

RESEARCH

KENTUCKY

2018

TODAY THE LABORATORY, TOMORROW THE MARKETPLACE

Kentucky universities are developing
new formulas for economic growth

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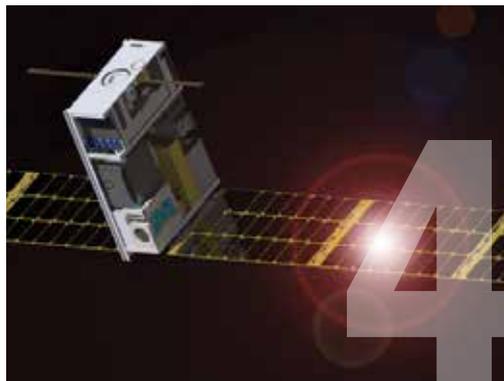
RESEARCH | KENTUCKY

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KENTUCKY STATE UNIVERSITY

KYSU faculty and students are active in a wide range of agribusiness research projects that directly affect Kentucky. They are studying crop-livestock rotation to better manage soil and water; working to repopulate the American chestnut tree; running the largest pawpaw breeding program in the world; and have one of the top aquaculture research programs in the U.S.



MOREHEAD STATE UNIVERSITY

MSU students and staff build nanosatellites placed into orbit by NASA, European and Russian rockets for clients around the world, including the U.S. Department of Defense. Technology they've developed is attracting aerospace and telecommunications companies to Eastern Kentucky. MSU's space science BS degree is one of only five in the U.S.



WESTERN KENTUCKY UNIVERSITY

WKU's new Center for Environment and Workplace Health now offers faculty, students and community partners a site for hands-on research and development of better practices in environmental, workplace and occupational health and safety. WKU's applied research center and Energy Systems Lab gives engineering students and faculty the platform to work with industry partners such as Samsung and Tempur-Sealy; there is 100 percent employment among the 60-plus students who've trained in the lab.



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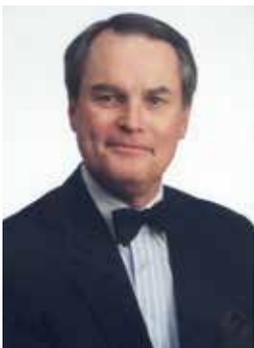
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Finding Wealth in Kentucky University Research

Kentucky universities and oftentimes private sector business and industry partners engage in direct application research that improves best practices for agribusiness, manufacturing, workplaces and nanosatellite engineering. They create value on a daily basis for the commonwealth's private sector with work that goes straight into the workplace or atop rockets that place cutting edge technology into orbit around our planet. Kentucky's university faculty and students have earned the respect of their peers, from government agencies and from top industry entities across the United States and in foreign countries. They continue to prove that no one is too small to think big and bring their ideas into reality. The state's legal community has a deep bench of expertise in protecting the intellectual property Kentucky's researchers and entrepreneurs create and helping them develop it into new businesses, jobs, incomes and wealth.



Kentucky's universities working with business to commercialize research and technology

Kentucky's research, technology and commercialization efforts remain a key element in the state's continuing economic growth.

Research Kentucky is Lane Communications' effort to bring academic research and profitable entrepreneurship together for

common benefit. Each biennial issue of the publication is designed to provide Kentucky's business, professional, political and civic leaders with updates on the activities and successes of research initiatives.

Research Kentucky also supports the state's official economic development, business recruitment and retention efforts.

Kentucky's economic future and competitiveness in the global marketplace are directly connected to these important research activities.

Knowledge-based technologies are the catalyst for Kentucky's future long-term prosperity.

Dick Kelly
Publisher/CEO
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Research Introduces Goats as Rotational Option for Organic Producers

KYSU's Organic Research Group is studying integrated crop-livestock rotations that will help farmers across the state better manage their soil and water resources. This five-year project will examine the impacts of integrating small ruminants—in this case, goats—onto land used for crop production. In this study, two years of organic grain production will be followed by three years of goats on pasture. Dr. Shawn Lucas, assistant professor of organic agriculture, and his research team will measure impacts of animal integration and crop production on soil quality, groundwater quality, crop yields and weed pressure in an organically managed rotation sequence. This research is funded through the U.S. Department of Agriculture National Institute of Food and Agriculture (USDA-NIFA) Evans-Allen Research Program. This work will provide farmers useful information on how to increase crop diversification and manage their soil and water resources.



Restoring the American Chestnut

Before the chestnut blight (*Cryphonectria parasitica*) that was first detected in America in the early 1900s, the



Assistant Professor Dr. Richard Cristan and his research team are working to restore the American chestnut tree.

American chestnut tree (*Castanea dentata*) was a staple of the economy of many rural communities in Kentucky. The tree provided income with its annual harvest of chestnuts and lumber, and it provided food for a large variety of wildlife. However, the blight virtually eliminated the tree's population from state forests. Today, Kentucky State University (KYSU) researchers are working with the American Chestnut Foundation to repopulate the once prominent tree of Kentucky's forests. Dr. Richard Cristan, assistant research professor, and his research team will plant American chestnut trees at the university's Environmental Education and Research Center in Henry County, Ky., and will carefully monitor their progress. This research could lead to establishing another option for small farmers looking to increase the profitability of their land through harvesting nuts and lumber.

Kentucky State's Organic Research Group introduce goats to organic crop rotation to help farmers manage soil and water resources.

Urban Agriculture Helps Growers Improve Production for Communities

Many believe that because Kentucky's acreage is mostly rural, urban agriculture does not apply to this state. However, urban agriculture is not limited to large cities. Kentucky State University's Dr. Leigh Whittinghill, assistant professor, is currently working to redefine what the average person pictures when they hear "urban agriculture." She is working with students and other faculty and staff of the Land Grant Program to incorporate a demonstration garden into a campus arboretum. The current design allows for 672 square feet of raised beds that will incorporate intercropping techniques that aim to produce enough vegetables to provide for a family



Dr. Leigh Whittinghill, assistant professor, talks with an elementary school competitor at the Fayette County District Science Fair. Dr. Whittinghill's research on urban ag helps identify problems Kentucky producers encounter.

of four. Dr. Whittinghill is also surveying urban agriculturalists across Kentucky to gain an understanding of what current producers are doing and what their needs are. The goal is to mirror in research what people are actually doing so that findings can be directly applied to Kentucky growers.

KYSU Revamps Beef Cattle Research

Dr. Ibukun Ogunade, assistant research professor, is working to revitalize the beef cattle research program at KYSU. His studies focus on applied beef cattle nutrition with an emphasis on improving forage quality and utilization, the use of alternative feed ingredients, the use of feed additives, and the development of laboratory and on-farm techniques to improve forage and feed analysis. Researchers also evaluate the use of alternative feeds, such as by-products, that may provide nutrients need-



Michael Rankin, farm technician at Kentucky State University's Harold R. Benson Research and Demonstration Farm helps care for the university's beef cattle.

ed by beef cattle at a lower cost to farmers than the conventional feeds that are available. Ultimately, this research aims to increase the profitability of Kentucky beef producers by improving the sustainability, productivity and efficiency of production.



Pawpaw Gold Jam is produced at Kentucky State University and provides a value-added option for growers across the country.

Pawpaw Breeding Orchard and New Jam Offer Value-Added Option for Farmers

KYSU is home to the largest pawpaw breeding program in the world and houses the USDA's National Clonal Germplasm Repository for pawpaw, which stores seeds from around the globe. In addition to the university's established pawpaw orchard on the Harold R. Benson Research and Demonstration Farm in Frankfort, the Land Grant Program recently established a new pawpaw breeding orchard with 1,000 seedlings. KYSU has bred and released two pawpaw varieties: KSU-Atwood and KSU-Benson. It also jars and sells Pawpaw Gold Jam, a preserve made from pawpaws grown on the research farm and processed in the university's Fruit and Vegetable Mobile Processing Unit with the help of students. Researchers continue to work to establish the marketability of Pawpaw Gold Jam to determine if this value-added product could be an option for pawpaw producers. Each jar's label includes a link to a consumer survey that will collect feedback on taste, cost and various other aspects of the product.

KYSU Aquaculture Research Continues to Excel Internationally

KYSU is home to one of the top aquaculture research and academic programs in the U.S. The Division of Aquaculture aims to increase the knowledge base of producers across the state and facilitate increases in farm income and the productivity of on-farm water resources in Kentucky and around the world. One research endeavor looks at the crop consistency and market



Dr. Andrew Ray, aquaculture professor, researches the viability and marketability of marine shrimp in Kentucky markets.

profitability of marine shrimp in Kentucky. Shrimp is the most popular seafood item in the U.S., but it is often of questionable quality and difficult to acquire affordably in the off-season. Production systems in Kentucky, such as high tunnels in which shrimp can be grown year-round, are a viable possibility for farmers. Dr. Andrew Ray and his research team are investigating ways of increasing the profitability and consistency with which shrimp are produced.



Morehead State University Missions Soar Into Space

Ben Malphrus¹, Jami Hornbuckle², Stewart Ditto³

Lunar IceCube is a CubeSat mission designed to prospect for water ice other lunar volatiles from lunar orbit. The mission, led by Morehead State partnering with NASA Goddard Spaceflight Center, JPL, and the Busek Space Propulsion Company, was selected under NASA's NextSTEP program and will fly on Exploration Mission-1 in 2019.

In 2013 aerospace manufactured products became the number one export in the Commonwealth of Kentucky as reported by the Kentucky Cabinet for Economic Development. The industry has skyrocketed to \$10.8 billion in exports in 2017 and accounts for over 17,500 jobs in the commonwealth. Kentucky has become an aerospace state. The Space Science Center at Morehead State University has played a role in establishing aerospace as the number one industry in Kentucky through workforce development and through its

contributions to research and development (R&D) in astronautics. In addition to producing graduates with exceptional skills to support the aerospace and defense workforce, Morehead State develops some of the world's most cutting-edge satellite technology.

The Center specializes in micro and nanosatellites and has evolved into an internationally-recognized center for research in these "smallsat" technologies. These small satellites can range from the size of loaf of bread-size to a small suit-

case and orbit Earth in formations. They are being used by NASA, the DoD and private aerospace companies for a variety of applications ranging from Earth remote sensing to astrophysics and planetary science research. Smallsats are considered "disruptive technology" by the aerospace industry because they can provide some of the same services as conventional satellites at a fraction of the cost and with short development times. Morehead State University is at the forefront of this emerging technology.

¹ Executive Director of the Space Science Center at Morehead State University

² Assistant to the President/Chief Marketing and Public Relations Officer at Morehead State University

³ Executive Director, Kentucky Aerospace Industry Consortium

Taking advantage of increased access to space made possible by new rocket companies like Space X, Morehead State faculty and students have built and launched six satellites to Earth orbit since 2006 (KySat-2, CXBN, Eagle-1, Eagle-2, UniSat-5, and CXBN-2) with a major mission currently under development (Lunar IceCube). These missions have ranged from technology demonstrations to astrophysics research and have been very successful, gaining international attention. The technology developed at Morehead



Students and Staff assembling the Cosmic X-Ray Background Nanosatellite-2 in the Spacecraft Assembly and Integration Facility at Morehead State University.

State has attracted aerospace and telecommunications companies to spin off subsidiaries in Eastern Kentucky and has also inspired small aerospace start-ups to locate in those regions.

To support the aerospace industry, Morehead State built the Space Science Center in 2009 with state-of-the-art laboratories that includes the infrastructure required to develop a variety of nanosatellite technologies. Entire spacecraft are now built under one roof- the concept and design, fabrication, testing and mission operations all take place at Morehead State. After being launched on NASA, European or Russian rockets, students and staff at the Space Science command the spacecraft and downlink data and telemetry using the Center's 21 meter deep space ground station. The 21 meter antenna system has been funded by NASA to become the first non-NASA node on the NASA Deep Space Network dedicated to providing ground operation services for interplanetary smallsat missions. Having the highly specialized research infrastructure has contributed to the Center's success. Strategic partnerships with NASA Centers (JPL, Goddard Spaceflight Center, and Marshall Spaceflight Center), the aerospace industry (Honeywell Space and Defense, the Busek Space Propulsion Company, Rajant and others), other universities (MIT, CalPoly, UoFL and KCTCS) and international

partners (University of Rome, GAUSS, the Keldysh Institute of Applied Mathematics) have also led to the development of key enabling technologies.

Perhaps the most exciting mission undertaken by the Space Science Center is Lunar IceCube, a NASA mission that was selected for launch on Exploration Mission One (EM-1), the maiden voyage of NASA's new heavy rocket - the Space Launch System (SLS). When SLS launches in 2019, it will be the most powerful rocket ever built. Morehead State leads the \$20 million mission in partnership with NASA Goddard Spaceflight Center, JPL, and the Busek Space Propulsion Company, who will send an orbiting 14 kg probe on a circuitous route to the Moon where it will orbit for a year and investigate the transportation physics of water ice on the Lunar surface in support of a lunar outpost that NASA plans to develop. These interplanetary CubeSats will likely open the door to a new era of space explo-

ration with interplanetary small satellite systems. Morehead State's Lunar IceCube is among these path-finding missions.

In addition, to the R&D efforts, the Center offers several innovative degree programs, a B.S. in Space Science (a unique hybrid science-engineering technology program that trains students for careers in space technologies and applications), an M.S. in Space Systems Engineering and a B.S. in Astrophysics. The B.S. in Space Science is a unique degree program - one of only 5 in the nation at the

undergraduate level - it is a hybrid astrophysics/aerospace engineering/space science program whose graduates are highly sought after in the space industry. Graduates of these programs are working at NASA Centers, in government laboratories and in the aerospace and defense industries all across the United States.

With the Lunar IceCube mission well underway, several other smallsat missions in planning phases and with Morehead State becoming the interplanetary smallsat node on NASA's Deep Space network, the future is looking up for aerospace at Morehead State University and in Kentucky.



Image of the Earth and Structures of the International Space Station taken by the DM-7 Experiment developed by Morehead State University and Honeywell Aerospace, Defense and Space. DM-7 is an experiment on the International Space Station's Nanoracks External Platform.



Official ribbon-cutting ceremony held to celebrate WKU's new Center for Environmental and Workplace Health. Speakers at the event included Timothy Caboni, president of WKU; Neale Chumber, dean, College of Health and Human Services; Ritchie Taylor, director, Center for Environmental and Workplace Health; and Rebecca Lauth, WKU alumnus and EHS coordinator at New Mather Metals, Inc.

WKUs Newest Center: Center for Environmental and Workplace Health

As a student-centered, applied research university, Western Kentucky University offers hands-on opportunities for students, faculty, staff, and community partners to collaborate on research that supports evidence-based practice.

The newly established Center for Environmental and Workplace Health (CEWH) addresses local, regional and national needs in environmental, workplace, and occupational health and safety through innovative research, education, outreach, and service that improves the health of the community. In the Center, students, along with faculty mentors study ways to prevent human exposures to environmental hazards, workplace hazards and accidents, and develop programs and methods to promote workplace health and safety. Students will also be able to witness the effectiveness of best practices and the broad aspects of the environmental health and occupational safety and health fields.

Addressing community partners' specific needs through hands-on learning is

a key to student success. CEWH investigators are working with firefighters in the Green River Firefighters Association to understand their exposures to fire smoke contaminants that include carcinogens, or cancer-causing substances. Faculty and students are working on research to discover ways to eliminate firefighters' exposures to carcinogens and improve health.

Center members include director, Dr. Ritchie Taylor, and core faculty, Dr. Cecilia Watkins, Dr. Jooyeon Hwang, Dr. Gretchen Macy, and Mrs. Jacqueline Basham, as well as adjunct faculty member Mr. Mac Cann. The current collaborators in the Center are all from WKU's Department of Public Health, but the Center will expand to create opportunities for multidisciplinary

approaches to solving environmental and workplace health problems. One example of this multidisciplinary approach is the collaboration between CEWH and the WKU Engineering Manufacturing Commercialization Center, working together to address the challenge of monitoring hazardous material transport in rural communities.

The Center for Environmental and Workplace Health (CEWH) was established on November 29, 2017 at Western Kentucky University. This is the first research Center in the College of Health and Human Services (CHHS) and was made possible by CHHS Dean Dr. Neale Chumber and CHHS Associate Dean for Research and Administration Dr. Vijay Golla.



Environmental and Occupational Health Science graduate student, Rebecca Lauth, prepares to conduct air quality sampling and analysis.

Primary Mission: Skill Development Through Project Delivery

Engineering students at WKU gain valuable, hands-on skills through the Energy Systems Laboratory, an innovative applied research center at WKU that focuses on teaching systems engineering skills in electrical and mechanical engineering, and project management.

Students trained in the Energy Systems Lab work on projects funded through research contracts established between WKU and world-class industry partners such as Samsung and Tempur-Sealy International.

Student work is guided and supervised by Dr. Farhad Ashrafzadeh, associate professor in the School of Engineering and Applied Sciences, senior research engineer, Ali Buendia Garcia, and research engineer, Molly Shircliff, who have over 30 years of combined experience in industrial research and more than 80 patents. Students in the Energy Systems Lab also interact with and learn directly from top engineers in industry through regularly scheduled project reviews with sponsors.

Established in 2013, funded projects in the lab have included work on the next generation of energy efficient appliances,

energy efficient motors, motor drives, and power electronics. Students gain core competencies in new prototype development, advanced and custom test-bed development, algorithm development, and system modeling and simulation.

More than 60 students have trained in the Energy Systems Lab since 2013, and 100 percent of these students were employed in jobs in related fields or entered masters or doctoral level programs upon graduation.



Engineering student, Joshua Ruggles (left), works on system modeling and simulation, leading to an estimation algorithm that provides new features for residential clothes washers.



Electrical engineering student, Tim Goodwin (left) demonstrates an innovative algorithm he developed for an industrial sponsor, to WKU President, Timothy Caboni (fourth from left) and Energy Systems Lab Director, Farhad Ashrafzadeh.

Intellectual Property

Patents, Trade Secrets, Copyrights, and Trademarks – Selecting the Right Protection for Your Intellectual Property Assets

By David W. Nagle Jr. and Terry L. Wright

Understanding and protecting your intellectual property assets is an important part of the research and development process. Although most researchers and investigators have a general understanding and awareness that patents and/or other forms of intellectual property exist, they may not fully appreciate which forms of intellectual property apply in which circumstances.

They may also not fully understand when and how to apply for and/or protect their intellectual property assets. Since timing is often critical, researchers and investigators need to engage with intellectual property professionals, such as university tech transfer personnel or private intellectual property attorneys, early in the research and development process.

Patents protect useful, novel and nonobvious inventions.

Patents protect inventions in the form of processes, machines, articles of manufacture, and compositions of matter. The grant of a patent allows the owner to exclude others from making, using, offering for sale, selling or importing the invention in the U.S. during the term of the patent.

Since the government is essentially granting limited monopoly rights when an inventor obtains a patent, an inventor must typically go through a rigorous and lengthy examination process before the U.S. Patent and Trademark Office (“PTO”) and must satisfactorily show that the invention is useful, novel and nonobvious. Meeting the utility requirement is not difficult, as most inventors do not undertake the process of inventing something that is not useful. To satisfy the novelty requirement, the PTO generally requires that the invention not be disclosed or used publicly before the filing of a patent application. There are some exceptions to this rule that allow an inventor a grace period to file a patent application, but it is typically recommended that an inventor file a patent

application before disclosing an invention publicly. Finally, an inventor must also demonstrate that the invention is nonobvious, which is a subjective determination as to whether the invention is sufficiently different from existing technology.

If the inventor can successfully navigate through this rigorous examination process, a patent is granted. Most patents have a 20-year term (provided that periodic maintenance fees are paid), but design patents only have a 15-year term.

Trade secrets refer to information that is not generally known or reasonably ascertainable by others.

Unlike patents, trade secrets are not registered at all. To have a protectable trade secret, the information (1) must have economic value that derives from the information not being generally known or readily ascertainable, and (2) is subject to reasonable efforts by the owner to maintain its secrecy. For example, recipes and manufacturing processes often meet these requirements and are considered trade secrets. If a third party then misappropriates the trade secret (such as by employee theft or other nefarious means), the owner would have a claim for misappropriation of the trade secret. However, trade secrets will not prevent or protect against someone independently discovering the information or by reverse engineering the information. Trade secrets can be protected for as long as the information remains secret and protected by the owner.

Copyrights protect original artistic and literary works, including computer programs.

Copyrights protect a broad spectrum of original artistic and literary works including: written works; works of the visual arts, such as paintings, drawings, graphical works, movies; and sculptural works. Furthermore, there is a protectable copyright

interest in computer programs, which extends to all of the copyrightable expression embodied in the program (or the code), but does not protect the functional aspects of a computer program (which may be protectable by patent).

To be copyrightable, an artistic or literary work needs to be original. In other words, the work needs to have some creative element added by the person or entity claiming the copyright. At the same time, ideas are not copyrightable. For example, the idea for a story cannot be protected by copyright, but once an individual authors the story, the resulting literary work is protected by copyright. Similarly, the idea for a computer program cannot be protected by copyright, but once an individual creates the source code, it is protected by copyright.

The owner of a copyright has certain exclusive rights. Specifically, only the owner of a copyright, or someone acting with the permission of the owner, is allowed to: (i) reproduce the work; (ii) prepare “derivative works” based on the work; (iii) distribute copies of the work; (iv) perform the work; and (v) display the work. In short, the owner of a copyright controls all commercial uses of the work.

A work is protected by copyright from the moment of creation. In other words, there is a valid and existing copyright once an individual creates an original work. However, to enforce a copyright against an infringer, the owner of the copyright has to seek and obtain a registration before a lawsuit can be filed, which can be obtained through the U.S. Copyright Office. Although registration is not required until a lawsuit is to be filed, it is highly recommended to seek a registration in advance because, if the copyright is registered prior to an infringement, the copyright owner can recover certain monetary damages and attorneys’ fees that would otherwise not be recoverable in an infringement lawsuit.



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Finally, copyrights often have very long terms of protection. As a general rule, for works created today, copyright protection lasts for the life of the author, plus an additional 70 years. In the case of an anonymous work, a pseudonymous work, or a work made for hire, the copyright endures for a term of 95 years from the year of its first publication or a term of 120 years from the year of its creation, whichever is shorter.

Trademarks indicate the source of a product or service.

Trademarks identify an individual or entity that produced, sponsored, or endorsed a product or service. Almost anything may serve as a trademark, provided that it performs this source-identifying function. A trademark may be comprised of: a word or words; designs; shapes of containers or other trade dress (such as the Coke® bottle shape); or even a color (pink home insulation) or sound (NBC chimes). Trademarks may be divided into various categories, such as trademarks for use with goods, ser-

vice marks for use with services, and certification marks for certifying that goods are made by members of a particular union or trade association or come from a particular region. However, the terms “trademark” and “mark” are commonly used to refer to any type of trademark.

A primary goal of trademark law is to avoid consumer confusion. Trademark law protects both consumers and sellers by avoiding situations where the marks of two sellers are so similar that a consumer familiar with one mark might believe that products or services marketed and sold under the other mark are produced by or associated with the owner of the first mark. Trademark protection helps to ensure that a consumer making a purchase is not deceived as to the source of the products or services. This protects consumers, who get what they think they are getting, and protects sellers from competitors who might unfairly sell products or services using a mark that is likely to be confused with an earlier mark.

Trademark rights arise from use of the mark in commerce. To obtain rights to a mark, one must normally sell products or services under the mark, and protection for the mark is normally available only in those geographic and economic areas where the mark is in use. However, through a federal registration of a trademark with the U.S. Patent and Trademark Office, a mark may be protected throughout the U.S., regardless of where the mark has been or is currently being used.

David W. Nagle Jr., Member, is co-chair of Stites & Harbison PLLC's Intellectual Property & Technology Service Group; and Terry L. Wright, Member, practices in the Intellectual Property & Technology Service Group.

These comments are intended only to provide a general introduction to intellectual property.



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IP protection key step in transfer of technology from research bench to commercialization

By Gail A. Van Norman, MD, and Roi Eisenkot, MBA
From ScienceDirect.com

Basic research currently accounts for about 18 percent of all U.S. R&D performance, with universities and colleges accounting for about 51 percent of all U.S. basic research. The federal government is still the single largest funder of basic research in the United States, accounting for about 47 percent of all such funding in 2013.

By contrast, the business sector performs the lion's share of applied research in the United States, accounting for 56 percent of the research and supplying 51 percent of the funding. In addition, the business sector performed 88 percent of all technology development in the United States in 2013, and supplied 81 percent of the funding.

Until the latter half of the 20th century, the government had few policies to encourage the public use of the huge reservoir of R&D it had amassed. No overall established policies or methods moved ownership of inventions or ideas arising from government contractors or grantees to private or commercial entities who were better equipped to develop some useful purpose or product from the research; there was also no consistent method to license government-owned inventions or patents to private enterprise for development.

Methods that evolved for obtaining ownerships or licenses varied widely, in some cases being governed by federal law (such as with the Department of Energy), and in others governed by the policies of local agencies (such as with the Department of Defense).

Efforts to bring uniformity to the federal patent system and to promote the more robust transfer of government R&D to private entities were initiated in 1963, when President Kennedy issued a memorandum acknowledging the federal government's responsibility to see that inventions created under government sponsorship were developed for the public good.

Memoranda from Presidents Kennedy and Nixon, later codified in federal law,

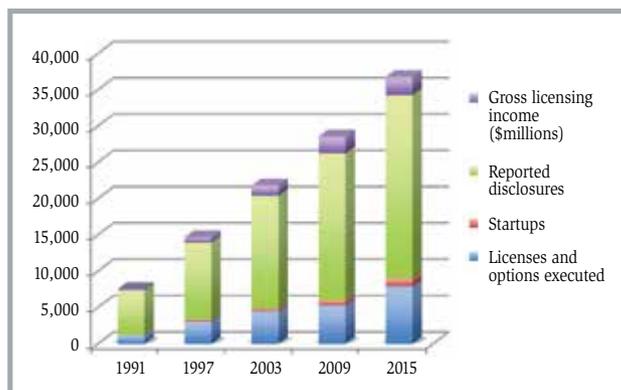
patents continued to grow. To further encourage commercialization of government-partnered innovations, Congress passed the Bayh-Dole Act of 1980 that with a few exceptions allowed the funded entity to retain title to any invention created as a result of government contracts and grants. The scope of the act was extended in 1983 under President Reagan, although the government retained so-called "march-in rights" to reclaim the titles to inventions if the contractor did not take effective steps to commercialize the invention within a reasonable period of time.

One concrete effect of the enactment of Bayh-Dole in 1980 is that the U.S. government currently takes title to virtually no inventions created by government contractors and grantees, although it continues to be the single largest sponsor of all R&D in the nation.

If the government does not hold the patent on ideas and inventions developed under government-partnership funding, who does? There is a distinction between ownership of an innovation and having access rights to it (i.e., permission, or license, to exploit it).

The Bayh-Dole Act gave research institutes ownership of patents resulting from federally funded research. But since research institutes' core "business" is teaching and conducting research, they generally commercialize such IP assets by granting access rights to (mostly) for-profit commercial entities by way of a license – while in most cases retaining ownership of the underlying IP.

A critical element of product development begins with patent protection and ownership. The development of a drug



Overall university research disclosures, startups, executed licenses and options, and reported gross licensing incomes grew roughly 600 percent from 1991 to 2015. The Association of University Technology Managers FY2015 Licensing Survey represents 169 universities, 31 hospitals and research institutes, 1 third-party technology investment firm, and 1 national laboratory.

established that many private contractors would retain exclusive rights to inventions and developments made during their partnership with the government in all but a few situations. These memoranda required the private contractor to bring the invention to the point of practical application within 3 years or risk losing the exclusive license from the government, and they also broadened the authority of agency heads to grant greater rights to contractors.

Despite these actions, the number of unlicensed (thus unused) government

or device is both risky and expensive. Achieving marketing approval for drugs requires an average of 12 years, and for medical devices about 7 years. Fewer than 1 in 10 putative drugs that survive preclinical testing make it all the way through to U.S. Food and Drug Administration (FDA) approval, at direct costs that are estimated at \$1 billion per drug, and growing. Forbes estimates the total cost of bringing a drug to market is about \$5 billion if total drug-approval failure rates and development costs of failed drug candidates are taken into account.

Once approved, it is relatively easy for other manufacturers to recreate a drug or device and generate profits without having undergone the expense of the development and regulatory approval steps. Without the protection of exclusive rights to the product and the ability to recoup development costs, there is little incentive for commercial manufacturers to pursue new therapeutics.

IP rights, principally in the form of patents, protect a developer's rights to prevent or stop another enterprise from copying the product, or else allow the developer to command fair compensation for the permission – or license – for others to do so. Such licenses are especially critical to academic institutions.

Universities and colleges generally do not commercially develop nor do they manufacture or sell such products. Rather, they must attract private manufacturers or investment bodies such as venture capital enterprises. The main attractions for such private entities are the strength of an academic institution's IP protection and the reputation of the researchers behind the relevant innovation: most critically it is the quality of research and the commercial opportunity the innovation addresses.

The transfer of technology from the academic to the private sector can happen in several ways: 1) through publication of innovations to the general public without taking further measures of a commercial nature; 2) through sponsored research agreements with private industry; and 3) through the formation of startup companies. The latter two routes involve the granting of access rights to IP in the form of licensing or an option to license (where the research institute retains ownership

Exceptions to Automatic Patent Assignment at a University

- The inventor is a student at the university, but not employed by the university, and did not receive any direct support from the university regarding the invention.
 - The inventor is an employee, but the invention was developed entirely on the employee's own time, did not involve the use of any university resources, and the invention is not related to university business, or to any actual or demonstrably anticipated research or development.

over such IP) or, rarely, assignment of ownership to such IP rights.

The Bayh-Dole Act of 1980 and the Bayh-Dole regulations that flowed from it form the basis of the current framework for technology transfer at academic institutions to this day. The regulations give universities the right to claim ownership of global patents to inventions created under U.S. Government grants and contracts and require that: 1) university employees report to their university the development of any inventions arising out of a government grant or contract, and inform the university of any public disclosures or sales of such inventions; and 2) that the university disclose to the government funding agency whether the university is going to elect to take title to the invention and apply for patents. If a university elects not to take title, the government agency has 60 days after being informed of the invention to determine whether the agency will take title.

The National Institutes of Health developed Interagency Edison (iEdison) as a tool to allow government grantees and contractors to report government-funded subject inventions, patents and utilization data via the web to the government agency that issued the funding award.

It should be emphasized that the government does not require that an inventor assign title of their invention to their university. Similar to rules regarding trade secrets, however, most all universities do require such assignment as a condition of employment, although there are some exceptions, and it behooves an inventor to be familiar with the specific requirements of their home institution. If both the university and the government agency waive title, the inventor may personally claim the patent.

Clearly, if an academic institution perceives that an invention may be valuable, then it would opt to take title to it. However, they will usually license those rights exclusively and under certain business terms to the startup company or incumbent market player engaged to do product development. In many cases, universities will take equity in a startup company in lieu of upfront license fees (cash) as partial consideration for the license, in order to preserve cash flow for the fledgling startup and also to enjoy equity-related upsides such as dividends or equity payouts.

In 2001, the Association of University Technology Managers found universities had executed at least 3,282 licenses and options, received \$852 million in income from licensing fees, and held equity in 70 percent of the 494 startup companies that were formed in that year around university-licensed technology. (See chart)

The 2014 AUTM survey indicates that these numbers continue to grow, with 5,435 licenses executed (a 4.5 percent increase over the previous year), 549 licenses including equity (17 percent over the prior year), 914 startup companies formed (an increase of 11.7 percent), and 965 new commercial products created (an increase of 34.2 percent).

The Bayh-Dole Act of 1980 applies only to inventions that arise during the course of government-partnered R&D, which accounts for the majority of university inventions. However, the technology transfer processes developed in response to the Bayh-Dole regulations generally inform most university policies and procedures with regard to all inventions created by their employees in the course of their employment.

Most universities have created technology transfer offices (TTOs), to source innovations, manage IP protection, provide commercialization-promoting resources (such as gap funding programs, access to business savvy mentors and entrepreneurs as well as regulatory consultants, connections to industry and investment bodies, etc.), and to negotiate and execute licensing deals. In the course of reviewing an invention (and whether the university will claim title to it), the TTO will determine whether an invention can likely be patented or copyrighted.

Ten Simple Rules to Protect Your Intellectual Property

By Mark Jolly, Anthony C. Fletcher and Philip E. Bourne

From PLOS Computational Biology, official journal of the International Society for Computational Biology

IP is a tool to help your endeavours, and not a goal in itself. IP can be crucial in commercializing research and running a successful science-based business, but having a patent and having a successful patented product are two very different things.

IP can only work for you if you understand what it is, why you want it, and what you are going to do with it. These 10 simple rules are intended to provide an overview of these issues; however, we must start with a warning. Laws relating to IP change all the time, they are complex, sometimes rather obscure, and are very different from country to country.

Rule 1 Get Professional Help

Although the process of obtaining IP might look deceptively simple, the devil is in the detail. Consider patents. Even if you draft a description in as much detail as you would for an academic research paper and file it yourself, the prospect it will be granted and enforceable is very low. There is skill and technique, even a language, that patent attorneys and patent agents have that allows them to describe and define inventions in the way a patent office requires.

The dangers are possibly even greater with trademarks and registered designs (“design patents”). If you want your IP to be valuable, you should seek professional advice at an early stage.

Rule 2 Know Your (Intellectual Property) Rights

IP rights come in various guises, and each is a defensive right to pursue legal action in the event that a third party infringes. In very basic terms:

- Patents protect inventions broadly, things that are new and not obvious – and the way they work, but there are numerous exceptions.

- Registered designs protect the appearance of products (not the function, which is protected by patents).

- Trademarks protect brands (e.g., trade names and logos).

- Copyright protects the expression of ideas – i.e., the words you choose to use to describe your idea – not an idea itself.

Most businesses do not need the trinity of patents, trademarks and designs; in fact, trademarks are probably the only IP most companies have or need.

Rule 3 Think about Why You Want IP

Any money spent on IP is capital that cannot be spent on production, marketing, etc., so think carefully about why you are investing in protecting your IP. There are many good reasons: to stop people from copying you; to add value to your company if you want to sell it; to sell or license to a third party; to hold it in your armoury if you suspect you are going to be sued and want to countersue (for example, Google has spent a substantial amount of money buying patents recently); even to reduce your tax bill (in certain countries profits attributed to patents can be taxed at a lower rate).

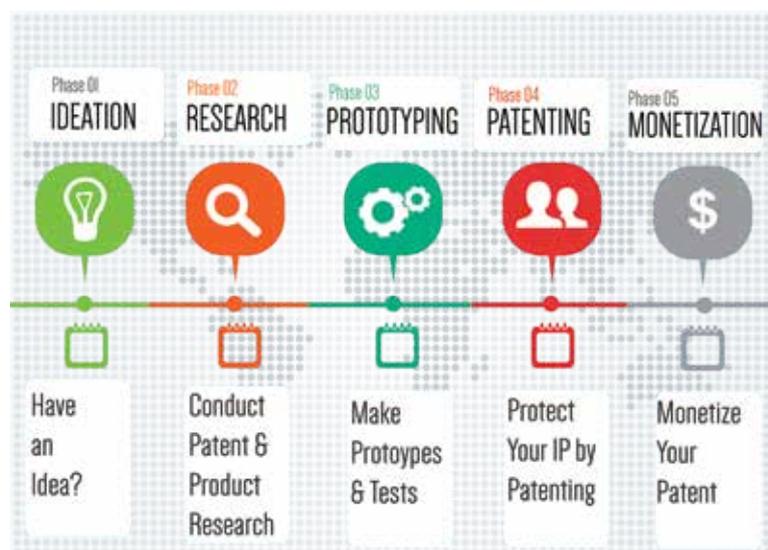
In general, IP is a right to prevent other people from doing something; owning IP does not necessarily give you the right to do anything yourself.

Indeed, the business model of “patent trolls” is to purchase patents, sometimes from those who cannot afford to enforce them, not to use the invention, but just to enforce against

infringing companies. On the other hand, the term “defensive IP” has been used to describe IP obtained, not to stop other people from competing, but to stop a competitor from patenting something that you may wish to use in the future.

Rule 4 If You Don't Protect the IP, Your Innovation Is Less Likely to Happen

Maybe you are not an entrepreneur but have an idea you would like to see exploited to make the world a better place.



Many inventors think by publishing their ideas freely they are more likely to have them exploited; however, lack of patent protection is often cited as a major reason for not following up an idea.

Most innovations require investment, and investors look for a return on their money. Ideas without any IP protection will often immediately attract competitors who perhaps can undercut the inventor (for example, with economies of scale). This decreases the likelihood of investment in the development of an invention (which is often more crucial than the invention itself) and increases the need for investment in marketing, etc. to obtain a competitive edge.

Remember, IP can be licensed and what happens to the resulting income is up to the IP's owner.

Rule 5 What's in a Name?

You have a great idea but it's not patentable, or you have applied for patent protection but are worried that it may not cover everything, and of course the protection will expire after 20 years. Unlike patents and designs, a trademark or brand can be protected with a registration at any time (unless someone got there before you) – you do not need to have kept your name a secret, and once registered the right will only expire if you stop using it or fail to renew it (generally every 10 years). So, you can protect your invention with a patent and sell it under your brand, which is also protected. Just make sure your brand is something memorable and unique to you.

Rule 6 Be Realistic about What You Can Protect

IP rights are, generally speaking, national rights provided by individual governments to regulate activity in that country. In some cases there are bilateral and multilateral agreements (for example, most of the world has signed up to the Berne Agreement, which accords the same level of copyright protection to foreign nationals of other Berne states that is provided to nationals of the state concerned).

In an ideal world, each incremental improvement would be patented in each national jurisdiction (there are approximately 200 countries in the world),

along with the name you trade under, and every brand would be the subject of a trademark, as would any color associated with your company and any sound you use, your products and their packaging would be the subject of registered designs, and your patent attorneys would be very wealthy!

In the real world a patenting regime covering more than the U.S., Europe, and a handful of other countries is a rare sight outside the realms of very large companies (such as big pharma), and even many big companies restrict themselves to key markets.

Rule 7 It's Big Business and Controversial

The world of IP is a big one. It has a huge impact on international relations and trade. It's controversial for political reasons, as many people feel that aggressive protection stifles the utility of products that have the potential to do good in the emerging world (again, for example, big pharma). The World Intellectual Property Organization (WIPO) is the United Nations agency dedicated to this area, and its overarching aims include reducing the knowledge gap between developed and developing countries, and ensuring that the IP system continues to effectively serve its fundamental purpose of encouraging creativity and innovation in all countries.

Even if your aim is totally philanthropic you may still need to invest to protect your innovation, perversely because this is what will give it the biggest chance of actually succeeding. Simply make sure you tell your patent attorney what your ultimate aims are.

Rule 8 Keep Your Idea Secret until You Have Filed

Little upsets a patent attorney more than hearing "I have a great idea – it's selling really well" or "I've shown it to a few companies and they seem very interested." A secret shared is not a secret anymore.

While a secret shared under a non-disclosure agreement (NDA) – documents most people probably have never read – ought to stay secret, discussing an invention under confidentiality is no substitute for being able to freely discuss or publish an idea protected by a patent application.

Novelty is key to patentability and your own disclosures count against you, so file a patent application before telling anybody who is not bound by confidence.

Rule 9 Trade Secrets

The economic reasoning behind the patent system is: the government allows you a monopoly, and your side of the bargain is to disclose fully your invention so that once your 20 years of protection is up, it can be freely exploited for the good of society. However, some ideas cannot be patented and indeed, some innovators don't want to patent their ideas. All is not lost here, however, as we fall back on an older idea: the trade secret.

If you really can keep a secret, your monopoly on an idea or product may never end. But once the genie's out of the bottle, like a champagne cork, you won't get it back in and you are unlikely to extract sufficient damages from whoever breaches confidentiality. Trade secrets are free – just prevent the secret being disclosed.

Rule 10 Make Sure the IP Is Owned in a Way That Allows Development

If you discover something whilst working as an employee (e.g., of a company or an academic establishment), there will certainly be something in your contract about this. Generally, the employer will have first call on the invention, but may have clauses that will return rights to the individual if it is not exploited within a certain time.

Ownership of IP can be particularly difficult in an academic setting where universities, as employers, are likely to have a right to employees' inventions; funding bodies may make their own claim; and in cross-border collaborations, national laws on ownership may compete with each other. Joint ownership is a complicating factor to avoid; instead, set up a company to own the IP and license it to partners if necessary.

If it is necessary to share IP, work out at the beginning who owns what, what rights each party has and importantly who will have the right to future inventions. A common theme in several of our Ten Simple Rules: as soon as money rears its ugly head, strife follows, so it's as well to plan for dispute resolution right from the beginning.

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