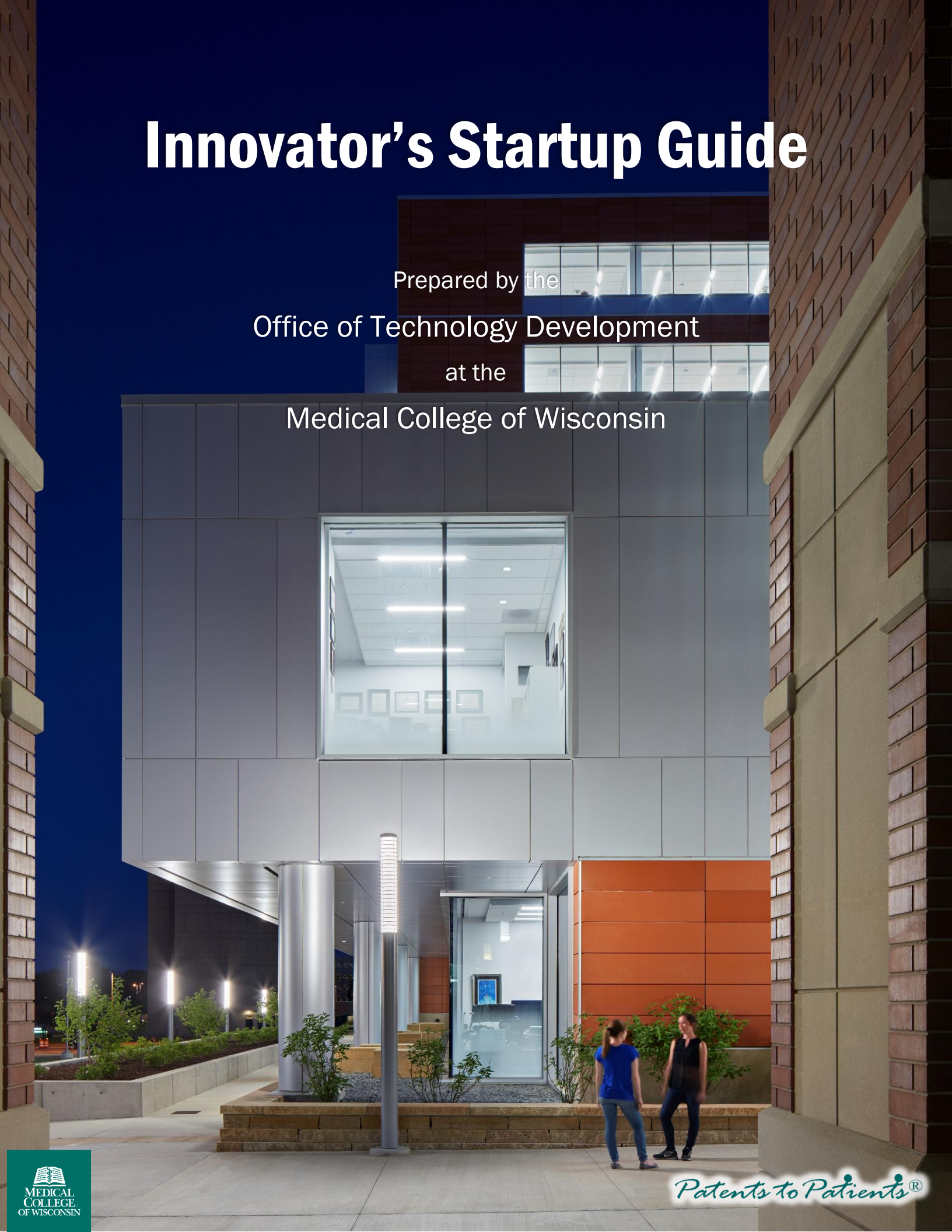
Innovator's Startup Guide

Prepared by the

Office of Technology Development

at the

Medical College of Wisconsin



Medical College of Wisconsin

Patents to Patients®

MEDICAL COLLEGE OF WISCONSIN

Office of TECHNOLOGY DEVELOPMENT

Patents to Patients®

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INTRODUCTION

MCW encourages and supports the formation of startup companies to help bring breakthrough MCW inventions to the patients and healthcare providers who need them.

This Guide is offered by MCW's Office of Technology Development as a source of important, foundational information that assists faculty, staff, trainees and students in navigating technology development and considering opportunities to engage in a startup.

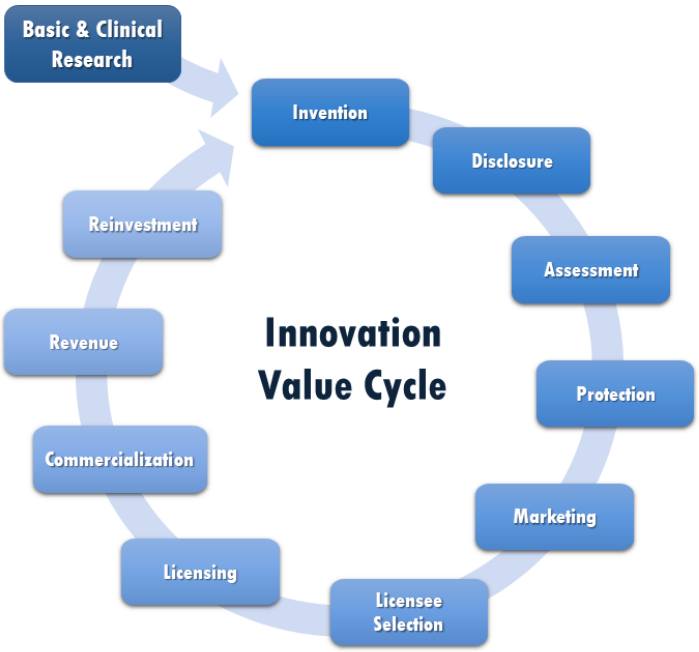
We want to hear from you! The OTD staff looks forward to working with any MCW personnel who have an interest in learning more about these and other startup-related topics. Let us know what questions you have. We are glad to schedule a time to talk with individuals, groups, divisions or departments.

Contact the Office of Technology Development anytime at inventions@mcw.edu

Kevin Boggs, MBA, PhD
Director
Office of Technology Development

TECHNOLOGY TRANSFER PROCESS

It can be helpful to think of the technology transfer process as a cycle. Each "turn" of the cycle begins with basic science discoveries and the ability to envision those breakthroughs becoming new products on the market and tools to address unmet medical needs. When MCW protects and subsequently licenses the intellectual property (IP) underlying those discoveries to the startups or existing companies that can then bring novel products to market, the revenue MCW receives helps support the research that can start another turn of the cycle.



Research Leads to Inventions

Insights generated during basic and clinical research activities often lead to discoveries, inventions, or the development of software and other copyrighted works. An invention is any useful process, machine, composition of matter (e.g., a chemical or biological compound), or any new or useful improvement of the same.

Invention Disclosure

The submission of a completed Invention Disclosure Form to OTD begins the formal technology transfer process. The Form is a confidential document that should be submitted as public disclosure of the invention. It should describe the invention in detail, including enabling data, to allow OTD to understand the novel aspects of the invention. If known, the disclosure should include the important problems it solves and its advantages and benefits over products on the market.

Find Invention Disclosure Forms on the OTD website

Assessing the Invention

The disclosure is assigned to a licensing professional within OTD, who will review it with the goal of assessing and clarifying the invention's market potential. This assessment may include patent searches, market analyses, regulatory overview and a comparison to competitive technologies that are on the market or known to be approaching the market. The results of this assessment enable the licensing team to make determinations regarding IP protection. It is important for OTD to assess the commercial potential of the invention to determine how large an opportunity may exist.

Intellectual Property Protection

Protecting IP via a patent begins with the filing of an application with the U.S. Patent and Trademark Office. When supported by commercial potential, applications are also filed in other countries' foreign patent offices. Once a patent application has been filed, it requires several years and tens of thousands of dollars to obtain an issued patent. The other common form of IP protection that MCW seeks for its technologies, primarily software, is copyright (see Useful Definitions). Biological materials, such as animal models, can be licensed without formal IP protection.

Marketing

With the inventor's input, OTD creates a marketing overview of the technology. Additionally, we identify candidate companies/potential licensees that have the expertise, resources, and business networks to bring the technology to market. These companies are contacted to generate interest and gauge commercial potential. An assessment of the opportunity to create a startup is also made at this stage.

Selecting the Licensee

A key responsibility of OTD is to license technologies to companies, including startups, that have the expertise, resources, and commitment to robustly turn MCW technologies into novel products that generate revenue and enhance healthcare. In the event that we have more than one potential licensee, which is somewhat uncommon, we will license to the company in the best position that is most committed and able to bring the technology to the marketplace.

Licensing

OTD negotiates license and option agreements on behalf of the institution. These agreements are contracts between MCW and a company in which certain MCW rights to a technology are granted in return for financial and other benefits. Startups generally seek an exclusive license agreement because they believe it is required to raise funding for the company. When MCW inventors are part of a startup, licensing to that company can raise concerns about conflicts of commitment and interest. MCW must maintain an arms-length relationship in all its business transactions, including negotiations. The final agreement must fall within the normal range of terms and conditions as that of similar licenses to non-inventor-associated companies. The unique circumstances of each technology and transaction are always taken into consideration.

See "Legal & Compliance Issues" for more on licensing

Commercialization

Most MCW inventions are very early in the development pathway and require further R&D to advance. In most cases, the licensee must make significant investments to bring the product or service to market. This may involve regulatory approval, sales and marketing, support, training, and other activities. The licensee will be expected to meet the commercialization milestones described in the license. Licensees, particularly early stage ventures, often evolve their strategy and development plans in response to company growth, technical challenges, and new market opportunities. OTD can work with licensees to amend and renegotiate agreements if the reasoning is accompanied by evidence of good faith efforts to achieve the milestones agreed to in the original license.

Revenue

Royalties and other fees that are received by MCW from licensees, including cash received from liquidation of equity, are distributed to inventors and departments according to MCW Patent and Copyright Policy RS.GN.060. A portion of such revenue is retained by MCW.

Reinvestment

Revenues generated from OTD-negotiated agreements are shared with inventors' departments to support further research and innovation.

WHY START A COMPANY?

While everyone involved in a startup has their own reasons for pursuing such an endeavor, consider these crucial factors to guide your fundamental reasoning:

- ✓ **Intellectual Property:** Are relevant patents or other IP available to protect the company's products? Are rights to background patents available? For instance, is freedom to operate available?
- ✓ **Product Development Stage:** Is proof-of-concept data available? What are the next steps required to bring the product closer to market? How long will they take to achieve?
- ✓ **Costs vs. Financial Return:** Is the market opportunity sufficient to justify the needed upfront investment?
- ✓ **Single Product versus Product Platform:** If multiple products can be developed from the technology, there is a lower risk of failure, a greater opportunity for multiple revenue streams and a higher probability of securing the required investment.
- ✓ **Market Structure:** Is the market you have identified large enough to pursue? How many companies are competing in the market? Do a small number of them dominate the market?

For more advise on planning, see "Am I Ready to Do This?"

LEGAL & COMPLIANCE ISSUES

MCW Intellectual Property Ownership and Licensing Policy

Per MCW's Patent and Copyright Policy, MCW owns IP generated by its employees. For startups to have the right to that IP, OTD negotiates patent and copyright licenses (see Technology Transfer Process). These licenses include a standard set of terms, including equity, royalties on product sales, patent cost reimbursement, and maintenance fees. Such licenses also include product development diligence milestones. These are important and help us assure that the company remains focused on taking the steps necessary to bring products based on the technology to market.

When in doubt, contact the OTD: inventions@mcw.edu

Types of Company Structures (LLC, C Corp, etc.)

The choice of the best legal structure for each startup depends on such issues as the amount and timing of funding needed and the categories of investors that will provide the initial capital. Generally, there are two options: C Corporations and Limited Liability Corporations or LLCs (see Useful Definitions). The benefits of using the C Corporation structure increase as the amount of funding required to launch a product increases. Companies that need less capital can often take advantage of the simpler LLC structure. If the startup seeks to obtain venture capital, they will need to be established as a C Corporation. The startup also must be a C Corporation to take advantage of Section 1202 for federal capital gains exclusion. It will be important to talk to a lawyer about incorporating in Wisconsin to take advantage of certain state tax credits. Many investors prefer to incorporate in Delaware—this is due to the fact that a company can be a Delaware corporation and still qualify for Wisconsin Tax Credits. This does, however, require that the company be qualified with the Wisconsin Economic Development Corporation as a Qualified New Business. For support, work with your lawyer or consult with OTD.

Protecting Yourself from Liability and Tax Issues

Hiring your own attorney, and if needed, tax consultant, will help assure you that you have the protection you need.

Lawyers

Why you need one: Startups face a variety of complex legal decisions and must enter a wide array of contractual agreements. Having an attorney who is experienced in the startup and early-stage investment world is critical to keep new companies from entering agreements that may have long term harmful impact on the company, such as limiting the ability to raise funds, license IP, and enter service agreements.

When you'll need one: Need for legal counsel will vary depending on company activities. If you will engage the company in a consulting role in exchange for equity, OTD strongly advises you to secure legal advice before signing any agreements. If you take a role that only provides cash compensation, OTD and the Office of General Counsel may be able to provide informal, non-legal advice.

Where to find them: Contact OTD for a referral. While we do not endorse any specific firm, we have a list of credible law firms in the area. You will need to choose a lawyer after you evaluate their credentials, experience, and fees, as you would any professional service provider.

How much a lawyer charges: Generally, hourly fees are charged, although some firms offer flat rates for some services such as filing incorporation papers or reviewing equity agreements. Hourly rates can range from $250-600. Flat rates vary depending on the scope of effort required.

What they do: Lawyers advise you on legal matters and some financial matters. As their client, your lawyer has the responsibility to put your interests first and maintain strict confidentiality. Among other things, they must inform you if they advise someone in conflict of interest with you, and make sure you understand how much their fees will be.

Before you hire an attorney: When interviewing a potential attorney, be sure to request references and ask them if they need to run a conflict check. If MCW is one of their clients, they may not be eligible to also work for your new company.

STARTUP FUNDING

Securing the initial round of funding is a huge, and often quite memorable, early event in the life of any startup. How much funding the startup needs, when it will be needed, and what the funds will be used for are fundamental questions that the startup's leadership must answer.

An important point to keep in mind is that in most cases, external funding may not be used to continue to answer basic research questions—the exception to this being SBIR/STTR grants (see page 12). Instead, external funding should be used in a focused manner to move a product along a commercialization pathway. If you need to conduct more research to better understand the role of your drug/device/software, you may not be ready to form a company.

How Much You Will Need and When

Pharmaceuticals: Whether small molecules or biologics, bringing new drugs through FDA clinical trials entails significant costs. Because startups that develop and test therapeutics through Phase 2 clinical trials can expect to be acquired by a larger pharma/biotech company, the more expensive trials are generally paid for by the larger, acquiring company.

- ✓ Preclinical cost $2-5M
- ✓ Phase 1 trials: $3-10M
- ✓ Phase 2 trials: $7M-$25M
- ✓ Phase 3: Varies widely depending on patient population, type of disease duration of trials: $12M to well over $500 million
- ✓ Total costs per approval of an investigational drug range between $161M - $2.6B. Review online articles from Eye for Pharma & Journal of Health Economics for more information.

Medical device/diagnostic: Devices and diagnostics are less costly to bring to market because testing required by regulatory agencies is usually shorter and less expensive. This cost depends largely on the level and degree of testing required by the FDA and other regulatory agencies. Devices for which product failure will cause little to no safety issues are designated Class 1. In the US, Class 1 devices have very low testing costs and typically require submission of basic information such as quality control of materials and manufacturing methods. Class 2 devices are more complex, and failure may put patients at more serious risk. According to a recent study, the cost to bring Class 2 devices to market average $24M. Finally, Class 3 devices are those that a patient's life depends on. Therefore, testing and approval costs can range several million dollars to $100M, depending on the complexity of the device and the duration of the clinical trials.

Software: The funding required to bring a software product to market within a healthcare application is so variable that it is best handled with a case-by-case analysis. The FDA has recently begun to approve select software as a device, in which case testing costs would be determined according to the class the software falls under.

Grants as Funding Sources

("Free" money, also known as non-dilutive funding)

SBIR/STTR: Contact OTD for questions about SBIR/STTR grants that are available through the state of Wisconsin.

Center for Technology Commercialization (CTC) Programs/Funds:

- ✓ IDEA-ADVANCE Seed Fund
- ✓ SBIR Ready: Building Skills, Proving Concepts
- ✓ Micro-Grants
- ✓ Pre-Submission Review Panels
- ✓ SBIR-ADVANCE Matching Grant

Equity Financing

Selling shares in the company to…

Friends and Family

- ✓ **How it works:** If the funding needs to launch the startup and de-risk the opportunity are modest (say, less than $100,000 total), then it may be possible to fund it through contacts in your personal network.
- ✓ **Pros:** Little need to prepare a "pitch" or to seek investors who are motivated by a potential financial return on invest.
- ✓ **Cons:** Usually only small amounts of capital are available. You will face disappointing your family and friends if they lose their investment. It's unlikely that this investor group includes anyone with industry expertise or relevant networks that you need to grow your business.
- ✓ **Key Issues:** Maintaining a legal structure and carefully managing expectations will be important to avoiding personal conflicts and strained family relationships.

Angel Investors

- ✓ **How it works:** Because Angel Investors (see Useful Definitions) are individuals or families, their motivations, the size of the investment, and industry expertise available can vary widely. Unless they are members of a network of other Angels, they make their own investment decisions.
- ✓ **Pros:** Investment decisions can be made quickly, although not always. Many Angels will invest early in a company's development when the highest risk exists. They may also have a longer time horizon compared to Venture Capitalists.
- ✓ **Cons:** Lower amounts of funding are generally available. The investor may have less relevant expertise and fewer industry connections.

- ✓ **Key Issues:** Carefully review each Angel investor's background and any previous investments they have made before accepting their money. If possible, talk to leaders of other companies they have invested in. Always have your attorney review any investment documents before you sign them.

- ✓ **Resources:** Angel Capital Association

Venture Capitalists

- ✓ **How it works:** VCs (see Useful Definitions) that make investments in early stage life science companies receive hundreds or thousands of unsolicited business plans and investment proposals on an annual basis. If these proposals are reviewed, it is by a junior associate. Very few of those result in a follow-up phone call from a partner who makes investment decisions. However, business plans and proposals that arrive at the firm from a trusted "gate keeper" are given more time from a senior member of the firm. Even if they pass on the opportunity, the firm will share their reasoning and feedback that can improve the odds that the plan will be funded in the future. OTD is glad to discuss accessing such gatekeepers as appropriate.

  If the firm believes that the plan has significant potential and fits within its investment criteria, a senior member of the firm will take over. This involves engaging the startup team in more detailed discussions about their plan, other investors they have spoken with, due diligence and next steps. The firm may require that the startup "syndicate the deal" by identifying other VCs to join in before any investment is made. As your CEO prepares to approach VC firms for investments, note that it is not uncommon to make several dozen pitches before finding a firm for which your opportunity is a good fit. It is also not uncommon for a VC to track progress over several years to get to know a company better before making an investment.

- ✓ **Pros:** Larger amounts of capital available. Investments from credible firms bring a level of validation, industry expertise, and connections.

- ✓ **Cons:** VCs generally invest later in a company's development, meaning VC funding is

rarely the "first money in". Founders give up significant aspects of control, and investment decisions may take longer.

- ✓ **Key Issues:** Successfully landing a first round of VC funding requires a familiarity with a new set of jargon (i.e., "round"). Concepts and issues that significantly impact your company's path forward with a VC are beyond the scope of this Guide. OTD is available to answer questions and, when suitable, to make introductions.

- ✓ **Resources:**

  - National Venture Capital Association
  - Several books by experienced Venture Capitalist Brad Feld, see especially "Venture Deals, 4th Edition"
  - "Secrets of Sandhill Road" by Scott Kapur is great resource for entrepreneurs

Banks

We include banks here for completeness. However, banks are very rarely, if ever, a source of early stage funds for life sciences startups.

CEO: Chief Executive Officer

Why? Having a full time CEO, or part time under some circumstances, is a key early step in the development of a company. The CEO is very important, both because they will be the one person who wakes up every morning with the sole mission of making the company successful, and because a credible CEO shows potential investors that the opportunity is real. They will also know that a professional with relevant experience will be a good steward of their investment funding.

When? As soon as it is clear that the technology works and that there is a market opportunity that will allow a CEO to raise funding, build a team, and develop the plan to bring products to market, potential CEO candidates should be engaged. This can start with informal discussions. OTD can assist by making introductions and doing informal background checks with our networks.

How to recruit the CEO? A credible and experienced startup CEO will have many options. They will be looking for an opportunity that excites them with a startup they believe they can add value to and have a solid chance to be successful. They also know that every early stage opportunity has a variety of risks, and that overcoming them will require working closely with the scientific founders. This means they have to have a high level of trust when interacting with those founders. If they only hear that there are no potential scientific problems, no market competition, and no IP issues, they will wonder what is being hidden, or what they will find when they start digging into the opportunity. Better to engage in radical candor about the science and any other issues that the scientific founders are aware of. This does not mean one should bury the compelling story in negative, "what-if" scenarios, but a sense of trust is essential to carry a team through challenging times.

How to select the CEO? Criteria for considering your CEO should include their track record of successful startups and their reputation among respected VCs. A highly credible CEO is often as important—or even more important—to VCs than the technology. Also, it is a common practice for VCs to insist on placing senior management in a Company that they are funding, even replacing the CEO, CSO, etc., that may have helped start the company.

What will the CEO expect? Your CEO will anticipate having a high level of autonomy to make key decisions, to report directly to the board of directors, and to have a market-comparable share of the company's equity (vested over time). The CEO should be accountable to the investors and either be the primary spokesperson for the company or appoint them. They may be positioned to defer most or

all their cash compensation until the first significant round of funding has been raised.

What is the CEO's job? The CEO should raise funding, develop and execute a business plan, make hiring decisions, manage the Board, and position the company to be acquired or to go public.

Be aware that the quality of company leadership is critical to VCs. In conducting their due diligence, VCs will consider if the CEO has a track record of successful startups and whether they are respected among other VCs. This is often as important or even more important than the science to a good firm. Do not be surprised if a VC insists on placing senior management in a Company that they are funding, even if you already have a CEO, CSO, or other senior leader in place.

Regulatory Consultants

Why? If the company's products are regulated by the FDA and similar agencies in other countries, a clear strategy to achieve regulatory clearance or approval in a timely and cost-efficient way is critical to a company's long-term success. Indeed, regulatory mistakes made early in a company's life can easily sink the company. However, most startups can't afford to hire a full-time regulatory expert and may not need one. Thus, an experienced regulatory consultant who works on a project basis is critical, even if only to advise on strategy and to review documents before they are submitted.

When? A consultant should be identified when proof of concept data is gathered, and the clear next step is to identify the regulatory path and a plan to achieve the key milestones.

How much do they cost? Like attorneys, consultants may charge in the range of $200-400/hr. Many also offer flat fees for well-defined projects.

Where to find them? OTD can make introductions. The Regulatory Affairs Professionals Society is also a source of useful information.

Reimbursement Consultants

Why? A reimbursement consultant is beneficial for the same reasons as a regulatory consultant. Choosing the optimal reimbursement path early on is becoming an important step that can have

lasting impact on the fortunes of the company. A consultant should be able to advise about strategy, tactics, likely outcomes, and the kinds of professionals you are likely to need and when. Investors will also want a clear path to reimbursement before making an investment.

When? Very preliminary discussions should occur as the product and indication are being finalized.

How much do they cost? Fees for reimbursement consultants are similar to regulatory consultants.

Where to find them? This is a more nascent profession. OTD can make introductions as can others in your network.

Chief Operating Officer/Business Development Lead

Why? While the CEO is the first and most important salesperson in the company, sales into markets with complex supply chains, long sales cycles, entrenched competitors, customers spread over a wide geographic area, and even additional regulatory issues will require careful planning and may depend on a well-structured sales force. Someone experienced with building sales plans and hiring and compensating a sales team is thus a key hire.

When? Variable, depending upon the product and the market.

How much do they cost? A Chief Operating Officer/ Business Development Lead will expect a compensation package that includes both cash (little deferred, if any) and equity.

For information on Lawyers, see "Legal & Compliance Issues"

Where to find them? The CEO and Board members should have networks that include experienced people that they trust.

NETWORKS & SUPPORT ORGANIZATIONS

Center for Technology Commercialization

CTC can be useful in helping you find the support and resources you need to bring your innovation to market. CTC offers services and assistance with your funding acquisition efforts through the federal Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs.

BioForward

BioForward is the only Wisconsin organization representing over 200 biohealth member companies including biotech, biopharma, medical device, diagnostics, digital health, as well as research institutions, and service providers. It is Wisconsin's official affiliate of BIO. BioForward's programs and memberships are designed to support members through business networking events, advocacy on behalf of the industry, exclusive rebates through our select savings program, and educational and speaker programming.

Biotechnology Innovation Organization (BIO)

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

Catalyst BioConsulting

Catalyst BioConsulting (formerly PICO – Postdoc Industry Consultants) is a business consulting group comprised of highly trained scientists that provides a broad range of consulting services for the many challenges faced by startup and established firms. They offer pro-bono services geared towards the sustainable development and growth of innovative biotech and health technology companies in Wisconsin and beyond.

NETWORKS & SUPPORT ORGANIZATIONS

Gener8tor

Gener8tor is a turnkey platform for the creative economy that connects startups, entrepreneurs, artists, investors, universities and corporations. The gener8tor platform includes pre-accelerators, accelerators, corporate programming, conferences, and fellowships focused on entrepreneurs, artists and musicians.

gBETA

gBETA is a program of nationally ranked startup accelerator gener8tor. gBETA is a free, seven-week accelerator for early-stage companies with local roots. Each program is capped at five teams and requires no fees and no equity.

Wisconsin Technology Council

WTC offers a wide variety of services to Wisconsin startups, including access to the Wisconsin Innovation Network (WIN) and Investor Networks. Annual events include the Wisconsin Entrepreneur's Conference, the Wisconsin Governor's Business Plan Competition, the Early Stage Conference, and the Tech Summit.

NSF I-Corps

The National Science Foundation (NSF) created the Innovation Corps (I-Corps) Program to help accelerate the transfer of academic research into the marketplace. The Program focuses on using "lean launch" methodology to help faculty-based researchers understand markets for their technologies. Since 2015, UWM and the UWM Research Foundation have been bringing this unique program to Milwaukee. From the Milwaukee I-Corps website:

What Is My Role?

Your role will evolve as the company grows and the products move along the development pathway.

Inventors are not CEOs: Your significant expertise is needed to continue the science. The tasks of a CEO would naturally put you in a conflict situation. Additionally, OTD strongly prefers to not negotiate license terms with the inventors. We are advocates for the inventors and this mixed role is best avoided. While MCW inventors are very intelligent people, there are many areas of business that few academically trained personnel have requisite expertise in.

Optimally: Inventors are well suited as Science Advisors or as head of the Scientific Advisory Board (SAB). This is the best role for researchers who want to engage with the startup. Some startups may offer a small amount of equity to SAB members. Some may also reimburse out-of-pocket costs to attend meetings or to meet with potential investors.

Potentially: An alternative role may be Acting Chief Scientific Officer. If the CEO and the early investors see the need for a higher level of engagement from the inventors than SAB membership would allow, the CSO can be a useful short-term role. Because the CSO ultimately will work with the other members of the leadership team to bring products into development in a way that will soon split off from the basic science aspects of the technology, the full time CSO will need to have more product development and testing knowledge, which often comes from industry experience.

Will I Need a Business Plan?

Eventually. As the company gets started, a well-reviewed slide deck will be the primary tool used to help tell its story. OTD will be glad to discuss slides and business plans. What you WILL need is a clear, focused and time-bound development plan that shows how much time and how much money are required to hit specific “Go, No-Go” decision points.

How Might I Benefit from Working with a Startup?

There are a variety of reasons that people choose to be involved in a startup. In some cases, the decision is purely economic: they need an income. In others, a person may believe that working for a large organization provides too little independence. If you are an MCW faculty member, these reasons are more likely to apply to others that are considering joining the effort, including post-docs and graduate students who have recently completed their course of study.

A few of the benefits that researchers have experienced from engaging with a startup include the opportunity to bring an idea from the lab to the people who can benefit most from it. Then, of course, there is the potential that their initial ownership stake, which will naturally decrease as investments are raised and employees are hired, has the potential to generate a financial return.

It is important to note that any equity you may be granted directly by the company will (1) be at the company's discretion, and (2) not be in exchange for your inventorship. Rather, it will be in exchange for your efforts to advance the company's business objectives. It will likely be vested as specific accomplishments are achieved. It is advisable to consult with your personal attorney about the terms under which such equity is granted to you.

Additional resource documents available in "Appendix"

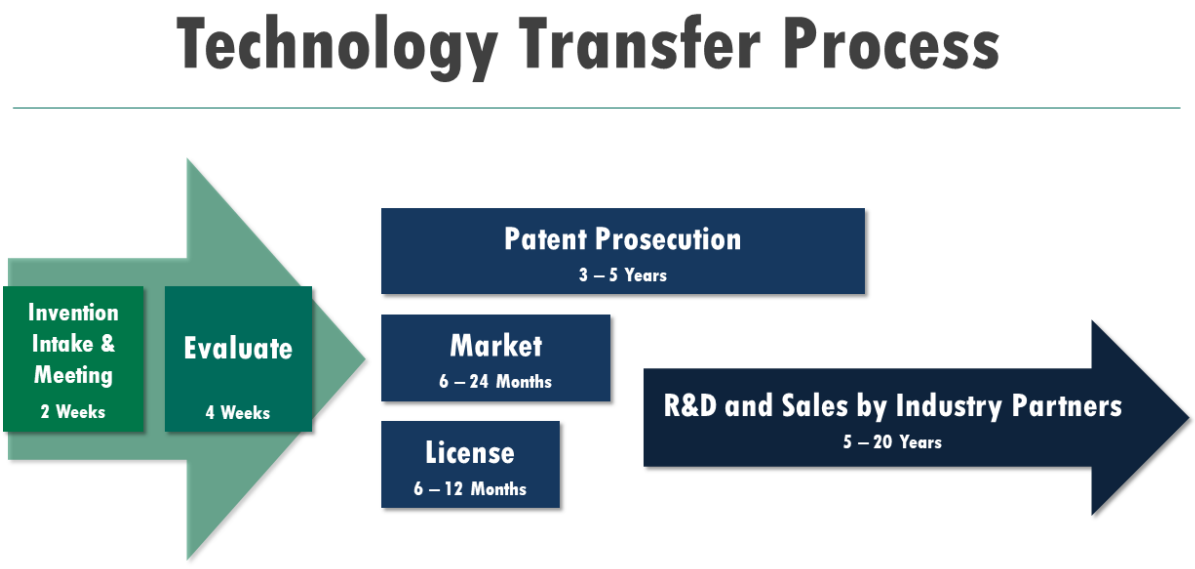
If MCW receives equity in exchange for an IP license and that equity is sold in the future for cash, that cash will be distributed to the inventors pursuant to the current MCW Patent and Copyright Policy RS.GN.060. The policy is applicable at the time of such distribution.

Should I Expect to Maintain Control Over the Direction of the Company?

No. Product development and testing, especially in life sciences, is very expensive. Raising the amount of money needed to bring a biotech or medical device product to market requires that the majority of the company would be owned by the investors which provide that funding. Those investors will also demand to have the right to make necessary decisions that keep the growing company on track, as well as preparing for future rounds of financing and acquisition and ensuring business development goals are met.

What Is the Estimated Timeline for Establishment, Development and Growth?

Average time frames for the various key stages of company development and growth are illustrated in the graphic below:



ROLES OF KEY MCW OFFICES

Office of Technology Development (OTD)

The mission of OTD is to support and educate MCW faculty, postdoctoral fellows, interns, students and staff. The OTD facilitates the transfer of technology generated from research and clinical practices into commercial products that benefit MCW, our community and the public. The OTD engages inventors, as well as internal and external stakeholders, to bring Patents to Patients®.

General Counsel

The Office of the General Counsel ("OGC"), is the in-house legal office for The Medical College of Wisconsin.

Grants and Contracts Office

The mission of the Grants and Contracts Office (GCO) is to support investigators and the MCW research community in submitting high quality, competitive and compliant research grants. The GCO also helps maintain commitments to our corporate and federal sponsors, ensures compliance with all applicable federal, state, local and institutional policies and regulations, and promotes best practices, policies and procedures that ensure consistency and efficiency in our interactions with sponsors, affiliates, collaborators, and investigators.

Compliance

The primary function of the Corporate Compliance program is to help ensure that the College is consistently following all federal and state regulations relating to our missions. The Division of Corporate Compliance has four offices that assist with this function: The Clinical Compliance Office, the Internal Audit Office, the Research Compliance Office, and the Risk Management Office.

Startups Are Hard Work

For many people, choosing to engage with a startup has an appeal that is partly derived from the splashy successes—and sometimes the failures—of startups that became legends. As with any legend, some of the stories have elements of truth while others that have been stretched beyond recognition in the service of some of the stakeholders. But, common threads of any of these stories include a great team, some luck and hard work. If you work with OTD on a startup, you will have the opportunity to meet entrepreneurs who have done that hard work.

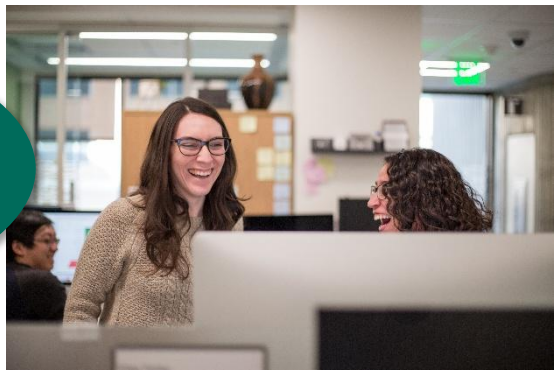
Startups Are Risky

While it depends on the type of product and the complexity of the path to market, startups generally have a 50-80% chance of failing. Starting with a strong team, seeking and heeding counsel from knowledgeable advisors, and remaining flexible in response to feedback from actual customers are three important elements that improve the odds for a fledgling company to be acquired for an attractive sum, or to gain a strategic position that will allow it to go public.

Startups Are Exhilarating!

Much like the common response to getting off a roller coaster that one had previously been anxious about: “I want to go again!”, exiting a role in a startup often leaves people looking for the next opportunity to re-enter that world. OTD can help you find people with that experience who are willing to share their story. Other stories are at the links below.

The OTD has helped launch over two dozen startups in the Milwaukee area and beyond!



APPENDIX

Resources

Digital:

How to Start a Biotech Company

Milwaukee NSF I-Corp program

National Venture Capital Association

WI Tech Council Entrepreneurs' Tool Kit

Startup Revolution

US Patent and Trademark Office

World Intellectual Property Organization

Various Cap Table Scenarios for a Hypothetical Biotech Startup

Recruiting Talent for University Startups

Print:

Books by Brad Feld

Books by Steve Blank

The Mom Test:
How to talk to customers & learn if your business is a good idea when everyone is lying to you

APPENDIX

Useful Definitions

Angel Investors ("Angels"): Wealthy individuals who invest their personal funds in startups. When Angels first appeared as a significant source of funding in life sciences companies, many were motivated by a desire to find a treatment for a disease that had impacted their lives. In recent years, more and more Angels are investing strictly to achieve a financial return on their investment. Some Angels have formed networks, or funds, that are quite sophisticated and often invest significant levels of capital along-side VCs. Angels must be accredited investors, which means they must meet minimum income or net worth thresholds defined by the U.S. Securities and Exchange Commission (SEC).

C Corporation: Any corporation that is taxed separately from its owners. C corporations are governed by laws of the state they are incorporated in. Investors tend to prefer the predictability of Delaware law.

Chief Executive Officer (CEO): The most senior leader of a company. Makes key strategic decisions. Reports to the Board of Directors.

Copyright: A limited-term, government-granted intellectual property right that gives the copyright holder the right to exclude others from copying and distributing their copyrighted work. Copyright protection applies and is enforceable as soon as a creative work is applied to a fixed medium of expression—on paper or on a computer server, for instance. Copyright applies to both published an unpublished works. The following are relevant examples of types of works that are protected by copyright: software code, including databases, websites, and user interface design.

Board of Directors: Investopedia defines a Board of Directors as: "A group of individuals elected to represent shareholders. A board's mandate is to establish policies for corporate management and oversight, making decisions on major company issues." At startups, boards are generally controlled by the investors but often include the CEO, a scientific founder and an independent member. After a significant first round of investment, boards are likely to meet at least quarterly. The fiduciary duty that boards of directors and officers owe is solely to the corporation and the shareholders collectively.

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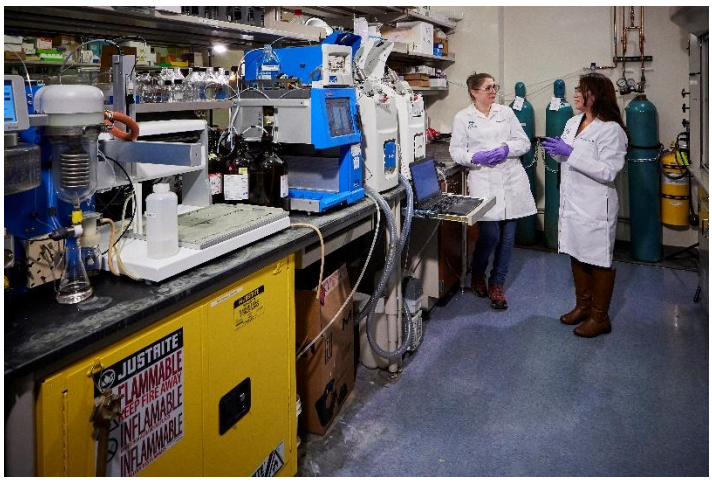

Conception of an Invention: To "conceive" an invention is defined in a legal sense as the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 Robinson On Patents 532 (1890). This means that all details needed to make the invention work must be available.

Embodiment of an Invention: An embodiment of an invention is a version of, or one specific way of practicing, the invention. For example, if the invention is a method of treat autoimmune diseases, a specific claim to treatment of lupus is one embodiment of the invention.

Enable an Invention: To enable an invention is to disclose sufficient details so that one of skill in the art can practice the invention.

Equity: Ownership stake in a company. One unit of equity of a corporation is a share. Ownership of LLCs is generally in units or percentages.

Food and Drug Administration: The FDA is the federal agency responsible for "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation."

Freedom to Operate: One does not infringe the IP rights of others while making, using, or selling a product or service. Or, that one has a license to any such IP rights that may otherwise be infringed.

Intellectual Property (IP): A government issued property right. Grants certain rights to products of the mind. Examples include patents, copyrights, and trade secrets.

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License: A contract that grants the licensee certain IP rights held by the licensor. May be exclusive (licensee is the only licensee), non-exclusive (may be several licensees), exclusive field-of-use (e.g., licensee will be the only licensee allowed to use the IP in a defined application or type or market) or exclusive by territory (e.g., licensee is the only licensee in a specified country or region).

Limited Liability Company (LLC): A legal structure for a company that limits the liability of its owners but allows pass-through taxation. LLCs are not corporations and are governed based on an operating agreement, which is an agreement among the owners.

Patent: A limited-term government-granted intellectual property right that gives the owner the right to exclude others from making, using or selling products or services that infringe the claims of the patent. Patent rights are specific to each country in which they are issued, meaning a U.S. patent is not enforceable in other countries. Patent protection is available for compositions of matter such as new molecular structures, machines, articles of manufacture, methods, and processes including computer-implemented software. It is not available for naturally occurring, unmodified molecules, natural processes, and laws of nature.

Reduction to Practice of an Invention: US patent laws define the reduction to practice of an invention as the step or steps in the formation of an invention after the conception of the invention. Reduction to practice may be actual, meaning the invention is actually physically created and is found to work for its intended purpose, or constructive, meaning a patent application is filed that has a sufficient description to the extent that the invention can be physically reduced to practice.

Small Business Innovation Research & Small Business Technology Transfer Grants: SBIR & STTR grants are provided by eleven (SBIR) and five (STTR) federal agencies, including the NIH. The grants are awarded via a competitive application process. While these funds are available only directly to US-owned and operated small businesses to engage in federal research and development that has potential for commercialization, a portion of such funding may be used to support work at a research institution under a sub-award.

Startup: A new company established to develop and commercialize novel technologies.

Trademark: A trademark is a brand name. A trademark or service mark includes any word, name, symbol, device, or any combination, used or intended to be used to identify and distinguish the goods/services of one seller or provider from those of others, and to indicate the source of the goods/services.

Venture Capital Firms (VCs): Specialized investment firms that raise funds from institutions and accredited investors, together called Limited Partners (LPs). VC firms invest using a clearly defined set of criteria. Investments are generally restricted to a set of industries, such as therapeutics or software, and are limited to a narrow range of company and product maturity profiles, such as pre-revenue, above $5M/year in revenue, etc. The members of the firm who make investment decisions, individually known as a General Partner (GP), often have significant knowledge about the types of companies the firm invests in. Access to these people and their networks is of significant value to startup companies.

Frequently Asked Questions

Q: Does disclosing my invention mean I can't publish it?

A: No. The OTD never interferes with publication or academic freedom.

Q: If a technology from my lab is exclusively licensed, do I lose the right to use it for research?

A: No. OTD always reserves our right to use licensed technology for research purposes.

Q: Can patents be extended?

A: Only in some specific situations. The one that is most relevant to MCW technologies is the 1984 Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act. This law gives patent holders the opportunity to apply for an extension on a patent that covers a pharmaceutical or medical device that is subject to regulation by the FDA. The maximum extension is 5 years and can be applied to only one patent covering the FDA-regulated product. The United States Patent and Trademark Office and the FDA work together to determine the length of extension they will grant. That extension is based on the amount of time required for product testing and data review required for FDA approval.

Q: If we file a patent application on unpublished work, will it be public via the Patent Office before I can publish in peer reviewed journals?

A: Very rarely and even then we have ways to avoid it. OTD, like many university technology transfer offices, often files the first patent application on an invention as a provisional application. This type of application, which must be replaced within 12 months by a non-provisional application, is not published. So, in most cases, papers are accepted and published before the end of the 12-month period. If it is something you are concerned about, please let us know.

Q: A patent gives the inventor the right to use their invention, right?

A: Actually, and surprisingly to some, it does not. Patents give their owners the rights to exclude others from making, using, or selling the inventions as described in the patent's claims. It is not uncommon for part of a functional invention to be covered by someone else's patent. In that case, to practice your invention, you would need to enter into a license with the owner of that patent. This is a key consideration OTD includes in our assessment of new inventions. For more information, please contact us.

Q: If my invention derives from federally funded research, does the government own it?

A: No. The Bayh-Dole Act of 1980 specifically gives nonprofit and small business recipients of federal research funding the right to retain ownership of IP developed under federal grants. This right comes with the proactive obligation to protect (via patents) and commercialize (via patent licensing) those federally funded technologies. For more information, please contact us.

Q: When a company licenses IP from MCW, what does MCW get in return?

A: For the rights MCW grants to companies in licenses, companies take on obligations and are required to pay fees. Obligations include requirements to diligently develop products based on the IP. Fees generally are in the form of royalties on sales of the product and flat fees on certain milestones (e.g., FDA approval). Net revenue earned from a licensee is distributed according to MCW's Patent and Copyright policy (RS.GN.060).

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Q: To support development of my invention, can I write an NIH SBIR/STTR (Small Business Innovation Research/Small Business Technology Transfer) grant?

A: Only small businesses can submit SBIR grants. The small business also needs to have at least one technically credible employee working 51% or more for the company and acting as principal investigator (PI) on the grant. STTR grants also require a small company that does at least 40% of the funded work but the PI does not have to work for the company. OTD has additional information as access to assistance from the State of Wisconsin.

Q: Do I have to start a company to commercialize my invention?

A: No. While OTD is happy to work with faculty members who are interested in exploring the idea of a startup, it is not required. OTD uses a variety of approaches to commercialize inventions by licensing to large companies, as well as to smaller ones, also startups. We are glad to talk with you if you have any questions.

Q: What are the differences between copyright and patents?

A: Copyright and patents are both forms of government-issued intellectual property rights and are enforceable only in the country that issued them. Copyright protects creative works such as books, plays, and movies and more relevantly to MCW, software. It gives the owner of the copyright the right to prohibit others from copying their work for commercial use. Copyrights expire 70 years beyond the life of the author. Patents, however, protect inventions including new materials (e.g., chemical compounds), processes, methods, and devices. Patents, with a few exceptions, expire 20 years after the date the initial application was filed. Patents allow the patent holder to exclude others from making, using, or selling their patented invention.

Q: I have an idea for a medical device. I believe it will help patients have better outcomes or will make clinicians' jobs easier. What do I do now?

A: The short and easiest answer is to contact OTD at inventions@mcw.edu

We can review the idea, the size of the need, and the level of competition. We can also schedule a design brainstorming meeting with MCW's in-house biomedical engineers.

Q: Is submitting a novel idea or research results to a generative AI platform a public disclosure for patent purposes?

A: Yes. Our patent attorneys advise us to treat entering ideas into any web platform as a public disclosure which significantly reduces the potential value of the intellectual property (IP) available for your idea.

Q: If my invention has more than one potential application, how does OTD help assure that all of them are developed?

A: When we talk with a company about licensing technologies with multiple applications, we make them aware of OTD's mandate to fully leverage all aspects of any IP that we manage. Which means that any license we enter with the company will include a requirement to either develop products in multiple applications (called "Fields of Use") or to sublicense any Field they are not developing to other companies capable of developing products in that Field. A typical example of Fields of Use that are easy to separate is human vs veterinary uses.

Q: How does OTD manage technologies that involve inventors from multiple institutions?

A: Inventions disclosed to OTD often include collaborators/co-inventors from other institutions. Those universities co-own the IP with MCW. OTD works with our counterparts at those institutions to enter agreements that allow one of us to manage the patenting and licensing process. We will work with you to determine how to allocate costs and licensing revenue based on relative contribution of each team to the value of the IP.

Q: What is the difference between a patent and a license?

A: An analogy with property deeds and leases is useful. A property deed for a piece of land defines the exact boundaries that the property owner has rights to. Those rights include blocking others from using the property for any purpose (building, growing crops, etc.). A patent allows the owner to block others from using the invention described in the claims (i.e., the boundaries of the property). If a property owner agrees to let another party use their land, they would enter a lease agreement. Similarly, if a patent owner agrees to allow another party to make, use or sell products or services that are protected by their patent, they would enter a license agreement to allow use of the patented invention under mutually agreeable terms. OTD has licensed dozens of patents to companies of all sizes since 1984. We are always glad to address any additional questions about patents and licenses from anyone in the MCW community.

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About the Guide:

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