Pennsylvania State University

Research Development Report

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Commercial Development of Research

The commercial development of research is the cornerstone of meaningful utilization of developed technology in the field of health-related projects. Over 788 U.S. patents have been issued to Penn State including 39 in 2012. Also, in calendar year 2012 Penn State filed 128 U.S. patent applications.

Two main paths exist depending on the readiness of the technology for commercialization. If the technology can be quickly and relatively easily assimilated into existing product lines and process capability at commercially-viable companies, the commercial development of research involves nothing more than developing an acceptable licensing agreement between the university and the commercial enterprise. While this approach may require lengthy negotiations to arrive at precise terms for royalty size and distribution, and to define fields of use of the technology, fate of sublicensees and who is responsible for issues like infringement and litigation, it is nevertheless a fairly well defined field with a full range of possible positions.

If, instead, the technology requires significant further development before it can be commercially useful, a significantly more complex process is required. The process that is required is strongly dependent on the nature of the environment and infrastructure existing near the site of development; rural universities require more extensive self-generated resources than universities near major metropolitan centers. This situation is particularly acute for access to venture capital, adequate incubation space and capability, reasonably-priced suitable space for expansion of a growing business and experienced professional business managers to guide the start-ups through their perilous early years. For Penn State’s situation, and for many other Research I universities not located in major metropolitan areas, it has been necessary to generate a complete “cradle to adulthood” capability encompassing every aspect of the commercialization process.

For faculty and students at Penn State, the opportunity to do relevant and commercially useful research is an important part of the educational experience, and fulfills a central mission of the University to serve the people of the Commonwealth. Through the integrated efforts of the Technology Transfer units, federal, state, and industry funds are transformed into benefits for all. These units cover every aspect of the commercialization process, from linking industrial research sponsors with faculty; to patenting and licensing; to assisting start-ups with incubation and advice; to providing financing, counseling, and technical assistance for small companies and convenient physical facilities for companies of all sizes at the expanding Innovation Park.
Management of IP

The primary objective of the IP management process is to transfer technologies from the University to companies with the interest, ability and resources to commercialize them such that the public can benefit from Penn State inventions. Another objective is to capture a fair portion of the value of the invention for the benefit of the inventors, the College in which the invention was developed and the University.

The management of IP from the submission of an invention disclosure to the execution of a license agreement is a complex, non-linear process involving multiple steps. Key elements of the most typical steps of the process are summarized below.

- An invention disclosure is submitted to the Penn State Office of Technology Management (OTM). Forms and guidelines are available. The OTM receives approximately 200 new invention disclosures per year.
- A two-part invention disclosure number is assigned. The first part of the number is the year in which the invention is disclosed. The second part of the number is a sequential number of all invention disclosures.
- A Technology Licensing Officer (TLO) is assigned to manage the invention. The TLO will be the principal point of contact between the disclosers and the OTM. Persons submitting an invention disclosure are called disclosers until inventorship is officially determined by a patent attorney.
- The TLO reviews the invention disclosure, discusses the invention with the disclosers and initiates an assessment to address the following:
  - Clearly identify the invention.
  - What is the state of development/reduction to practice of the invention? Is further development necessary? If yes, are the resources (personnel, funding, facilities and equipment) available?
  - Is the invention marketable?
  - What is a rough estimate of the size of the market?
  - Is the invention patentable? Is the invention new, non-obvious and useful? Is there prior art? Is the invention an improvement of an existing invention?
  - If the invention is patentable, is the patent enforceable? Will it be difficult to determine if others are infringing the patent?
  - Have there been any enabling public disclosures (publications, presentations, thesis/thesis defense or non-confidential discussions outside the University) of the invention? If yes, when. If no, are there plans to publicly disclose the invention? Any enabling public disclosure has an immediate and irreversible effect on patenting.
- Based on this initial review and assessment, the TLO will formulate an appropriate strategy to protect the invention, typically involving either patent protection or copyright protection. A typical patent protection strategy is outlined below.
  - File a provisional patent application either: 1) immediately prior to the first enabling public disclosure or 2) immediately if there is concern about competing technologies under development. In order to file a fully enabled provisional patent application, the inventors must provide a full and complete disclosure of
the invention to the patent attorney preparing the application. Inventors must be available to assist the attorney preparing the application.

- It is important to file a provisional patent application soon enough to fully protect the invention, but not unnecessarily early. A provisional patent application provides one year of protection in both the U.S. and internationally. This allows time for additional research, development, sample preparation, prototype development and assessment of the invention. Filing a provisional patent application unnecessarily early will limit the time available for further development and assessment.

- The next patenting decision is whether or not to convert the provisional patent application to a “full” U.S. patent application and/or a Patent Cooperation Treaty (PCT) patent application. This is a difficult decision due to the expense involved. A typical U.S. patent costs $20,000 or more. International patent protection is highly dependent upon the countries involved, but typically begins at $50,000.

- If the invention is licensed (or optioned) to a company prior to or during the one year of protection provided by the provisional patent application, then the provisional will be converted to a “full” U.S. patent application and/or Patent Cooperation Treaty (PCT) patent application and the licensee (optionee) typically pays all patent expenses.

- If the invention is not licensed during the one year of protection provided by the provisional patent application, then the decision whether or not to convert is made by the Patent Review Committee with input from the inventors, the TLO and the OTM.

- If the decision is made not to convert the provisional patent application, then: 1) the provisional is abandoned and no further action is required, 2) depending upon the date of enabling public disclosures of the invention (if any), another provisional patent application could be filed or 3) the inventors could petition the University to release the invention to them. The inventors should discuss the above options with their TLO.

- If the decision is made to convert the provisional patent application to a “full” U.S. patent application and/or PCT patent application, then it is essential that the inventors cooperate fully and be available to offer their input to the patent attorney preparing the patent application. The inventors’ insights and inputs in response to patent office inquiries and office actions will be required throughout the patent prosecution process.

- When appropriate (as determined by a variety of factors) the TLO will begin marketing the invention to potential licensees with assistance from the inventors. Marketing activities may occur before, during and/or after the patenting process as necessary. A marketing strategy may include any combination of the following:
  - Pursuing leads and contacts developed by inventors. 75% of university license agreements result from contacts provided by the inventors.
  - Focused/directed informational mailings.
  - Posting inventions available for licensing on OTM and commercial websites.
  - Leads developed from databases and the Internet.
  - Publicity from publications, presentations at conferences and newspaper and trade journal articles.
After a company or companies with interest in the invention are identified, discussions begin and it is likely that a series of agreements will be negotiated and executed. These may include the following.

- Confidential Disclosure Agreements allow the parties to share proprietary information under confidentiality.
- Material Transfer Agreements allow one party to share materials, samples or prototypes with another party for evaluation purposes and to determine if there is interest in licensing. This sharing of materials occurs while maintaining control of the invention, ownership and rights.
- In an Option Agreement the owner of an invention grants certain limited rights to another party for a defined period of time for the purpose of evaluating and/or further developing the invention.
- License Agreements transfer well-defined rights from one party to another party for the purpose of commercializing an invention in return for some form of compensation, usually financial benefit. Key elements of License Agreements include:
  - Identification of rights being licensed.
  - Definition of the Field of Use.
  - Type of license – exclusive, non-exclusive or semi-exclusive.
  - Fees – up-front fee, milestone payments.
  - Royalties – running royalty, minimum annual royalty.
  - Equity.
  - Due diligence – licensee’s obligations to make progress toward commercialization of the invention.
  - Reimbursement of all patent expenses associated with the invention.
- After the execution of license agreements the OTM continues to communicate with licensees.
  - To follow up on the payment of fees, royalties and equity.
  - To monitor due diligence requirements.
  - To seek licensee’s input regarding patenting decisions and payment of patent expenses.

Research Licensing Agreements

While the standard agreement is used in the vast majority of agreements, it is occasionally modified to fit extraordinary circumstances.

Training Students and Health Professionals

The comprehensive resources and organizations assembled at Penn State to effect commercialization of developed technology described above are used extensively to train and educate students, faculty and research staff in the processes of licensing and commercialization including business formation and entrepreneurship.
Commercial Research Development Training

The TechCelerator@State College was launched in 2012. TechCelerator @ State College is a co-location partnership to create a one-stop-shop that offers a variety of business support services. It offers a series of business startup classes designed to help the region’s entrepreneurs, students, and faculty members get the training they need to further develop their business concepts. Members include the Centre County Industrial Development Corporation, Ben Franklin Technology Partners, Penn State Small Business Development Center, Ben Franklin’s Transformation Business Services Network and Venture Investment Forum, the Penn State Office of Technology Management and Innovation Park at Penn State. The link to TechCelerator@State College can be found at: www.techceleratorstatecollege.org.

A new program in Venture Mentoring was introduced in 2012. The creation of this formal, organized mentoring program for entrepreneurs at the university will enhance entrepreneurship by the coordination of initiatives and activities. An overview of the program was held in September 2012 and presented to a broader audience at Penn State and community individuals that support entrepreneurship. This program is under the direction of the Research Commercialization Office. The collateral impact of the mentoring program: 1) builds stronger entrepreneurs; 2) supports Penn State University and community entrepreneurship; 3) furthers the educational mission of Penn State University; 4) enhances technology transfer; and 4) strengthens ventures for potential investment.

Outreach to Businesses Regarding Recent Research Developments

Ben Franklin Technology Partners (BFTP) of Central and Northern PA serve 32 counties in central and northern Pennsylvania, with four regional offices. Their portfolio of companies range from startups to mature, existing businesses representing a variety of industry sectors. In addition to investing in innovative emerging and existing companies, Ben Franklin also invests in Business Incubators that provide low-cost space to area entrepreneurs, workforce development projects that help an organization’s employees develop and maintain a competitive edge, and Centers of Excellence that partner with area universities to conduct research that will further technology development. Ben Franklin/CNP’s Transformation Business Services Network (TBSN) nurtures and assists technology-based businesses, helping them define opportunities and set realistic goals.

The goal of the Penn State Office of Technology Management (OTM)) is to commercialize new products and services through the transfer of Penn State technologies to existing and start-up companies. The OTM, working with the faculty and researchers who have developed commercializable technology, markets technology to those companies most likely to have an interest in and ability to maximize the commercial viability of that technology. The OTM is now posting technologies available for licensing on the iBridge Network. The iBridgeSM Network provides a web-based platform that enables and facilitates collaborative research and technology commercialization activities which span the boundaries of research institutions, entrepreneurs and corporations. Though continually growing, at present over 100 research universities have listed over 10,000 innovations on the site which receives on average 15,000 page views per month coming from 153 countries. BFTP is supporting the participation of 5 distinguished
Pennsylvania research universities in the iBridge Network; the BFTP supported iBridge community can be found here. Once at the BFTP community you can navigate through the larger iBridge site. The iBridgeSM Network is a program of the Kauffman Innovation Network, Inc., an initiative of the Ewing Marion Kauffman Foundation of Kansas City.

The Research Commercialization Office assists Penn State faculty and staff with the creation of new companies based on University research and technologies. It provides a University interface with multiple sources of early stage capital, identifies mentors and potential management team members, and coordinates with the Office of Technology Management to identify and focus available expertise and resources.

Through this host of different linkages with industry, the Penn State Technology Transfer organization optimizes the commercialization of newly-developed health research.

**Research Development Collaboration**

The Innovation Transfer Network (ITN) of Ben Franklin Technology Partners connects entrepreneurial faculty from a select group of colleges and universities in Central Pennsylvania with business owners to drive commercialization. The organization acts as a bridge between education and business to accelerate technology transfer and leverage innovation in the marketplace. The link to ITN can be found here.

Healthcare providers and policy makers list six important goals for overall healthcare delivery: it should be safe, effective, patient-centered, timely, efficient, and equitable. To address these objectives, the [Center for Integrated Healthcare Delivery Systems](https://www.psu.edu) (CIHDS) was created at Penn State to promote a holistic approach to understanding and solving problems of access and quality in healthcare. A key differentiator of this Center is that it is truly a university-wide initiative with faculty from the Colleges of Engineering, Medicine, Health and Human Development, and Information Sciences and Technology. The CIHDS will focus on discovering, applying and improving these existing methods for the current healthcare model, via telemedicine, system dynamics, and patient-centered workflow projects. Examples of current research projects are hospital design (with partners Hershey Medical Center, Susquehanna Health and Siemens), increasing quality outcomes with a pay-for-performance program, and health information technology.