Vanderbilt University's **Commercialization Process**





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The Center for Technology Transfer and Commercialization's mission is: to provide professional technology commercialization services to the Vanderbilt community, optimizing the flow of innovation to the marketplace and generating revenue that supports future research activities, while having a positive impact on society. This cannot be accomplished without the active engagement of the faculty and staff whom we serve. Vanderbilt's commercialization process is illustrated in this document to help university inventors better understand the process by which we make commercialization decisions. Each step of the process is dissected and detailed within the document.

Most of what is developed during a research project is academic knowledge that is disseminated through peer-reviewed journals. However, new inventions, discoveries, materials, and the like can also have commercialization potential. We help identify opportunities and how they can best be protected and commercialized.

Research

Research performed by Vanderbilt faculty and staff commonly leads to new discoveries, technologies, and inventions that are protectable, usually with a patent. Patent protection may be sought for new and useful processes, machines, articles of manufacture, compositions of matter, or improvements to the foregoing. Research can also result in other forms of protectable intellectual property. Software or other tangible expressions of creative works can often be protected by copyrights. Biological materials can be patented in special circumstances, but are often licensed (transferring intellectual property from Vanderbilt to a company for commercial exploitation) without patent protection.

Many of the useful processes and methods that are developed during the course of a research project can be transferred to industry even though they may not be protected by patent or copyright. Of course, most of what is developed during research projects is academic knowledge, and publication is usually the preferred route for disseminating such results. If any questions ever arise regarding whether a technology is protectable or worth pursuing commercially, CTTC is here to help talk through such issues.

- ► Keep good lab notes and have them witnessed periodically
 - Documentation can help preserve rights in a patent interference proceeding
- ► Make sure contracts are in place
 - Inter-institutional collaborations require a Joint Development Agreement to protect against loss of patentability (see CREATE Act of 2004)
 - Contract researchers/programmers may require an "obligation to assign" subcontract agreements involving a clause to preserve Vanderbilt's rights
- ► Be aware of what constitutes an invention
- ► Engage CTTC as early on as possible

Disclose

Submitting a completed invention disclosure form launches the CTTC review process. This document allows CTTC to record the invention, identify publication deadlines, evaluate the technology based on information disclosed, and fulfill obligations to government, foundation, and industry funding sponsors.

Disclosure of new inventions resulting from Vanderbilt research activities are made to CTTC by completion and submission of an invention disclosure form, thereby initiating the commercialization process. The form collects information regarding funding and/or third party material that we use to fulfill Vanderbilt's obligations to the sponsor, including reporting of federally funded inventions to the government, and to accurately assess ownership of the invention. The disclosure form is used to create a record of an invention and to convey all of the information we may need to evaluate and protect the invention. Disclosure forms provide, among other things, detailed information about the invention (what it does, why it's needed, and how it's better than the state of the art), the current state of its development, potential companies that may have an interest in it, and names of contributors to the invention and the departments or centers with which they are associated.

For each disclosure form submitted, CTTC creates a unique VU number and database entry for the invention—creating an official disclosure date and record of the invention. Each named contributor receives a confirmation email informing them that their invention was received and processed and identifying the licensing officer assigned to their case. During the initial assessment, the disclosure is reviewed for completeness and accuracy. Inventors will receive notice of any missing information within a few days after receipt. It is vitally important that invention disclosure forms are as complete as possible so that we have all necessary information needed to adequately protect the invention and fulfill all of Vanderbilt's requirements related thereto.

- ► Provide a detailed description of the invention
 - Describe enablement and best mode of this invention for inclusion in the patent application
 - Proper patent searches and market analyses cannot be done without a full description
- ► Identify companies you have a relationship with or that you know of in a relevant industry
 - 70% of licensing leads come from inventors
- ► Identify sources of research funding (including grant numbers)
 - We need to fulfill all reporting/IP obligations to the funding sponsor(s)
- ► Specify plans for ongoing development efforts
- Identify any publications of the invention—past or future

Evaluate

A CTTC licensing officer will review the disclosure and its scientific details with the inventor in order to achieve a deep understanding of the innovation. The officer will then perform an assessment of market potential, patentability, capabilities for future development, and other salient issues affecting commercialization efforts.

The evaluation process provides us with a better understanding of the invention in order to facilitate its protection and commercialization. CTTC works to understand the significance, ownership, technical and commercial aspects, and potential of the invention. The evaluation process can be broken into two distinct steps: Cursory Assessment and In-depth Analysis. These two steps can typically be completed in about two months. The entire evaluation process often requires multiple discussions with the inventors to optimize the outcome.

Cursory Assessment

Once CTTC has received all the salient information regarding the invention, the assigned licensing officer studies the disclosure to gain a full and complete understanding of the invention and all of the potential applications and limitations it may have. This step often involves meeting with the inventors to learn about their future plans for publications and development of the invention, to experience the technology in action (if possible), and to better understand the perspectives of the inventors regarding the advantages of the invention over the current state of the art and its potential applications. In addition to the technical aspects of the invention, the licensing officer will need to learn more about the invention from an ownership perspective. For example, if the invention was jointly created with another institution or was created with resources from an outside source such as a company, foundation, or other funding source, there may be particular ownership issues related to the invention which will need to be understood and considered. The licensing officer will typically contact the lead inventor(s) within 1–2 weeks to discuss the invention and the next steps of the process, including a more detailed evaluation.

In-Depth Analysis

After discussing the invention with the lead inventor(s), the licensing officer will conduct an in-depth analysis of the invention, which usually requires a one to two months of focused activity. During this in-depth analysis, the invention is assessed for protectability and market-ability to determine the best course of action to facilitate the commercial translation of the invention. The licensing officer will begin to evaluate the invention's market opportunity by utilizing a variety of tools including Web searches, proprietary databases and professional services, and discussions with industry contacts. This evaluation determines if there is a need for the invention and how it compares to the current products or methods being used.

In concert with the market evaluation, the licensing officer will assess the invention and types of intellectual property protection available. There are many ways in which intellectual property can be protected and value can be extracted. The licensing officer will discuss which forms of protection are most appropriate for the invention and how such protection can be accomplished. Often the market analysis further clarifies which forms of protection would be most advantageous for the invention.

In the typical case when patent protection is desired, the licensing officer will not only investigate whether the invention is patentable, but will also gauge the scope, breadth, and potential value of protection available. The patentability assessment will include searches of the United States Patent Trademark Office (USPTO) and World Intellectual Property Organization (WIPO) databases, and in some cases a domain–appropriate patent attorney may be engaged. The results of this analysis are shared with the inventors for their review and comment. It is not uncommon for the inventors to provide more details to help differentiate their invention from the prior art that is uncovered in this process.

The resulting marketability and patentability assessments enable us, in consultation with the inventors and other stakeholders, to determine a plan for disposition of the invention. Patentable inventions that lack market potential, or for which the likely scope of protection is too narrow to provide adequate value in the marketplace, are closed. Sometimes inventions may need further development before they are ready for patenting, and in those cases the commercialization efforts are put on hold.

- ► Work with CTTC to:
 - Describe potential products that could result from the invention
 - Discuss utilization of such products
 - Determine relevant markets for such products
 - Distinguish the invention from current products—focus on novel features and advantages
- ► Review prior art references identified and help differentiate your invention from the prior art
- Perform independent patent searches (www.uspto.gov) and get a feel for other similar products that have been invented

Market

The licensing officer will identify and approach companies operating in relevant markets in order to spark interest in licensing the invention. During this stage, details of the invention may be shared with companies under confidentiality agreements, and scientific discussions may be arranged with the inventors—often a key factor in generating market interest.

The marketing process consists of two individual steps: Market Analysis and Active Marketing.

Market Analysis

During market analysis, a licensing officer performs a comprehensive investigation of the market for the invention, whereas the market opportunity is investigated in the evaluation process. This analysis includes an assessment of the products that may be manufactured based on the invention, a tabulation of the advantages and disadvantages of such products, and an analysis of the market penetration for these products. The licensing officer will also identify specific industry partners to target for licensing discussions, based on factors such as research and patenting activities, development, manufacturing, sales capabilities, access to resources, financial health, compatibility with existing product lines, ability to meet customer needs, experience with regulatory hurdles, market share, and technical experience in relevant fields. This information is identified and gathered through the use of several sources, including proprietary databases, publications, industry contacts, interviews, prior transactions, and inventor information. Though the inventors are not responsible for the marketing of their inventions, their knowledge related to products, markets, and company contacts does help with marketing efforts. This assessment enables the licensing officer to form a marketing strategy and prioritize how to best implement such strategy.

As part of the strategy, a decision regarding preliminary patent protection is made. A U.S. provisional patent application may be filed quickly and cost effectively in order to gain market feedback on the importance and usefulness of the technology, while preserving the ability to pursue worldwide patent rights. However, a provisional patent application has a lifetime of only one year, so it is important for the licensing officer to aggressively pursue the active marketing campaign after such patent rights are secured. Supporting data and refinements made to the invention during this period may lead to the filing of supplemental provisional patent application is just the beginning of the patenting process, and if sufficient marketing interest is gained, a nonprovisional application must be filed prior to the one-year expiration of the provisional application.

Active Marketing

Once a marketing strategy has been developed, and after any necessary provisional patent applications have been filed, we transition to an active marketing campaign. First, a one-page Non-Confidential Summary (NCS) of the invention is prepared and reviewed by the inventors. This summary specifies the particular market opportunity for companies to consider, and explains the advantages of the invention over the current state of the art, without disclosing any details of the invention or how it is made or used. Disclosure of details can adversely affect the ability to obtain patent protection, particularly in markets outside the U.S. The NCS is posted to the CTTC website and distributed to interested parties.

Next, the licensing officer reaches out to individual target companies. The purpose of the contact is to create interest in the invention sufficient to lead to more confidential, detailed discussions, which often involve the inventors who can best champion the invention and its benefits. The licensing officer follows up the initial discussion by providing the NCS to remind the company contact of what was discussed and to provide a summary to share with other decision-makers in the company.

During the marketing campaign, the licensing officer will record and share all relevant information and feedback from industry contacts with the inventor(s). This may include perceived level of interest, positive and negative comments, suggestions for pivotal experiments, or other development activities needed to make the licensing opportunity more compelling.

In the event that a company is interested in learning more about an invention, the parties will most likely enter into a Confidentiality Agreement (CDA), or Non-disclosure Agreement (NDA). Once a CDA is negotiated, we provide the company with confidential information, including market information and a copy of the patent application, for its consideration. In addition, CTTC works to connect the company scientists with the inventors to enable technical discussions to proceed unencumbered.

The length of the marketing process, particularly the active marketing step, varies greatly due to many factors. This process can take many months—even a few years in unique circumstances when further development projects are factored in. If one or more companies express interest in licensing a particular invention, the licensing officer proceeds to the Licensing Process.

If the marketing team is unable to identify an industry partner during the marketing process, the licensing officer, in consultation with the inventors, will either close the case or put the invention on hold for further research and development.

CTTC actively pursues sponsored research or similar collaboration opportunities with companies that show interest in a particular technology, but find it too early and therefore too risky for immediate development investments.

- Review and edit marketing documents
- Identify and approach potential industry partners
- Participate in in-depth discussions with interested parties
- Continue to refine and develop the invention, making use of product development funds when appropriate
- Evaluate the fit and capabilities of potential licensees
- Continue to publish, publish, publish (just let us know before you do)
 - Publications provide excellent marketing materials

Start-up

CTTC and Vanderbilt are highly supportive of inventor interests in creating a new venture to commercialize their technology. We seek to help investigators evaluate the start-up potential of their technologies against more standard licensing approaches, and for the right projects, connect them to capital, managers, advisors, and other service providers.

New ventures can generate substantial return on investment for Vanderbilt and contribute to the economic growth and diversification of the local, regional, and state economies. They also have the potential to provide employment opportunities for graduates and spouses of university employees. However, leading the formation and growth of a new venture is a formidable task for a university employee to undertake, and should be committed to only after careful consideration.

Entrepreneurial/New Venture Support

CTTC is positioned to assist inventors in making sound, market-driven decisions when determining whether to embark on an entrepreneurship pathway and, if the decision is made to move ahead, to improve the new venture's odds of success.

If an inventor expresses an interest in creating a new company, we will sit down with him/her to vet the opportunity, investigating the many factors it takes to build a successful technology business. This vetting process includes evaluating issues related to: (i) capital and technology development, (ii) regulatory hurdles and reimbursements, (iii) time to market, and (iv) competing products and companies. This vetting escalates from our internal review of the business opportunity to an external review by seasoned entrepreneurs, investors, and other key opinion leaders and relevant experts.

Most projects will not pass the internal and external vetting process and pursuit of the opportunity will be halted. However, a few of those projects will become candidates for internal incubation, whereby development funds will be identified and translational research and risk mitigation will commence. Others will move into the more traditional marketing and licensing pathway.

For those projects that do advance, a more detailed market analysis will be conducted and we will work with the faculty member to create a preliminary working plan for the company. A team consisting of an entrepreneur, business student, technologist, advisor, and one or more members of the CTTC staff will be assembled to advance this planning stage. This step will culminate in the formation and launch of the new venture.

Efforts will then focus on assembling the rest of the management team, raising capital, and finalizing the Licensing Agreement with Vanderbilt. From that point, the company is positioned as a stand-alone, independent entity that CTTC will continue to provide assistance to as needed.

- ► Even if you aren't central to forming the company, you can still play a significant role by:
 - Becoming an aggressive force/cheerleader for the invention
 - Reviewing technical presentations and business plans
 - Participating in the creation of the marketing pitch
 - Following established Vanderbilt consulting and conflict of interest policies

Protect

Depending on the type of invention, protection may include patents, copyrights, or other forms of intellectual property protection. CTTC works with inventors to determine the best form of protection for each technology. Patenting is an element of the commercialization process, not a goal in and of itself.

There are various forms of intellectual property—patents, copyrights, and trademarks being the most common. Patent protection is available for new and useful processes, machines, articles of manufacture, and compositions of matter. Patents provide protection in the form of a limited monopoly to an invention, but are also expensive, more complicated to obtain, and have a limited lifetime in comparison to other forms of protection. Copyright protection covers creative expressions put into tangible form, such as computer software, books, journal articles, sound recordings, video recordings, works of art, and other forms of creative works. The cost of copyright protection is typically quite low and has a fairly long lifetime, but provides limited protection. Other forms of protection, such as trade secrets, trademarks, service marks, trade dress, and mask works are not as often employed in an academic setting. CTTC will work with the inventors to determine the best form of protection for the invention during the evaluation process.

Patent Protection

Patent protection can be prohibitively expensive, which is one of several reasons why it is important for us to carefully weigh the reasons for filing. The typical cost for patent protection in the U.S. is \$25,000 per invention, and another \$150,000-\$200,000 for other major international markets.

Patent protection begins with the drafting and filing of a patent application. The licensing officer contacts patent counsel to begin the drafting process. To prepare the application, the selected attorney reviews the disclosure, performs an independent prior art search, and meets with the inventor(s) to discuss details of the invention. In cases where a provisional patent application has already been filed, the attorney will likely ask the inventors about any updates to the technology and any additional data that may have been generated. The drafting process is iterative and each new draft is reviewed by the inventor(s). Depending on the type of application being filed and the level of detail needed to protect the invention, it is not uncommon for the drafting process to take up to two months to complete.

Provisional patent applications are the starting point to obtaining a patent, however a subsequent nonprovisional application will need to be filed and prosecuted before a patent will issue. If there is sufficient market interest to merit further investment prior to expiration of the application, the provisional is converted into a U.S. nonprovisional patent application and/or international patent application. Obtaining a patent in the U.S. can take up to six years.

Copyright Protection

Unlike patents that take years to issue, copyrights for creative works exist from the time the work is reduced to a tangible medium (e.g. written in some form). However, for commercialization purposes, it is often important to register the copyright with the federal government. Registration creates a tangible record of the property right and provides greater protections should the rights need to be enforced. Registering a copyright is usually a quick and easy process, depending on the type of work being registered. Steps include submitting a completed form to the U.S. Copyright Office and paying a small fee. Though a software product may have potentially patentable algorithms embedded in its code, copyright protection is sufficient for commercialization of software in most cases.

Other Forms of Protection

Not all technologies need formal legal protection to be commercialized. Some results of research, such as cell lines, antibodies, mouse models, and other forms of biological materials may be commercialized as "tangible research property" without any form of formal protection, even if such protection may be available. Often control over the source of the material is sufficient, and the limited financial return from the licensing of such materials does not warrant the cost of patenting.

Sometimes processes or other tips for implementing a technology may be critical to the successful use of a technology but may not in itself qualify for patenting. This "know-how" may be better protected as trade secrets and not included in a patent at all. The idea of trade secrets is somewhat counter to the guiding principles of academia, so CTTC does not guarantee any licensees that such information will remain unpublished. However, companies will often want to make sure that they have access to this information as part of a license agreement, regardless of whether or not it is written into a patent application.

- ▶ Review applications in a thorough and timely manner
- Disclose ALL references that you believe to be relevant to patentability (Under patent law, you have a duty to disclose all such references—failure to do so can result in a loss of the patent)
- Disclose all embodiments of the invention
- Brainstorm ways to broaden patent claims
- ► Assist with arguments to traverse rejections issued by the U.S. Patent Office
- Contact legal counsel or a CTTC representative before publishing patentable subject matter

License

Licensing is the means by which CTTC transfers intellectual property from Vanderbilt to a company for commercial development. Each license is unique and includes a grant of rights to the company in return for financial and other consideration. We seek inventor input regarding terms and obligations being written into the contract, and keep them abreast of changes as the negotiation process takes place.

A license is the principal means for transferring intellectual property from Vanderbilt to a company for commercial exploitation. A license is essentially a promise that Vanderbilt will not to sue the company for the company's planned infringement of intellectual property rights in return for financial and other consideration. Most patent licenses are exclusive in nature, whereas most licenses for materials are non-exclusive.

The licensing process is comprised of Institutional Due Diligence, Negotiation of Business Terms, and License Agreement Negotiations.

Institutional Due Diligence

Institutional due diligence includes comprehensive research into a particular company's capabilities, resources, finances, products, management, and other factors relevant to determining the fit and viability of the company as a licensing partner. Occasionally it turns out that a particular commercial partner may not share Vanderbilt's vision or goals for commercialization, or may otherwise cause hesitation about creating a partnership. In such cases, the licensing officer and inventor(s) will determine the best course of action, which may be to seek out other potential partners or focus on development activities that will expand the pool of potential industry partners with which to work. Since some company due diligence is performed as part of the marketing process, this deeper dive only takes a few weeks to complete if the company is public, but can take longer or produce only cursory information for small privately held companies.

Negotiation of Business Terms

If institutional due diligence does not turn up any issues, the licensing officer begins to negotiate basic financial terms and conditions to be received from the licensee in consideration for the grant of a license. Other typical threshold issues for each party are addressed as well (e.g., indemnification obligations and publication rights) as well as other deal-specific terms (e.g., appropriate diligence provisions and selection of countries for patent protection). The negotiated financial terms and conditions are memorialized in a Term Sheet. The Term Sheet generally specifies the intellectual property to be licensed, the scope of the license grant (e.g., level of exclusivity, territory restrictions, field of use, etc.), licensing fees, milestone payments, earned royalty percentages, minimum royalties, patenting expenses, sharing of revenues from sublicensees, and the various diligence actions taken by the licensee to further develop and commercialize the invention.

License Agreement Negotiations

Once the parties have agreed upon financial terms under a Term Sheet, in-depth negotiations will begin with the drafting of a License Agreement. The License Agreement is typically a 25–30 page document of dense legal prose that codifies the details of the relationship forged between Vanderbilt and the licensee. Vanderbilt, in its role as the licensor, is generally responsible for drafting the initial version of the license by customizing a standard template agreement. It is common for both sides to work through several drafts of this agreement in order to iron out detailed business issues and legal terms and conditions not covered during the business terms negotiations step. Items to be negotiated are: specific definitions included in the agreement (e.g., net sales, equity, sublicensing revenue, licensed products), dispute resolution provisions, method and timing of payments, access to unpatentable know-how, enforcement of patents, and the amount of product liability insurance required to protect Vanderbilt.

Due to the legal complexity of licensing transactions and the need to address a myriad of multifaceted business issues to satisfy both parties, finalizing a License Agreement is a team effort involving the licensing officer and other members of CTTC, the inventor(s), the Office of the General Counsel, and occasionally other groups such as the Office of Contracts and Research Administration, Office of Contracts Management, Office of Corporate Relations, and the primary department or center in which the technology was developed. The licensing officer walks the inventor through all salient aspects of the agreement before its execution.

It is not uncommon for a potential licensee to express interest in an invention, yet demonstrate reluctance to commit to the diligence and financial obligations required of a License Agreement. Such reluctance may stem from uncertainties regarding the operability of the invention, the long timeline to first sale, regulatory hurdles, or the expense associated with product development and testing. In the absence of other industrial partners, we may grant such company an option to license the invention. An Option Agreement is a short agreement—generally 5–6 pages in length—under which CTTC agrees not to license the invention to third parties for a specified period of time in exchange for a cash payment and, potentially, coverage of patent costs. The term of the Option Agreement is variable, spanning from a few months to as long as one year. The option fee is based on the length of the option and the value of the opportunity reserved. During the option term, the company has the exclusive opportunity to research outstanding questions, either internally or under a Sponsored Research Agreement at Vanderbilt, thereby reducing the company's risk. If the company elects to exercise its option, the parties negotiate a License Agreement. If the option is not exercised, the licensing officer continues to market the invention.

- ▶ Refer all communications to a licensing officer if you're approached directly by a company
- Provide feedback to the licensing officer on the proposed terms
- ► Advocate for how the end product benefits patient care
- Advocate for collaborative, industry-funded research to advance the technology

Monitor

Licenses are monitored to ensure that licensees are meeting their contractual obligations to develop and market the licensed technologies. In addition, this process affirms payment and reporting obligations are being met in a timely manner. License audits are carried out at this stage as well. A rigorous compliance function often separates exemplary programs from the norm.

In order to support our mission of optimizing the flow of innovation to the marketplace while having a positive impact on society, it is necessary for CTTC to make sure that our licensees are fulfilling the promises they made in their License Agreement with us. Lack of compliance on the part of the licensee can take many forms, but often centers around obligations for diligently developing products based on the licensed technology, or for paying royalties and other fees that come due under the license.

The licensing officer assigned to the technology keeps in contact with the licensee after execution of the agreement, facilitates the receipt of all reports from that licensee, and verifies that all financial obligations and diligence provisions are met. In the event that the licensee is not in compliance with their License Agreement, CTTC's compliance officer employs more proactive measures to bring the licensee in line with its obligations. If the issue cannot be easily resolved, the compliance officer, in conjunction with the licensing officer and the inventor(s), will work with the licensee to determine mutually workable arrangements that enable the licensee to help meet their obligations. These arrangements may include setting up a payment plan to help the licensee meet their financial obligations to Vanderbilt, setting new deadlines by which the obligations under the license might become due, or amending other terms and conditions as may be necessary and appropriate. For issues that cannot be resolved through negotiations, other means may be considered, such as initiating proceedings to terminate the license, collections, and even commencement of legal action in extreme circumstances. Such activities are not unilaterally made and involve other parties, including the inventors and the Office of General Counsel.

- ► Watch for products in the marketplace that are substantially similar to your concept
- ► Keep track of company sales of your product and licensee stock price
- ▶ When the opportunity presents itself, play an active role in the auditing process

Close

Inventions lacking sufficient market potential to justify the cost of protection, or for which the potential patent scope is deemed to be too narrow for commercialization, are not likely to be commercialized. If an invention is not pursued, it is offered back to the inventors to pursue at their own expense if they so choose.

As most innovators can appreciate, it is not possible to successfully protect and commercialize all innovation resulting from Vanderbilt research activities. Human and financial resources are limited, and value-driven decisions must be made when electing which technologies to pursue and which to abandon. National statistics show that fewer than 20 percent of all technologies disclosed in academic institutions are licensed to industry.

In accordance with the Vanderbilt Policy on Technology and Literary and Artistic Works, inventions for which patenting and marketing are not pursued are generally offered back to the inventors to pursue at their own expense. It is important to note that certain conditions and obligations apply in this circumstance. A principal expectation is that the inventor will actively pursue commercialization of the invention. If there is no intention to pursue commercialization, the invention is better served by staying with Vanderbilt to avoid conflicts that may arise from ongoing research efforts to advance the technology. CTTC is happy to investigate return possibilities with interested inventors if a case is closed.

Further Development Needed Results of an evaluation may indicate that a technology needs further development, prototyping, or proof of concept before it is ready for commercialization. In such cases, the invention will be put on hold until further data can be generated and the details of the invention can be expanded. CTTC will assist in identifying funds for further development.