT may elect to abandon some or all patent applications or patents.
- OTT may determine that, for an unlicensed invention, the likelihood of finding a licensee is no longer possible or highly unlikely and the expense can no longer be justified. In this instance, OTT may elect to abandon some or all patent applications or patents.
- The most desirable and positive outcome is that, in one or more countries, the patent examiner agrees to allow claims, and patent issuance will result.

Protection provided by a patent lasts for 20 years from the initial filing of the PCT application.

Prior Art

Prior Art is the public knowledge in the form of publications, public records, offers for sale, or other public disclosures that might be relevant to the subject matter of a patent's claims before the effective filing date (or "Priority Date") of a patent application for an invention.

Priority Date

The priority date is the date of filing of a specification, which first discloses the claimed invention in a manner that is clear enough and complete enough for the invention to be performed by a person skilled in the art and from which the claim is entitled to claim priority. It is essential for determining whether any subsequent patent application for the same invention is novel. It also makes it possible to determine whether the subject-matter of a patent application is prior art on a particular date.

Office Action

In United States patent law, an Office Action is a document written by a patent examiner in response to a patent application after the examiner has examined the application. The Office Action cites prior art and gives reasons why the examiner has allowed the applicant's claims, and/or rejected the claims. Once an Office Action is issued by the Patent Office, there is a certain time frame for an applicant to respond for prosecution to continue, even in the case in which claims have been allowed by the examiner. Moreover, if any claims have been rejected or objected to by the patent examiner, the reply from the applicant must be responsive to each ground of rejection and objection made by the examiner.

Claims

The claims define the limits of exactly what the patent does, and does not, cover. Upon issuance of a patent, it is the content of the issued claims that the patent holder has the right to exclude others from making, using, or selling, as opposed to other information included in the patent application that is not included in the issued claims.

Issued Patent or Granted Patent

This is a term of art for the status of a patent application after a patent office has granted the patent holder the right to restrict others from the claims therein. Before becoming an Issued Patent, a patent is pending, meaning that it is a patent application and that no claims have yet been allowed that can be enforced by the owner of a patent.

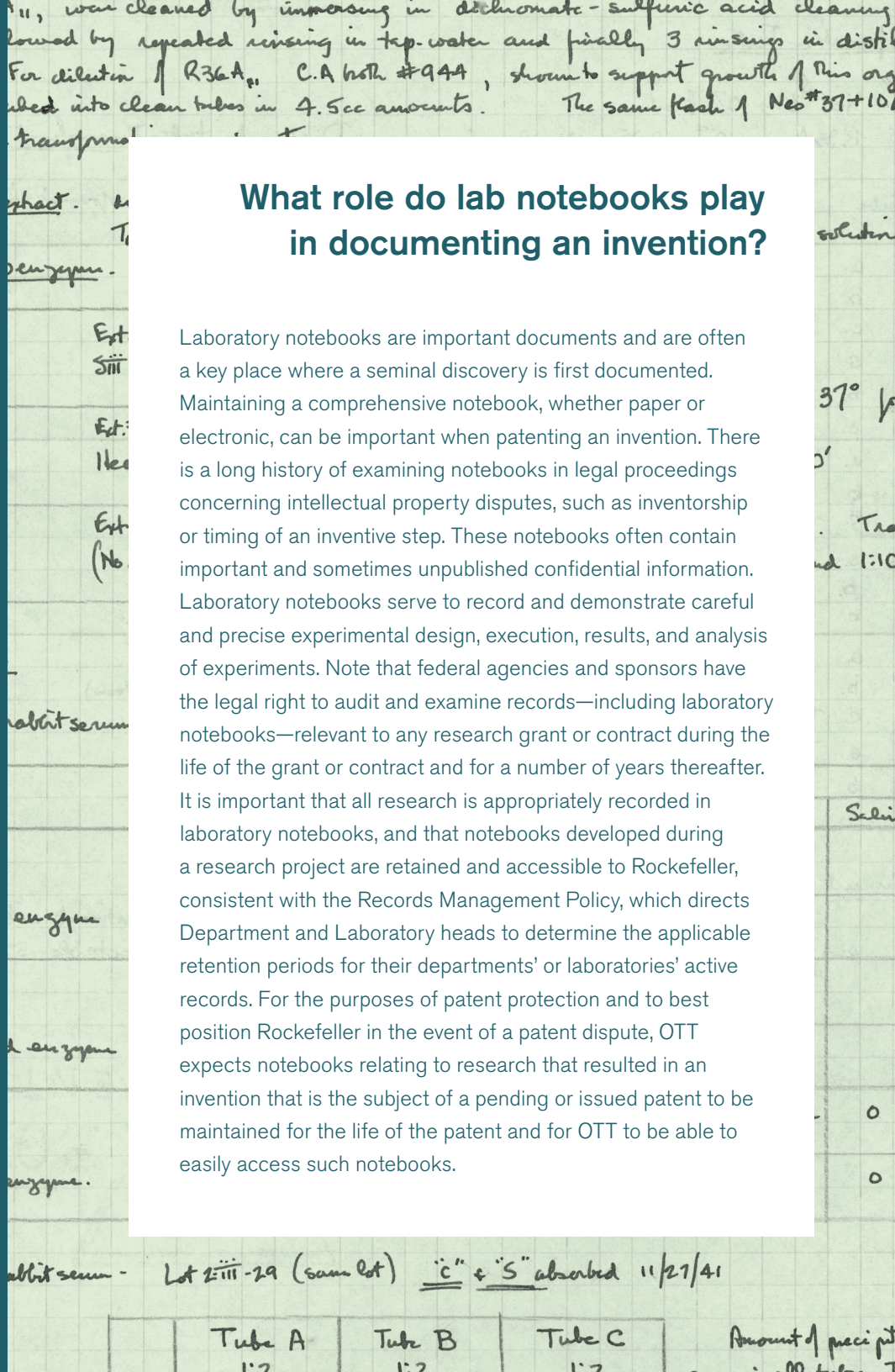
Provisional Patent Application

This is a document submitted to the US patent office that establishes a date of filing and a priority date, and helps protect a new invention from being copied during the 12-month period before a formal patent application is filed through the conversion process. It is intended to give an inventor and patent holder time to refine and add more supporting documentation before committing to the expensive and time-intensive process of a formal application.

Specification

Just as the claims are part of a patent application or patent, the specification is also a part of this document. The specification describes in a highly technical manner the subject matter that the owner of the patent intends to claim as the invention.

Research Considerations



What role do lab notebooks play in documenting an invention?

Laboratory notebooks are important documents and are often a key place where a seminal discovery is first documented. Maintaining a comprehensive notebook, whether paper or electronic, can be important when patenting an invention. There is a long history of examining notebooks in legal proceedings concerning intellectual property disputes, such as inventorship or timing of an inventive step. These notebooks often contain important and sometimes unpublished confidential information. Laboratory notebooks serve to record and demonstrate careful and precise experimental design, execution, results, and analysis of experiments. Note that federal agencies and sponsors have the legal right to audit and examine records—including laboratory notebooks—relevant to any research grant or contract during the life of the grant or contract and for a number of years thereafter. It is important that all research is appropriately recorded in laboratory notebooks, and that notebooks developed during a research project are retained and accessible to Rockefeller, consistent with the Records Management Policy, which directs Department and Laboratory heads to determine the applicable retention periods for their departments' or laboratories' active records. For the purposes of patent protection and to best position Rockefeller in the event of a patent dispute, OTT expects notebooks relating to research that resulted in an invention that is the subject of a pending or issued patent to be maintained for the life of the patent and for OTT to be able to easily access such notebooks.

Can I publish research results and still protect potential commercial value of IP?

Yes! However, if you wish to have OTT consider the subject matter contained in the publication for a potential patent filing, you will need to be mindful of the timing of publication. Depending on the complexity of the technology, it can take days or weeks for OTT to review and evaluate a technology, a process that requires participation of the researchers involved as evaluation is difficult if there is insufficient information provided to OTT. If OTT determines that a patent application is possible and desirable, the preparation of a comprehensive patent application is an iterative process with external patent counsel, the inventors, and OTT. There will be additional time needed to complete that step.

Since patent rights are affected by publication, it is important to involve OTT well before communicating or disclosing the invention to others outside of RU. There are significant differences between the U.S. and other countries as to how publication prior to patent filing impacts the ability to obtain patent protection. In most countries, once publicly disclosed (published or presented in in any other form), an invention is considered to be donated to the public, with restricted or minimal potential for patent protection outside of the United States, which may significantly impact the ability to attract a commercial entity for licensing. Although United States patent law provides a one-year grace period after publication for the filing of a patent application, the U.S. law does not reflect international rights, which are more important for commercialization than ever. Companies seeking to commercially develop an invention will most often need international protection for a viable business model.

What constitutes a public disclosure?

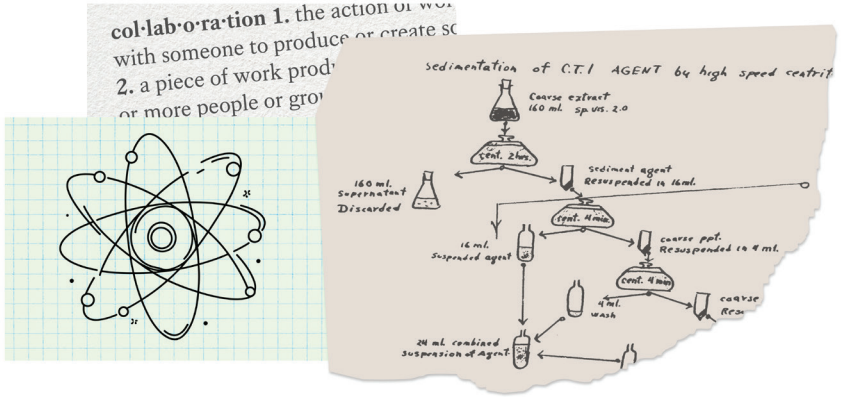
The ability to pursue patent protection can be severely compromised if a public disclosure of the invention is made in advance of the filing of a patent application. Public disclosures are generally considered disclosure of the invention with respect to patent law if there is sufficient information to enable a "person skilled in the art" (i.e. graduate school level researcher) to make and use the invention without additional undue experimentation. Public disclosure can come in many forms, including a postdoc talking about their research in a job interview with a possible employer, a detailed abstract of an awarded and published federal grant, or a poster at a conference. OTT can assist researchers in considering possible public disclosures and should be contacted to discuss planned activities (beyond closed Rockefeller laboratory meetings) if the researcher reasonably believes the output of the research may have potential commercial relevance.

Will I be able to share materials, research tools, or IP with others?

Yes. Sharing of materials or research tools should be documented using a **Material Transfer Agreement**. OTT can assist in that process. Regarding patent protected inventions, other academic researchers are free to do research that may fall within the scope or claims of the patent, and this is not considered infringement of patent right. Generally, this is referred to in patent law as the **"research exception."** Additionally, Rockefeller will reserve the right to use the invention for academic research in any license to those patents granted to a commercial entity, both for Rockefeller researchers and researchers at other academic organizations.

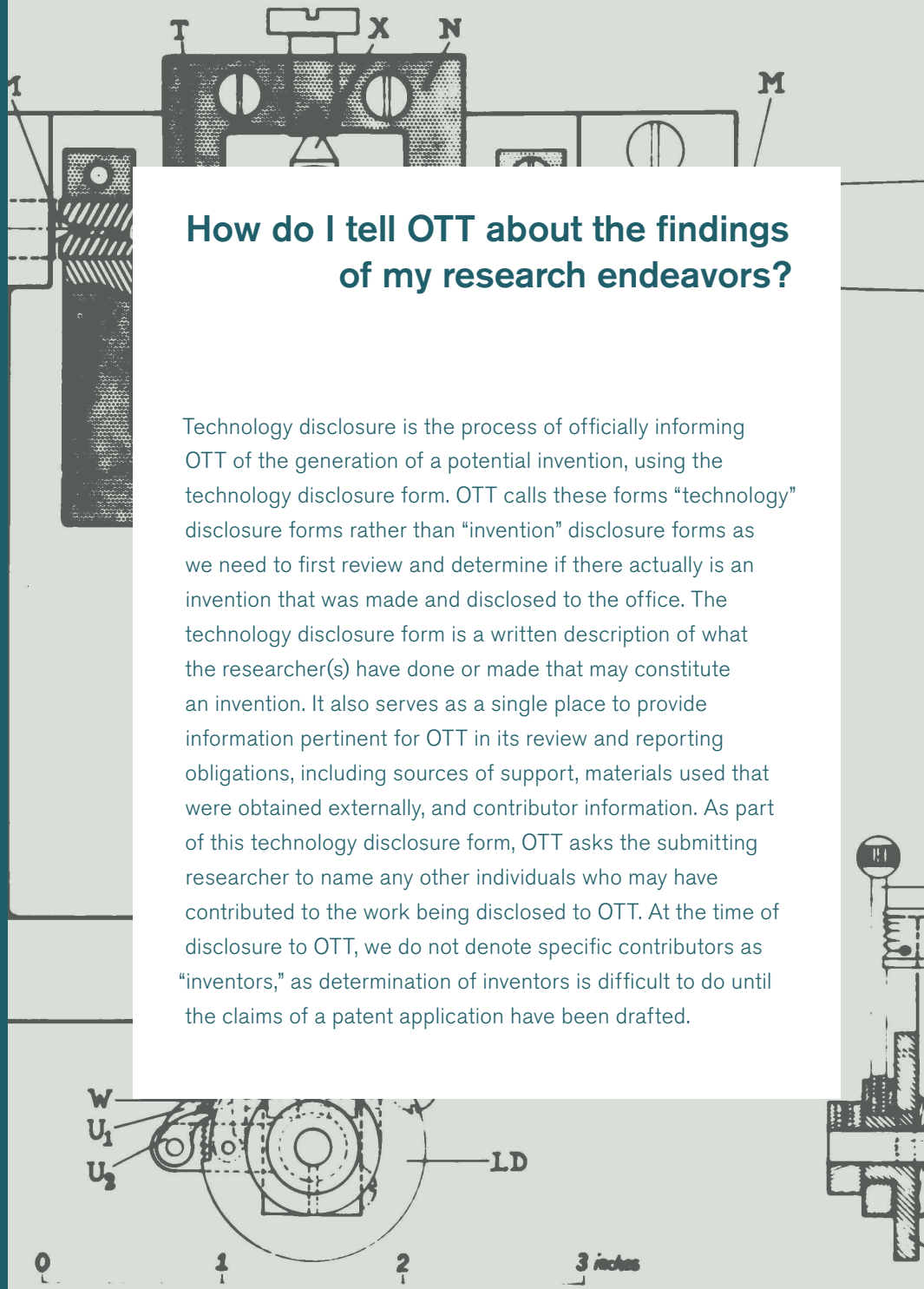
May I use materials or IP of others in my research?

Yes, but it is important to document the use in your research and to ensure that you disclose this to OTT as requested in the technology disclosure form. The use of third-party materials may influence ownership or license rights of the research results. As one common example, Rockefeller enters into Material Transfer Agreements with other research organizations. When a researcher receives materials from an external collaborator, the Material Transfer Agreement dictates what the provider allows Rockefeller to do with the materials. In some cases, this can be limiting for the filing of patent applications on inventions including, or generated using, those materials. For this reason, if you have received any materials from an external collaborator, it is important for OTT to be aware and to review any such limitations.



Laboratory of James B. Murphy, Smith Hall (room 211), 1947.

Disclosure: Invention and Technology



How do I tell OTT about the findings of my research endeavors?

Technology disclosure is the process of officially informing OTT of the generation of a potential invention, using the technology disclosure form. OTT calls these forms “technology” disclosure forms rather than “invention” disclosure forms as we need to first review and determine if there actually is an invention that was made and disclosed to the office. The technology disclosure form is a written description of what the researcher(s) have done or made that may constitute an invention. It also serves as a single place to provide information pertinent for OTT in its review and reporting obligations, including sources of support, materials used that were obtained externally, and contributor information. As part of this technology disclosure form, OTT asks the submitting researcher to name any other individuals who may have contributed to the work being disclosed to OTT. At the time of disclosure to OTT, we do not denote specific contributors as “inventors,” as determination of inventors is difficult to do until the claims of a patent application have been drafted.

Why and when should I submit a technology disclosure form to OTT?

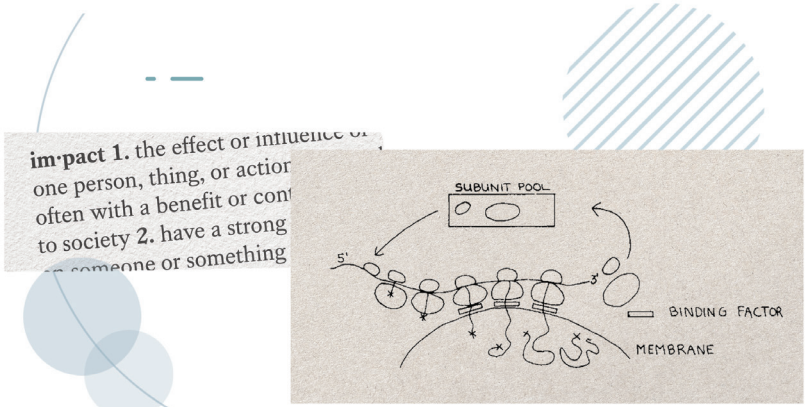
Ideally, the right time to submit a technology disclosure form is when a researcher reasonably believes that an invention has been both conceived and reduced to practice and is in a state that is complete and not likely to change significantly. OTT appreciates that this may not always be the case, and that a technology disclosure form may be submitted before fully fleshing out an invention or that a near term public disclosure that would otherwise prove challenging to the patenting process necessitates an earlier review of the technology. OTT can help researchers understand when the right time for a technology disclosure form is if there is any uncertainty. A consultation in advance of submitting a disclosure is likely to clear up any uncertainty about whether an invention has been made or answer any questions or cover specific matters that a researcher may wish to discuss.

The technology disclosure form can be downloaded from the OTT website.

A technology disclosure form is required for OTT to be able to begin a formal evaluation process and to fulfill reporting obligations, including those to the U.S Government whose reporting requirements include providing a completed technology disclosure form as part of the reporting submission for any invention made using federal funding. While we hope there is an early and ongoing dialogue between the Business Development team and Rockefeller researchers and while it is likely that a researcher will be in touch with OTT prior to submitting the form, submission of the form serves as the formal "kick-off" of the technology transfer process. OTT needs to report to funders (federal, foundation, or industry) when an invention has been made. OTT has greatly simplified the form, asking for minimal information needed to begin the evaluation and fulfill reporting obligations.

What happens after I submit a technology disclosure form to OTT?

After a technology disclosure form is submitted to OTT, it will be assigned a technology ID number, receipt of the form will be confirmed with the submitting researcher, and a member of the Business Development team will schedule a meeting to obtain more information for the evaluation of the invention. Typically, an initial meeting will include verification of some key information included in the form. The Business Development team will likely have a preliminary assessment and additional questions for the researchers. The technology disclosure form is not intended to be a stand-alone document for evaluation by OTT, but is a springboard for evaluation and inclusion of the researchers in the process. While the results of academic research are quite far from the product a company would offer to the public, OTT welcomes in-depth discussions with inventors about all possible applications of what a final marketed product might be used for and what the broadest impact and accessibility might look like.



How are disclosures assessed?

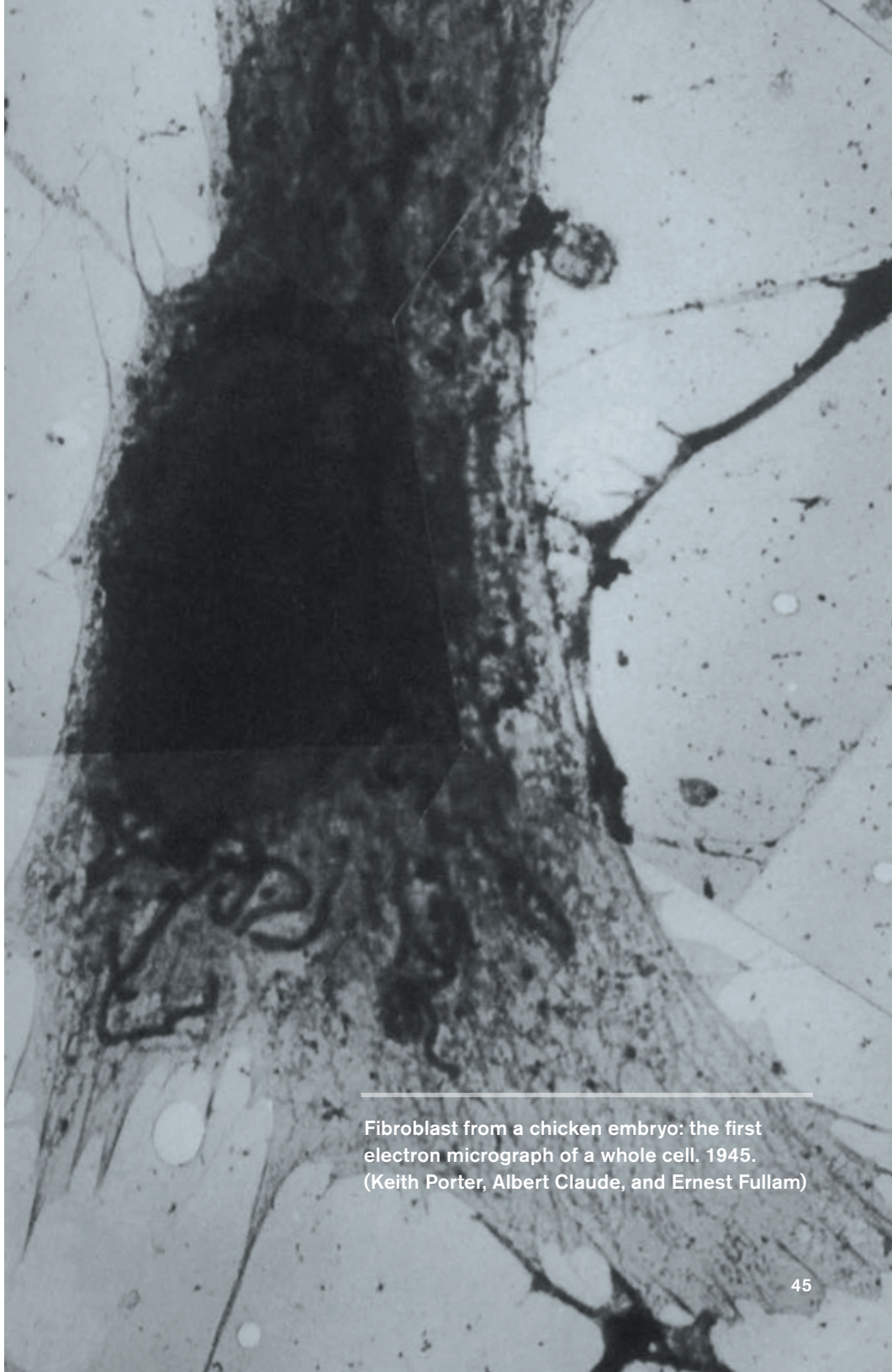
If OTT has determined that an invention has been made, the invention is reviewed in greater detail. For some inventions, such as a tangible research material, this can be a straightforward process. These kinds of inventions are not typically the subject of patent filings, and so the review is commonly limited to determining the source of the material and any third-party ownership or obligations.

For patent-eligible subject matter, potential patent claims that could be made in a patent are reviewed, including for possible breadth, scope, and enforceability. OTT considers potential positioning in the market, asking questions about what a possible commercial product could be, who the user might be, who might pay for or buy the product, and other factors that could impact the decision to move forward with patenting.

OTT may also assess the appropriateness of pursuing other intellectual property protection, such as copyright.

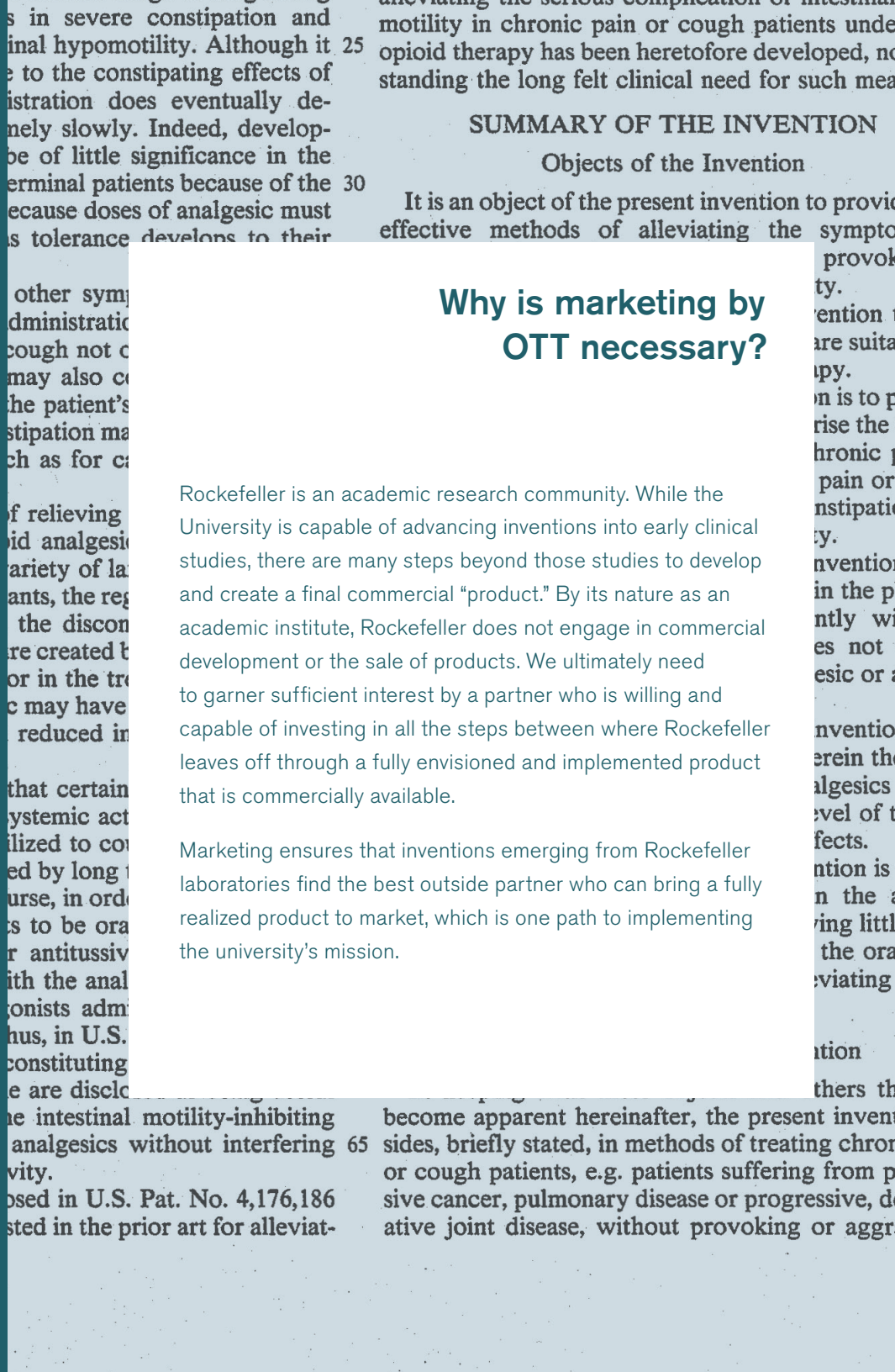
Can a student contribute to an invention?

Students may contribute to inventions and be inventors of such. It is important to note that all technology disclosure forms submitted to OTT require the approval and signature of the HOL, so if a student desires to make a disclosure to OTT, they should first confer with their HOL.



Fibroblast from a chicken embryo: the first electron micrograph of a whole cell. 1945. (Keith Porter, Albert Claude, and Ernest Fullam)

Marketing an Invention



Why is marketing by OTT necessary?

Rockefeller is an academic research community. While the University is capable of advancing inventions into early clinical studies, there are many steps beyond those studies to develop and create a final commercial "product." By its nature as an academic institute, Rockefeller does not engage in commercial development or the sale of products. We ultimately need to garner sufficient interest by a partner who is willing and capable of investing in all the steps between where Rockefeller leaves off through a fully envisioned and implemented product that is commercially available.

Marketing ensures that inventions emerging from Rockefeller laboratories find the best outside partner who can bring a fully realized product to market, which is one path to implementing the university's mission.

How are licensees found?

Business Development & Licensing professionals within OTT utilize many sources and strategies to identify potential licensees and to market inventions. Most often, existing relationships—of the inventors and the OTT staff—are useful in marketing an invention. Market research can assist in identifying prospective licensees. We also examine other complementary technologies and agreements to assist our efforts. We leverage conferences and industry events to make direct contacts. We also leverage relationships with existing licensees and investors that may be interested in new licensing or business formation opportunities.

Faculty publications and presentations are often excellent marketing tools. We find that scientists or other leaders within industry or among the investment community are often the biggest champions of a particular Rockefeller researcher's work. Some technologies, typically tangible research materials that would be non-exclusively licensed, require little pro-active marketing by OTT. Rather, a scientific publication is typically sufficient to garner interest.

Sometimes, despite the enthusiasm of the inventors and OTT about the potential of an academic discovery to become a product, there is no company that is interested in licensing and further developing the technology into a product. In those instances, a startup company may be the only viable alternative for commercial advancement. A startup company typically involves significant time and effort from one or more inventors at the early stages of formation and funding.

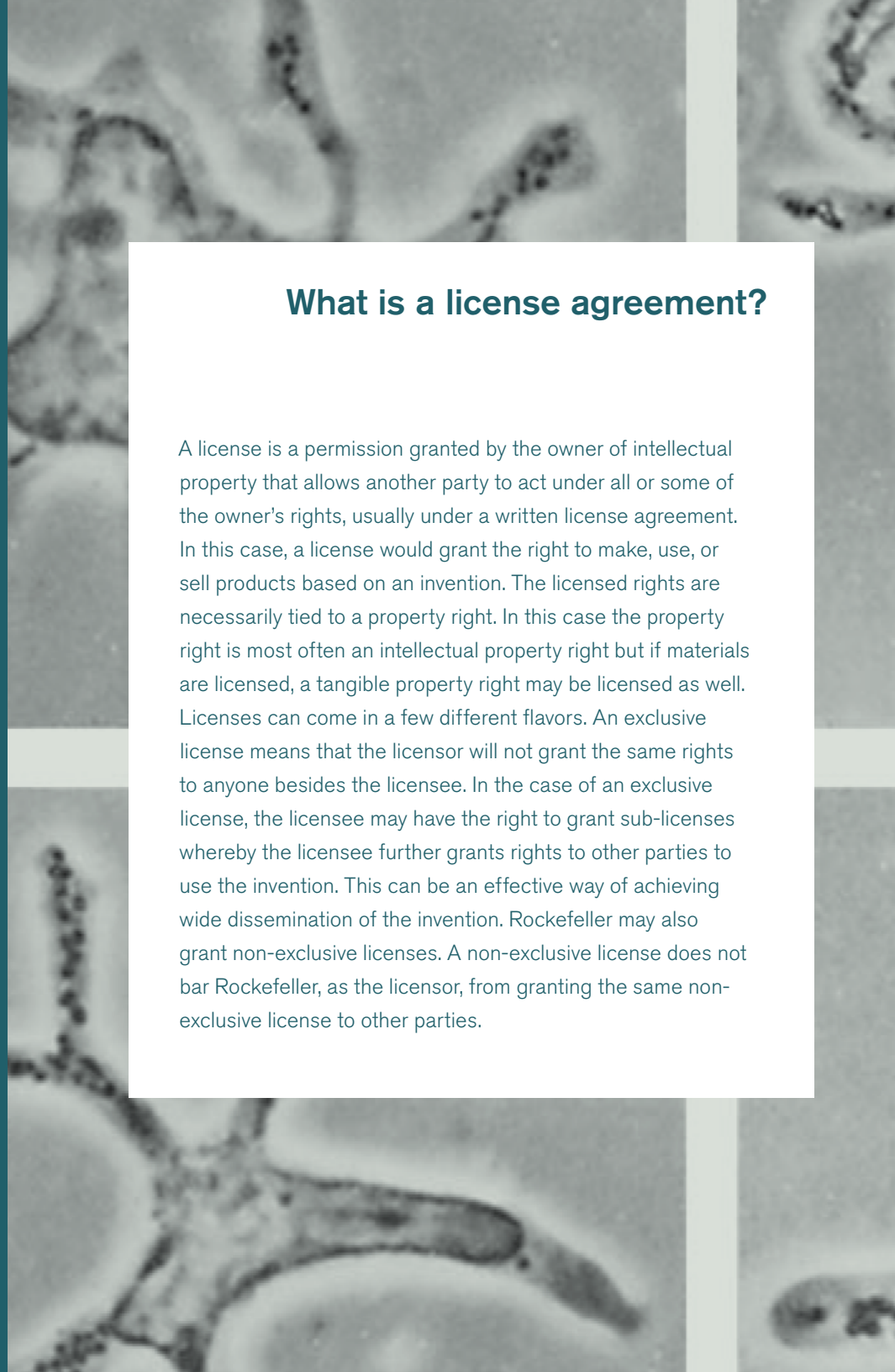
How long will it take to find a licensee?

It can take months or years to identify, engage, and obtain bona fide interest from one or more potential licensees. Sometimes, a licensee is never found. There are many reasons why it may be difficult to attract a licensee and many factors that play into the attractiveness of a technology, including the intellectual property position, size, and potential of the market that is being addressed, competing technologies, and the stage of the invention. These considerations all are part of the overall assessment of an academic invention by a potential industry partner when making the determination to create a product and bring it to the public.

What is the inventor's role during marketing?

The active involvement of inventors can dramatically improve the chances of matching an invention to an outside company (or an investor interested in creating a company). Once interested companies are identified, the inventor is the best person to describe the details of the invention and its technical advantages. While the Business Development team can often create initial interest by non-confidentially pitching the invention and its commercial promise, the scientific diligence questions that arise in subsequent conversations are often best addressed by the inventor. Positive results are most frequently seen when OTT and the inventors work as a team on this process.

Licensing and Commercialization

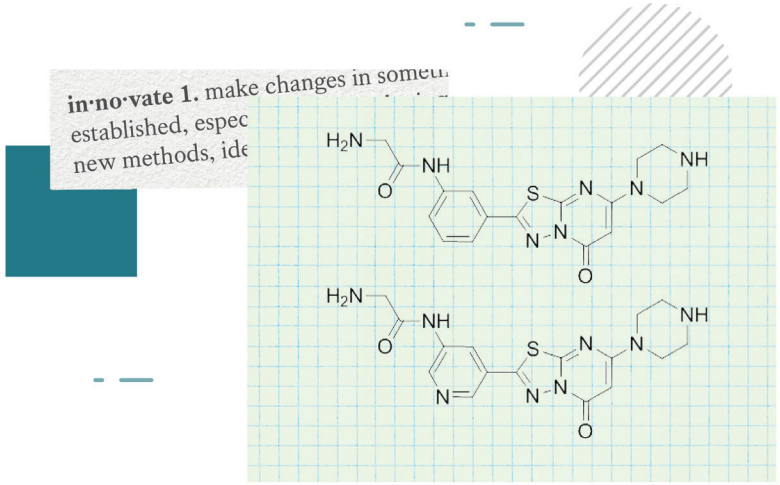


What is a license agreement?

A license is a permission granted by the owner of intellectual property that allows another party to act under all or some of the owner's rights, usually under a written license agreement. In this case, a license would grant the right to make, use, or sell products based on an invention. The licensed rights are necessarily tied to a property right. In this case the property right is most often an intellectual property right but if materials are licensed, a tangible property right may be licensed as well. Licenses can come in a few different flavors. An exclusive license means that the licensor will not grant the same rights to anyone besides the licensee. In the case of an exclusive license, the licensee may have the right to grant sub-licenses whereby the licensee further grants rights to other parties to use the invention. This can be an effective way of achieving wide dissemination of the invention. Rockefeller may also grant non-exclusive licenses. A non-exclusive license does not bar Rockefeller, as the licensor, from granting the same non-exclusive license to other parties.

How can a license affect the continuation of my academic research?

Rockefeller grants license rights existing as of the effective date of the license. While an existing licensee may be an ideal partner for a new invention researchers may make in the future, OTT does not a priori grant to existing licensees any rights in future inventions that researchers may pursue. Thus, the license will not create future licensing obligations or encumber future work in the inventor's laboratory.



What happens if the company/licensee is unsuccessful?

OTT includes diligence terms in licenses to ensure that reasonable efforts are pursued by commercial partners to develop the invention into a final product. **Diligence terms** in licenses are milestone events that are often tied to a time requirement (such as raising a certain amount of equity financing in an allotted time frame or initiating a first-in-human clinical study of a licensed product within a set period of time following the granting of the license). If the company does not achieve the required diligence events, Rockefeller can renegotiate or terminate the license. If the license is terminated, all grants to Rockefeller's intellectual property rights are canceled, and Rockefeller will be free to license to another party.

It is not always easy to find a new licensee. Time will have passed, and the length of coverage by intellectual property rights will be shorter. There is often a negative perception around a "failed" asset, even if the original science is solid.

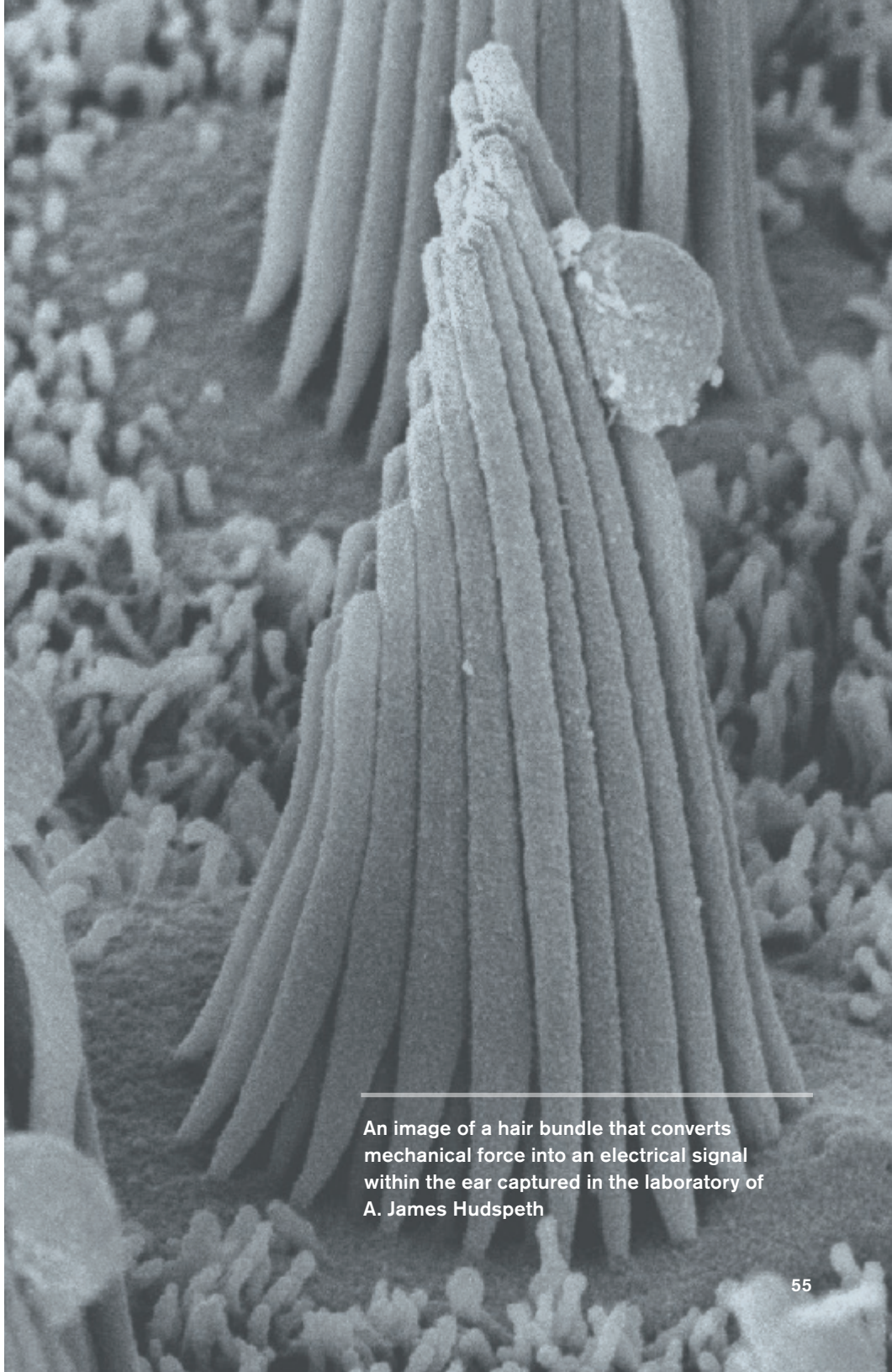
What activities occur during the life of a license?

Once a license is granted, the licensee is responsible for making diligent efforts to develop a product. The activities pursued by the licensee can vary widely depending on the type of product planned, as can the length of time to bring a product to market. A therapeutic asset can take many years, while a research tool may be available to the public in months.

For exclusively licensed inventions, OTT requires a development plan from the licensee at the start of the license, and periodic reports (at least annually) on the activities, achievements, and near-term plans to advance a product. This is one way that OTT can monitor diligence.

Depending on the structure of the license, different types of payments will be due to Rockefeller. A license will typically include many or all of the following: an upfront fee for the grant of the license, an annual license maintenance fee, development or regulatory event milestone payments, a fee based on a set percentage of income received by the licensee for the grant of a sublicense, and royalties based on sales. In startup companies, OTT will consider taking equity in the company in lieu of or in addition to certain cash payments.

After a license is in place, OTT's activities include monitoring the licensee's diligence efforts to develop and commercialize a product based on a Rockefeller invention and intellectual property. OTT may rely on the inventor to assist in the scientific review of the licensee's reporting. A researcher will be responsible for ensuring that any technical information or materials licensed to a company are robustly and timely provided to or made available to the company in accordance with the license provisions.

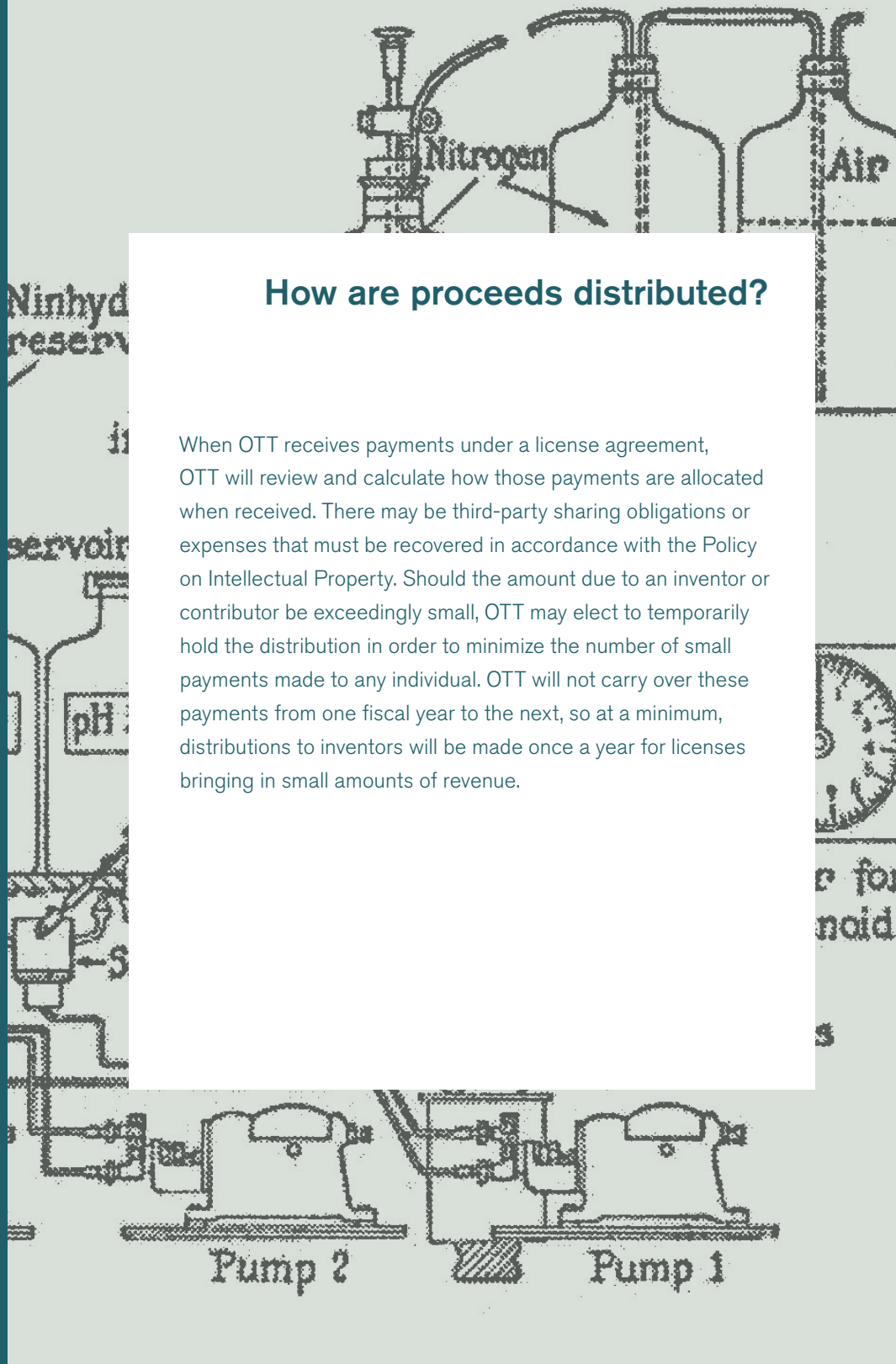


An image of a hair bundle that converts mechanical force into an electrical signal within the ear captured in the laboratory of A. James Hudspeth

Distributions of Proceeds and Revenue

How are proceeds distributed?

When OTT receives payments under a license agreement, OTT will review and calculate how those payments are allocated when received. There may be third-party sharing obligations or expenses that must be recovered in accordance with the Policy on Intellectual Property. Should the amount due to an inventor or contributor be exceedingly small, OTT may elect to temporarily hold the distribution in order to minimize the number of small payments made to any individual. OTT will not carry over these payments from one fiscal year to the next, so at a minimum, distributions to inventors will be made once a year for licenses bringing in small amounts of revenue.



What about multiple inventors?

The Policy on Intellectual Property provides a detailed description on how a percentage of revenue received in exchange for the grant of a license is shared with one or more inventors. When there is more than one inventor, the inventors are required to agree in writing on the revenue share and provide this information to OTT. OTT will not distribute any revenue in the absence of an agreement.

There may be multiple inventions included, or "bundled" into one single license. While each invention in the bundle has codified sharing instructions for the inventors of that specific invention (and non-inventing contributor, if appropriate), OTT will rely on the HOL for guidance about the relative value of each invention bundled in the license. The sharing of revenue across inventions will be memorialized in writing by OTT.

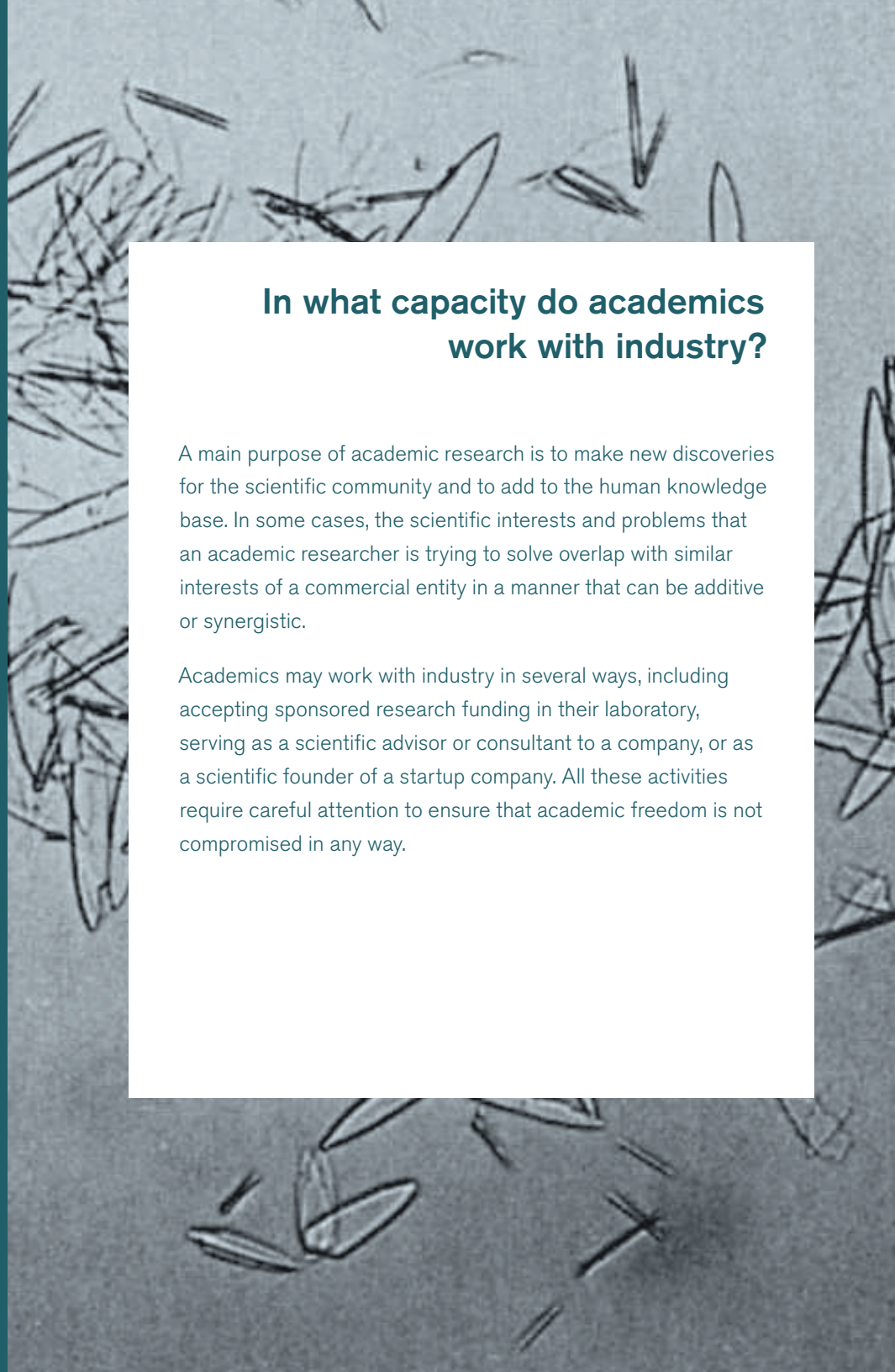
What are the tax implications?

Neither Rockefeller nor OTT will provide tax advice to individual inventors (or non-inventing contributors) on their respective share of licensing revenue or royalties. Such individuals should contact their individual tax advisor to determine the tax treatment on distributions made to them.

What revenue goes to the university, the inventor/s, and other contributors involved?

The **Policy on Intellectual Property** provides a detailed description about how a percentage of revenue received in exchange for the grant of a license is shared with one or more inventors. While this percentage is designated for and shared by the inventor, OTT welcomes the inventor to consider dedicating a portion of the amount they would otherwise receive to others who contributed to the project in a meaningful way, even though the contribution did not rise to the level of formal inventorship.

Working with Industry



In what capacity do academics work with industry?

A main purpose of academic research is to make new discoveries for the scientific community and to add to the human knowledge base. In some cases, the scientific interests and problems that an academic researcher is trying to solve overlap with similar interests of a commercial entity in a manner that can be additive or synergistic.

Academics may work with industry in several ways, including accepting sponsored research funding in their laboratory, serving as a scientific advisor or consultant to a company, or as a scientific founder of a startup company. All these activities require careful attention to ensure that academic freedom is not compromised in any way.

What is consulting?

A consulting agreement is an arrangement with a company or other entity in a researcher's capacity as an individual. Consulting agreements (including Scientific Advisory Board member agreements and agreements for seminars, conferences, and talks) are private contracts between researchers and companies, but these agreements must be consistent with the researcher's obligations to Rockefeller.

Since Rockefeller does not review consulting arrangements, the researcher should be clear about the delineation between Rockefeller work and private consulting. Rockefeller strongly recommends that researchers hire their own legal counsel to advise them of their rights and obligations under a proposed consulting agreement. Rockefeller researchers cannot enter into any agreement that creates intellectual property obligations that conflict with their assignment obligations to Rockefeller. The following sentence should appear in all consulting agreements: "Consultant is employed by The Rockefeller University, and Consultant's obligations to The Rockefeller University supersede any and all provisions of this agreement." Specific Rockefeller policies that concern researchers' obligations are referenced in the **Model Consulting Agreement**, which is provided so that researchers may inform themselves about what might appear in a consulting agreement.

Prior to entering into any consulting agreement, the researcher should consider all relevant policies. Of note:

- The Rockefeller University **Policy on Conflict of Commitment in Research** should be consulted to determine when prior approval to engage in extramural activities is necessitated for postdoctoral appointees and for doctoral students.

- Researchers are not permitted in the course of their consulting duties to assist a company in obtaining rights to any Rockefeller intellectual property.
- Any Significant Financial Interests under the consulting agreement that are subject to the Conflict of Interest Policy must be reported.

What is OTT's role in managing consulting?

OTT does not manage consulting arrangements or disputes that may arise from them. OTT's role in managing consulting roles is primarily limited to reporting the licensing of a technology and relevant information related to such licenses to the Conflict of Interest Committee, in order for them to review any potential conflict that the licensing of a technology may create for a researcher or Rockefeller more broadly—in particular, for researchers who may be a consultant to a company that licenses a technology from which the researcher may be eligible to benefit financially (e.g., where the researcher is an inventor or contributor of an invention licensed to the company).

Confidentiality Agreements

A confidentiality agreement, also known as CDA (confidential disclosure agreement) or NDA (nondisclosure agreement), is a legal contract between two or more parties that describes information shared between or among the parties and restricts the usage and additional disclosure of the shared information.

A CDA (or NDA) is sometimes desired when OTT or a researcher is speaking to a third party and disclosing information that should have some limits on what can be done with the information and ensures the disclosure is not considered a public disclosure for patenting purposes. For example, a CDA (or NDA) may be used when, during the process of marketing an invention, OTT (and inventors) need to have in-depth discussions with a potential commercial partner. Often, these discussions occur when the patent application or relevant research paper has not yet been published and can include confidential information generated by inventors that may not be included in the patent. This confidential information may include new experimental results, additional protocols, or information related to the invention or other unpublished information. Generally, CDAs (and NDAs) are time-limited with the obligations typically extending for up to five years.

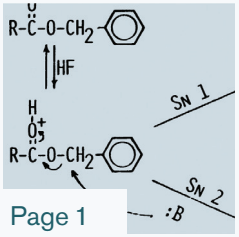
Material Transfer Agreements

Material Transfer Agreements (MTAs) are used for documenting and governing the use of incoming and outgoing tangible materials. These agreements are administered by OTT. For outgoing materials, these MTAs describe the terms under which Rockefeller researchers may share materials with outside researchers and what the permissions or limits are placed on the outside researchers regarding the use of such materials. For incoming materials, these MTAs describe the terms under which Rockefeller researchers may use the materials they receive. MTAs largely document ownership of materials, but may include language that addresses publication, sharing of research results using the materials, or further sharing of the materials received. Intellectual property rights can be endangered if materials are exchanged without a proper MTA. Special care should be taken to obtain an appropriate MTA for any materials that may be subject to export control regulations.

Conflict of Interest

The Rockefeller University strives to conduct all activities in a transparent manner, identifying and managing, and mitigating any actual or perceived conflicts of interest. The licensing of an invention by OTT may create a conflict of interest. Rockefeller researchers are urged to review and follow all relevant policies.

EASTER EGG INDEX



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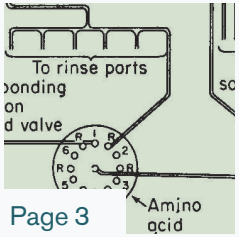
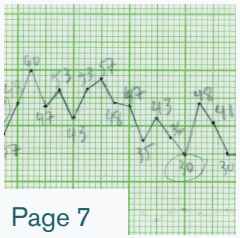
1963 paper on solid phase peptide synthesis (Bruce Merrifield)



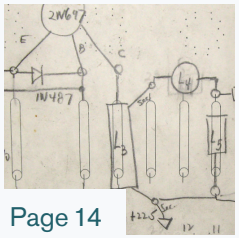
Page 3

Schematic drawing of the apparatus for automated peptide synthesis from a 1966 paper (Bruce Merrifield laboratory)



Page 7

Data on fruit fly activity and rest cycles from research on the molecular mechanisms of circadian rhythm (Mike Young laboratory)



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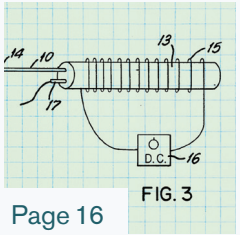
Drawing of radio-frequency cardiac pacemaker, first implanted in a patient in 1959 (Alexander Mauro in collaboration with heart surgeon William Glenn)



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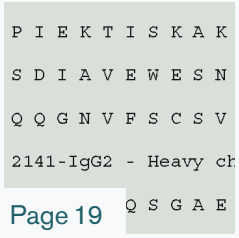
1993 patent for method for detecting post-translation modifications of peptides using mass spectroscopy (Brian Chait laboratory)



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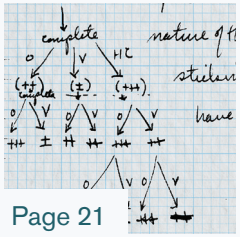
2021 patent for antibodies to CD40, shown to modulate immune response to cancer cells (Jeff Ravetch laboratory)



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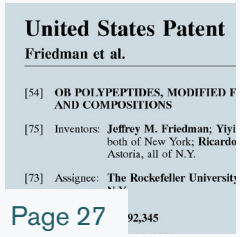
Experiments in the genetics of bacteria from 1946-47 lab notebook of Joshua Lederberg



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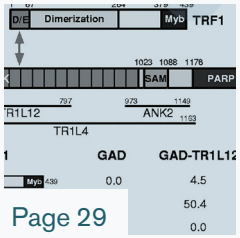
Patent springing from the discovery of leptin (Jeff Friedman laboratory)



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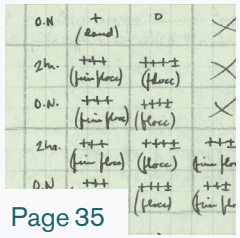
1998 paper on tankyrase in human telomeres (Titia de Lange laboratory)



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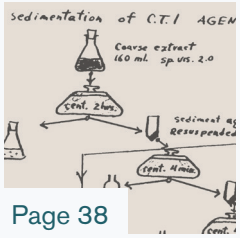
Page from Maclyn McCarty's 1941 lab notebook (the year he joined Oswald Avery's laboratory)



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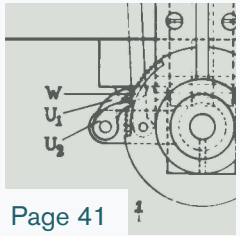
1935 drawing of cell fractionation scheme of chicken tumor 1 (Albert Claude)



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1950 blueprint of Porter-Blum microtome—Rockefeller's Instrument Shop built these machines before they went into commercial production

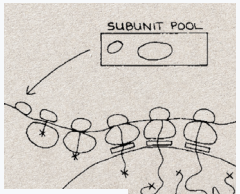

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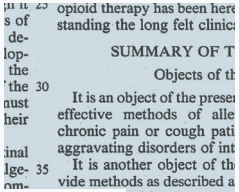
Illustration of 1971 signal hypothesis for secretory proteins (Günter Blobel and David Sabatini)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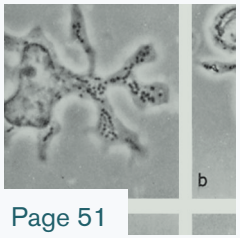
Page 47

1987 patent arising from research to understand addiction (Mary Jeanne Kreek laboratory)



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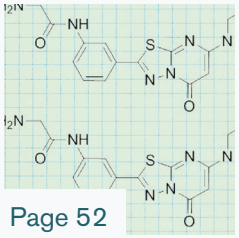
Phase-contrast micrograph from 1973 paper detailing the discovery of dendritic cells (Ralph Steinman and Zanvil Cohn)



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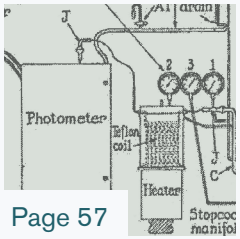
RUC-4, an antagonist for prehospital therapy of myocardial infarction (Barry Coller laboratory)



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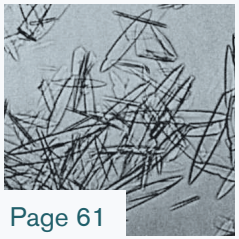
1958 schematic diagram of automatic amino acid analyzer (Stanford Moore and William Stein)



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1939 image of gramicidin crystals; gramicidin was the first clinically tested antibiotic agent (Rene Dubos and Rollin Hotchkiss)

Resources for Rockefeller Researchers

Rockefeller's Policy on Intellectual Property – page 23

www.rockefeller.edu/office-technology-transfer/for-rockefeller-researchers/ip-policy/

Model Consulting Agreement – page 62

www.rockefeller.edu/office-technology-transfer/for-rockefeller-researchers/consulting/

Policy on Conflict of Interest – page 62

www.rockefeller.edu/conflict-of-interest/

Commitment in Research – page 62

www.rockefeller.edu/conflict-of-interest/

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