RESEARCH & INNOVATION
News and Information

Kansas State University Research Foundation

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Examining NIH Policy To Enhance Public Access to NIH Funded Research Information

University research leads to not only the generation of important information and knowledge, but also the creation of new intellectual property having a potential commercial use and value. To encourage this commercial use and protect its value, ownership rights in the invention are often sought in the form of a patent or copyright.

Patents may be issued for any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof. However, the right to patent an invention can be lost as the result of certain activities.

This article will discuss important issues associated with securing patent rights, including the effect of the final NIH policy to Enhance Public Access to NIH funded research information.

Public Disclosure

Of particular relevance to those in an academic setting is the effect of public disclosure on patent rights.

University researchers are routinely encouraged to seek government funding, file for patent protection and publish their discoveries in peer reviewed scientific journals.

In the United States if the invention has been described in a printed publication anywhere, or has been in public use or on sale more than one year prior to the date on which an application for patent is filed in this country, a patent cannot be obtained. In most countries outside the United States, the inventor is required to file a patent application *prior* to the date of *any* pubic use or disclosure in order to preserve patent rights in those countries.

Careful coordination between the inventor and KSURF is essential to ensure that the invention is not publicly disclosed before a patent application is filed.

NIH Public Access Policy

The NIH Public Access policy is designed to increase public accessibility to NIH-funded research information. In accordance with the policy, researchers are now *requested* to post all final version manuscripts resulting from NIH funded research in PubMed Central—a digital repository for biomedical research. Final version manuscripts are defined as scientific articles accepted for journal publication including all modifications made during the peer-review process.

The purpose of the pubic access policy is to share results of government-funded research in order to promote dissemination of new scientific information to other scientists, healthcare providers, students, teachers, and other Americans seeking credible medical information.

The policy provides for flexibility for researchers to specify the timing of the posting of their final manuscript for public accessibility through PubMed Central. However, if the publisher agrees, public access to the publisher's final version can occur sooner than the time originally specified by the author. Within twelve months after acceptance for publication of an NIH funded project, documents will be made available freely to the public by posting on PubMed Central.

Practical implications for patenting:

Inventors who wish to protect the commercial value of an invention by securing a patent must be aware of the potential loss of the right to file that may result from a public disclosure of the invention prior to filing a patent application. Published NIH documents could jeopardize U.S. patent rights if patent applications are not timely filed and could entirely destroy patent rights in many foreign countries.

The NIH does not believe that **submission** to PubMed Central under the Public Access Policy will constitute a printed publication. While the document would be indexed and catalogued, the publication itself would not be available to the public.

Researchers should remember that publications may be released sooner than anticipated in some instances. Therefore, for NIH funded projects patentable subject matter should be adequately protected by a patent application prior to acceptance of manuscripts.

Resources:

NIH Public Access to Information

www.nih.gov/about/publicaccess/index.htm

Federal Register Notice and Text of the Final Policy

www.nih.gov/about/publicaccess/Enhanced_Public_Access.pdf

Invention Reporting Requirements Under the Bayh-Dole Act: The Implications of Non-compliance

Invention Reporting: What is required?

Passage of the Bayh-Dole Act in 1980 had a profound impact on the disposition of intellectual property arising form federally-sponsored university research. Prior to the Act, patent ownership resided with the federal government. Under Bayh-Dole, universities are not only permitted to take title to inventions, but they are required to be diligent in seeing that the patents are licensed and that the products and services of the inventions become items of commerce. Bayh-Dole further stipulates that where practicable, preferential consideration should be given to small businesses.

In exchange for funding, and the right to retain title to the inventions, Universities are required to report inventions to the funding agency within two months of their disclosure by the inventor. The United States, via the funding agency, retains the right to use the invention non-commercially.

For institutions conducting federally funded research, there are numerous obligations under the funding agreement pertaining to patent rights. A variety of consequences can result from the University's failure to comply with the obligations included in the funding agreements. As an inventor at K-State, your responsibilities include:

- Prompt disclosure of any inventions to KSURF and the University Sponsored Programs Accounting Office;
- Invention reporting should be executed via the form specified in the funding agreement, if any;
- Ongoing cooperation in execution of patent documents in order to ensure that the patent application is not deemed abandoned.

Loss of Patent Rights and Future Funding

The funding agency can dictate the formalities required for invention reporting. Failure to comply with the reporting requirements can result in the loss of patent rights, with the funding agency taking title to any patents that resulted from the funding agreement.

In addition to the loss of licensing revenue it was receiving by licensing the patent, the University and the Research Foundation could be subjected to financially costly lawsuits by others (e. g. the licensee) who are adversely affected by such non-compliance.

The University could also suffer other significant consequences such as damage to its reputation. If such non-compliance is found to be systematic, the University, or the Principal Investigator, may be viewed as unable or unwilling to comply with its funding agreements, thus risking future funding opportunities.

Invention Disclosure at K-State

To disclose an invention at K-State, an Invention Disclosure form should be completed. This form is available from KSURF or on line at www.ksu.edu/tech.transfer.

In addition, the University must submit a Final Invention Statement and Certification, whether or not an invention results from work under the grant. The final invention statement/certification must be signed by the PI and must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, from the original effective date of support through the date of expiration or termination, whether or not previously reported. If there were no inventions, the statement should indicate "None."

These forms are sent to the Principal Investigator by Sponsored Programs Accounting and should be completed and signed in a timely manner.

The Role of Technology Commercialization in a University Setting

By R.W. Trewyn, President, KSU Research Foundation, and Vice Provost of Research & Dean of the Graduate School, Kansas State University

The mission of state land grant universities traditionally has included education, research, and service components that address not only the diverse needs of the state's citizenry, but also those of the global community. Historically, universities have fulfilled their mission through scholarly works and open publication.

From World War II forward, the nature of science and engineering research on university campuses changed significantly. Federally funded research increased substantially, and research focus areas were defined by federal agency missions for the purpose of providing solutions to perceived national problems.

Passage of the Bayh-Dole Act in 1980 had a profound impact on the disposition of intellectual property arising form federally-sponsored university research. Prior to the Act, patent ownership resided with the federal government. Under Bayh-Dole, universities are not only permitted to take title to inventions, but they are required to be diligent in seeing that the patents are licensed and that the products and services of the inventions become items of commerce. Bayh-Dole further stipulates that where practicable, preferential consideration should be given to small businesses.

Today, most research universities have established technology transfer organizations. These range in size from one-person operations to offices with over fifty technology transfer specialists. Interestingly, K-State organized its technology transfer operation well over half a century ago in 1942, as the Kansas State University Research Foundation (KSURF).

Even in its most successful manifestation, university technology transfer activities provide only modest revenue streams relative to the overall university research funding. So why engage in such activities at all? First of all, it is a requirement of the Bayh-Dole Act. Acceptance of federal research support includes an obligation of diligence with respect to inventions. More importantly, faculty and student engagement in the invention process and technology transfer actives has many positive features beyond simple financial considerations.

Students. Upon graduation, many of K-State's students will join firms that place a high value on and have a high reliance on intellectual property protection. Having had practical experience can enhance a student's ability to compete for employment and to perform to high standards while on the job.

The Faculty. Faculty who complement their traditional activities with intellectual property pursuits can benefit in several ways. Benefits can include i) accessing new private sector funding opportunities, ii) understanding new, commercially important scientific and engineering problems, iii) seeing the benefits of their research endeavors applied in the "real world", iv) being able to add to the skill set that can be imparted to their students, and v) bringing new revenues to their department, the university, and themselves. Success in this area can also serve as a magnet to attract the best graduate students into a research program. While conflict of interest issues must be openly addressed, most can be managed for the benefit of all parties involved. Diligence is also required to ensure that exemplary faculty performance in the intellectual property arena is recognized on campus as positive and productive.

Community. Some inventions are most appropriately commercialized through the creation of local start-up companies. When this path is followed, not only is the community job base expanded, but the quality of the newly created jobs are at the high end of the pay scale. K-State graduates who would otherwise need to leave the area, and probably the state, will fill the majority of these jobs. Considering that small, high tech-based companies are driving the new economy in the U.S., it should serve the local community well to foster and enhance this approach to technology commercialization at K-State.

Consumers. A professionally conducted university technology transfer process ultimately makes it more likely that the results of research will actually be developed and brought to the marketplace to meet real consumer needs. That's what a land grant university is suppose to do.

Did You Know……

- KSURF has been issued 181 U.S. patents since its beginning in 1942.
- KSURF paid royalties of $250,302 to K-State inventors in 2004.
- KSURF paid royalties of $100,834 to K-State departments in 2004.

"Under Bayh-Dole, universities are not only permitted to take title to inventions, but they are required to be diligent in seeing that the patents are licensed and that the products and services of the inventions become items of commerce."

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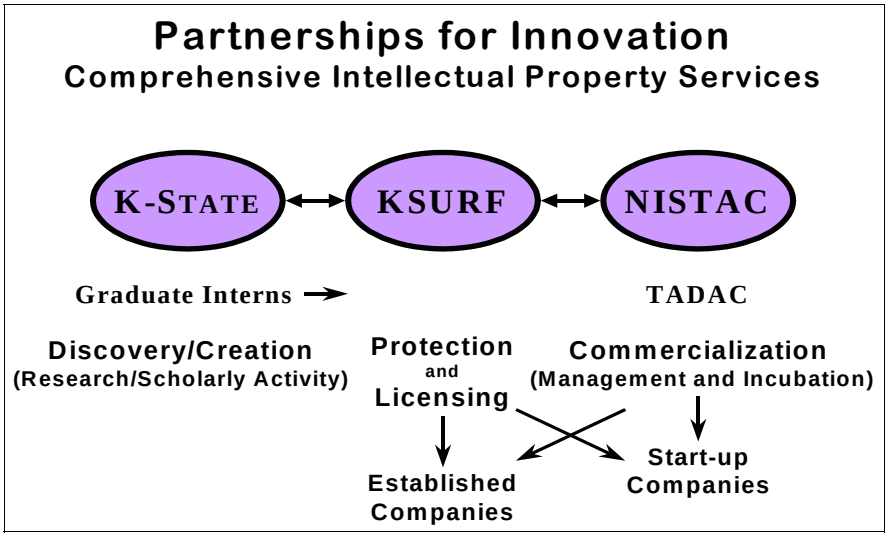
KSURF's disclosure form, information on patents and the patent process, and other general information are available at our web site.

www.ksu.edu/tech.transfer

The Kansas State University Research Foundation is a non-profit 501(c)(3) corporation responsible for managing the technology Transfer activities of Kansas State University. KSURF secures legal protection and facilitates commercialization of intellectual property created at the University. Responsibility for licensing and entrepreneurial initiatives is contracted to the National Institute for Strategic Technology Acquisition and Commercialization (NISTAC).

KSURF and NISTAC work in partnership to protect and commercialize innovations created at K-State.



U. S. Patents Issued to KSURF in 2004

Patent No. 6,706,833 "Polymers Incorporating Covalently Attached Organoimido Polyoxometalates" Eric A. Maatta and Aaron Moore. Issued March 14, 2004.

Patent No. 6,713,605 "Synthetic Peptides That Inhibit Leukocyte Superoxide Anion Production and/or Attract Leukocytes" Frank Blecha and Jishu Shi. Issued March 30, 2004.

Patent No. 6,716,002 "Biodegradable and Edible Feed Packaging Materials" Greggory Karr and Xiuzhi Sun. Issued April 6, 2004.

Patent No. 6,727,277 "Compounds Affecting Cholesterol Absorption" Duy Hua, Sung I. Koo and Sang K. Noh. Issued April 27, 2004.

Patent No. 6,740,490 "Identification and Applications of Porcine Reproductive and Respiratory Syndrome Virus Host Susceptibility Factor for Improved Swine Breeding" Sanjay Kapil and Kumar Shanmukhappa. Issued May 25, 2004.

Patent No. 6,750,299 "M2GlyR Derived Channel Forming Peptides" James R. Broughman, Takeo Iwamoto, Bruce D. Schultz and John M. Tomich. Issued June 15, 2004.

Patent No. 6,756,526 "Drought Tolerant Plants and Methods of Increasing Drought Tolerance in Plants" Yongming Sang and Xuemin Wang. Issued June 29, 2004.

Patent No. 6,790,521 "Glass Composite Including Dispersed Rare Earth Iron Garnet Nanoparticles" Kenneth J. Klabunde and Christopher M. Sorensen. Issued September 14, 2004.

Patent No. 6,828,450 "Triptycene Analogs" Duy H. Hua and Jean-Pierre H. Perchellet. Issued December 7, 2004.

Patent No. 6,830,895 "Method and Kit for Typing Feline Blood" Gordon A. Andrews and Joseph E. Smith. Issued December 14, 2004.