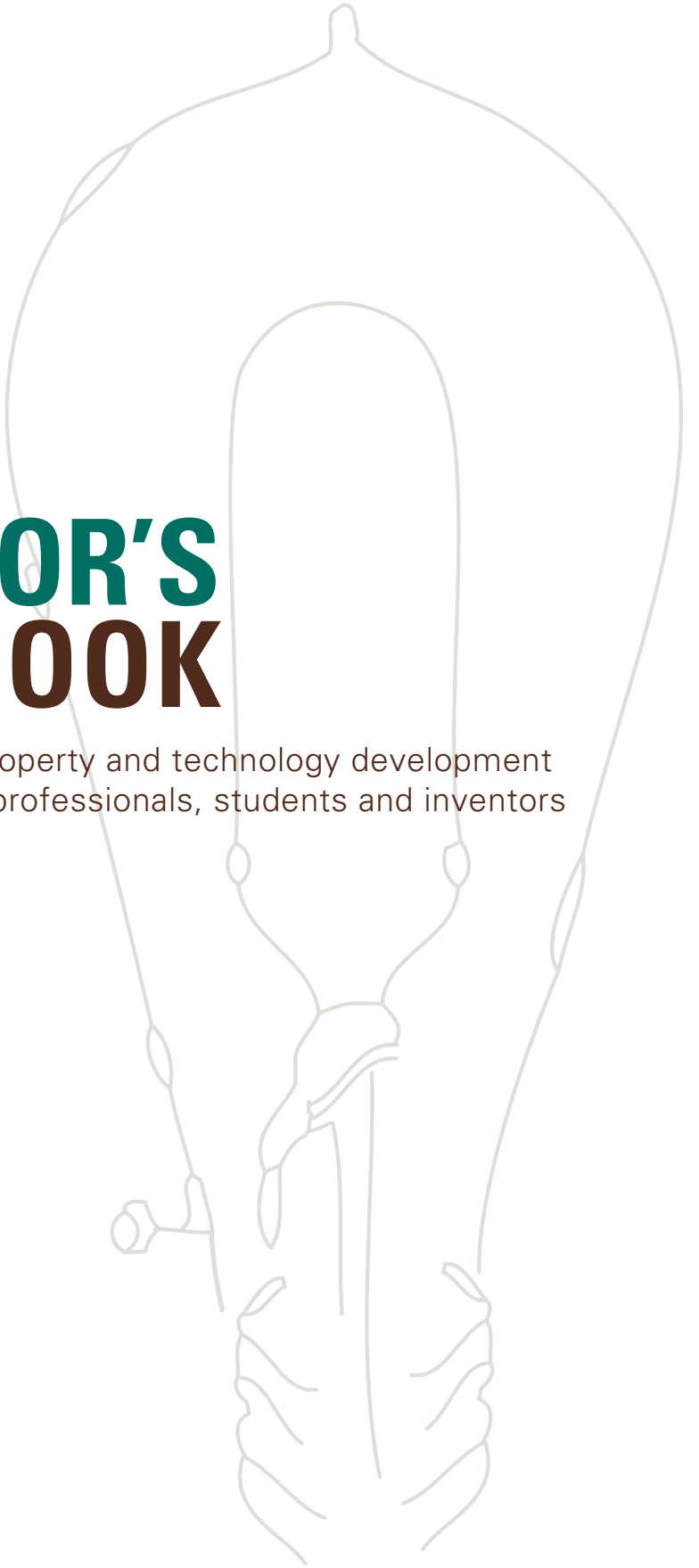
THE INVENTOR'S HANDBOOK

a guide to intellectual property and technology development for physicians, medical professionals, students and inventors



WESTERN MICHIGAN UNIVERSITY
Homer Stryker M.D.
SCHOOL OF MEDICINE

INNOVATION CENTER

The Innovation Center on the medical school's Parkview Campus is a 69,000-square-foot, purpose-built incubator and accelerator created to support life science, technology, and engineering ventures of all kinds, from the earliest startups to maturing companies. With access to specialized equipment, flexible lease terms, and the ability to grow or contract as needed in a fully managed facility, you can focus on your business without unexpected hassles or expense.

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Together, we make life better for our patients and the world

The mission of Western Michigan University Homer Stryker M.D. School of Medicine (WMed) is to educate and inspire lifelong learners to be exceptional clinicians, leaders, educators, advocates, and researchers of tomorrow.

One way in which we do this is by fostering inquiry, research, and scholarly activities for faculty, students, and staff. As we see it, a good idea can come from anywhere whether it is a surgeon developing a new instrument, a biostatistician designing a novel database interface, or a research scientist discovering a new cancer therapeutic.

Basic medical research that advances human knowledge is valuable in and of itself. But when that medical research results in new technologies that can save lives and ease human suffering, it is even better. At WMed, we want to discover those innovative technologies and help them find a path to market. The way we do that is through technology transfer.

This handbook is designed to serve as a guide for physicians, medical professionals, students, and inventors interested in developing intellectual property. From fostering ideation to supporting creation to managing deal negotiation, WMed can help turn ideas into commercial opportunities. Together, we commercialize to make life better for our patients and the world.

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SECTION 2: Identifying Intellectual Property

Intellectual property encompasses all forms of intangible creations of the human intellect such as inventions, software, discoveries, creative or artistic works, know-how, processes, and unique materials.

Examples of intellectual property include devices, chemical compounds, biological materials, machines, instruments, computer programs, algorithms, circuits, books, videos, photographs, paintings, sculptures, songs, and more.

As a business asset, intellectual property can be protected by law through patent, copyright, trademark, and trade secrets. A single piece of intellectual property may utilize multiple forms of protection. For example, computer software can be protected by copyright, patent, trade secret, and trademark. Agreements which control access and use of intellectual property are also protection mechanisms.

Patent

Patent law derives from the Constitution, which recognizes the need to reward the efforts of inventors by protecting their inventions for the purpose of advancing science and technology for the common good. A patent grants an inventor rights for a limited time to exclude others from making, using, importing, or selling the invention. Typically, exclusive patent rights are granted to the inventor for 20 years. Generally, it takes 3 or more years for a patent to issue.

Trademark TM

Trademarks are the names, logos, and tag lines that consumers use to identify your goods and services. A strong trademark quickly and easily identifies your unique business to your customers. Over the life of a business, trademarks are often the most valuable intellectual property assets. Protecting your trademark is an important step in establishing your brand.

Copyright ©

A copyright is a form of protection provided by the laws of the United States for "original works of authorship", including literary, dramatic, musical, architectural, cartographic, choreographic, pantomimic, pictorial, graphic, sculptural, and audiovisual creations. "Copyright" literally means the right to copy but has come to mean that body of exclusive rights granted by law to copyright owners for protection of their work.

Trade Secret

Trade secrets protect the valuable confidential aspects of your business, such as a formula, technique or process, by simply not disclosing information to the public. When your valuable business information is difficult to reverse engineer, your best protection may be to take steps to maintain its secrecy through a well-drafted confidentiality and non-disclosure agreement. A significant benefit of trade secrets over utility patents is that trade secrets last as long as you are able to keep the information secret, whereas patents expire 20 years from their filing date.

SECTION 3: Defining Technology Transfer

In the most general sense, technology transfer is the transfer of knowledge, ideas, discoveries, and innovations to the public.

There are many ways to accomplish this, including publication, student graduation and employment, participation in scientific meetings, collaboration with industry, and licensing innovations. For the purposes of this handbook, technology transfer is the evaluation, protection, marketing, and licensing of intellectual property to start-ups and existing companies.

While we use the terms technology and intellectual property (IP) interchangeably, there are subtle differences between the two. Technology is a type of intellectual property and typically refers to commercially useful intellectual property.

The Bayh-Dole Act

Adopted in 1980, the Bayh-Dole Act was established to promote economic development by allowing small businesses and non-profit organizations (including academic institutions) to own inventions made under federally-funded research programs. Prior to the enactment of Bayh-Dole, the U.S. government had accumulated 28,000 patents, but fewer than 5% of those patents were commercially licensed. Under the Act, control of federally funded inventions was ceded to the institution or company receiving a grant, with certain responsibilities to the government, the inventor, and the public. In regards to academic institutions, these responsibilities include:

- Responsible for the management of inventions in compliance with the terms of the Bayh-Dole Act
- Expected to file patent applications on inventions they elect to own
- Encouraged to collaborate with commercial entities through licensing, to promote the utilization of inventions arising from federal funding
- Expected to give licensing preference to small businesses

The Bayh-Dole Act is the basis of most academic technology transfer activities. The government retains certain rights which include requiring use of licensed inventions to prevent sequestering, requiring U.S. manufacture for exclusive licenses, and retaining non-exclusive rights for government purposes.

Benefits of Technology Transfer

- Leverages WMed's technologies to benefit society
- Strengthens WMed's education and research programs
- Assists in recruiting and retaining faculty, staff, and students
- Supports the growth and development of the Michigan and U.S. economies
- Builds enduring connections between WMed, industry, and public agencies

Commercializing Your Invention

Commercialization of discovery and innovation ensures that others will benefit from your research and development. Technology Transfer is the movement of knowledge and discoveries from the minds of those who have created it to the hands of the general public. It is the formal licensing of technology to third parties, under the guidance of professionals knowledgeable of the technical subject matter and the activities of commercialization.

The Office of Technology Development (OTD) (med.wmich.edu/OTD) manages the intellectual property of WMed, including marketing and licensing inventions. We assist investigators in transitioning their technologies from compelling research results to technology that has commercial value.

We provide numerous services to WMed personnel that otherwise would be done at the inventor's own time and expense, including:

- Assessment of patentability of discoveries or ideas for research
- Filing of patent applications
- Preliminary market research and analysis (market size, competition)
- Facilitating collaborations (identifying external expert R&D partners, legal agreements)
- Facilitating funding
- Marketing of inventions
- Licensing
- Revenue distribution
- Contract management

Maintaining realistic expectations is important. Although your intellectual property may appear unique and valuable to you, the commercial application may not be as apparent, or the applicable market may be too small to justify the investment of WMed resources. Also, it is sometimes difficult to obtain a patent and subsequently attract the interest of companies or investors willing to commit resources to commercialize the technology. Although a great deal of time and money may be invested into your invention, it may not be commercialized for a varied number of reasons beyond the control of the inventor or the OTD.

SECTION 4: Getting Started with Invention Disclosure

When is the right time to complete an IP Disclosure Form?

Contact the OTD when you believe you have a scientific or technical discovery with potential for partnering or commercial development, and well before publicly disclosing your observations or publishing a manuscript. Federal grants require disclosure of inventions conceived or reduced to practice during the course of work under a grant or federal award through submission of a Final Invention Statement (HHS Form 568) upon closeout. Inventions disclosed to OTD prior to grant closeout must be disclosed to the Federal government within 60 days. OTD will be alerted by Sponsored Program Administration (SPA) of any inventions disclosed through this process. OTD recognizes that publishing and scientific discussion are of paramount importance, and when addressed at an early stage, IP can be protected while these activities proceed unfettered. After you report your invention to us, we evaluate it for patentability and marketability.

Why is reporting important?

Reporting your invention is vital to the protection of a valuable intellectual asset. With proper safeguarding, your invention can be developed to its fullest capacity. If this step is not taken, it is unlikely that the invention will be commercialized so that it can provide its maximum benefit to society. In addition to initiating commercialization, reporting inventions is the crucial first step to required reporting of new inventions arising from federal or private-sponsor funding.

Intellectual Property Disclosure Form

The invention disclosure process begins when an Intellectual Property Disclosure Form (IPDF) is submitted. We will contact you to assure all essential aspects of your invention have been understood and conveyed. Following this discussion, the IPDF review will proceed to determine whether WMed will accept the invention for patenting. There are some characteristics that are often present in inventions that are ready for commercialization, including:

- Improvement over Existing Practice or Standard of Care — the technology is an improvement in care or value
- Need Fulfillment — there is an unmet need this technology addresses
- Technical Feasibility — technology can be readily developed with minimal existing resources or funding and may provide a platform for further advances or indications
- Commercialization Entry — minimal regulatory and development hurdles
- Scientific Merit — field is well characterized; need widely acknowledge; and literature supports the approach proposed by the technology; there is no literature describing the technology itself
- Ease of Implementation — fits into widely accepted practices and supports readily available ancillary technology
- Competitive Product Advantage — technology characteristics would be deemed clearly superior to existing products
- Likelihood of Peer Adoption — technology could result in widespread adoption and recognition as state-of-the-art; advantageous, value-basis
- Stage of Development — prototype produced and tested; identified commercial interest; clinical data

Tips for Tackling the IPDF

Your project description should contain the aspects of the invention which differentiate it from current technology in terms of performance, capability, or operation. Focus on the problem being solved and the benefits of a new compound, device, or approach. Write in simple language, avoiding acronyms and jargon.

Throughout the application, cover as many of the points listed below as applicable.

- Fully disclose all aspects of the invention; please highlight the novel and non-obvious features of the invention.
- Technically describe the invention. Identify it as a process, machine, manufacture, composition of matter, or as an improvement thereof.
- List possible variations and modifications within the scope of the invention.
- Cite examples of different embodiments of the invention.
- Emphasize the best mode of employing the invention.
- Disclose the invention completely so that others, with similar skills and experience, could replicate the invention.
- Describe the invention in terms of competing technologies.
- For software disclosures, identify any code not developed by the individuals listed. Indicate if the code is dependent on other files, libraries, etc.

When listing dates in you IPDF, include when (if) the following have occurred:

Event:	Description
Initial Idea	The first time an inventor thought of the initial concept embodied by the invention.
Fully Developed Invention, Conception	Record the date the complete and permanent mental idea of the invention is completed so that nothing but reducing the invention to practice is left.
Physical Reduction to Practice	First time the embodiment of the invention occurs by creation of some construct or compound. A physical model or demonstration of the invention.
First Public Disclosure	Date the public could access an enabling disclosure of the invention. Proposals to government agencies which are not subject to further publication are not considered public disclosures. Journal articles, conference talks, and thesis publications are examples of public disclosures.
Planned Future Public Disclosure	If public disclosure has not yet occurred, please list the earliest date such disclosure might occur.

If you are unsure if the time is right to complete an IPDF, contact the OTD and ask. It is never too soon to have a discussion. IP Disclosure Form: https://bit.ly/2LV8sws

SECTION 5: Assessing Commercial Considerations

A critical part of the disclosure process involves helping the OTD make the best possible commercial evaluation of your invention. You know your technology and are likely in the best position to define your invention's economic domains and commercial advantages. As you complete the IPDF, please consider in detail the commercial advantages and applications of your discovery.

Does the invention offer improved performance?

Does it save operating costs or will it replace a more costly technology?

What are the benefits over existing products to the buyer, the user, or the manufacturer?

What companies may be interested in a license?

Regardless of technical merit, an invention cannot be effectively licensed without commercial advantages. These advantages must be significant enough for a company to take the risk and commit the resources necessary to commercialize the invention.

SECTION 6: Public Disclosure

As soon as you tell someone about your intellectual property, patent rights can be lost. Once an invention has been disclosed through a publication, conference presentation, poster session, job talk, or other presentation to non-WMed participants, the possibility of patent protection can be significantly limited.

Although not an all-inclusive list, the following activities constitute a public disclosure and should be avoided until you have secured your intellectual property. When in doubt, inventors are encouraged to contact OTD for initial review to avoid forfeiture of patent rights.

- Publishing an article or abstract
- Sharing relevant details with external parties about the invention without a Confidentiality Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA)
- Participating in a poster presentation, providing a Power Point presentation, or giving a talk at a scientific meeting
- Sharing/transfer of scientific materials with/to outside parties without a Material Transfer Agreement (MTA)
- Posting messages on the Internet describing the invention
- Receipt and close-out of a government grant/contract under the Freedom of Information Act

Disclosure to WMed does not constitute public disclosure. Also, simply telling a colleague that you have made an invention but not telling how to make or use it is usually not considered a disclosure that could prevent you from obtaining a patent. Be aware that disclosing your invention to WMed, though confidential, does not protect your IP. Disclosure to anyone outside of WMed prior to the filing of a patent application, without a confidentiality agreement, could result in the loss of patent rights.

Special care should be taken when describing your invention in grant applications. Some of the federal agencies will publish abstracts of successful grant applications. You may want to avoid disclosing details of the invention in the abstract. It is best to notify OTD regarding any grant applications and request appropriate actions (i.e., submitting a patent application prior to publishing the abstract).

For grant applications to private foundations or companies, it is important to review the intellectual property section of the grant document. Some of the foundations or companies may require the IP to be assigned to the granting agency. It is important to bring this to the attention of OTD.

SECTION 7: Understanding Inventorship

Inventorship is governed by a precise legal definition, unlike authorship, which is determined by looser guidelines. An inventor is someone who actually conceives an invention.

An inventor is not someone who reduces the invention to practice, unless conception also occurs during the reduction. You cannot name someone as an inventor on a patent unless they meet specific criteria. You cannot add them just to "be nice" or because they "helped."

Conception

Conception refers to the earliest date that the invention is shown to have been completely formed in the mind of the inventor. Conception is established when the invention can be described in a manner which would enable someone skilled in the art to practice the invention without significant further experimentation.

Reduction to Practice

Reduction to practice is the physical aspect of the inventive process. Reduction to practice can occur in two ways. In actual reduction to practice, the invention is constructed, tested, and shown to work for its intended purpose. The date of constructive reduction to practice is the filing date of a patent application that describes the invention in such detail as to enable a person of ordinary skill in the art to practice the invention.

Inventor(s)

An invention can be the product of a sole inventor or joint inventors. Each person who contributed to the conception of an invention is considered an inventor. Inventors contribute factually to the element of the patent, called claims. An inventor should be able to look at the claims of the patent application and indicate with specificity which claims represent their inventive contribution.

In some cases, problems or issues arise during reduction to practice causing the invention not to work as intended. A technician may devise a way to work around this problem, or develop a better solution than was originally conceived. In some cases, the technician may be an inventor if it is shown that the invention was incomplete without the technician's contribution.

Inventorship Analysis

A patent application must be filed in the names of the true inventors as defined by U.S. patent law. Broadly, an inventor is one who alone or together with others conceived the ultimate working invention. Inventorship is not a reward for hard work to someone who only worked under direction. Inventorship is tied to the claims in a patent application and is determined at the time the patent application is filed. As the claims in an application change, so may inventorship. Failure to name all who meet the legal criteria for inventorship, or to include those who do not meet these standards, may cause a patent to be invalidated. For patent applications submitted by WMed, inventorship will be determined by a patent attorney, NOT WMed or the OTD, based on contribution to the invention.

Statement of Ownership Rights

Inventorship does not equal ownership. In most cases, organizations own the inventions developed by their employees. WMed owns all intellectual property created by any employee in the performance of employee duties at the WMed or created by anyone, including students and others, using WMed facilities, equipment, or funds. Per WMed's IP Policy, in the event that WMed receives revenue from WMed Intellectual Property, net income (after subtraction of certain costs) will be divided as follows:

- To the Inventor or Inventors (in the event there is more than one Inventor) — 30%. In the event there is more than one inventor, all royalties shall be split evenly among the partner investigators unless otherwise agreed to by the inventors and through formal approval of the WMed IP Committee.
- To a WMed account for the inventor to support his or her research. — 20% (for 3 years. After 3 years, the 20% goes to the Office of the Associate Dean for Research (OADR) as the administrative support for technology transfer efforts and continued research funding)
- To the Inventor's designated WMed department — 15%
- To the WMed general fund — 35%

Inventors must disclose to OTD all WMed Intellectual Property produced by them. Inventors cannot assign, or license rights in Intellectual Property to third parties without the written consent of WMed.

SECTION 8: Making Patentable Material

Utility patents are awarded to inventions that are new and useful including:

Process

A process is a method of doing something to produce a result, e.g. a method to detect cancer cells in blood.

Machine

A machine is a device that does something. It usually has moving parts. A machine can be patented independently of the product it produces or acts upon, e.g.: a musculoskeletal vibration system for jointed limbs.

Manufacture

A manufacture includes anything that is made by humans or by a machine. This class of utility patents includes inventions which aren't easily placed into the other categories, e.g.: a genetically modified bacterium able to break down oil.

Composition of Matter

A composition is a combination of two or more materials or chemicals into a new product, e.g. a new drug molecule (as when Romanian chemist Lazr Edeleanu first synthesized the molecule amphetamine in 1887) or combination of molecules (the drug Adderall which is a mixture of different amphetamine salts).

Design Patent

Design patents are awarded for new, original, and ornamental design of an article, such as furniture designs or toys.

Plant Patent

Plant patents are awarded for asexually reproduced, distinct, and new varieties of plants not found in the wild (excluding tubers, e.g. potatoes). An example is new citrus cultivars.

SECTION 9: Meeting Basic Patentability Requirements

Much research conducted at WMed can lead to inventions that may be patentable. A few examples are:

- **Engineering:** laboratory instruments, diagnostic tools, and medical devices
- **Biotechnology:** genetic promoters, genetic markers, gene transfer methods, expression vectors, and microorganisms
- **Chemistry:** new compounds, new drugs, drug targets, drug design, and separation methods
- **Software and Algorithms:** methods and processes in computer programs, operating systems, networking, data mining and storage, security, and supercomputing

An invention is a device, method, composition, or process made by man, as long as it is new, useful, and not obvious. Inventions may include many types of discoveries and technological innovations such as processes, methods, machines, articles of manufacture, devices, chemicals, and compositions of matter. In order for an invention to be patented it must first be conceptualized and reduced to practice, or described with detailed drawings, procedures, and instructions. The heart of a patent is the detailed information that allows others to make the invention. Think of a patent as an instruction manual. Inventions can be protected by patents, ideas cannot.

In addition to falling within one of the patentable materials described in Section 8 (Making Patentable Material), an invention must also be shown to have the attributes of usefulness, novelty, and non-obviousness.

Usefulness

The characteristic of usefulness is typically the easiest of the three requirements to demonstrate. To be useful an invention must have a purpose and work as intended. It must be of some benefit to humanity, even if that benefit is to amuse or entertain. Demonstrated benefit in animals, even in the absence of demonstrated benefit to humans, meets the usefulness criteria. However, inventions for atomic weapon production are not patentable. It is very important to note that new uses or improvement of existing products/inventions can be patented as long as the new use represents a significant change from the original intent.

Novelty

Novelty is the easiest attribute to lose through publicly disclosing your invention before you have protected it. An invention must be novel (new), useful, and non-obvious in order to be granted a patent. The invention can't be prior art, which includes anything found in printed media or described in a patent application. If the invention is deemed prior art, the submitted patent cannot be protected.

Non-Obviousness

Non-obviousness is the least straightforward of the three basic requirements. It essentially asks whether the combination of technologies that created this invention would be obvious to someone who understands the technical field. Even if you think your invention may be obvious please talk with OTD first.

SECTION 10: Reviewing Prior Art

The standard for determining novelty and non-obviousness is a review of the "prior art." Prior art generally refers to other patents, printed publications and disclosures which are in the public domain at the time of the discovery.

To be considered novel, an invention or discovery must not be described in the prior art; to be non-obvious, an invention or discovery must not have been apparent to a person of ordinary skill in the art (someone familiar with the field of study).

At WMed, the library staff is available to assist you with basic patent and prior art searches (http://med.wmich.edu/library). The inventor is expected to perform the initial patent and prior art searches as part of completing the IPDF. This basic information must be provided to the OTD as a starting point for its more detailed assessment.

Patent Application Prosecution

If a technology is accepted for patenting, patent attorneys are selected by the OTD based on their corresponding technical expertise. After a final review by the inventors, a patent application is submitted to the patent office.

As the owner of the intellectual property, WMed will prosecute the application at its discretion, but will consult the inventors regarding technology issues. WMed will pay the patenting costs associated with the development of a commercially viable invention. Filing of foreign patent applications will be undertaken only after careful evaluation of the technology and its potential market value due to cost considerations.

SECTION 11: Contributing to the Patent Application Process

WMed may choose to protect intellectual property with patents and copyrights. A patent is a written document published by the United States Patent and Trademark Office (USPTO) and is accessible to the public. It includes a specification (description), drawings (invention illustrations/figures), and claims of the invention (discovery). The patent claims distinctly state and define the scope of the patented rights.

Not infrequently, two entirely different groups invent the same or very similar inventions. What happens then? In most of the world, including the U.S., the first inventor to file a patent application is entitled to the patent. This is referred to as a first-to-file system. Prior to March 2013, U.S. patent law held that the inventor who could document that he or she was the first to conceive an invention was entitled to a patent. This is referred to as a first-to-invent system. The America Invents Act changed the U.S. patent system from first-to-invent to first-to-file. To help avoid losing patentability due to public disclosure or not filing first, contact the OTD as early as possible in the invention process.

Provisional and non-provisional patents are the two first steps in the application for a utility patent.

Provisional Utility Patent (cost of $4-6K)

A provisional utility patent is often filed prior to the non-provisional utility application as a placeholder to secure an earlier patent filing date. This type of application does not require claims, is not examined, and becomes abandoned unless it is converted to a regular U.S. application or a Patent Cooperation Treaty (PCT) application within one year of filing. This one year period allows time for further evaluation of the market potential and licensability of the technology. Approximately nine months after a provisional patent application is filed, WMed's OTD will make a decision on whether to file a utility patent. (Provisional applications for patent may not be filed for design inventions.)

Non-provisional Utility Patent (cost of $18-30K)

This is the most common type of patent filed and issued. A non-provisional utility patent application includes specifications describing how to make and use the invention and one or more claims that define the scope of what is new about the invention. The claims are used by courts to determine invention infringement. This application is filed in the USPTO and assigned to a patent examiner who specializes in the particular technology area. The examiner considers the scope or breadth of the claims against prior patents and publications. They then issue an office action accepting (rarely) or rejecting (typically) the claims (some or all) as not distinguishing over what is already known. In the case of claim rejections, the patent attorney, with the assistance of the inventor, rebuts the examiners' arguments and/ or responds with modifications (amendments) to the claims. Two to three iterations are typically required to obtain allowance of the patent application. Once issued, generally a patent has a life of 20 years from the filing of the first regular patent application. In the U.S., maintenance fees are required at 3½, 7½, and 11½ years to keep the patent in force.

Patent Pending

Patent pending is the term used to describe a patent application that has been filed with the patent office, but has not been issued as a patent. Marking an invention "patent pending" puts the public on notice that the underlying invention may be protected and that copyists should be cautious. Any applicant who has a non-expired provisional application or a pending non-provisional application can indicate that the related subject matter is "patent pending".

Foreign Patent Applications

A Patent Cooperation Treaty (PCT) application is an international place holder application filed in the home country of the inventor that reserves the right to file in the U.S. and many foreign countries at a later time. Just like provisional applications, PCT applications will never issue as a patent and will become abandoned if they are not converted to regular applications in the U.S. and each foreign country in a timely manner.

For the majority of inventions reported to WMed, only U.S. patent protection is considered. Foreign patent applications are prohibitively expensive and often difficult to market. However, this decision is made on a case by case basis and careful consideration is given regarding foreign markets and potential for revenue generation.

Unpatentable Inventions (Subject Matters)

In addition to tuber plants and inventions useful solely for atomic weapons, listed below are types of inventions (subject matters) that are generally not patentable:

- Laws of nature (e.g.: Newton's laws of motion)
- Natural phenomena (e.g.: metabolism)
- Naturally occurring articles (e.g.: DNA)
- Abstract ideas (e.g. the business of health insurance)
- Mathematic algorithm (the mathematic formula - "1+1 = 2" is not patentable as this is widely used. The algorithm is patentable if it is confined in a context, in conjunction with a physical matter such as a novel way to operate a surgical robot)

Patents & Freedom to Operate

Having a patent doesn't necessarily mean you have the right to practice your invention and make products covered by it. Commercializing a technology can involve many processes, methods, and materials that may not be covered under your patents, but may be covered under patents owned by others. The owners of these other patents may have the right to stop you from commercializing your invention unless you obtain their permission to practice under their patents. Obtaining rights to all the intellectual property needed to commercialize a technology without infringing the intellectual property rights of others is called freedom to operate. A Freedom to Operate Opinion Letter is another legal document that is often secured, especially if investors are involved. These FTO letters are quite expensive, often in the neighborhood of $50,000.

SECTION 12: Marketing & Licensing

Inventions accepted by WMed will be managed by the OTD. Most often, active marketing and licensing begins when a patent application has been filed with the USPTO. The OTD may use one or several methods to license your technology, including:

- Direct personal contacts
- Direct marketing and technical presentations to targeted companies
- WMed website
- Conferences and trade shows

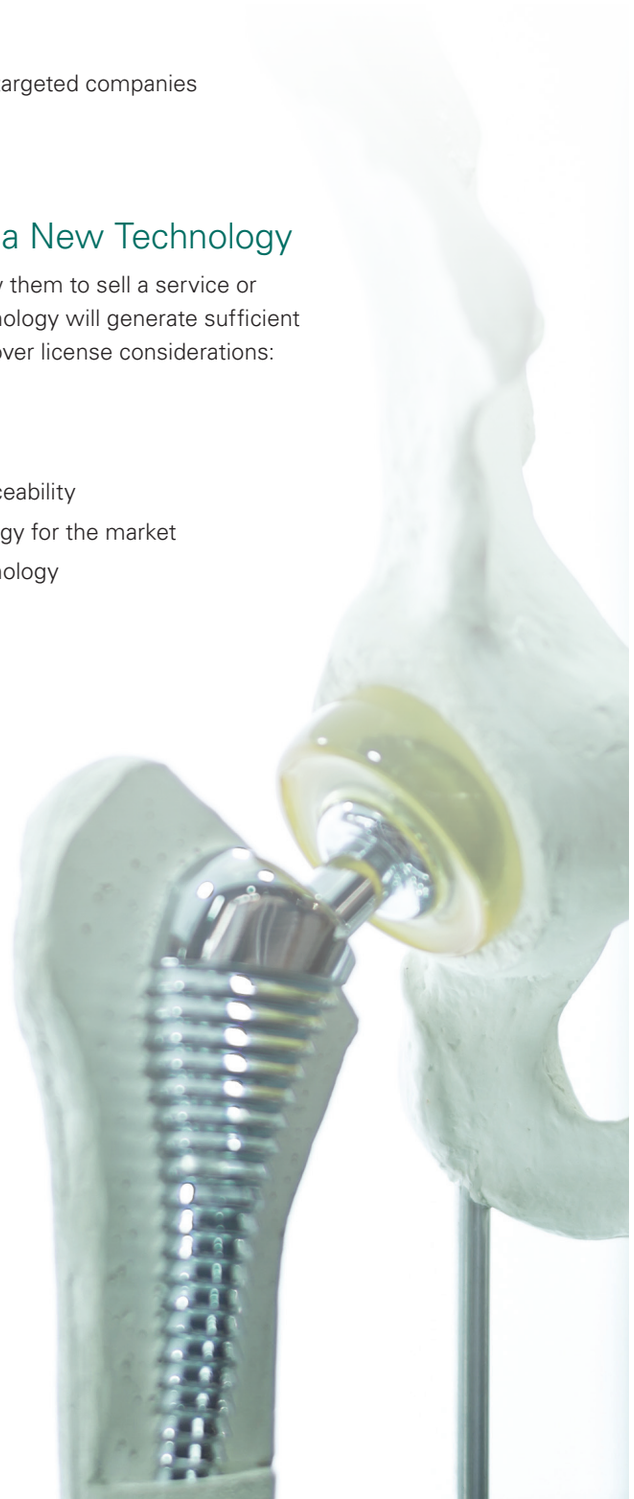
Considerations Regarding Licensing a New Technology

Companies seek competitive advantages that will allow them to sell a service or product to a large market. The key is whether the technology will generate sufficient return on investment. They will evaluate the following over license considerations:

- Market size
- Technology advantage over competing products
- Patent breadth and likelihood of long term enforceability
- Investment needed to fully develop the technology for the market
- Cooperation from inventor(s) to further the technology

Examples of Marketable Products

- Medical devices
- Diagnostic tools
- Surgical instruments
- Therapeutics/drugs
- Patient assist devices
- Healthcare software
- Education or training materials or software



Inventors as a Valuable Resource

As the technology inventor, you are often in the best position to help identify potential licensees (e.g.: industrial connections) for your work with your knowledge of trading activities, industry experts, and those working actively with competing technologies. Inventors can promote licensing by:

- Providing information or activities that relate to the marketing and commercialization of your own, related, or competing technologies
- Directing contacts from potential licensees to OTD
- Referring all commercial and contract matters to OTD
- Making an effort to answer a reasonable number of questions from potential licensees

Once a licensee has been identified, we will negotiate the details of an agreement with the interested company, including the licensing fee and royalties.

What if my Invention is Declined?

WMed may decline to commercialize IP because the IP is not WMed associated IP or because the market potential for a specific IP does not warrant the expense of legal protection and/or commercialization. Sometimes WMed may decide to cease either patent prosecution, or maintenance, or ongoing commercialization efforts altogether.

Necessary literature and database searches will be conducted in an effort to compile the most up-to-date information available. A decision to accept or decline the invention will be made based upon all information available. If the invention is accepted, the patenting process continues. If the invention is declined, the inventors are encouraged to resubmit inventions to WMed after further advancements are made.

WMed associated IP declined due to a lack of market potential can be assigned to the inventor if the inventor chooses to pursue commercialization of the associated IP at their own acccount. The inventor is encouraged to then re-involve OTD if commercial interest in the IP is generated. In such instances, the inventor can request to OTD to release the invention so that he or she can seek patent protection at his or her own cost. An obligation to federal government agencies such as NSF or NIH may exist if the invention was made with the aid of federal grants. Check with OTD to determine if a release from federal funding agencies is necessary. WMed may have further restrictions on marketing and licensing of an invention.

If re-assignment occurs and commercialization is successful, the inventor must agree that WMed will retain a royalty-free, irrevocable, worldwide, perpetual license to use the applicable Intellectual Property for any purpose within the WMed organization. Any ensuing WMed-associated IP developed will remain subject to the existing IP Policy.

SECTION 13: Starting a Company

Starting a new company is one way to further develop and commercialize technologies created at WMed. A start-up can be a preferred route for commercialization because it can provide the professional guidance and development needed to demonstrate commercial viability, and thus improve the chances that an early-stage technology reaches the market.

Resources exist within WMed to support the development of promising WMed intellectual property. The WMed Pilot Research Project Support Program is reserved for projects that are in their initial or early stages of development, are not currently funded, and that engage medical students or residents in the research activities. In addition, the WMed Innovation Center is a technology business incubator located in the WMU Business, Research & Technology Park. The Innovation Center provides low-cost fee-based facilities and services to start-up technology companies.

Many factors are involved in the OTD's decision to license a technology to an existing company or to a start-up company. Considerations include optimization of stakeholder positions (WMed, faculty, etc.), improvement of the probability that the technology will reach the market, and techniques to accomplish further commercial development outside the research laboratory. The licensing or optioning process begins with somewhat standardized templates that tend to provide both equity and royalty consideration to WMed in exchange for commercial rights to the technology.

When a start-up includes one or more WMed faculty members, a conflict of interest management plan is required. That plan outlines the relationship between a faculty member's activities with the company and his or her research and teaching responsibility. The plan identifies and mitigates possible areas of conflict, such as those related to conflict of commitment and/or conflict of interest and lays out a plan for disclosure and management of these conflicts. To initiate a conflict of interest management plan, contact the Office of the Associate Dean for Research.

Start-Up Q&A

Q: What is a start-up company?
A start-up company is a new business entity created to market a specific invention. It is an alternative to licensing an invention to another already existing company.

Q: What role does the inventor play in the start-up company?
The inventor usually serves as a consultant or adviser to the new company. That role may change as the company develops. However, much more time is required early in the process of establishing the company.

Q: What support does WMed provide to start-ups?
WMed provides resources and services that make start-up formation easier, such as a Pilot Research Project Support Program and incubation facilities.

WMed licenses to start-ups are structured so as not to overburden the company financially during the first years.

Startup Company Formation Guide & Checklist

- ☐ Review the company's business model with professionals to determine whether a viable business case is possible. The Innovation Center and the Office of Technology Development can help with the review.
- ☐ Let the OTD know you are interested in forming a start-up. You may then want to enter into a standstill or option agreement to ensure the WMed won't license the technology to a third party. This allows time for an individual or a company to develop a business plan and satisfy other licensing requirements.
- ☐ Develop a preliminary business plan and submit to the OTD. The business plan should include a business description, market analysis, management team, financial plan, and marketing plan.
- ☐ The plan should also identify what technologies are needed and their benefits to the company. The business plan needs to be specific enough that the OTD and the company can begin to negotiate the deal framework and to identify meaningful milestones for the license.
- ☐ Negotiate a license deal framework with the OTD. The deal terms represent a package whose value depends upon the type and significance of the technology being licensed and external market factors. Components of the package include exclusivity, field of use, equity, royalty rates, sublicense sharing, diligence milestones, minimums, and other payments. The terms are interrelated, and there is trade-off among terms in arriving at the entire deal. Equity is typically taken in start-up company deals in exchange for lessening the cash burden on the company in the early years.
- ☐ Seek conflict of interest management plan approval. When a start-up company involves a WMed faculty member, a plan is developed describing the relationship between the company and the faculty's WMed research and students. This plan identifies and mitigates potential conflicts of interest and should be initiated as early as possible with the Office of the Associate Dean for Research.
- ☐ Establish company as a legal entity. A license for a technology will only be granted to a company demonstrating the capability of developing the technology into a commercial product. Documentation needed includes articles of incorporation, bylaws, and founders agreements or equivalents.
- ☐ Finalize the license agreement. License drafts are exchanged, and the final deal terms and contract language are negotiated and agreed upon.
- ☐ Complete a business plan acceptable to WMed.
- ☐ Finalize the investment agreements. Investment documentation and agreements are reviewed and approved by WMed and should be ready for signings. These types of agreements can include, but are not limited to:
    - o Charter (Articles/Certificate of Incorporation)
    - o Rights Agreement
    - o Stockholders Agreement
- ☐ Have experienced management on board at the time of signing the license agreement. If that management is on an interim basis, specify that a qualified management team will be assembled within a period of time after execution of the license agreement.
- ☐ Provide a capitalization plan and capitalization table. A start-up must disclose the current levels of financing, equity value, or capitalization at the time of license signing and must reach specified levels of such financing within an agreed-upon time.
- ☐ Sign license and investment agreements and provide stock certificate.
- ☐ Monitor agreements. The company, WMed, and the investors monitor company progress toward commercialization obligations and milestones.

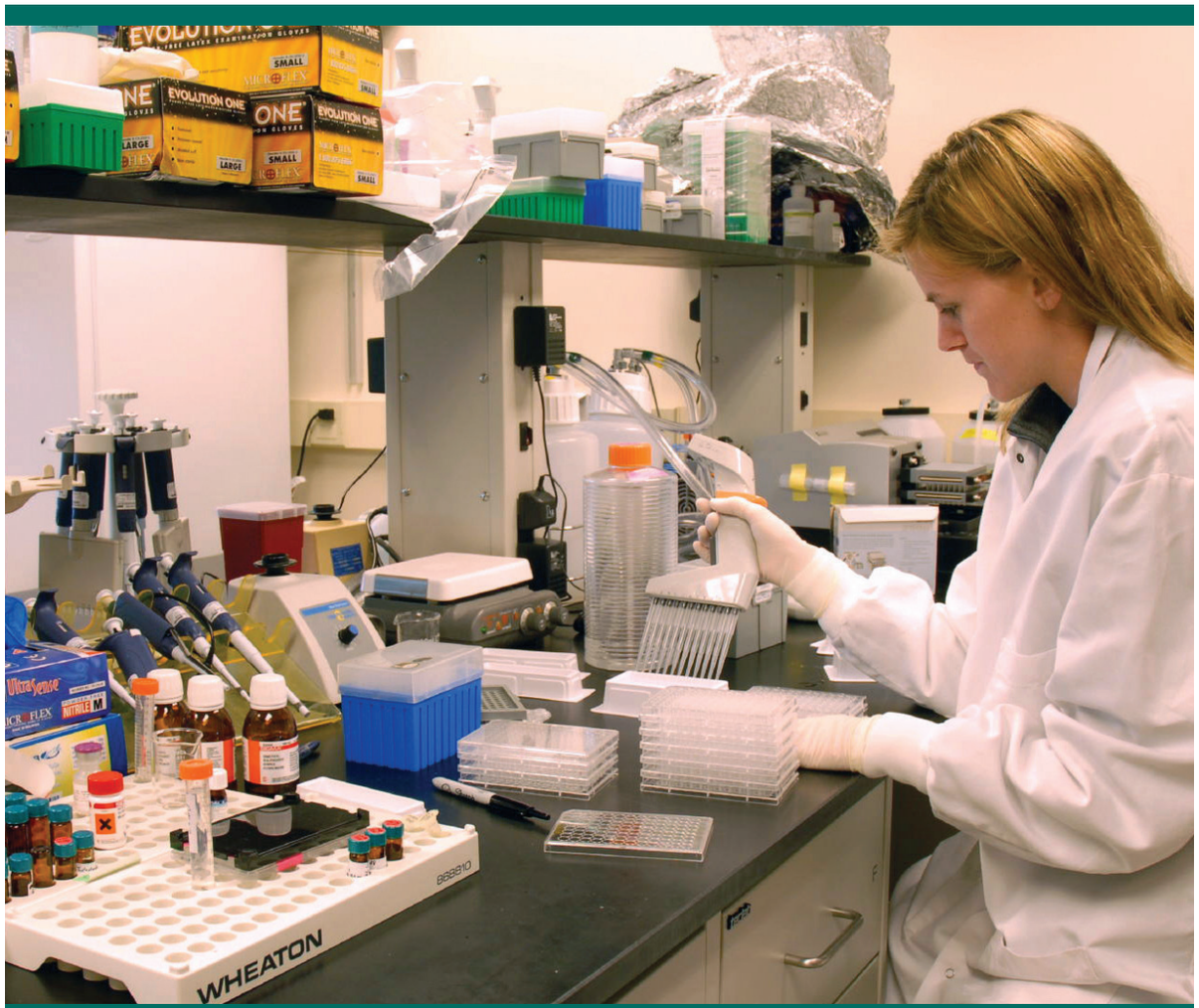
SECTION 14: The WMed Innovation Center

WMed's technology business incubator, the Innovation Center, supports and nurtures the growth of early-stage companies.

It provides an on-campus environment where technology-based businesses can access business resources and research infrastructure for early-stage companies that require wet laboratory capacity for product research and development. The Innovation Center is a 69,000 square foot start-up business incubator in the WMU Business, Technology, and Research Park. It is owned and operated by WMed to help launch successful start-up companies. Since the incubator opened in 2003, its incubator facilities have become the launching pad for over 130 startup companies.

The Innovation Center provides an ideal environment for starting a high-growth technology venture with dedicated wet-labs, furnished office space, an extensive array of shared equipment, co-working office, lab, and engineering prototyping areas, and conference rooms with complete presentation facilities and high-speed wireless Internet access. The Innovation Center offers many support services for its clients including:

- **GrowthWheel:** A visual toolbox and online platform for decision making and action planning for startup and growth companies. It helps entrepreneurs build their businesses through a simple action oriented process that stays true to the way most entrepreneurs think and work.
- **1 Million Cups:** A national monthly event designed to educate, engage, and connect entrepreneurs from across the Kalamazoo region.
- **Kalamazoo Venture Tuesday:** An investor pitch event offered as a teaching opportunity for participating companies and members of the audience. At each event, three investors reveal what three company presenters did right and wrong.
- **NSF Introduction to Customer Discovery:** A taste of the Lean LaunchPad method gives early-stage technologists a working knowledge of how to think about their opportunity from a business and customer perspective, as well as how to properly conduct customer discovery interviews. Offered in conjunction with Western Michigan University and Michigan Technological University, this program covers the two main concepts in NSF I-Corps—value propositions and customer segments.



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SECTION 15: SBIR/STTR Program

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs provide qualified small businesses, including faculty start-ups, with opportunities to propose innovative projects that meet specific federal needs.

These programs offer more than $2 billion dollars annually to support the research and technology development of small businesses across the nation. Awards are based on small business qualifications, degree of innovation, technical merit, and future market potential.

SBIR funds support research by businesses with or without academic partners. STTR funds are also awarded to businesses, but recipients must collaborate with a U.S. research institution. The SBIR/STTR programs are structured in three phases, the first two of which are supported by SBIR/STTR funds.

Phase I. The objective of Phase I is to determine the scientific or technical merit and feasibility of the proposed R/R&D efforts. The Phase I period concentrates on the R&D efforts that prove the scientific or technical feasibility of the approach or concept and that which are a prerequisite for further support in Phase II. SBIR/STTR Phase I awards are for periods of up to twelve months in amounts of up to $225,000.

Phase II. The objective of Phase II is to continue the research or R&D effort initiated in Phase I with approaches that appear sufficiently promising because of Phase I. SBIR/STTR Phase II awards are for periods of up to two years in amounts of up to $1,000,000.

Phase III. An objective of the SBIR/STTR program is to increase private sector commercialization of innovations derived from Federal R/R&D. During Phase III, the small business concern is to pursue commercialization with non-SBIR/STTR funds.

Federal Agencies Participating in SBIR

Each year, 11 federal departments and agencies reserve a portion of their R&D funds for award to small business through the SBIR program. These agencies include:

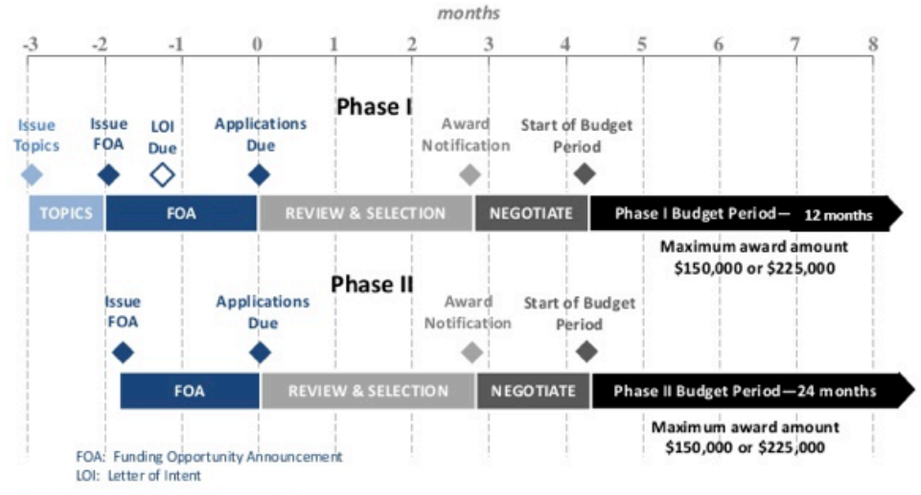
- Department of Agriculture
- Department of Commerce
- Department of Defense
- Department of Education
- Department of Energy
- Department of Health and Human Services
- Department of Homeland Security
- Department of Transportation
- Environmental Protection Agency
- National Aeronautics and Space Administration
- National Science Foundation

Federal Agencies participating in STTR

Each year, five federal departments and agencies reserve a portion of their R&D funds for award to small business or nonprofit research institution partnerships. These agencies include:

- Department of Defense
- Department of Energy
- Department of Health and Human Services
- National Aeronautics and Space Administration
- National Science Foundationdation

Application & Award Timelines



SBIR/STTR Eligibility

Both the SBIR and STTR programs have specific eligibility criteria for participation.

Small businesses must fulfill the following criteria to participate in the STTR Program:

- 50% of firms' equity must be directly owned and controlled by one or more individuals who are citizens or permanent resident aliens of the US
- For-profit
- Principal researcher need not be employed by small business
- Company size limited to 500 employees

While there is no size limit for a nonprofit research institution, the nonprofit research institution must also meet certain eligibility criteria:

- Located in the U.S.
- Nonprofit college or university
- Domestic nonprofit research organization
- Federally funded R&D center

The agencies participating in the SBIR/STTR programs have differing requirements for program involvement, and it is very important to understand and comply with these individual requirements. Each agency publishes a proposal solicitation at least annually. These solicitations can be viewed on their individual websites accessible at https://zynsys.com/sbir/.

SBIR/STTR Q&A

Q: May a portion of an SBIR award be used to pay for outside services or assistance from a university or other nonprofit research institution?

Yes. In Phase I, up to one-third of the award can be used for outside assistance, and in Phase II, up to one-half of the award.

Q: What is the minimum percentage of research that can be conducted by the small firm and institution receiving an STTR award?

Small business must perform at least 40 percent of the work, and research institutions must perform at least 30 percent.

Q: When are the proposal deadlines?

Information on solicitations and proposal deadlines can be found at https://www.zynsis.com/sbir/scomp.htm

SECTION 16: Technology Transfer Q&A

Q: Can I still publish my findings after I submit an IPDF?
Yes, findings can still be published, and disclosure to the OTD does not alter your publication timetable. However, because publishing can affect the ability to obtain a patent, it is best to submit a disclosure prior to publishing or communicating your findings in a public forum.

Q: When should I submit a IPDF?
It is best if inventors submit a disclosure between 8 and 12 weeks before publication so that, if necessary, actions can be taken to protect both U.S. and foreign rights. Once publicly disclosed, an invention may not be patentable. To be safe, inform the OTD of any imminent or prior presentations that include the IP.

Q: What is my role in the screening process?
Inventors typically meet with OTD staff to discuss the invention and clarify aspects of the disclosure. Once a decision is made on whether to pursue patenting, the inventor will be contacted to discuss the outcome.

Q: What is my role in patenting?
Inventors and OTD professionals speak with the patent attorney during the patenting process. Also, inventors will need to review drafts of documents, as well as sign assignments and other legal documentation. OTD will guide the inventors during the process.

Q: What is my role in marketing?
Inventors are encouraged to work closely with their technology manager to market their invention. Inventors are often quite involved in the early stages of recruiting commercial partners and licensees, as the inventor's expertise is often critically important. This involvement includes exchanging information and materials, and sometimes results in further sponsored research (dubbed pre-licensing agreements). Inventors are often involved in crafting the details of such pre-licensing agreements.

Q: What is my role in licensing?
Licensing is the primary function of the OTD, and inventors will be informed of progress. Inventors often are closely connected to others in their field and may be consulted by the OTD on the business terms of the license. Further, the inventor's role in licensing is an extension of their role in marketing since their expertise is often critically important to transfer the technology and related know-how to the licensee. The WMed license places only nominal obligations on the part of the inventor to assist in the transfer of the licensed technology. When more than minimal time and effort is necessary, the licensee might negotiate a separate consulting arrangement with the inventor.

Q: What effect does a license have on my ability to do research?
You can still continue research using a licensed invention, even if it is exclusively licensed. WMed will always retain the right to use licensed inventions in academic research and teaching.

Q: What if an industry partner funded my research and invention?
The OTD will review the terms of the contract, send a copy of the disclosure to the company, determine the company's interest, and take action based on the company's decision.

SECTION 17: Appendix

Type of IP, Description, Examples

Trade Secret
- Confidential information used to gain an advantage over those without the information
- It may relate to a formula, algorithm, device, pattern, or any type of information that gives a competitive advantage
- A trade secret can be enforced indefinitely given that the secret remains confidential
- Examples: Sales methods, consumer profiles, advertising strategies, lists of suppliers/clients, manufacturing processes

Trademark or Service Mark
- A word, name, or symbol used in trade, indicating the source and distinguishing the product from others
- Exclusive use rights that do not expire if continuously used, but registered trademarks must be renewed
- A registered mark is valid for 10 years and is renewable as long as it continues to be used commercially
- Does not prevent others from making or selling the same goods under a clearly different trademark or service mark
- When WMed departments want trademarks associated with academic and research activities, the University's legal counsel (not OTD) helps advise and file
- Examples: Band-Aid, ChapStick, Kleenex

Copyright
- Protects authors of original works of authorship, including literary, musical, dramatic, or artistic
- The expression must be original and be in a fixed and tangible form for a copyright to be available
- For scientific writings, copyright does not protect the procedures, systems, processes, concepts, formulas, discoveries, or devices described in the work. Similarly, for software, copyright does not protect the underlying concepts, processes, systems, algorithms, program logic, or layouts.
- Does not prevent others from making and selling the idea or a similar expressive work that they created from scratch based on the same concept/idea
- Good for the duration of the author's life, plus additional 70 years. Employer owned copyrights lasts for 120 years from creation or 95 years from the first publication of the work, whichever is shorter.
- Examples: Writings, architectural drawings, paintings
- Copyright applies automatically. Unlike patentable inventions, copyrighted works are automatically protected under U.S. copyright laws without having to undergo a formal registration process. However, it is still important to affix an appropriate copyright notice so others are aware that they are not free to use the work without permission. Works owned by WMed should bear the following copyright notice: Copyright © 20XX WESTERN MICHIGAN UNIVERSITY HOMER STRYKER M.D. SCHOOL OF MEDICINE. All right reserved.

Patent

Utility

- 90% of all US patents issued
- A new and useful process, machine, manufacture, or composition of matter, or a new and useful improvement thereof
- 20 years patent life from the date of application with maintenance fees due in year 3, 7, and 11
- Example: Chemical compound, mouse model, medical tools/supplies

Design

- A new, original, and ornamental design of an article
- 14 years patent life from the date of issuance without maintenance fee
- Example: Furniture designs, toys

Plant

- An asexually reproduced distinct and new variety of plants not found in the wild, excluding tubers, e.g.: potatoes
- 20 years patent life from the date of application without maintenance fee
- Example: New citrus cultivars

Definitions

102 Rejection: This rejection is based on the novelty requirement of an invention. By issuing this form of rejection, it is the examiner's position that the invention disclosed in the application is not novel because it has been anticipated by prior art or other patents; the invention was publicly disclosed by the inventor over a year prior to the filing date of the application; the invention had been abandoned, and/or the invention was filed in another country over a year prior to filing of the U.S. application.

103 Rejection: This rejection is based on the non-obviousness requirement of an invention. By issuing this form of rejection, the examiner believes that although the invention is not completely described in any one prior art reference, the invention is obvious in light of one or more prior art references.

Assignee: The assignee is an individual or legal entity (company, university, etc.) that has an ownership interest o ver the patent or patent application. The assignee receives this ownership interest through an assignment from the inventor(s).

Assignment: The legal action of transferring property ownership rights to another.

Bar Date: A bar date is a date that acts as a deadline for filing a patent application. Bar dates are most commonly triggered by events such as public disclosures and publications. Failure to file a patent application by the bar date may result in the prevention of receiving a patent for an invention.

Classification: The classification of a patent application depends on the technological area in which the invention resides. Ultimately, an application's classification determines the technological division within the USPTO to which the application will be sent and the patent examiner.

Declaration: A declaration is required statement with a warning indicating that willfully false statements are punishable by law. A declaration must certify that the inventors are the first inventors of the subject matter, the inventors understand the contents of the application, and that the inventors have a duty to disclose all information to them that is relevant to the patentability of the invention.

Freedom to Operate (FTO): Freedom to operate, sometimes abbreviated "FTO," refers to whether a certain action, such as testing or commercializing a product, can be done without infringing patent rights or other intellectual property rights of others.

Government Rights: These are rights granted by the government, such as the right to exclude others from selling, importing or using a patented invention in the case of patents. In terms of trademarks and copyrights, government rights include the right to exclude others from using a certain commercial name or logo, or the right to exclude others from copying an audiovisual or literary work.

Information Disclosure Statement (IDS): A document that may be required by the USPTO from the inventor and/or applicant for aiding the examiner's search for prior art references.

Maintenance Fee: Maintenance fees are required to be paid three times throughout the full life of a utility patent, but are not required for design or plant patents. These fees, in the case of a U.S. patent, are due at 3 ½ years, 7 ½ years, and 11 ½ years after the patent had been granted.

Non-Provisional Patent Application: Unlike a provisional application, this patent application undergoes examination by a USPTO examiner and may result in an issued patent. A non-provisional application may claim the benefit of an earlier filing date from a provisional patent application or another non-provisional patent application.

Office Action: An Office Action is a communication from the USPTO. There is always a deadline to reply to these communications, and this deadline must be met in order to continue with the patent prosecution process.

Prior Art: Documentation of technology that is similar or material to the technology in the invention described in the patent application. Prior art can consist of U.S. patents, journal articles, foreign patents, publications, or any other piece of literature that is publicly available.

Provisional Patent Application: This patent application is not examined and does not result in a patent, but rather reserves the effective filing date for a later non-provisional patent application with respect to that which was disclosed in the provisional application. Provisional patent applications have a life of one year before they expire; therefore, the subsequent non-provisional patent application should be filed within this one-year period.

Patent Cooperation Treaty (PCT): A multinational treaty enacted to economize and facilitate the process of obtaining patents in multiple countries. This treaty brought forth the PCT application, which allows an inventor to apply internationally and designate various target countries as locations to obtain patents. The inventor can then pursue the patent process in each individual country while retaining the filing date of the international application.

United States Patent and Trademark Office (USPTO): The governmental office that handles the patent and trademark applications and has the administrative power to grant or deny patents and trademarks.

Public Disclosure: The public disclosure of an invention can forever bar the inventor from receiving a patent on that invention. If an inventor publicly discloses an invention, he or she has one year to file a patent application or the inventor will be barred from receiving U.S. patent rights on the disclosed invention. An inventor's public disclosure also bars the inventor from receiving patent rights in most other countries unless the inventor had filed a patent application in that country prior to the disclosure. A public disclosure may be journal publications, scholarly article publications, website blogs, presentations, displays such as poster presentations, etc.

Reduction to Practice: Reduction to practice is an action towards the realization of a patent; it can be either actual or constructive. Actual reduction to practice consists of building the invention, testing the invention, etc. Constructive reduction to practice can be the filing of a patent application.

Restriction Requirement: If the examiner finds that a patent application has claims that describe two independent or distinct inventions, the examiner may issue a restriction requirement. A restriction requires the applicant to elect one of the two or more inventions to continue with the patent process. The non-elected invention(s) can be pursued in a separate patent application(s).

Specification: The specification is the part of a patent that has a written description of the invention, with an explanation as to how to make and use it.

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