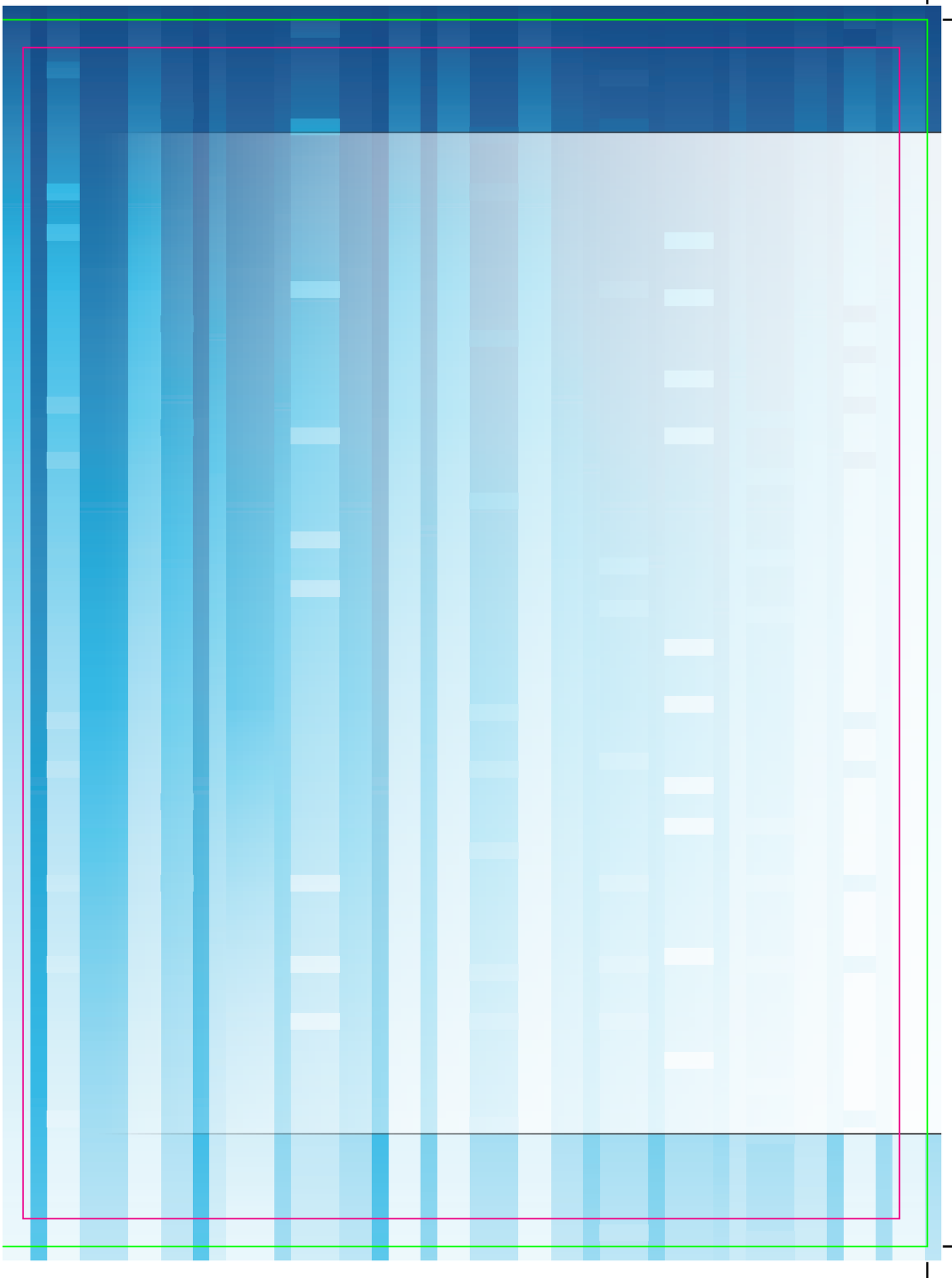

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This Innovator's Guide is intended to serve as a quick reference material for any MUSC faculty, staff, students, employees, or visitors who are interested in the translation of research into commercial products and services. In this guide, you will find descriptions of forms of intellectual property (IP) such as patents, copyrights, trademarks, and trade secrets. You will also find a summary of how the Foundation for Research Development (FRD) converts those forms of IP into commercial endeavors.

Who is MUSC FRD?

The MUSC Foundation for Research Development is an independent not-for-profit company existing solely to facilitate the commercialization of MUSC intellectual property. To this end, FRD works to properly protect IP via patent filings, copyright and trademark registrations, and the like. Once protected, FRD uses its marketing channels to find partners in industry who are willing to license the IP to move it to the marketplace.

Revenues received by FRD from IP licensing are distributed pursuant to the MUSC IP policy, which can be found at http://academicdepartments.musc.edu/frd/inventors/policy. If you have questions regarding the IP policy, please feel free to contact an FRD staff member.

Other functions performed by FRD include:

- Helping interested faculty members form startups to license their technologies from MUSC
- Reviewing IP terms of sponsored research and materials transfer agreements to ensure that faculty are able to produce IP
- Consulting with existing faculty startups regarding small business grant applications, such as SBIRs/STTRs
- Working to form relationships with pharmaceutical and biotech companies that could precipitate sponsored research and other university funding in the future

We hope you find this guide helpful, and please contact us if you have any questions. Happy reading!

THE Patent PROCESS

HOW YOUR INVENTION GOES FROM CONCEPTION TO PATENT.

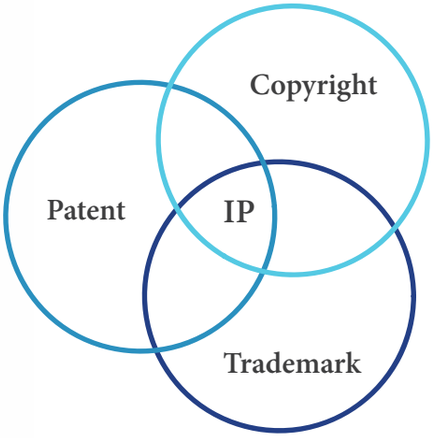
Forms of Intellectual Property (IP)

Before diving into what a patent is and how it is obtained, we must first understand, at least at a basic level, the different forms of intellectual property—commonly referred to as "IP". IP is a legal term that refers generally to any intangible property that consists of ideas, inventions, rights in creative works, or branding. The main categories of IP are patents, copyrights, trademarks, and trade secrets. We'll discuss all these in more detail later, but here's a quick primer.

Patents are the strongest form of IP, and they form the backbone of the tech transfer process. Patents cover any process, machine, manufacture, or composition of matter—generally, these cover inventions. Obtaining a patent is a fairly complex and expensive process, and this will be outlined in greater detail in this booklet.

Copyrights are rights in film, literary works, artistic works, musical compositions, or other creative works. Copyrights may also be obtained covering software programs. These are much easier and less expensive to obtain than patents, but the protection they offer is somewhat limited. Copyrights protect the creative aspects of a work, such as the look and feel or particular arrangement and wording, as opposed to the underlying ideas or facts. Our organization, for instance, retains a copyright in the organization and language of this guide, but others are free to use facts about the patent process to make a different guide of their own.

Trademarks are primarily source identifiers. These cover logos, slogans, and other information that identifies the source of goods or services. Essentially, trademark protection exists to allow companies to develop goodwill around their products without fear of others using that goodwill to mislead consumers as to the source of the products. Who wouldn't think of McDonald's when you see the golden arches?



Forms of Intellectual Property (IP)

What are the requirements for a patent?

To obtain patent protection, an invention must meet four requirements—the invention must consist of patentable subject matter, and must be novel, useful, and non-obvious in light of the prior art. "Prior art" is, generally, any public information, prior patent or patent application that would disclose the invention. Public disclosures which may be used as prior art to disallow an invention include poster presentations, published grant applications, and of course journal publications.

Patentable Subject Matter: Patentable subject matter consists of the categories listed previously—any process, machine, manufacture, or composition of matter. A more useful exercise is to mention several categories of things that are not patentable. For instance, anything naturally occurring cannot be patentable, such as isolated gene or peptide sequences and the like. Likewise, algorithms, formulae and other theoretical ideas are not patentable. Einstein could not patent his theory of relativity.

Novelty: The novelty requirement ensures that no invention can be patented which has already been disclosed or invented previously. If the patent examiner finds a reference published prior to your patent application that contains all of the elements which you claim as novel, then the application will be rejected on grounds of novelty. This type of rejection is known as "anticipation".

Utility: An invention must be useful to be eligible for patent protection. This requirement is not typically an issue; so long as the invention serves any useful purpose, the utility requirement can be met.

Non-Obviousness: The non-obviousness requirement is by far the most difficult to predict. Whether an invention is obvious in light of some piece of prior art is a highly fact-based inquiry that depends greatly on the specific circumstances involved for your invention. If the FRD believes that non-obviousness may be a hurdle in patenting your invention, we will discuss with you in more detail the nuances of this requirement.

An additional requirement, known as enablement, requires that the patent application sufficiently describe the invention such that one skilled in the particular area of expertise could make and use the invention without undue experimentation. This prevents inventors who have not fully conceived or developed their invention from filing for a patent prematurely.

The Patent Process: A Step-by-Step Guide

This will serve as a guide to the overall process of obtaining a patent. The simplified process given here will detail how a US patent is procured. If we are seeking international protection for your patent, then we will typically file a form of international application known as a PCT. If you have a question or concern about a specific step of patenting your invention, don't hesitate to contact the FRD.

I. Pre-disclosure considerations

Whenever any faculty member believes that his or her research may lead to a viable invention, the best possible course of action is to notify the FRD about the research as soon as possible. Even if the invention is far from final development, it is immensely helpful to keep the FRD apprised of your progress.

Specifically, if any disclosures are to be made concerning your research, including poster presentations, journal publications, or otherwise, you should absolutely contact the FRD. Knowing about the disclosures before they occur will allow us to work with you to develop a strategy for keeping your invention protected while preserving your ability to present your findings to the academic community. This is one of the most common areas where possible inventions are rendered unpatentable. Because public disclosure can have such huge consequences on our ability to obtain a patent, it is imperative that you contact us before disclosing your invention.

II. Invention Disclosure

The first real step in the process of obtaining patent protection is the filing of a record of invention (ROI) with the FRD. This form can be found online at http://academicdepartments.musc.edu/frd/inventors/inventors.forms. The form requires that you briefly describe how your invention works, its possible purposes, and any companies that may be interested in licensing your invention (more on licensing later). Any data or manuscripts that you may have concerning the invention should also be attached. Once your ROI has been received, you will receive confirmation from our office, and we will begin the next step of the process.

III. Invention Assessment

Once an invention has been received, the FRD will perform a detailed assessment of your invention to determine whether it is feasible to obtain a patent. This assessment consists of two prongs: a patentability assessment, and a commercial viability review.

First, we perform a detailed patentability search to determine whether there are any patents, published patent applications, or other references which may render the invention unpatentable. We compile a list of sources that could cause some issue as to either novelty or non-obviousness, and determine from there whether patenting the invention is a viable option. At this stage, we also review the history of your invention to determine whether any previous disclosures you may have made could prevent us from obtaining a patent. If it is determined that your invention is not patentable, then we will contact you with a detailed explanation as to why we cannot move forward.

If your invention is patentable, then we perform a commercial assessment of your invention. Several experts in industry, academia, and the patent space give comments on the commercial viability of the particular invention. Because obtaining a patent can be such a costly process, it is prudent to ensure that the invention can be successfully commercialized before filing an application.

IV. Provisional Filing

After the assessment has been completed, the FRD may elect to file a provisional patent application on your invention. A provisional application is essentially a place-holder, in that is not terribly expensive to file and it grants the filer a one-year time period in which to further develop the invention without worrying about being "scooped" by another filer. After the one-year time limit expires, the office must decide to either convert the application to a non-provisional (or utility) application, or abandon it if the invention is still not ready.

V. Utility Application/Patent Prosecution Process

If the provisional application is converted to a utility application at the conclusion of its one-year lifespan, then the process of patent prosecution will begin in earnest. "Prosecution" of a patent describes the process by which the patent examiner investigates the application and communicates arguments, objections to formalities, and other issues that may inhibit the issuance of a patent.

Formal communications concerning reasons for rejection of the application are called Office Actions. Office Actions require responses giving various arguments and making any changes which may be required to overcome the issues in the action. This process takes a minimum of eighteen (18) months, but often goes on for years. In fact, the average US patent application takes 3 to 5 years to complete prosecution, and costs a total of 20 to 30 thousand dollars.

VI. Notice of Allowance

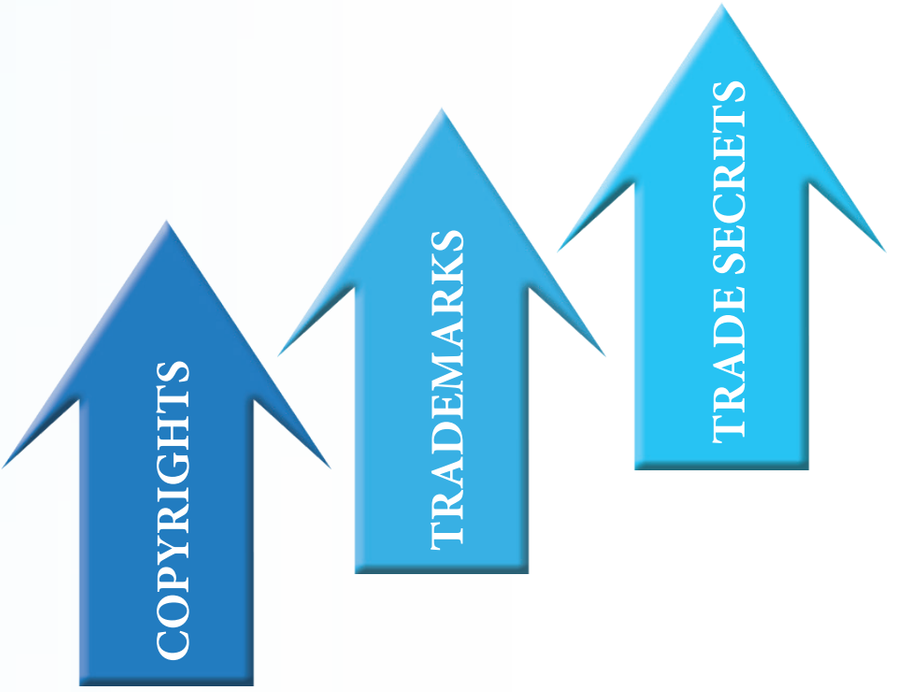
Once all changes have been made and/or the arguments have been successful, a notice of allowance will be issued. This notice serves to inform the inventor that, once all of the requisite fees have been paid, a US patent will be issued on the invention.

VII. Maintenance/Patent Lifespan

A US patent has a 20-year lifespan that generally begins from the initial filing date. Therefore, once the patent is issued, its lifespan will be 20 years, less the amount of time from filing to issuance. At certain intervals throughout the lifespan of the patent, maintenance payments must be made to the USPTO. The FRD generally coordinates payment of these fees.

OTHER Intellectual Property

COPYRIGHTS, TRADEMARKS, AND TRADE SECRETS



OTHER
Intellectual Property

3 Main Categories of IP Besides Patents

While patents are undoubtedly the typical form of Intellectual Property commercialized by FRD, there are several other forms that are just as important to properly protect. As we mentioned previously, the three main categories of IP other than patentable inventions are copyrights, trademarks, and trade secrets.

Copyrights

Copyright protection is unlike other forms of intellectual property in that it does not protect ideas or facts on a substantive level. Whereas a patent protects the idea of an invention, and a trade secret may protect any number of ideas or facts, copyrights protect only the expression of those ideas or facts.

What is protectable under copyright?

The traditional legal definition of copyright states that a copyrightable work is any "original work of authorship fixed in tangible form". However, given the advent of software and online-based works, the fixation requirement has been relaxed considerably over the past several decades. Essentially, the requirements for a work to be protectable under copyright can be broken down into two elements:

Originality – The first requirement for a copyrightable work is some element of originality. This element is not meant to require a highly artistic expression; rather, it requires that at least some characteristics of the look-and-feel or organization of a work are original. For instance, the arrangement of words and the graphic design in this guide are protected by copyright. However, a list of items in alphabetical or numerical order would likely not be copyrightable, as there is nothing original about that arrangement.

Fixation – As briefly mentioned above, the fixation requirement has been modified over the years to better contemplate copyrightable works using various technologies, such as software and the internet. The requirement that the work be fixed "in a tangible medium" has been pared back to only require that there be some form of permanency attached to the work. For example, a live performance of a ballet carries no copyright protection; however, a videotape of the performance, or a written script or set of choreography instructions would carry copyright.

How and when is copyright protected?

Unlike most statutory forms of intellectual property, copyright vests automatically upon creation of a work that is eligible for copyright protection. As soon as the words of this guide are written down, they become copyrighted material. There are no additional requirements for the creation of copyright.

While copyright may be registered with the US Library of Congress, this process typically does not justify the cost and time required. Since copyright is created

automatically, registration adds little value to copyright protection. Typically, FRD only registers copyright if a licensee specifically requests it. Under most circumstances, copyright registration is only useful if the holder of the copyright plans to sue for infringement, as having a registered copyright lessens the burden of proof as to damages for the plaintiff.

How can a copyright be noted?

Although it is no longer required by law to protect copyrights, a copyright notice is still commonly used to alert others that a work contains copyrighted material. Placing this notice on your work puts others on notice that the work is viewed as copyrighted, and that unauthorized reproduction could result in infringement.

The standard copyright notice is: © [year of first publication] [copyright holder].

For instance, a copyrighted work that is created at MUSC in 2015, and that falls under the MUSC IP Policy, should contain a copyright notice that reads "© 2015 MUSC Foundation for Research Development." FRD's name is used rather than MUSC's, because FRD is MUSC's designated holder of all intellectual property.

Trademarks

Trademarks are a form of intellectual property meant to protect the source identifier of a product or service. Technically, marks will be called either a "trademark" or a "service mark" based on whether a product or service is the commodity, but the differences are not important from a practical standpoint.

What is protectable under trademark?

As defined by the Lanham Act (the statute giving rise to trademark protection in the US), a trademark is "any word, name, symbol, or device, or any combination thereof—(1) used by a person, or (2) which a person has a bona fide intention to use in commerce and applies to register on the principal register established by this chapter to identify and distinguish his or her goods… ." This definition has been interpreted broadly by the US Supreme Court to include any logo, slogan, or other distinguishing characteristic that is used by a business to identify itself as the source of goods. Common examples of famous trademarks are the McDonald's golden arches, the Pepsi symbol, and even the classic shape of a Coca-Cola bottle.

The single most important requirement for any potential trademark is that the mark be more than "merely descriptive". This requirement serves to prevent important descriptors from becoming proprietary. As an example, there could be no trademark protection for "Red" brand fire trucks. The mark "Red" is merely describing the color of the trucks, and allowing a trademark on that term would mean that no other fire truck manufacturers could describe their trucks as red, even though the description is true.

How is trademark created?

The creation of trademark is built in to the definition given above. A trademark application is submitted to the United States Patent and Trademark Office (USPTO). Essentially, for statutory trademark to vest, two elements must be present. First, the mark must either be used in commerce as a source identifier, or there must be intent to use the mark within six months. Second, the examiner will perform a search of existing trademarks to ensure that the new mark would not be "confusingly similar" to any previously registered mark. If both of these conditions are met, then the office will register the trademark, and statutory trademark protection will vest.

Trade Secrets

Trade Secrets are different from the other forms of IP covered in this guide, because they do not derive their existence from a uniform federal statute. Most states have enacted Trade Secret Acts, which govern trade secret law in their respective jurisdictions.

What is protectable under Trade Secret protection?

Essentially, trade secrets can protect anything. Algorithms, recipes, inventions, know-how, methods, software, and just about anything else could conceivably become trade secrets. The definition of a trade secret is any information that can be used in the operation of a business or other enterprise, and that is sufficiently valuable and secret to afford an economic advantage over others. Put more succinctly, anything that is secret, and that has commercial value due to its secrecy, is a trade secret.

The most common example of a trade secret is the recipe for Coca-Cola. The company maintains the secrecy of this recipe by allowing only a select few employees to learn the entire thing, and by using extensive confidentiality agreements with even those employees.

How is Trade Secret protection created?

Because trade secrets require no registration with any governmental entity, there are no specific requirements for their "creation." Essentially, trade secret protection accrues once some piece of information with value (or potential value) is kept secret by a business or other enterprise. Unlike other forms of IP, this protection lasts indefinitely, for as long as the information is kept secret. Coca-Cola could theoretically protect its recipe until the end of time, so long as secrecy is maintained.

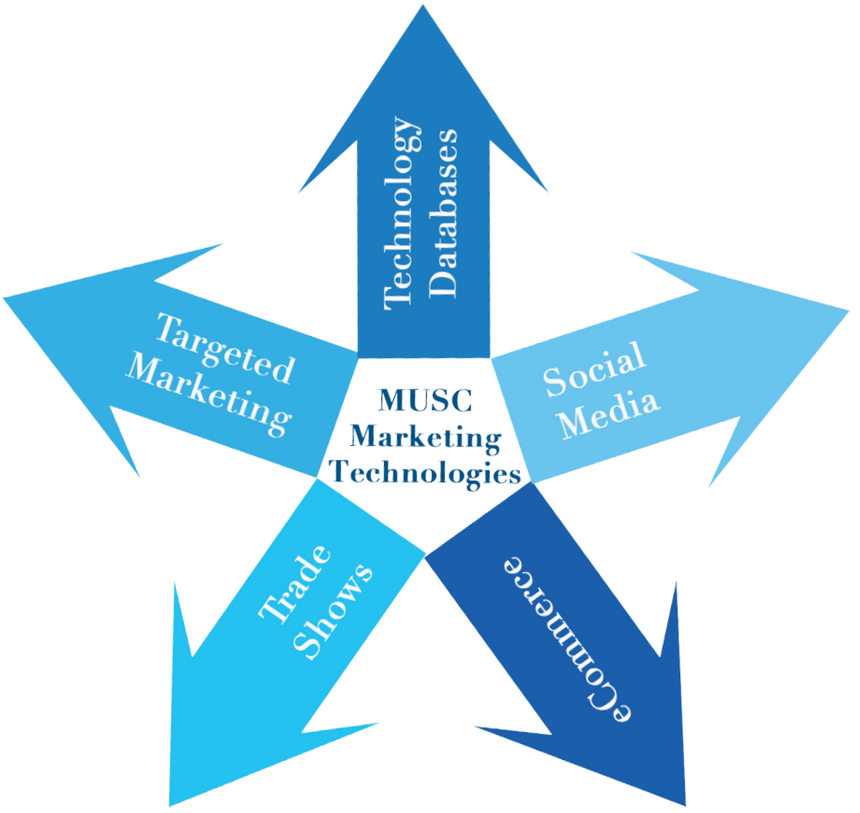
Due to this structure, it follows logically that the most important element in managing trade secrets is the maintenance of secrecy. The law requires that reasonable measures of maintaining secrecy be put in place for trade secret protection to survive. These may include non-disclosure agreements, limitation of access to the information, keeping the physical copy of the information in a safe place (i.e. a safe), and any other measures that make sense under the circumstances.

If these measures are maintained, then anyone who takes the information by fraudulent means and uses or discloses it will be liable for the misappropriation of the information. If one were to steal Coca-Cola's recipe and disclose it, then Coca-Cola's trade secrecy would be lost. That thief would be liable to Coca-Cola for damages for all of the market share lost by the company as a result of other companies' ability to replicate the formula. Those damages would be astronomical.

If you have any questions about any of the forms of IP discussed above, or about whether you have developed any of this IP in your research at MUSC, please contact FRD and a staff member will be happy to speak with you.

Technology COMMERCIALIZATION

MARKETING, OPTION AND LICENSE AGREEMENTS, AND STARTUPS



Marketing MUSC Technologies

FRD is committed to finding the best possible industry partner to commercialize MUSC technologies. FRD endeavors to connect with marketing targets that specialize in the field of the technology and will commit significant resources to bring the technology to market. FRD pursues multiple avenues to market MUSC technologies. These include listing the technology in numerous databases used by industry scouts, targeted marketing campaigns, trade shows, eCommerce, and social media outlets.

Technology Databases

With feedback from the inventors, FRD develops a one to two-page summary of the technology, called a Non-Confidential Summary (NCS). The NCS includes an overview of the technology, a brief market analysis, a listing of inventors, and hyperlinks to publications and published patent applications/patents.

FRD posts the NCS for all MUSC technologies via Technology Publisher, an online database through which users can search and view MUSC postings. Technology scouts and representatives from biomedical industry companies use these databases for new technology alerts and to search for relevant listings. These listings are centrally located on the Technology Publisher database and are accessible either via FRD's website or via internet searches. The NCS is then posted to four additional databases – iBridge Network, Association of University Technology Managers Global Technology Portal, Flintbox, and Collective IP.

Databases with MUSC's NCS listings:

- **FRD** (https://academicdepartments.musc.edu/frd/)
- **iBridge Network** (http://www.ibridgenetwork.org/)
- **Association of University Technology Managers Global Technology Portal** (http://gtp.autm.net/)
- **Flintbox** (http://flintbox.com/)
- **Wellspring** (https://search.wellspringsoftware.net/search)

Targeted Marketing

The FRD generates individualized marketing campaigns for technologies at varying points in the development process. Through surveying the marketplace, FRD identifies the key players and builds a contact list that encompasses a blend of large-cap companies, mid-cap companies, startups, and accelerators that will be interested in the technology being offered. FRD develops a non-confidential package to convey to the identified contacts. Depending on the stage of the technology, the non-confidential package may include any of the following: a non-confidential executive summary, publications, presentations, and published or issued patent applications. Additionally, FRD confers with the inventors to ensure that it has contacted all the companies with whom the inventor has a relationship.

Trade Shows

FRD attends several trade shows a year, which serve to connect directly with corporate decision makers of companies that in-license technology. FRD sends delegates to BIO International (sponsored by the Biotechnology Industry Organization), SC BIO, and Southeastern Medical Device Association conference. Trade shows provide FRD centralized access to executives from companies varying from start-ups to the largest pharmaceutical and medical device companies.

eCommerce

Additionally, FRD is pioneering the use of an eCommerce platform to market and license certain software and copyrighted materials. Interested parties view a technology listing in an online, global database, agree to a license agreement, pay securely, and instantly download materials. This avenue is often suitable for technologies such as curricula, software, or checklists and protocols that can be delivered online.

Social Media

FRD also promotes MUSC technologies through social media outlets. FRD utilizes LinkedIn to connect and communicate with potential commercial partners, researchers, and MUSC alumni. FRD tweets pertinent information to its Twitter followers at least twice a week. The FRD also distributes a monthly newsletter via email which highlights activity at the FRD and groundbreaking technologies. Currently, more than 1100 people are subscribed to the FRD newsletter.

Option Agreements

An option agreement provides a company short-term exclusive rights to negotiate a license to a technology. The option agreement prohibits FRD from licensing the technology to a third party during the term of the option agreement. Options are often used with faculty startups that may not yet have adequate funding to support the fee schedule of a full license agreement, but still need to acquire some rights in an FRD technology. The payments required for an option agreement are considerably lower than those for a license, and thus provide a much lower-cost method by which a faculty startup may acquire temporary rights in a technology. An option agreement is sufficient to support an SBIR or STTR grant application.

It is important to note, however, that options only provide the startup with a right to license, and a full license agreement will always be necessary before a company can obtain long-term exclusive rights in a technology. Additionally, option agreements limit the company's use of the technology to research and development. Option agreements do not permit a company to generate revenue from the technology. A company must have a license in order to financially benefit from the technology.

License Agreements

License agreements are the mechanism that allows a company to have access to, use, and financially benefit from MUSC intellectual property. Licenses are intricate documents that are negotiated on a case-by-case basis, depending on the needs of the parties and how to best serve the technology. There are many provisions that are common to license agreements, including the license grant, sublicensing rights, diligence provisions to ensure continued development of the technology, royalties, minimum annual royalties, milestone payments, transaction fees, term/termination clauses, and indemnification.

Since license agreements are a very specialized type of contract, FRD always recommends that licensees hire an experienced licensing attorney to represent the company's interests, especially for startup companies. While FRD wants to put startups on the path to success, the fact is that in license drafting, FRD represents MUSC's interests. Thus, licensees should have counsel representing the company's interests.

License Grant

The License Grant is typically the first major section of a license agreement, following the introductory language and the definitions. The Grant section details which rights associated with the given technology FRD is giving to the licensee. Specific provisions in the License Grant will determine whether the license is exclusive, whether the license is restricted to the use of the technology in certain fields of use or geographic regions, and whether the licensee may sublicense their rights to the technology (see paragraph D, "Sublicensing Rights").

Also contained within this section are two important provisions. First, all FRD licenses will contain a Reservation of Rights, which allows MUSC and any entity thereunder to continue to use the technology for educational, research, and medical care purposes. This allows the MUSC inventors to continue their research on the technology without infringing on the license. Second, this section will contain an acknowledgment that any technology based on federally-funded research must comply with the provisions of the Bayh-Dole Act.

The full text of that act can be found at-

https://www.law.cornell.edu/uscode/text/35/part-II/chapter-18. If you have specific questions about Bayh-Dole, please contact the FRD.

Sublicensing Rights

Sublicense agreements occur when a third party wishes to utilize the rights granted under a license. The sublicense is negotiated by the licensee (the original company which licensed the technology) and the sublicensee (the additional company which wants rights to the technology). FRD is not involved in the actual sublicense negotiations, but reserves the right to approve or deny sublicenses. Sublicense agreements are required to maintain certain terms and conditions of the original license agreement.

Diligence

The Diligence portion of a license agreement governs the efforts the Licensee must make in order to maintain its license to the MUSC technology. From a philosophical standpoint, this is the most important section of the license, because FRD wants to ensure that the licensee will work steadily towards bringing the technology to the marketplace, and thus to the bedside.

Often, this section will begin with a "general diligence provision", requiring the licensee to diligently proceed with the development of the technology using earnest and commercially reasonable efforts. This is typically followed by a laundry list of "specific diligence provisions", which vary greatly from license to license. These will set milestones in product development that must be completed by a specified date. The Diligence section will also contain a requirement for annual progress reports to be sent to FRD, to keep us apprised of the development of the technology, and to help enforce compliance with the specific diligence provisions.

Royalties, Milestones, and other Consideration

The Royalties and Consideration section of the license contains the various payments due to FRD throughout the lifespan of the license. These are all highly variable, and are negotiated from license to license. The fees may consist of one or more of the following types:

- A flat license fee due at signing, commonly called the "Upfront Fee";
- A "Transaction Fee" due upon any sale, merger, or other liquidation event of the licensee company;
- Royalty payments, which are calculated as a percentage of sales of licensed products or methods;
- Maintenance fees and minimum annual royalties (MARs), which are payments made annually to continue to the rights granted under the license; MARs count towards royalties that accrue in the year following the payment of the MARs, but are not refunded if royalties do not accrue
- Sublicense fees, which are calculated as a percentage of any revenue attributable to the sublicensing of rights to a 3rd party; and/or
- Milestone payments at various points (IND filing, various points in clinical development, FDA approval, first sale of product, patent issuance, etc.). The amounts and types of payments will depend largely upon the totality of the rights conveyed under each particular license. While it is not typically included in the Royalties and Consideration section of a license, one cost that is universally paid by the licensee is patent prosecution costs.

Term and Termination

The Term and Termination portion of a license agreement contains provisions that lay out the term, or lifespan, of the license, as well as the circumstances under which one or both parties may terminate the license. Typically FRD makes this section very licensee-friendly. Licensees may be allowed to terminate at any time with a set notice period, whereas FRD generally can only terminate under very specific circumstances. License lifespan is highly variable, and depends largely on the particular technology covered by the license. Often, if the technology is a patentable invention, the term of the license will be coextensive with the lifespan of the all covered patent claims.

Indemnification

Indemnification provides one party to an agreement protection from lawsuits resulting from the acts of the other party related to the agreement. The indemnifying party agrees to pay any and all losses, including legal fees for defense, arising from its conduct in relation to the agreement in place of the indemnified party. As a state entity, MUSC is legally unable to indemnify others. MUSC also requires that all potential licensees provide indemnification to the University in their licenses.

For example, Bouncyballs International licenses an innovative ball called the Bouncyball 3000 from MUSC. Bouncyballs International manufactures the Bouncyball 3000 and sells them to the general public. Bouncyballs International uses radioactive material in the production of the balls. If consumers were to sue Bouncyballs International and name MUSC in the lawsuit, Bouncyballs International is required to pay for MUSC's costs associated with defending the suit and any judgment against MUSC.

Of course, these sections are only an overview of the terms contained within a license agreement, and there are numerous other specific provisions, which are also important for licensees to read and understand when licensing a technology.

Startup Companies

What is a startup company?

A startup is a new company, formed by one or more entrepreneurs for the purpose of commercializing one or more pieces of intellectual property. Startups based on MUSC technologies can be formed by the inventors, outside parties interested in developing the technology, or a combination of the two. Startups serve an essential function for advancement of technologies that are too nascent to attract investment from larger, more established companies. Often, a startup will invest in several stages of technology development and then transfer the rights to a larger entity through sublicensing or acquisition of the startup.

Can a startup license technologies from FRD?

In short, yes. When appropriate for continued development of a technology, FRD licenses technologies to faculty members who have created startup companies. Importantly, however, startup companies will be evaluated by the same standards used to evaluate all potential licensees. Therefore, if a faculty member wishes to license his or her invention by creating a startup, FRD will require that the startup has a clear business plan, is able to raise capital or other development funds, and has a comprehensive product development plan. The section of this Guide entitled "Starting a Technology Company" can provide you with a step-by-step guide to this process.

Conflict of Interest Considerations

MUSC recognizes that the pursuit of innovation and technology development may lead to conflict of interest in relation to an inventor and/or entrepreneur's MUSC activities and responsibilities. Conflict of interest does not imply wrongdoing; however, federal regulations require that academic Institutions identify potential COI and ensure that they are effectively managed.

The first step in COI compliance is timely disclosure of all outside activities. Employees are required to submit an annual disclosure (www.musc.edu/coi) during the annual disclosure cycle, April 1-30 each year. Throughout the year, the disclosure must be updated within 30 days if an existing relationship changes or a new relationship develops. Disclosures must include reporting of licensed technology, equity in faculty start-ups, income from faculty-start-ups, receipt of royalties related to licensed technology, and concurrent research related to these interests. It is important that employees notify the COI Office when planning to engage in MUSC research related to their intellectual property and/or equity interests so that potential COI can be reviewed and managed in compliance with federal COI regulations. Additionally, research on technology developed at or by MUSC (i.e., technology in which MUSC has intellectual property rights) may require review for potential Institutional COI. It is recommended that investigators seeking to conduct research on MUSC technology first consult with the COI Office to determine whether an Institutional COI may exist and whether the project will require review by the Institutional COI Committee to determine how/if the research may move forward at MUSC.

Please contact the college of Graduate Studies for guidelines regarding the involvement of students and trainees on projects in which a faculty member has a financial interest.

Employees should read and understand the MUSC/MUHA COI Policy and the Industry Relations Policy to ensure their compliance with relevant university, state and federal guidelines.

If you have any questions or need guidance on COI issues, please contact the COI Office at 843-792-6521 or conflicts@musc.edu.

Starting a TECHNOLOGY COMPANY

A STEP-BY-STEP GUIDE TO STARTING YOUR OWN TECHNOLOGY COMPANY

Startup 101

Starting a company can be an intimidating and confusing process, especially if you don't know where to go to get the information you need. The internet is always a good place to start, but you can easily waste several hours of time looking for answers that may not directly apply to your situation. This chapter is meant to serve as a good starting point. It contains a basic outline of the steps you will need to take and some resources available to you both inside and outside of MUSC, to insure a smooth transition from idea to an actual company.

Assuming that you have an idea or invention, you have filed an ROI with FRD, and a preliminary patent search has shown no immediate red flags, a provisional patent application will be filed. This period before the provisional gets converted to a utility patent (a year) is a perfect time to get the business side in order. The following steps are meant as a suggested order, but by no means needs to be followed exactly.

Write an Executive Summary

An executive summary is an important first step in defining your product or service. A well-written summary should: briefly explain your company, the problem/therapeutic area you are addressing, your solution, and why it is needed along with a short description of the team. It should serve as a basic road map for your business. Understand that this may change several times during the start up process and this most likely will not be the summary you give investors. FRD can help guide you through the process. Below are links to great examples of Executive Summaries to get you started.

Samples:
Garage.com
Inc.com

Do Some Research

Not lab research, but do market research. Understand your market, who else is doing what you are doing, alternative products, potential conferences or articles to help gather data. This will help determine the need for your product or service and trends that are occurring in your area. The Internet is a great place to start. With a few clicks of a mouse you can obtain just about all of the information necessary to understand the competitive landscape and information about your industry. At a minimum, you need to be able to communicate to investors why your product or service is different, who your potential customers are, and why it is needed now.

Find a Mentor

It may surprise you that some of the world's most famous entrepreneurs had mentoring relationships to help them in their quest for excellence. Mentoring is a brain to pick, an ear to listen, introductions to capital or new customers, and a push in the right direction. A mentoring relationship can give you an edge that differentiates you from your peers and/or your competition. There are several mentor networks around town such as the South Carolina Small Business Development Centers (SBDC, http://www.scsbdc.com) and The Harbor Accelerator (http://www.harborec.com).

Decide on the Legal Structure of Your Business

One of the most important decisions you make when you start up your company is the type of legal structure you select. Not only will this decision have an impact on how much you pay in taxes, but also it will affect the amount of paperwork required (cost) at tax time, the personal liability you face and your ability to raise money. The most common forms of business are sole proprietorship, partnership, corporation and S corporation. A more recent addition to these forms of business is the limited liabilty company (LLC) and the limited liability partnership (LLP). Because each business form comes with different tax consequences and liability profile, you will want to make your selection wisely and choose the structure that most closely matches your business' needs. The entity that will probably best fit most MUSC start-ups will be an LLC. They are relatively easy to set-up, inexpensive, and offer sufficient liability protection, but it is highly advised that you consult a small business attorney or the Small Business Development Center. FRD has a relationship with some good firms and will be happy to make an introduction. A note of caution: your uncle or family's real estate attorney maybe helpful for setting up an LLC, but this is not recommended when negotiating your license agreement. All lawyers have specific areas of expertise just like researchers, and academic technology licenses are a highly specialized field.

Choose a Company Address

The company address is where you will receive all of your company correspondence. It can be your actual business address, your home address or your attorney's address. It doesn't matter whose it is, along as you know you have reliable access to the mail and it is a physical address and not a P.O. Box. You will need this physical address to set up your entity with the IRS and the state at the time of company formation. You can transition to a P.O. Box once you are formed.

Register your Company Name

After you have decided on a company name, you can check to see if that name is available at the South Carolina Department of Revenue business portal. While checking, you can also register your company at the same time. All of this information can be found at South Carolina Business One Stop www.scbos.sc.gov.

Get a Tax I.D. Number

As much as you don't want to pay taxes, you have to register with the Internal Revenue Service and your state to pay your share of employment and earnings taxes. It is also helpful in those years when you are accruing losses so that you can record those to be written off against future income. All companies must be registered with the Internal Revenue Service. This can be done at www.scbos.sc.gov or directly with the IRS at www.irs.gov. It is a very easy process and only takes a few minutes, because they want to make sure it is as easy as possible for you to start paying right away.

Register with the South Carolina Department of Revenue

This is the same as the IRS requirement above, but registers your company for purposes of State tax payments as opposed to federal taxes. You can find these forms, along with a lot of other helpful information, at South Carolina Business One Stop www.scbos.sc.gov.

Obtain Business Licenses and Permits

This is also the same as the step above and all information can be found at South Carolina Business One Stop www.scbos.sc.gov. Additionally, if you are selling anything in Charleston or your operations are in the City of Charleston, you must obtain a city business license. Information on that license can be found at the City of Charleston's website here http://www.charleston-sc.gov/

Write a Complete Business Plan

A business plan is a blueprint. It should be used as a tool for understanding how your business is going to function. It is not meant to be a document that you write and follow precisely, but rather a guide that you should expect to change and allow for flexibility in your strategy. You can use it to monitor progress, hold yourself accountable and control the business's fate. Eventually it will serve as a sales and recruiting tool for courting key employees or future investors. Writing out your business plan forces you to review everything at once: your value proposition, marketing assumptions, operations plan, financial plan and staffing plan. Chances are, you'll end up spotting holes or inconsistencies you otherwise would have missed and can start to formulate a plan to remedy them. It is also a tool for "how you drive the future" and whether your assumptions are reasonable. The plan lays out targets in all major areas: sales, costs, employee needs and financing goals. Once laid out, the targets become performance goals. Ultimately the plan can be used for managing yourself, for operating the business, for recruiting and much more.

For examples of actual business plans and templates, please visit SBDC or Chamber workshop, or make an appointment for a consultation with the FRD. We are always happy to help and have a lot of experience writing business plans.

Fund It

Before you begin to raise funds you should have a general idea of how much capital you will need. It is important that you don't underestimate your expenses and try to anticipate future capital needs. When asking for capital, you must have a clear use of the funds. Good uses of funds are toxicity studies, lab space, patent costs, materials, etc. Bad uses of funds are paying salaries, excessive travel, and an extraordinary amount of overhead and administrative costs. The funding sources want to see that their capital is going to further improve the business and give them a clear path to see how they will get their capital back. Paying yourself a huge salary does nothing to further the business and most investors would rather pay themselves than someone else. Remember they have a lot of ideas to choose from, so you must find a way to convince them to pick yours, not the other way around. There are many different sources of capital: Friends and Family, Angel Capital (http://www.chapsc.com), Seed Capital (http://www.garage.com), SBIR Funding (https://www.sbir.gov), Foundation Funding (http://www.ddcf.org) and crowdfunding. Each of these sources has benefits and drawbacks, so it is important to learn what they are before you raise any capital. Please set up a consultation with the FRD before you decide to raise capital.

Some additional helpful funding resources and articles are below:
Forbes.com

Understand employer obligations

Before you hire employees, that are not founders, for your business, be sure you know about employment and labor laws to make sure your business is in compliance. If you are not well-versed in this area be sure to consult an attorney. This will save you a lot of headaches and future legal bills if you handle it correctly in the beginning.

These are the suggested steps for starting a company. Remember these steps are only suggested, and you may follow some of the order or none at all. There are many more parts to each of these steps that if discussed would make a chapter that would be too verbose. As you start down this path, understand that the FRD is available to help you along the way. There are also several other external resources, most of which are free, that are available to you as well. The important thing is to remember that you don't have to go through the process on your own. It should be a fun process and soon you will be on your way to creating a sucessful start-up.

Glossary of Common Terms

Abandonment (of patent application): A patent application becomes abandoned if we elect not to respond to a required action, typically an office action. Common reasons to decide not to respond are insurmountable prior art issues, or a lack of commercial interest that doesn't justify further expenditures. The patent application is abandoned and allowed to expire.

Allowance: A patent examiner has agreed that the patent application claims are novel and non-obvious, but the patent hasn't issued yet (usually because the issuance fee has not yet been paid).

Art: References of any kind that impact the novelty and/or obviousness of an invention.

Assignment: Generally, the transfer of rights and obligations in some item from one party to another. As applied to technology transfer, FRD will require assignment of ownership of an invention from the inventors to MUSC (as required by the IP Policy), and will once again require formal assignments be recorded with the patent office upon the filing of an application.

Author: Anyone who contributes to either the arrangement of words/code/elements, or to the look-and-feel of a copyrighted work.

CDA (Confidential Disclosure Agreement): A short agreement between parties to a disclosure to keep the disclosure confidential. These are necessary to protect potentially patentable inventions before a patent application has been filed. CDAs may either be unilateral (one side agrees to confidentiality) or bilateral (both sides agree).

Claim(s): A section in a patent application containing one or more statements that describe in exact terms what aspect or aspects of the invention the applicant believes to be novel over the prior art. If granted by the patent examiner, the claims will be what dictate the subject matter for which the patent will grant a 20-year monopoly. Narrower claims are easier to obtain, but broader claims are more valuable.

Continuation Patent Application: A patent application filed to pursue additional claims to an invention disclosed in a prior, parent application. The application will have the same specification as the parent application, and the new claims must be supported by information in that original specification. The continuation is entitled to the priority date of the parent application.

Continuation-in-Part Patent Application (CIP): A patent application, which adds new subject matter to its parent application, but shares at least one inventor with the parent, and maintains a large portion of the same specification. For continuations-in-part, any claims directed to the original specification material are granted the parent priority date, while claims to the new matter are only given a priority date as of the date of filing of the new application.

Conversion: At the end of a provisional patent application's 1-year lifespan, the application must "convert" to either a non-provisional, utility filing in the US, or to a PCT filing for international protection. Conversion is when patent offices will begin examination of patent applications, and so this is an important transition in the lifespan of the application.

Copyright: Any original work or authorship fixed in tangible form. Examples of copyright pertinent to MUSC are software works, websites, curricula, checklists, training modules, etc. For more information, see the "Other forms of IP" section of this guide.

Declaration: Also known as the oath, a Declaration is a legally binding form filed with a patent application in which the inventor declares that (1) to the best of his or her knowledge, all residence information is correct, and (2) that he or she believes him-or-herself to be the true inventor of the subject matter covered in the patent.

Diligence Provisions: Clauses in a license agreement either requiring the licensee to use commercially reasonable efforts to develop a technology (general diligence) or to complete certain development milestones by a specific date in time (specific diligence).

Divisional Patent Application: An application filed after having received a restriction requirement on a parent application (see definition of "restriction requirement" below). The divisional contains claims to a second invention that are supported by the parent specification. Divisionals are granted the parent application's priority date.

Family Member/Patent Family: A patent "family" includes the original parent application (typically a provisional), as well as applications stemming from that original downstream. These child applications may be US utility applications, PCTs, divisionals, continuations, or continuations-in-part.

Field of use: A specific area to which an intellectual property license may be limited (e.g. FRD licenses to ABC Corp. the use of this therapeutic for use in treatment of disorders of the kidney only)

Government Support Clause: This is a clause that must be added into any patent application for an invention that was funded by the federal government (i.e., NIH-funded grants). This clause allows the federal government "walk-in rights," or rights allowing the government to use the invention should it deem this necessary.

IIA (Inter-Institutional Agreement): Agreement between FRD and another institution governing the management of the commercialization of a technology in which both institutions have rights. This is a necessary agreement when a faculty inventor has one or more collaborators at another University.

Indemnification: A standard contractual provision requiring one party to pay any costs to the other party resulting from first party's actions or omissions. For more information, see the "Technology Commercialization" section of this guide.

Information Disclosure Statement (IDS): A list of art provided by the inventors disclosing every reference that they are aware of at the time of the patent filing that may impact the examiner's view of patentability.

Intellectual Property: Any intangible property, including ideas, discoveries, know-how, trade secrets, inventions, copyrightable works, and other forms, which may be protected by patent, trademark, copyright, or other means.

Invention: Any innovation that is or may be patentable under Title 17 of the U.S. Code. This includes any possibly patentable discovery.

Inventor: Anyone who contributes in a significant way to the "inventive step" of an invention. The inventive step involves both the conception and reduction to practice of the truly novel element(s) of an invention. Importantly, only enabling an invention does NOT constitute inventorship. For example, a lab tech who carries out all the experiments leading to an invention, but does so at the direction of his/her supervisor, is not an inventor.

Issue Date/Grant Date: The date on which a patent becomes enforceable.

License Agreement: Agreement that entitles the licensee to make, use, or sell the particular subject matter. Licenses may be exclusive or non-exclusive, or may be field-specific (see "Field of Use") or for all uses.

Mandatory Sublicensing: A license provision allowing FRD to require that a licensee sub-license the licensed technology to another entity to meet an unmet market need. This is often included to allow FRD to better ensure that the technology is being developed consistently.

Milestone Payments: Payments required in a license agreement based on the occurrence of certain events. For example, a license to a new therapeutic may include a payment due within 30 days of the commencement of a Phase II clinical trial.

Minimum Annual Royalties (MARs): Set annual payments required in a license agreement beginning on a certain date (usually a certain anniversary of the effective date). As their name suggests, MARs are set off toward any royalties paid by the Licensee in a given year. For example, if a License requires a $20,000 minimum annual royalty beginning on the 5th anniversary of the effective date, and $80,000 in royalties are generated that year, then the Licensee would only owe the remaining $60,000.

Nationalization: Once an international application, or PCT (see below), has been filed, the application will eventually enter the nationalization phase. This phase requires the applicant to select which countries the patent application will be examined in (and the resulting patent will be protected in). Fees must be paid for each individual country selected, and these can be very expensive.

NCS (Non-confidential Summary): A one-sheet summary of a technology containing no confidential information, which is used to market the technology to potential industry partners.

Non-Provisional Patent Application (Utility Patent Application): This is a full patent application that will be published and examined by the Patent Office. The examination process can take anywhere from 2 years to as long as 7 years. However, inventions may be publicly disclosed and classified as "patent pending" during this process.

Office Action: A communication from a patent examiner listing one or more reasons why the claims of an application are non-patentable. The examiner may have issues with the form of the application (objections) or issues with the patentability of the subject matter of the application (rejections).

Option Agreement: A term-limited agreement that affords the optionee the exclusive right to negotiate a license agreement to a particular technology. The option period may be for 6 months, one year, or any other negotiated time period reasonable under the specific circumstances. Once the option period has concluded, if the optionee has not exercised the option right, FRD is free to license the technology to other third parties.

Patent (issued patent): A patent application becomes a patent once it has passed through the examination process at the US Patent and Trademark Office (USPTO). The examiner approves the claims of the patent as being novel and non-obvious. Once a patent has issued, it becomes enforceable, in that the patent-holder has the right to stop others from making, using, or selling, the invention covered in the claims. For more information on the requirements for patenting, see the "Patent Process" section of this guide.

PCT (Patent Cooperation Treaty): Typical terminology representing an international patent application. A PCT may be filed before designating which countries are specifically targeted for patent protection.

Priority Date: The date from which a patent is considered novel. This is generally determined by the earliest filing in the patent's "family". For example, in the most basic scenario, a US utility patent may claim priority back to the date of filing of the provisional that converted into the utility application.

Provisional Patent Application: This application is filed with the Patent Office, and serves as a one-year placeholder while more data is collected and the invention is further developed. This filing allows for a timestamp preventing others from patenting the invention, but the contents are kept confidential and not examined by the Office for one year. At the end of the one-year time frame, the application must either be converted to a non-provisional utility application, or be allowed to go abandoned.

Publication of Patent Application: Generally, patent applications in the US are published 18 months after the earliest filing date.

Rejection (Final/Non-final): The patent examiner has rejected the claims of a patent application due to one or more issues with novelty/non-obviousness or other requirements.

Request for Continued Examination (RCE): This is a procedure by which an applicant may extend the examination period of a patent application, despite the application being under a final rejection. This can be a very expensive process.

ROI (Record of Invention): A form disclosing a new invention, copyrightable work, trademark, trade secret, or other form of IP developed under the MUSC IP Policy. These forms are required for all inventions due to MUSC's duties of reporting to the federal government, and for FRD's internal record-keeping purposes.

Royalty: Generally a fee in a license agreement requiring the licensee to pay to FRD a certain percentage of revenues generated by the licensed technology. There are many ways royalties may be structured, but this is the typical scenario.

SBIR/STTR: Two federally-funded granting mechanisms designed to support startup companies commercializing innovative technologies. For more information on SBIRs/STTRs, see the "SBIR/STTR" section of this Guide.

Service Mark: A legally recognized, unique expression that identifies the source of services for commercial purposes. Nearly indistinguishable from a trademark, other than the distinction of whether goods (trademark) or services (service mark) are provided by the source company.

Specification (or "Spec"): The largest portion of a patent application, which provides background information, detailed description of different possible embodiments of the invention, and examples of potential uses for the invention, among other things.

Startup Company: A company formed by one or more entrepreneurs, for the purpose of commercializing a specific technology. "Faculty Startups" are startups in which one or more MUSC faculty members are founding principals of the company.

Trade Secret: Generally, any formula, device, pattern, process, or information that affords a business advantage over competitors due to its secret nature. For more information, see the "Other IP" section of this Guide.

Trademark: A unique expression that identifies the source of goods for commercial purposes. This may be a set of words, or a logo. Common trademark examples are Coca-Cola, the golden arches of McDonald's, and the Dallas Cowboys star. For more information, see the "Other IP" section of this Guide.

Upfront Fee: A fee in a license agreement requiring the Licensee to pay a designated fee within some time period after execution of the license (typically 30 days).

Contact MUSC FRD

If you feel that you may have created intellectual property, please contact us. We would love to meet with you and discuss your work, or any questions you may have.

Phone: (843) 876-1900

Email: frd@musc.edu