Inventor's Guide to Technology Transfer

University of Nebraska Medical Center

unemed

the science of innovation

The Inventor's Guide to Technology Transfer outlines the essential elements of technology transfer at the University of Nebraska Medical Center.

This guide is organized to answer the most common questions that UNeMed, the technology transfer arm of UNMC, typically fields from the UNMC research community and provides a broad overview of the technology transfer process and services available for researchers.

Useful and new information can be found at www.unemed.com, or, if you have specific questions call UNeMed directly at (402) 559-2468 or email us at unemed@unmc.edu.

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TECHNOLOGY TRANSFER OVERVIEW

What is technology transfer?

Technology transfer is the transfer of knowledge and discoveries to the public. It can occur through publications, educated students entering the workforce, exchanges at conferences, and relationships with industry, among other things. For the purposes of this guide, technology transfer refers to the formal licensing of technology to third parties under the guidance of professionals employed by universities, research foundations, and businesses.

What is UNeMed?

UNeMed is a for-profit corporation owned by the Board of Regents of the University of Nebraska that is responsible for a spectrum of technology transfer activities including protecting, marketing and commercializing UNMC inventions.

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

One main reason is to have the satisfaction of knowing that their scientific research can lead to the development of a commercial product that would benefit humankind, other reasons may include:

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

How is technology transferred?

Technology is typically transferred through a license agreement, in which the University grants its rights in the defined technology to a third party for a specified period of time, often limited to a particular field of use and/ or region of the world. The licensee (the third party licensing the technology) may be an established company or a new start-up (that may be founded by the researcher). Licenses include terms that require the licensee to meet certain performance requirements and to make financial payments to the University. These payments are shared with the inventors and are also distributed to the schools/colleges, departments/units, and central administration to provide support for further research, education, and participation in the technology transfer process.

What is the Bayh-Dole Act?

The United States 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. These obligations include making efforts to protect (when appropriate) and commercialize the discoveries, submitting progress reports to the funding agency, giving preference to small businesses that demonstrate sufficient capability, and sharing any resulting revenues with the inventors. The Bayh-Dole Act is credited with stimulating interest in technology transfer activities and generating increased research, commercialization, educational opportunities, and economic development in the United States.

"A critically important requirement of a world-class medical center is our effort to create and commercialize research that improves healthcare"

-Chancellor Harold M. Maurer, M.D.

TECHNOLOGY TRANSFER PROCESS

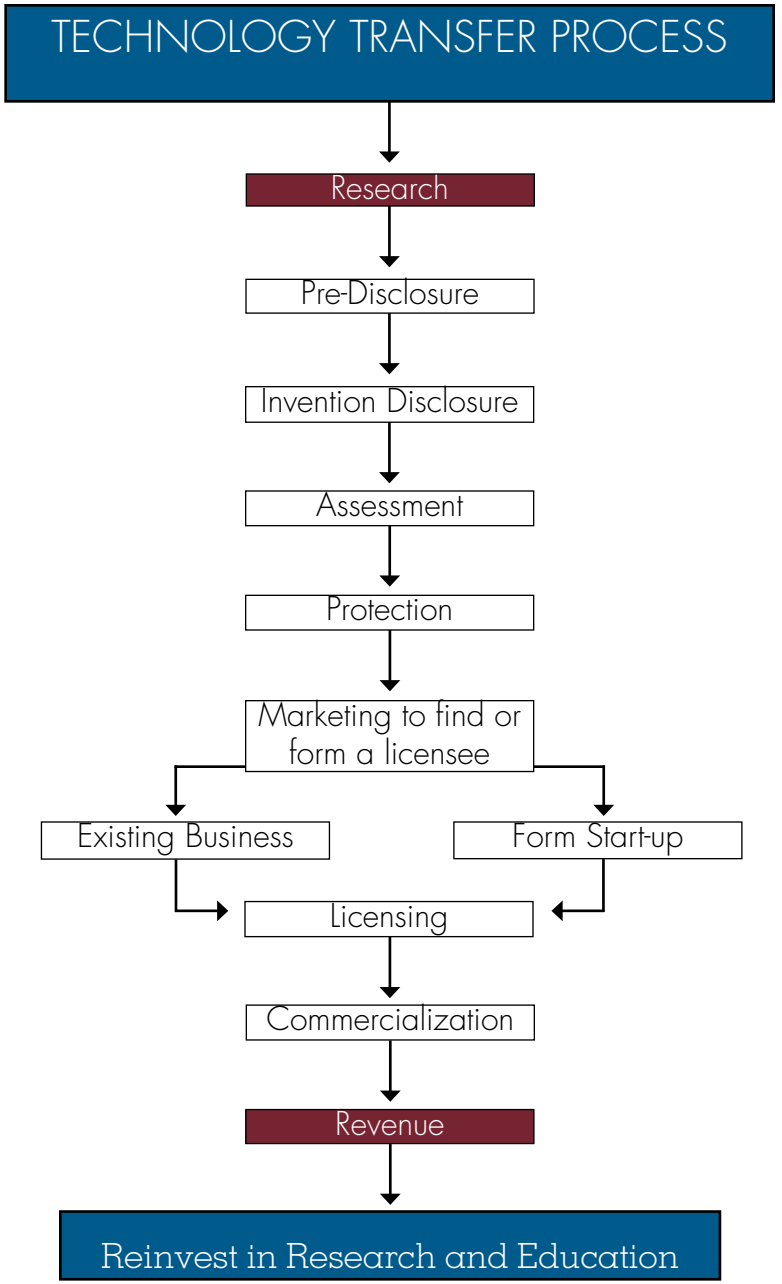
How do I work with UNeMed?

We encourage you to contact UNeMed during your early research activities to be aware of the options that will best leverage the commercial potential of your research. UNeMed staff are trained to assist you with questions related to marketability, commercial partners, patenting and other protection methods, new start-up considerations, University policies and procedures, and much more.

Our team approach provides you with an assigned licensing associate supported by additional expertise in areas such as contracts and intellectual property (IP).

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.


TECHNOLOGY TRANSFER PROCESS
Research
Pre-Disclosure
Invention Disclosure
Assessment
Protection
Marketing to find or form a licensee
Existing Business
Form Start-up
Licensing
Commercialization
Revenue
Reinvest in Research and Education

How long does the technology transfer process take?

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

How can I help in this process?

- Call UNeMed at (402) 559-2468 when you believe you have created or discovered something unique with potential commercial or research value.
- Complete and submit the NIN form (www.unemed.com) **before** publicly disclosing your invention or submitting a manuscript for review and publication.
- To avoid risking your patent rights and possibly hindering the opportunity to market your invention, contact UNeMed **before** any form of public disclosure (seminars, publications, grants, abstracts, posters, etc.). You must avoid public disclosures or your patent rights can be lost. Fortunately, simple steps, that typically take less than a week, can protect your invention before you publish abstracts, manuscripts, or present at meetings. Call your licensing specialist before a public disclosure. We will repeat this advice again, and again.
- On the NIN Form, include companies and contracts you believe might be interested in your invention or who may have already contacted you about your invention. Studies have shown that over 70% of all licenses are executed with commercial entities known by the inventor, so your contacts can be extremely useful.
- Respond to UNeMed and outside patent counsel requests. While some aspects of the patent and licensing process may require significant participation on your part, we will strive to make efficient use of your valuable time.
- Keep UNeMed informed of upcoming publications or interactions with companies related to your IP.

10 STEPS TO COMMERCIALIZATION

1 RESEARCH: Observations and experiments during research activities often lead to discoveries and inventions. An invention is any useful process, machine, composition of matter, or any new or useful improvement of the same. Often, multiple researchers may have contributed to the invention. (Note: To protect new inventions it is critically important that research is properly documented in a laboratory notebook; following the guidelines provided on page 31.)

2 PRE-DISCLOSURE: An early contact with UNeMed personnel to discuss your invention and to provide guidance with respect to the disclosure, evaluation, and protection, processes described below.

3 NEW INVENTION NOTIFICATION (NIN): The written notice of invention to UNeMed that begins the formal technology transfer process. A NIN is confidential and should fully document your invention so that the options for commercialization can be evaluated and pursued.

4 ASSESSMENT: The period in which your UNeMed licensing associate reviews the NIN, conducts patent or other IP searches, and analyzes the market and competitive technologies to determine the invention's commercialization potential. This evaluation process, which may lead to a broadening or refinement of the invention will guide our strategy on whether to focus on licensing to an existing company or creating a new start-up.

5 PROTECTION: Patent protection, a common legal protection method, begins with the filing of a patent application with the U.S. Patent Office and, when appropriate, foreign patent offices. Once a patent application has been filed, it will typically require several years and tens of thousands of dollars to obtain issued U.S. and foreign patents. Other protection methods include copyright, trademark, trade secrets, and contractual use restrictions (e.g., for databases and materials.)

6 MARKETING: UNeMed 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 or forming a start-up. Your active involvement can dramatically shorten this process.

7a EXISTING BUSINESS: If one or more appropriate and interested existing companies are selected as a potential licensee, UNeMed works with those potential licensees to develop the appropriate financial and diligence terms to fully commercialize the technology.

7b FORM A START-UP: If creation of a new start-up has been chosen as the optimal commercialization path, founders must provide an acceptable business plan before a license is executed.

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

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

10 REVENUE: A Portion of revenues received by UNeMed from licenses are distributed to inventors according to Board of Regents Policy, and the remainder is invested to fund additional research and education and to encourage further participation in the technology transfer process.

RESEARCH CONSIDERATIONS
AND MATERIAL TRANSFER AGREEMENTS

Will I be able to publish the results of my research and still protect the commercial value of my IP?

Yes, but since patent rights are affected by these activities, it is essential to submit a NIN (discussed in next section) well before a public disclosure. There are significant differences between the U.S. and other countries as to how early publication affects a potential patent. Once publicly disclosed (published or presented in some form), an invention may have restricted or minimal potential for patent protection outside of the United States. Be sure to inform your UNeMed licensing associate of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, thesis, grant submission, publication, or other public presentation including the invention.

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

Yes, but it is important to document carefully the date and conditions of use so that we can determine if this use may influence the ownership of your subsequent research results. If you wish to obtain materials from outside collaborators, an incoming Material Transfer Agreement (MTA) should be completed. Contact UNeMed at (402) 559-2468 or unemed@unmc.edu for more information on incoming MTAs.

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

Yes. However, it is important to document items that are to be shared with others and the conditions of use. If you wish to send materials to an outside collaborator, an outgoing MTA should be completed for this purpose. It also may be necessary to have a Confidential Disclosure Agreement (CDA) completed to protect your research results or IP. Contact UNeMed at (402) 559-2468 or unemed@unmc.edu to complete outgoing MTAs or CDAs.

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

A Sponsored Research Agreement (SRA) should specify the IP rights of the sponsor. The University generally retains ownership of the patent rights and other IP resulting from sponsored research. However, the sponsor may have rights to obtain a license to the defined and expected outcomes of the research. Often, sponsored research contracts allow the sponsor a limited time to negotiate a license for any patent or IP rights developed as the result of the research. Even so, the sponsor generally will not have contractual rights to discoveries that are clearly outside of the scope of the research. Therefore, it is important to define the scope of work within a research agreement.

What about consulting?

When researchers enter into consulting agreements, they are deemed to be acting outside of the scope of their employment. Therefore, consulting arrangements are not negotiated by the University nor formally reviewed by UNeMed or UNMC. Researchers who enter into consulting agreements should familiarize themselves with the Board of Regents and UNMC policies relevant to consulting activities. The researcher is expected to ensure that the terms of the consulting arrangement are consistent with University policies, including those related to IP ownership, employment responsibilities and use of IP. UNeMed is available to provide informal advice on how your consulting agreement relates to your UNMC IP. Be careful not to advertently give up your IP rights by overly broad agreements.

NEW INVENTION NOTIFICATIONS

What is a NIN?

A NIN is a written description of your invention or development that is provided to UNeMed. The NIN should list all collaborating sources of support and include all of the information necessary to begin pursuing protection, marketing, and commercialization activities.

Based on your NIN, UNeMed may generate a non-confidential description of your invention to assist in marketing the technology. Once potential partners have been identified, and CDAs have been signed, more detailed exchanges of information can be made.

Why should I submit a NIN?

There are at least three reasons to submit a NIN. First, if you are an employee of the University of Nebraska, it is required under the terms of your employment. Second, if the research was conducted using federal funds, investigators are required to report inventions to the University, and we, in turn, are required to report to the government (failure to do so can actually jeopardize future federal funding). Finally, disclosure starts a process that could lead to the commercialization of your technology. This may involve beginning the legal protection process and working to identify outside development partners.

How do I know if my discovery is an invention?

One good measure is if you have a research finding or development that you feel may solve a significant problem. Or, perhaps it is something totally novel and not yet in the literature. If you are in doubt, contact UNeMed to discuss the invention and strategies for commercialization.

When should I complete a NIN?

You should complete a NIN whenever you feel you have discovered something unique with possible commercial value. This should be done well **before** presenting the discovery through publications, poster sessions, conferences, press releases, or other communications. Once publicly disclosed (i.e., published or presented in some form), an invention may have restricted or minimal potential for patent protection outside of the United States. Differences exist between the United States and other countries concerning the impact of early publications on a potential patent. Be sure to inform UNeMed of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal, thesis, publication, or other public presentation including the invention.

Should I report research tools to UNeMed?

Yes, if your new tools would benefit other researchers and you are interested in providing them to those researchers and other third parties. Typically, research tools are materials such as antibodies, vectors, plasmids, cell lines, mice, and other biological materials used as "tools" in the research process. Most research tools do not necessarily need to be protected by patents to be licensed to commercial third parties and/or generate revenue for your laboratory. If you have research tools that you believe to be valuable or wish to provide to others (including research collaborators), UNeMed will work with you to develop the appropriate protection, licensing, and distribution strategy.

How do I submit a NIN?

- You can download the NIN form and simple instructions from www.unemed.com.
- Submit NINs to UNeMed at zip code 6099 or email to unemed@unmc.edu.
- If you have any questions, call UNeMed at (402) 559-2468.

ASSESSMENT
OF A NIN

How does UNeMed assess NINs?

UNeMed licensing associates examine each NIN to review the novelty of the invention, protectability and marketability of potential products or services, relationship to related IP, size and growth potential of the relevant market, amount of time and money required for further development, pre-existing rights associated with the IP, and potential competition from other products/ technologies. This assessment may also include consideration of whether the IP can be the basis for a new start-up.

What happens if UNeMed decides not to protect an invention?

If UNeMed decides not to pursue patent protection and/or chooses not to actively market the invention, the inventors may request a license from UNeMed to protect/commercialize the invention themselves. Such a license may include favorable terms; however it would be limited to the current invention (not future improvements).

PATENTS
AND OTHER LEGAL PROTECTION

What is a patent?

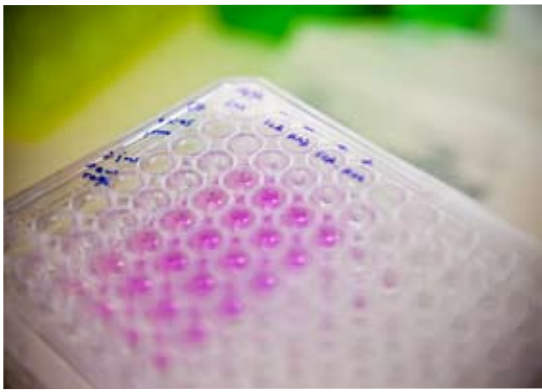
In the U.S., a patent gives the holder the right to exclude others from making, using, selling, offering to sell, and importing the patented invention. A patent does not necessarily provide the holder any affirmative right to practice an invention since it may fall under a broader patent owned by others.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

What type of subject matter can be patented?

Patentable subject matter includes processes, machines, compositions of matter, articles, some computer programs, and methods (including methods of making compositions, methods of making articles, and even methods of performing business).

Can someone patent a naturally occurring substance?

No, unless some underlying utility has been discovered. A variation of a naturally occurring substance may be patentable, however, if an inventor is able to demonstrate substantial and non-obvious modifications that offer advantages of using the variant.



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

The USPTO is the federal agency, organized under the Department of Commerce that administers patents on behalf of the government. The USPTO employs patent examiners skilled in technical fields 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 the ideas set forth in the claims section of a patent application. Thus, inventorship of a patent application may change as the patent claims are changed during prosecution of the application. An employer or person who only furnishes money to build or practice an invention is not an inventor. Inventorship is a legal issue and may require an intricate legal determination by the patent attorney prosecuting the application.

Who is responsible for patenting?

UNeMed contracts with outside patent counsel for IP protection, thus assuring access to patent specialists in diverse technology areas. Inventors work with the patent counsel in drafting the patent applications and responses to patent offices in the countries in which patents are filed.

What is the patenting process?

Patent applications are drafted by a patent attorney with an advanced degree in your field of research. UNeMed and the patent attorney may ask you to review a patent application before it is filed. At the time an application is filed, the inventor(s) will sign a Declaration indicating that they are an inventor and an Assignment, which formally assigns the application to the University. Two or three years later, the USPTO will send the patent attorney written notice as to whether the application and its claims have been accepted in the form filed. Usually, the USPTO rejects the application because either certain formalities need to be cleared up, or the claims are not patentable over the "prior art" (anything that workers in the field have made or publicly disclosed in the past). The communication sent by the USPTO is referred to as an Office Action. If the application is rejected, the patent attorney must file a written response, usually within three to six months. Generally, the attorney may amend the claims and/or point out why the USPTO's position is incorrect. This procedure is referred to as patent prosecution. Often it will take two USPTO Office Actions and two responses by the patent attorney – and sometimes more – before the application is resolved. During this process, input from the inventor(s) is often needed to confirm if the patent attorney understands the technical aspects of the invention and/or the prior art cited against the application. Patent prosecution ends when the USPTO sends notice that the application is allowable or when UNeMed and the patent attorney determine that the USPTO will not allow any subject matter.

Is there such a thing as a provisional patent?

No. However, there is a provisional patent application, which is described below.

What is the difference between a provisional patent application and a regular (or "utility") patent application?

In certain circumstances, U.S. provisional patent applications can provide a tool for preserving patent rights while temporarily reducing costs and perhaps providing extra time to prepare a regular application. This occurs because the provisional application does not need to include claims and is not examined during the year in which it is pending. A regular U.S. application and related foreign applications must be filed within one year of the provisional application to receive its early filing date. However, an applicant only receives the benefit of the earlier filing date for material that is adequately described and enabled in the provisional application. As a result, the patent attorney may need your assistance when an application is filed as a provisional.

What's different about foreign patent protection?

Foreign patent protection is subject to the laws of each individual country, although in a general sense the process works much the same as it does in the United States. In foreign countries, however, an inventor will lose any patent rights if he or she publicly discloses the invention anywhere in the world prior to filing a patent application. In contrast, the United States has a one year grace period.

Is there such a thing as an international patent?

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

What is gained by filing a PCT patent application?

A PCT patent application delays the need to file costly foreign applications until the 30 month date, often after an applicant has the opportunity to further develop, evaluate and/or market the invention for licensing.

What is the timeline for the patenting process and resulting protection?

Currently, the average U.S. utility patent application receives its first Office Action two or three years after filing and then undergoes patent prosecution for another two to three years. Once a patent has issued and all USPTO mandated maintenance fees are paid, a patent is enforceable for 20 years from its earliest filing date.

Why does UNeMed protect only some IP through patenting?

Potential commercialization partners (licensee) need patent protection to safeguard the often sizable investment required to bring the technology to market. Due to the expense and length of time required to obtain a patent, patent applications are not possible for all UNMC inventions.

Who decides what gets protected?

UNeMed considers many relevant factors when making recommendations about filing patent applications. Based on a recommendation from the licensing associate, the UNMC patent administrator ultimately makes the final decision whether to file a patent application or seek another form of protection.

What does it cost to file for and obtain a patent?

Filing a regular U.S. patent application may cost between $8,000 and $18,000. To obtain an issued patent may require an additional $12,000 to $20,000 for patent prosecution. Filing and obtaining issued patents in other countries will cost $25,000 or more per country. Also, certain maintenance fees are often required to keep the patent alive.

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

Generally, the invention will be jointly owned by the University of Nebraska and the other institution or company. Each inventor will assign his or her rights to their employer. If the co-owner is a company, UNeMed may license the University's IP rights to the co-owning company. If the co-owner is another research institution, UNeMed and the institution will decide which entity will manage and market the invention.

Will the University initiate or continue patenting activity without an identified licensee?

Often UNeMed accepts the risk of filing a patent application before a licensee has been identified. After the University's IP rights have been licensed, the licensee usually pays the patenting expenses. At times UNeMed 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 cannot be obtained reasonable claims from the U.S. or foreign patent office).

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 creators of "original works of authorship." This includes literary, dramatic, musical, artistic, and certain other intellectual works, as well as computer software. This protection is available to both published and unpublished works. The Copyright Act generally gives the owner of copyright the exclusive right to conduct and authorize various acts, including reproduction, public performance, and making derivative works. Copyright protection is automatically secured when a work is fixed into a tangible medium such as a book, software code, video, etc. In some instances, the University registers copyrights, but generally not until a commercial product is ready for manufacture.

What is a derivative work?

A "derivative work" is a work based upon one or more preexisting works, such as a translation, musical arrangement, dramatization, fictionalization, motion picture version, sound recording, art reproduction, abridgement, condensation, or any other form in which a work may be recast, transformed or adapted. A work consisting of editorial revisions, annotations, elaborations, or other modifications, which, as a whole, represent an original work of authorship, is a "derivative work." The owner of a copyright generally has the exclusive right to create derivative work.

How do I represent a proper University copyright notice?

Although copyrightable works do not require a copyright notice, we recommend that you use one. For works owned by UNMC, use the following notice: © 201X University of Nebraska Medical Center. All right reserved.

What is a trademark or service mark and how is it useful?

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

What is a trademark registration?

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

OWNERSHIP
OF INTELLECTUAL PROPERTY

What is Intellectual Property?

IP is inventions and/or material that may be protected under the patent, trademark and/or copyright laws.

Who owns what I create?

Ownership depends upon the employment status of the creators of the invention and their use of University facilities. Considerations include:

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

As a general rule, the Board of Regents owns inventions made by University of Nebraska employees acting within the scope of their employment or using University resources. In some cases, the terms of a SRA or MTA may impact ownership. When in doubt, it is best to call UNeMed for advice.

What is the University of Nebraska's policy on ownership of inventions?

The Board of Regents' Bylaw 3.10 and policies 4.4.1 and 4.4.2 address the University of Nebraska's policies regarding IP ownership and technology transfer. These regulations are available at: http://nebraska.edu/board/bylaws-policies-and-rules.html.

Who owns rights to discoveries made while I am consulting?

The ownership of inventions made while consulting for an outside company depends on the terms of your consulting contract. It is important to clearly define the scope of work within consulting contracts to minimize any issues with ownership of inventions created for University research. Don't engage in "unprotected consulting," and if you have questions, UNeMed is available for informal advice.

Should I list visiting scientists or scientists at other institutions on my NIN?

All contributors to the ideas leading to a discovery should be mentioned in your disclosure, even if they are not University of Nebraska employees. UNeMed, along with legal counsel, will determine the rights of such persons and institutions. It is prudent to discuss with UNeMed all working relationships (preferably before they begin) to understand the implications for any subsequent inventions.

Can a student contribute to an invention?

Yes, many students work on inventions at UNMC under a wide variety of circumstances. The University of Nebraska promotes student entrepreneurism, and students can be named as inventors under the Board of Regents' Policies. The Board of Regents' policies indicate student inventors are subject to the same rules and receive the same benefits as University employee inventors.

MARKETING
TO FIND A LICENSEE

How does UNeMed market my inventions?

Licensing associates use many sources and strategies to identify potential licensees and market inventions. Sometimes existing relationships of the inventors, UNeMed staff, and other researchers 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 use our website to post inventions, leverage conferences and industry events, and make direct contacts. Faculty publications and presentations are often excellent marketing tools as well.

How can I assist in marketing my invention?

First, once patent protection has been sought, publish as many papers and give as many presentations describing your invention as possible. Second, talk with your licensing associate about your research and consulting relationships.

These relationships are often helpful in both identifying potential licensees and technology champions within companies. The most successful technology transfer results are obtained when the inventor and the licensing professional work together as a team to market and sell the technology.

How are most licensees found?

Studies have shown that 70% of licensees were already known to the inventors. Thus research and consulting relationships are often a valuable source for licensees. Licensees are also identified through existing relationships of UNeMed's staff. Over time, our licensees often license more than one UNMC technology from UNeMed. We attempt to broaden these relationships through contacts obtained from website posting inquiries, market research, industry events and the cultivation of existing licensing relationships.

How long does it take to find a potential licensee?

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

Can there be more than one licensee?

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

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 inventions. Forming a start-up company is an alternative to licensing the IP to an established business. Typically, forming a company is pursued to attract capital (e.g. Investment, Small Business Innovation Research (SBIR) grants), aggregate human resources toward a common goal, and create the opportunity of equity return. A few key factors when considering a start-up company are:

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

UNeMed staff has experience with start-up companies and are happy to help you evaluate these and other factors.

What role does a UNMC inventor usually play in a company?

UNMC inventors typically serve as technology consultants, advisors or in some other technical developmental capacity. Rarely do faculty inventors choose to leave the University and join the start-up. In many cases, the inventor's role is suggested by the start-up investors and management team, who identify the inventor's best role based on their expertise and interests. As the company matures, and additional investment is required, the inventor's role may change. Faculty involvement of any kind in a start-up is also reviewed by a UNMC Conflict of Interest Committee. Student inventors and post-docs may choose to join the start-up upon graduation but rarely have the experience or business skills to serve as the company's sole management.

How much time, money and effort does it take to form and operate a start-up company?

Starting a company requires a considerable amount of time, money and effort. Having a management team experienced in business is of critical importance. Until the start-up team is identified and engaged, the faculty member will need to champion the formation effort. After the team is in place, effort is required for investor discussions, formal responsibilities in or with the company, and University processes such as conflict of interest reviews.

Can UNeMed accept equity in the start-up company?

UNeMed can accept equity as part of the financial terms of the license. Equity may be substituted for other case considerations that are often difficult for a start-up. It is also a way for UNeMed to share some of the risk associated with the start-up. A decision to take equity must make sense for both UNeMed and the company.

Will the University pay for incorporating a start-up company?

No. As a separate entity, the start-up should pay for its own legal matters, including all business incorporation matters and licensing expenses.

What legal assistance is needed in creating a start-up?

In addition to corporate counsel, the start-up may need its own IP counsel to assist with corporate patent strategy, especially if the company will be involved in a patent-rich area. The start-up's counsel must be separate from University counsel, though it is advisable and recommended that the corporate IP counsel and the University's patent counsel coordinate activities. Also, it is wise for investors to have agreements regarding their roles with the start-up reviewed by their own counsel to ensure that all personal ramifications – including taxation and liabilities – are clearly understood.

LICENSE AGREEMENTS

What is a license?

A license is a permission that the owner or controller of IP grants to another party, usually under a license agreement.

What is a license agreement?

License agreements describe the rights and responsibilities related to the use and exploitation of IP developed at the University. University license agreements usually stipulate that the licensee should diligently seek to bring the IP into commercial use for the public good and provide a reasonable return to the University.

How is a company chosen to be a licensee?

A licensee is chosen based on its ability to commercialize the technology for the benefit of the general public. Sometimes an established company with experience in similar technologies and markets is the best choice. In other cases, the focus and intensity of a start-up company is a better option.

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

Per University policy, one third of the net proceeds from a license are provided to the inventor(s). For more information, review the Board of Regents policy 4.4.2 at http://nebraska.edu/board/bylaws-policies-and-rules.html or UNMC's Policy for Royalty and Equity Distribution at http://www.unmc.edu/dept/policy. Most inventors enjoy the satisfaction of knowing their inventions are being developed for the benefit of the general public. New and enhanced relationships with businesses are another outcome that can augment one's teaching, research and consulting. In some cases, additional sponsored research may result.

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

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

What other types of agreements and considerations apply to technology?

CDAs and Non-Disclosure Agreements (NDAs) are often used to protect the confidentiality of an invention during evaluation by potential licensees. CDAs and NDAs also protect proprietary information of third parties that University researchers need to review to conduct research or evaluate research opportunities. UNeMed enters into CDAs for UNMC proprietary information shared with someone outside of the University of Nebraska system.

- MTAs, used for incoming and outgoing materials at the University. These agreements describe the terms under which UNMC researchers and outside researchers may share materials, typically for research or evaluation purposes. IP rights can be endangered if materials are used without a proper MTA.

- Inter-Institutional Agreements describe the terms under which two or more institutions (generally two universities) will collaborate to assess, protect, market, license, and share in the revenues received from licensing jointly owned IP.

- Option Agreements, or Option Clauses within research agreements, describe the conditions under which UNeMed preserves the opportunity for a third party to negotiate a license for IP. Option clauses are often provided in a SRA to corporate research sponsors or Option Agreements are entered into with third parties wishing to evaluate the technology prior to entering into a full license agreement.

- SRAs describe the terms under which sponsors provide research support to the University.

COMMERCIALIZATION

What activities occur during commercialization?

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

What is my role as an inventor during commercialization?

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

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

Most licenses have licensing fees that can be very modest (for start-ups or situations in which the value of the license is deemed to warrant a modest license fee) or can reach hundreds of thousands of dollars. Royalties on the eventual sales of the licensed products can generate revenues, although this can take years to occur. Equity, if included in a license, can yield returns, but only if a successful equity liquidation event (public equity offering or a sale of the company) occurs. Most licenses do not yield substantial revenues. A recent study of licenses at U.S. universities demonstrated that only 1% of all licenses yield over $1 million. However, the rewards of an invention reaching the market are more significant than the 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.

NAVIGATING CONFLICT OF INTEREST

How does the University define a conflict of interest?

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

When should I seek guidance on conflict of interest?

Whenever a question of uncertainty arises, you should seek guidance from your Sponsored Programs Administration (SPA) representative for research-related issues and/or your UNeMed licensing associate for license-related issues. There are two times in particular when guidance is required: when research proposals are submitted to external sponsors (SPA) and when a license, option or MTA is being considered with a company in which the faculty member, or any university employee, has an equity or management interest (UNeMed). UNMC's Conflict of Interest Policy is located at http://www.unmc.edu/dept/policy.

What kinds of issues concern conflict of interest reviewers?

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

What are examples of a conflict of commitment?

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

REVENUE DISTRIBUTIONS

How are license revenues distributed?

UNeMed is responsible for managing the expenses and revenues associated with technology agreements. Per the University of Nebraska Technology Transfer Policy (Regents' 4.4.2), one third of all net proceeds are shared with inventor(s).

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

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

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

After a license agreement is signed, the inventors enter into a Royalty Sharing Agreement (RSA) and file the original agreement with UNeMed. Once UNeMed receives net proceeds, UNeMed follows the RSA to distribute the inventor proceeds. If UNeMed does not receive an RSA from the inventors before net proceeds are received, then UNeMed distributes the inventor proceeds equally amongst the inventor(s).

What is a Royalty Sharing Agreement?

A Royalty Sharing Agreement is a formal document signed by each inventor of one more technologies included in a license. The RSA spells out how inventor proceeds from the license will be distributed by UNeMed between the inventors.

LABORATORY NOTEBOOK
GUIDELINES

The laboratory notebook is a critical document for both scientific and legal reasons. The proper recording of your ideas and accurate dating of when they occurred is the first step toward ensuring their protection. The notebook provides a permanent record detailing what experiments were conducted during the study and what inventions were made and when. The two most important events that should be documented in the notebook are 'conception' and 'reduction to practice'. In general, a sketch and/or a brief written description are enough to establish proof of conception. Reduction to practice is detailed during the actual experimental process and successful testing of a device or idea. Records must be sufficiently detailed and clear to allow someone skilled in the art to recreate the work and to conduct additional work without any assistance from the original scientist. Vague entries, those entries that require interpretation by the original scientist and entries that do not include a date do little to prove conception or reduction to practice.

The annotated notebook page that follows shows the main details (listed below) that should be included in a laboratory notebook to provide the best documentation for inventions.

- Notebook number, page, date and project, signed and witnessed (1, 14, 17, 18, 19)
- Organized and legible entries (in ink - blue preferred) (2, 10)
- Defined and referenced abbreviations and designations (3)
- Detailed methods (4)
- Referenced methods (5)
- Identified suppliers (6)
- Well known abbreviations do not need to be defined (7, 15, 16)
- Single line initialed corrections (8, 9)
- Raw data identified and included (11)
- Results of the experiment included (12)
- Blocked out blank regions (13)
- Abbreviations not common should be defined (15, 16)

434 (1)
Continued from Page 3 PROJECT: TAT3 Blockers Page 4 DATE: Jan. 3 1996

Title: Inhibition of MabTat3 binding by test compounds ANTAT3-1 and ANTAT 3-10

(2)
Purpose: To test compounds (3) ANTAT3-1 and ANTAT3-10 for their ability to competitively block antibody binding to TAT3. As described (nbk. 425, p.1). We have isolated a cell surface molecule, TAT3, involved in spermatozoa maturation and development. Monoclonal antibody MabTAT3 binds TAT3 with high affinity. Testing and preparation is described in nbk. 426, pp 67-92. TAT3 is characterized in nbk. 425, pp. 5-32. The preparation (5) id initial screening of ANTAT3-1 and ANTAT3-10 is described in nbk. 432, pp. 1-22.

(6)
Methods: ATCC cell line 7456A was cultured and plated (10^4 cells/well) in 35-mm^2 wells and grown to confluency. Culturing conditions are described in (4) 425, p. 3. ANTAT3 1 and ANTAT3-10 were diluted in HBSS (GIBCO) in 10-fold dilations ranging from 4 x 10^{-3} ug/mL to 40 ug/mL. MabTAT3 was dilut (7) from from a stock solution of 25 ug/mL and used at between 0.05 ug/mL to 10ug/mL 15ug/mL obtained from MLP. (15)

(10) (8) 10ug/mL MabTAT3 JCL 1/4/96 not all reagents (9)
Samples were distributed in the cells samples as diagrammed on page 5. Cells were incubated for 2 hours 37 C and harvested and lysed as described (nbk. 426, p. 140)
MabTAT3 bound to 7456A-cells was quantitated by modified ELISA described in nbk. 432, p. 80.
Raw data are proved on p. 6. (11)

(12)
Results: The experiment failed, no ANTAT3-1 or ANTAT3-10 binding was detected in any of the wells except at the highest doses, but I think this is an artifact.

(13)

(14)
1/3/96 Title: Ability of ANTAT3-1 (16) d ANTAT3-10 to inhibit spermatozoa maturation in mice.
Method: BalbC mice were injected i.p. with 0.5 mL of a 1-mg/ul solution of

Work continued to page 5

SIGNATURE: Julie Lawson	DATE: January 3, 1996 (17)
READ AND UNDERSTOOD BY: Mark Folger (18)	DATE: March 10, 1996 (19)
READ AND UNDERSTOOD BY:	

NOTES

This booklet is based on the University of Michigan's "Inventor's Guide to Technology Transfer," with adaptations for the University of Nebraska Medical Center and UNeMed. We are extremely appreciative of Ken Nisbet, Robin Rasor, Mark Maynard, and the rest of the staff of the U-M Office of Technology Transfer for their kind permission to use their excellent material and to the University of Michigan for permission to use its copyright. We would also like to thank Madison Area Technical College, Lisa Seidman and Jeanette Mowery, for use of their Annotated Laboratory Notebook page.

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