Introduction to IP Issues In the University Setting: A Primer for Scientists

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ABSTRACT

Intellectual property (IP) is inherent to many of the research, teaching, and extension functions of the university, and IP issues can occur in all phases of the corresponding programs. A research program may utilize IP generated and protected by others in its planning and execution phases. As a research program advances, decisions made regarding disclosure of results may affect whether or not discoveries made by the program can eventually be protected.

A successful research program will generate discoveries—and therefore IP—and decisions must be made regarding whether to protect, and how to deploy, those discoveries. The decisions must consider the management of IP as well as the goals and priorities of the research program and the university. It is also important to consider IP in the teaching and extension functions of the university, including the creation or use of written materials, software, networked resources, or designs.

IP and IP issues are not the sole or even the primary focus of a university. However, failure to properly consider IP issues can lead to frustrating and costly problems. Fortunately, realistic and efficient management of IP in research, teaching, and extension requires only a minimal working understanding of the issues and an ability to access on-campus assistance in dealing with them.

This chapter presents basic information that any scientist should know about IP, discusses the importance of IP management in a scientist's work, and reviews additional sources of information regarding IP. We hope, this chapter will assist the reader in avoiding simple yet costly errors in IP management.

1. WHY YOU SHOULD LEARN ABOUT IP AND TECHNOLOGY TRANSFER

1.1 *Faculty and staff*

A working understanding of intellectual property (IP) is needed to realistically evaluate and manage IP issues and make informed decisions, from starting and running programs to deciding how best to handle the resulting inventions. Lack of basic information regarding IP and technology transfer issues can result in problems that are costly in terms of time, opportunity and money. You must take an active role in decisions regarding IP management within your program. This will have an impact on the directions you provide to undergraduate and graduate students, postdoctoral fellows, and/or technicians working in your program.

Ignoring IP management issues will not make them go away. Failure to manage IP and make informed decisions are de facto decisions that may result in outcomes that are undesirable and irreversible. Errors made by students and staff in your program can materially affect IP issues. Regardless of whether you knew of the errors when they occurred, you may still be ultimately responsible.

Acquisition of the basic information regarding the management of IP by faculty and staff need not be difficult or time consuming. You are not expected to become an expert in IP

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management and technology transfer, just to be sufficiently aware of the issues so that you can use the resources available to avoid problems and maximize your opportunities. This chapter provides many links in the text to important online resources. Pertinent additional resources are listed in the endnote.[1]

1.2 *Graduate students, postdoctoral fellows, and technicians*

Obtaining a basic understanding of IP is an important part of your training, whether your future career lies in government, academia or industry. Basic IP training is important to how you will proceed in your research. Do not assume that your advisor or supervisor—or the technology transfer office (TTO)—can reverse the effects of IP errors you make. Your status as a student or postdoctoral fellow, and thus your status of being "in training," does not alter the regulations regarding the use of IP protected by others or the requirements that must be met for any inventions you generate to be properly handled. In fact, basic IP training is important in the direction of staff you may be responsible for supervising in the course of your activities.

1.3 *Difficulties caused by a lack of IP knowledge*

Depending on the nature of the error, misjudgments in handling IP issues can result in difficulties protecting your discovery or licensing your invention. Even if these difficulties are surmountable, they can be extremely frustrating, time consuming, and costly. Errors may even result in the complete loss of opportunity to protect your discovery, or in a severe narrowing of the scope of protection obtained. Reduction or loss of opportunity to market your discovery/invention can result. In fact, you may even suffer a reduction or loss of opportunity to use your own discovery or incur liability due to an inadvertent infringement of IP protected by others. However, with proper IP protection and management, you can decide how to handle the intellectual property you create as you see fit and make sure that you receive the rewards that mean the most to you.

1.4 *Applying basic information*

As university faculty, staff, and students, you are not expected to become experts in the management of IP. However, acquisition of some basic information about management will allow you to:

- make informed decisions day to day, to avoid errors that are time consuming and costly
- know when to contact IP/TT personnel
- interact efficiently and successfully with the university's technology transfer staff
- achieve your goals

Furthermore, remember that there is most definitely a lack of sufficiently trained personnel in the field of university IP management and technology transfer, and thus considerable employment opportunities exist if this area appeals to you.

Further information. To find out more about employment opportunities, see the Association of University Technology Managers (AUTM) Web site: www.autm.net/directory/job_list.cfm.

2. UNIVERSITY INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER POLICIES

A university will have a policy covering intellectual property that will be available to all university personnel. All personnel are required to operate according to this policy. The university home page is a central site for searching for university policy on many topics. Your university may also have a policy office, a technology transfer office or research foundation, and a office of university counsel.

2.1 *Bayh-Dole and university policy*

The policy of any U.S. university must conform to the obligations imposed by the Bayh-Dole Act (Public Law 96-517). The Bayh-Dole Act is intended to promote investment by the private sector in commercialization of federally funded research discoveries for the public good. It includes preferences for small businesses and for manufacturing in the United States. Under Bayh-Dole, a university is required to file patents on those inventions they elect to own and to encourage collaboration with industry to promote the utilization of inventions.

Rights retained by the government under Bayh-Dole include a nonexclusive license to practice the patent and march-in rights. *March-in rights* allow the government to "march in" and take over an invention if commercialization of an important invention is not being executed with due diligence by a university or licensee. The government has not, to date, invoked march-in rights, but it is possible that someday march-in rights could be applied. One situation that could warrant such action might be one in which a drug or vaccine is needed to control a pandemic.

Further information. To find out more about the background of Bayh-Dole as well as its implications for university IP policies in the U.S., see the Web site of the Council on Government Relations (COGR), "The Bayh-Dole Act: A Guide to the Law and Implementing Regulations," October 1999. To find our more about similar legislation in developing countries see chapter 6.1.14 by Gregory D. Graff titled "Echoes of Bayh-Dole: A Survey of IP and Technology Transfer Policies in Emerging and Developing Countries" in this *Handbook*.

2.2 *Ownership of intellectual property*

A central part of IP policy at any organization concerns the ownership of intellectual property. The approach differs somewhat between corporate and university contexts.

2.2.1 *Typical corporate policy*

In industry, employment contracts regarding the issue of IP ownership are binding. A company usually holds total ownership of ideas and inventions, while an employee's salary is considered the compensation to an employee/inventor for his or her "inventing services" rendered to the firm. Noncompete clauses are often included in employment agreements and apply when an employee leaves the company.

2.2.2 *Typical university policy*

In the university, employment contracts or IP agreements are likewise binding with regard to the issue of IP ownership. University policy covers all personnel, including faculty, postdoctoral fellows, technical staff, graduate students, and visiting scholars. The employee contracts usually assign property rights in all IP to the university, but the inventor(s) typically are given a significant share in any revenues that are earned, typically in the range of 25% to 50% of royalties. One major exception to the policy of assigning IP rights to the university involves copyrighted materials (with some exclusions). In addition, the IP agreement covers inventions and creations in the individual's area of employment. Thus, if a molecular biologist invents a better lawn mower at home in his or her free time without use of university resources, that invention would not be included under the employment agreement.

3. THE UNIVERSITY TECHNOLOGY TRANSFER OFFICE

3.1 *A university's IP, licensing, or technology transfer office executes its IP policy*

The university's IP or technology transfer office is your most important source of information and assistance. The structure and functions of such an office may differ somewhat from institution to institution. Most often the technology transfer office will be in or affiliated with the office of research, although in some cases it may be an independent foundation owned by or affiliated with the university. Most university IP or technology transfer offices will evaluate inventions and pursue appropriate protection for them. Some offices will also market or license the inventions.

The technology transfer office will indicate what materials you must provide so that the transfer manager can service your needs. Reasonable expectations regarding this process will make it as efficient as possible and prevent misunderstandings. The technology transfer personnel will not be experts in your area of endeavor. You must provide them with detailed information regarding the creation and characteristics of your invention. Expect that creating this documentation—and working with the IP/tech transfer personnel to create the documents supporting a utility patent

or other forms of IP protection—may require as much time and effort as creating a collaborative grant proposal or a major publication.

Further information. For general information about university technology transfer offices see the following:

- G Graff, A Heiman and D Zilberman. 2002. University Research and Offices of Technology Transfer, California Management Review, vol. 45, no. 1. are.berkeley.edu/~ggraff/Graff-Heiman-Zilberman-CMR-2002.pdf
- EM Rogers, J Yin and J Hoffmann. 2000. Assessing the Effectiveness of Technology Transfer Offices at U.S. Research Universities, Journal of the AUTM. www.autm.net/pubs/journal/00/assessing.html

3.2 *The mission of the IP or technology transfer office*

The mission of a technology transfer office as the responsible agent, fiduciary, or trustee for the university's intellectual property is to:

- foster creativity and inventiveness at the university
- support the university's educational and research missions
- enhance and protect the IP interests of the university and its employees
- manage IP for the benefit of the university's research and educational enterprise and its inventors

The roles of the office—in providing for the protection and commercial development of inventions—are typically to:

- determine what type of protection, if any, is possible and desirable for an invention
- evaluate commercial potential of an invention
- obtain the appropriate intellectual property protection
- locate suitable commercial development partners or research and developmen collaborators and market the intellectual property to them
- negotiate and manage licenses over the intellectual property

4. IP AND TECHNOLOGY TRANSFER ISSUES THAT MAY AFFECT UNIVERSITY SCIENTISTS ON A DAILY BASIS

Important issues and agreements that may affect university faculty or staff members include the documentation of work with appropriate recordkeeping methods, the use of materials and methods originating elsewhere, dealing with collaborators outside the university, executing legally binding agreements, and publicly disclosing research results.

4.1 *Documenting work: Notebooks, films, electronic information, and beyond*

Work must be efficiently and fully documented. Documentation can of course be important for the preparation of publications, reports, and grant proposals, and it can be essential for the preparation of documentation supporting an application for IP protection and for supporting IP rights in the rare event that they are challenged. The types and quality of documentation are important, but there are ways this can be done efficiently, so that proper documentation is not an undue burden.

Further information. For good examples of guidelines for keeping notebooks, see the following:

- Cornell Center for Technology, Enterprise, and Commercialization, "Lab Notebook Guidelines." www.cctec.cornell.edu/cctec/researchers/protocols/guidelines/index.cfm
- Northwestern University, Technology Transfer Program, "Maintaining Laboratory Notebooks." www.northwestern.edu/ttp/investigators/lab_notebooks.html
- Florida State University, Office of IP Development and Commercialization, "Notebook Guidelines." www.techtransfer.fsu.edu/notebookguidelines.html

4.2 *Using materials or methods originating elsewhere*

The issue of using materials or methods originating elsewhere arises in a number of ways or under various circumstances including the use of copyrighted material and the use of protected materials or processes. Using protected materials and

processes in research could end up affecting your *freedom to operate* (FTO).

4.2.1 *Using copyrighted material*

There are standard rules governing the use of copyrighted materials in publications, teaching, and research. University libraries can provide information regarding the use of copyrighted materials for such purposes as class readings and reserve lists. A university's information technology (IT) or computing policy may cover, specifically, the use of copyrighted material on course Web pages. Often the university counsel rather than the technology transfer office handles copyright issues on campus, including the acquisition of copyrights on materials owned by the university.

4.2.2 *Using protected materials or processes*

Protected materials and processes vary widely, depending upon the field of endeavor. They can include such things as:

- vectors used in genetically engineering organisms
- enzymes, reagents, and other supplies used in a laboratory
- computer programs

The use of protected materials or processes leads to the question: Do you have full freedom to operate in your research program, or do unrecognized, unresolved FTO issues exist?

4.2.3 Freedom to operate

Freedom to operate indicates that you are "free" to use all of the materials, methods, and other resources needed for your programs and projects and that this use does not infringe on the property rights of others. Just as your invention may be protected because you are using some form of intellectual property, the inventions of others may also be protected. Use of such protected inventions of others, without permission, might constitute infringement of their rights. The legal and appropriate use of protected inventions may require a formal agreement or license with the inventors.

Published does not mean unprotected! A *publication* by the scientist about a discovery or invention merely indicates that if there is protection, the application for that protection predates the publication. You must be aware of IP protection of any materials or processes you use in your programs and projects.

A *research exemption* might apply to your use of the materials or methods in your work at the university, but this cannot be assumed in all cases. In U.S. patent law there is no formal research exemption for university research. However, there are strong social norms in place such that patent owners have virtually never exercised their property rights against university researchers for conducting academic research. There are several practical limitations that prevent patent lawsuits from being filed against university researchers:

- In most cases it is a benefit to patent holders to have academics testing, validating, and refining the technologies they already own.
- It may be difficult to define what damages are suffered by the owner of a patent if the technology is used in an academic research project.
- Because establishing a clear precedent against research use of patented technologies by universities could open the door for widespread litigation against universities—thereby slowing down the pace of academic research and draining public resources—patent owners generally view the pursuit of such cases as detrimental to their own long-term interests, or, if more shortsighted, simply conclude that it is highly unlikely that any judge or court would want to establish such a precedent by ruling in their favor.

Thus, there is something of a *de facto* research exemption for university research.

FTO problems resulting from the use of others' proprietary materials and methods are more likely to show up further downstream, such as when you attempt to patent and commercialize the results you obtained. Your technology and any patents you might receive are likely to be dominated by their patents. If your invention embodies their technology (for example, if you create a

plasmid that contains their promoter), then they may be able to stop you from commercializing your invention altogether.

To prevent or at least to be cognizant of such risks, consider freedom to operate issues when you start using any new method or material, not after your project is completed. After all, a patent holder is not obligated to give you a license. If in doubt whether freedom to operate issues apply to your work, contact your technology transfer office representative.

Examples of FTO issues are, in fact, common in the university setting. Be aware of materials or methods that can be used *for research purposes only*. Examples of this can be found in the fine print in molecular biology supply catalogs. Likewise, be aware of limitations in an agreement allowing use of protected materials or processes. The agreement may limit you to use for research purposes only, or it may restrict you to a certain range of use for commercial products, affecting your ability to protect and commercialize any inventions that may result from your work.

It is advisable to search the patent literature just as you would search for recent publications in your line of research. While this might seem tedious or redundant, in fact there can be important fringe benefits. Someone may have already made the discovery or invention you are pursuing. If a patent already exists, you can study it to determine whether your project can proceed as planned, should be modified, or if you should seek a license to the patented invention. In addition, patents can be an excellent source of information. Since an application must fully disclose the invention, including the best method for its *practice*, a patent document may provide more detail on how to reproduce a result than a peer-reviewed research publication.

Further information. Your technology transfer office representative or university counsel should be approached regarding concerns or questions on freedom to operate, as ultimately it is a legal question. Other chapters of relevance in the Handbook are:

- Intellectual Property Freedom to Operate: The Law Firm's Approach and Role, by GM Fenton, C Chi-Ham and S Boettiger. www.ipHandbook.org
- Freedom to Operate: The Preparations, by SP Kowalski. www.ipHandbook.org
- Freedom to Operate Strategies: Why the Public Sector Needs to Learn How to Manage Risk, by A Krattiger. www.ipHandbook.org

4.3 *Dealing with outside collaborators*

It can be critical to discuss and document collaborative agreements in the development of a project. Consider which part of the work will be performed by each cooperator, how responsibility and credit will be shared, and who will be authors on publications. It is best if such questions are considered at the onset of a project and are reassessed as the program continues. Problems are most likely to occur if this is put off until a discovery is made.

4.3.1 *Material transfer agreements*

A *material transfer agreement* (MTA) is a legal agreement used when giving material to others that limits the rights they have to use the material and lists their obligations with regard to use of the material. In short, it details the conditions of the agreement between the owner of protected IP and the party wishing to use it. An MTA is executed if you want to use material or methods protected by others or if others want to use materials or methods protected by you. An MTA must be crafted carefully since it will be legally binding. And it must be created and signed before the transfer of the material in question occurs, not after the fact.

Consult with your technology transfer representative regarding any MTA needed for obtaining other's materials or for the release of your materials. However, different offices of the university may manage MTAs for incoming materials (often sponsored programs or the research office) and for outgoing materials (often the technology transfer office).

Further information. To learn more about material transfer agreements see the following:

- Cornell Center for Technology, Enterprise, and Commercialization, "Material Transfer

Agreements." www.cctec.cornell.edu/cctec/researchers/protocols/mta.cfm
- Northwestern University, Technology Transfer Program, "Material Transfer Agreements (MTAs)." www.northwestern.edu/ttp/investigators/material_transfer.html
- Council on Government Relations (COGR), "Material Transfer in Academia." www.cogr.edu/docs/MTA_Final.pdf

4.3.2 *Confidentiality and confidentiality agreements*

A *confidentiality agreement* is a legally binding agreement regarding the disclosure and use of confidential proprietary information. A confidentiality agreement should be in place before either sharing proprietary information with another party or seeking proprietary information from another party.

Consideration of confidentiality agreements can be different in a university setting than in an industry setting. A faculty or staff member may be asked to sign a confidentiality agreement if he or she is consulting for a company outside of the university. In this situtation, the *individual* signs, and is obligated by the agreement, *not the university*. Faculty and staff are not empowered to obligate the university under a confidentiality agreement and attempting to do so may make them personally liable. The offices that are authorized to sign these agreements and create a legal obligation for the university are typically in the technology transfer office (signatory authority for licenses, agreements, contacts, and so forth dealing with inventions) or an office such as sponsored programs or the office of research (signatory authority for outgoing grant proposals and agreements accompanying incoming funds from the funded grants).

For example, the representative of a company interested in possibly licensing intellectual property handled by the technology transfer office would sign a confidentiality agreement before obtaining detailed information on the technology. Drafting and obtaining signatures on the confidentiality agreement is handled by the technology transfer office for the inventor. This helps assure that the agreement is properly drafted, and that the correct individuals sign the agreement.

4.4 *What constitutes public disclosure?*

A *public disclosure* is made when an inventor reveals previously undisclosed (that is, secret) information to members outside the circle of inventors and the personnel they directly supervise. There is interplay between the need for secrecy, in order to be able to protect an invention, and the need to reveal information to operate a program within a university where disclosure and transparency are the norm. The presence of various functions important to the university—educating students, publishing, efforts to acquire grant funding, and others—which are generally not part of a corporate environment, might have ramifications regarding disclosure. Among the many different vehicles for disclosure are lectures, discussions, seminars, group meetings, annual reports, grant proposals, and radio and TV interviews.

Unintended public disclosure can have major ramifications for protection of intellectual property. The more valuable the invention, the harder companies will search for any inadvertant disclosure that will invalidate IP protection.

Further information. A good discussion of disclosure by publications and by posting online can be found in these online publications:
- GP Malilay, AM Mueting and AS Viksnins. 1996. Prior Art: Silent Time Bombs that Can Blow Away Your Licensing Deals. *Journal of the AUTM*, pp 18–28. www.autm.net/pubs/journal/96/3-96.html
- SJ Braman. 1996. Are Your Patent Rights Disappearing over the Internet? *Journal of the AUTM*, pp. 29–31. www.autm.net/pubs/journal/96/4-96.html

5. SO YOU (THINK YOU) HAVE AN INVENTION! GREAT! WHAT NEXT?

5.1 *Overview*

There are a few things that are important to understand about working with the technology transfer office. Foremost, it is essential for the

inventor to be actively involved in all of the phases of the protection and marketing of the invention. There are two main reasons for this: first, the inventor has unique, detailed knowledge that is critical to the characterization and description of the invention and the drafting of the patent and its claims; and second, inventors often have useful leads, such as company contacts, that will assist in the marketing of the invention. Collecting the information and documentation needed to draft a disclosure and a patent application takes time and effort on the part of the inventor, something on the order of the time and effort required to write a major publication or grant proposal. If you expect to seek patent protection for your invention, you need to make the commitment and create time for it. This will make the process run far smoother.

It is helpful to remember that the breadth of research covered at a university is often far greater in scope than that at even the largest of companies. At the same time, university technology transfer offices have less staffing than analogous offices in industry. As a result, a technology transfer officer at a university may be dealing with more inventors and a broader scope of inventions than his or her counterparts in industry. Input from the inventor will directly assist the technology transfer staff in bringing projects to successful completion.

Cooperative, responsive inventors often have the best experiences, since they enable the technology transfer staff to provide prompt and complete service.

The steps in the technology transfer process follow a typical pattern:

- *disclosure*: starting the process of protecting/marketing an invention
- *evaluation*: deciding whether the invention should be protected and, if so, how
- *protecting*: proceeding with an application (also called prosecution)
- *marketing*: finding a licensee
- *licensing*: making a deal

5.2 *Invention disclosure*

The inventor's role in disclosure is to provide information, including:

- a description of the invention
- details about the funding of the research that led to the discovery
- an explanation of why the invention may be important or valuable in industry
- reasons why companies might be interested in the invention
- the identity of the inventor (or inventors)
- a description of how the invention was made

Remember, a clear, detailed disclosure allows the technology transfer staff to serve you better and faster.

The technology transfer officer's role in disclosure is to help the inventor fully describe the invention by considering the material provided and asking questions to elicit further information or details. In the process of discussing the disclosure and deciding upon a protection and licensing strategy, the technology transfer officer will conduct an intellectual property audit. This will reveal whether there is any preexisting IP that may affect the process.

Further information. Details regarding the disclosure process, including forms, can often be found on a university's technology transfer office Web site. Some examples include:

- Cornell University, Center for Technology, Enterprise, and Commercialization, "Invention Disclosure Process." www.cctec.cornell.edu/cctec/researchers/disclosures/index.cfm
- University of California, Office of Technology Transfer, "Disclosing an Invention." www.ucop.edu/ott/faculty/disclose.html

5.3 *Evaluation*

The purpose of evaluation by the TTO is to determine what the technology does and what its commercial potential may be. For example:

- Is it a research tool, software, compound, new method, diagnostic, or therapeutic?
- Does it fill an unmet need, or fill a need better than current methods?
- What is the size of the potential market or markets?

- Would it have competition from other technologies in those markets?
- What companies are in those markets?
- Who is investing in those markets? Why would investors be interested in the technology?

Answering these questions will enable the TTO to estimate the commercial value of the technology.

5.4 *Deciding whether and how to protect*

After disclosure and evaluation of an invention, decisions must be made as to whether to protect the invention and, if so, how. These decisions are made jointly by the inventor(s) and the technology transfer office, based upon all of the technical and legal information available and based upon economic considerations.

Some disciplines routinely employ a particular form of protection for the technology generated in that discipline. Examples include copyrights on writings; patents on vaccines, medicines, chemicals, engineered processes and materials; design patents on figures, graphics, or artwork; and plant patents or plant variety certificates (PVCs) on new varieties of plants.

In some areas, protection has long been possible but not routinely employed by universities. For example, plant patents have been available since 1930; however, prior to 1982 the apple breeding programs at the Geneva Agricultural Experiment Station in New York developed and released apple varieties without protecting them. These unprotected cultivars include a number of widely grown varieties, such as Empire (1968), Jonagold (1972), and Liberty (1978). However, cultivars released after 1982 were protected using plant patents and are generating returns to the inventors and their research units. These protected cultivars include Freedom (1983), Empress (1988), Royal Empire (1990) and Fortune (1995).

In some areas, the possibility of protecting IP is a more recent development. For example, before changes were made in the interpretation of U.S. patent law beginning in the 1980s, it was not possible to protect inventions involving modified life forms with utility patents.

It is important to realize that the laws, interpretations of laws, and strategies used in protecting intellectual property develop and change over time. It is the responsibility of the technology transfer office to keep abreast of these developments and to advise and assist university inventors as needed.

5.5 *Marketing and licensing*

An invention will not generate financial returns for a program unless it is successfully marketed and licensed. Depending on the nature of an invention, the personnel of the technology transfer office may or may not have a comprehensive list of potential licensees for the technology. The inventors may play a critical role in providing such information.

Depending on the invention, and the companies interested in the invention, the license granted may be *exclusive* (made to only one company, with that company holding all rights to sublicense) or *nonexclusive* (made to more than one company). In some cases, a license to a company transfers rights to the invention for just a limited subset of its potential uses, rather than for any and all possible uses. The decision as to the nature of the license granted (that is, the uses it will cover) is made by the technology transfer office in consultation with the inventor, and is thoroughly negotiated with the licensee.

There are other options as well. In some cases, the university, through the technology transfer office, encourages use of the invention in the development of a new start-up venture.

Patents require periodic servicing, such as periodic payment of fees to the U.S. Patent Office (PTO), which is managed by the technology transfer office. The technology transfer office also manages the license: receiving and distributing payments, billing the licensee, and monitoring whether the terms of the license are being respected by the licensee.

If an invention is valuable, it is not unusual to find companies infringing the property rights over it by using the invention without a license. If this is determined to be occurring, the technology transfer office will take the lead in rectifying the matter, seeking assistance as needed from

the inventor. This involves a series of steps, from contacting the infringing company and requesting that it either cease infringement or obtain a proper license, to filing a law suit. The more valuable the invention, the more likely it is that some company will test the resolve of the university to assert its IP rights. Such situations occur regularly, but they are manageable, given the proper expertise on the part of the technology transfer office and other legal counsel representing the university.

Marketing and licensing is obviously a large and complicated endeavor. The best information regarding this process can be obtained from representatives in the technology transfer office.

6. TYPES OF INTELLECTUAL PROPERTY PROTECTION

6.1 *Overview*

Types of IP protection tend to be specific to particular kinds of creations or technologies, but they are not always mutually exclusive. There are instances when an invention may be protected by more than one type of IP.

The types of protection vary in many features including:

- requirements to acquire the protection
- cost
- type of technology covered
- type of protection afforded
- length of time provided

A full study on any one type of IP protection would be a book in itself. What follows is a brief introduction to each of the types of IP protection that might be of possible use to a university researcher.

6.2 *Patents: utility patents, design patents, and plant patents*

A *utility patent* is what most people think of when they hear the word *patent*. A utility patent is a grant of a property right by the U.S. government to the inventor for a term of 20 years.

The applicant is required in the patent application to fully disclose the invention, and, in so doing, to fully describe the best means of practicing the invention so that an expert in the relevant field of technology (one *skilled in the art,* in patent terminology) can actually make and use the invention relying only upon the information presented in the application.

Subjects of patents can be any of the following:

- *mechanical devices*: a machine or device
- *processes*: methods of doing or creating something, for example, a diagnostic or therapeutic method
- *articles of manufacture*: the paper clip is the classic example
- *compositions of matter*: a new formulation of plastic, a new alloy, a new medicinal compound
- *improvements* in any of the above

Certain characteristics are required for an invention to be patentable. The invention must, of course, be of proper subject matter. It also must be novel. The invention must be something that would not be obvious to an expert in the field. And the invention must have some useful application industrially or commercially (that is, the invention is not *trivial*).

There are two types of patent applications: a *regular application* and a *provisional application.* (A provisional application merely starts the ball rolling and gives the inventor one year to file a regular application.)

Once granted, a U.S. patent gives the owner of the patent the right to exclude others from making, using, offering for sale, or selling the invention in the United States or importing it to the United States for the term of the patent. It is important to remember that patents are country specific. For instance, a patent granted by Canada gives the owner of that Canadian patent similar rights within Canada. It is up to the inventor and their technology transfer office to decide in which countries to apply for foreign patents (which *foreign filings* to make). In those countries where rights are not sought or granted over a technology, it is, in effect, left to the public domain (unless some other means of protection is utilized.)

The inventor or inventors must be listed on the patent application. The question of inventorship—*Who is the inventor?*—is sometimes a point of contention, so consider this carefully. The rules used under U.S. patent law to determine who is an inventor for purposes of patent protection are very different from the means generally used to determine who should be an author on a publication. Inventorship depends specifically on the claims of patent. A person who gives pivotal advice, even just once, in the course of a research project could be an inventor. A technician doing much of the work under supervision, but not making decisions, would probably not be an inventor. However, if the technician made unexpected observations or suggestions critical to the development of the invention, he or she might well be an inventor. Advice from the university IP/technology transfer office may be useful in cases in which inventorship is unclear.

Further information. To learn more about inventorship, see SH Lieberstein. 1998. Relevant Concepts in Determining Difficult Disputes Over Ownership. *Journal of the AUTM*. www.autm.net/pubs/journal/98/lieberstein.html.

6.2.1 *Utility patents*

A utility patent is costly in terms of time and effort. The time and effort you spend on filing and prosecuting a utility patent could be equivalent to the time and effort you would spend on producing a major publication or a large collaborative grant proposal.

A utility patent is also costly in terms of money. The cost of a U.S. patent application typically ranges from about US$15,000 to US$30,000, although it can cost more. Costs of foreign patent applications depend on the country but typically are within a similar range in Germany, England, France, Australia, and Japan. After a patent is issued, there are patent maintenance costs to cover. At times, there are additional costs for defending the application or the patent. The more valuable a property is, the more likely it is to be challenged, either as an *interference* (issuance of a conflicting patent claiming some of the same technology) or as an *infringement* (actions of a company using the technology without permission).

At most universities, patent costs are initially borne by the office of technology transfer, but they are the first thing to be reimbursed once revenues begin to come in when an invention is licensed. It is crucial to consider whether a license on the invention is even likely to return more than the costs of applying for, maintaining, and defending the patent; otherwise, perhaps a less costly form of protection should be used. A good rule of thumb is that if the technology is not worth defending, one should not be applying for a patent. Consultation with a technology transfer representative can help to determine if a utility patent is the appropriate means of protecting the invention.

Further information. For useful information, in increasing order of detail and complexity, on the requirements and protection afforded by utility patents, see the following:

- L von Bargen Mueller. 1995 (with revisions by JT Sorensen, 2002). *An Inventor's Guide to Patents and Patenting*, AUTM Educational Series No. 1
- American Bar Association, "Inventor's Committee: Short Description of the Patent Process." www.abanet.org/intelprop/comm106/106patent.html
- U.S. Patent and Trademark Office, "Frequently Asked Questions about Patents." www.uspto.gov/web/offices/pac/doc/general/faq.htm
- U.S. Patent and Trademark Office, "A Guide to Filing a Utility Patent Application." www.uspto.gov/web/offices/pac/utility/utility.htm
- American Bar Association, "Comprehensive Information on Patents." www.abanet.org/intelprop/comm106/106general.html

6.2.2 *Design patents*

A *design* is a visual ornamental feature, such as a logo, embodied in, or applied to, some article of manufacture (for example, a mug, sweatshirt, or poster), the shape of a bottle or the shape of headlights of a car. *Design patents* protect new, original, and ornamental designs for an article of manufacture. The design patent protects the appearance of design on the item, and not the

structural or utilitarian features of the item—that is, the design of the logo, not the cloth of the sweatshirt or the ceramic of the mug. The term of protection in the United States is 14 years from the date the grant is awarded.

A design patent application must include:

- a preamble stating the name of the applicant, the title of the design, and a brief description of the nature and intended use of the design
- drawings or photographs of the design claimed (Since this is the critical part of the design patent, the PTO site listed below has considerable detail about this portion of the application.)
- a written description of the elements of the design, shown in the drawing or photograph
- a written description of the features of the design
- the single claim for the design
- an executed oath or declaration by the applicant

Further information. To learn more about design patents, see the Web site of the United States Patent and Trademark Office, "Frequently Asked Questions (FAQ) about Design Patents." www.uspto.gov/web/offices/pac/design/desfaq.html.

6.2.3 *Plant patents*

A *plant patent* protects a distinctive new variety of an asexually reproduced plant. Asexual reproduction is the creation of identical genetic copies of a plant without using genetically reproducing seeds. Asexual reproduction includes the use of:

- root cuttings
- apomictic seeds
- bulbs
- slips
- rhizomes
- runners
- corms

...and methods such as:

- grafting and budding
- division
- layering
- tissue culture
- nuclear embryos

Most plants covered by plant patents are horticultural crops, such as apples, raspberries, and almonds, or ornamentals, such as rhododendrons, roses, and tulips. For historical reasons, tuber crops, such as potatoes and Jerusalem artichokes, were specifically excluded from consideration. For the purpose of plant patents, algae and macro fungi are allowed; bacteria are not.

A plant patent application must meet the same requirements of utility patents. The plant to be protected must have been developed or discovered by the applicant. It must fulfill the requirements for novelty and nonobviousness. The plant cannot have been sold or released in the U.S. more than one year prior to the date of the application.

A plant patent must include a complete description of the botanical features of the plant and the characteristics that distinguish that plant from known, related plants. A drawing or photograph of the plant showing its most distinguishing characteristics and text describing what is being shown in the drawing or photograph help to document the plant's novelty.

Once granted, the *plant* that is protected includes mutants, hybrids, and genetically transformed plants. The grant lasts for 20 years from the date the application is filed. During this period, the plant patent protects the inventor's right to exclude others from asexually reproducing, selling, or using the plant so reproduced. As with utility patents, when the plant patent expires, the subject matter of the patent (that is, the plant variety) enters the public domain.

Further information. To learn more about plant patents, see the Web site of the United States Patent and Trademark Office, "General Information about Plant Patents." www.uspto.gov/web/offices/pac/plant/.

6.3 *Plant variety protection*

Plant variety protection (PVP) is a means for protecting sexually reproduced plant varieties. Plant variety protection is a form of IP administered and granted by the U.S. Department

of Agriculture (USDA), rather than the U.S. Patent Office. This is basically the U.S. version of plant breeders rights, as agreed upon internationally under the convention known as UPOV (International Union for the Protection of New Varieties of Plants). A PVP grants 20 years of protection (for new varieties of plants) from date of issue (and 25 years for trees and vines). A PVP cannot be granted for uncultivated plants or materials found in nature.

PVP regulations require that the plant cultivar to be protected must be:

- *novel or new*: cannot have been sold in the United States for more than one year
- *distinct*: is clearly different from other common varieties of the crop
- *uniform*: has no more variability than other varieties of the crop
- *stable*: remains unchanged when reproduced, particularly with regard to the distinctive characteristics of the variety

In the application for the PVP, the applicant provides the genealogy of the variety and describes the variety and its novelty. A public deposit of seed of the variety is also required.

Protection provided by the PVP applies to the single variety claimed. The PVP prevents others from selling, sexually or asexually reproducing, or distributing without a license from the holder of the PVP. Since the mid-1990s, a PVP also prevents others from producing a hybrid variety using the claimed variety as a parent.

Exclusions to the protection include use of the cultivar in breeding, by farmers saving seed for their own use, and for the sale of limited amounts of seed.

Further information. To learn more about plant variety protection, see the Web site of the USDA Plant Variety Protection Office. www.ams.usda.gov/science/PVPO/pvpindex.htm.

6.4 *Copyright*

Copyright provides legal protection of an original work set down in a fixed form or medium of expression. The term of protection for works owned by corporate entities is the lesser of 95 years from publication date or 120 years from the creation of the copyrighted work. The term of protection for works owned by individuals is the life of the author plus 70 years.

Items that can be copyright protected include:

- literary works
- musical works, including accompanying words
- dramatic works, including any accompanying music
- pantomimes and choreographic works
- pictorial, graphic, and sculptural works
- motion pictures and other audiovisual works
- sound recordings
- architectural works

Examples of things that cannot be copyright protected include:

- ideas or concepts
- lists showing no originality
- titles, names, short phrases, and slogans
- type styles
- factual information
- public domain information
- works not fixed in tangible form

A copyright gives to the holder the right to reproduce one or more copies of the protected work. Notwithstanding copyright protection, other parties, such as archivists, educators, and members of the media may reproduce protected works for certain types of use known as *fair use*. The copyright also gives certain limited rights to distribute or disseminate copies, prepare derivative works (including translations), and perform or display publicly (with exceptions for instructional use, broadcasting, and religious services). Excluded from the *fair use* are digital movies, digital games, and similar products since the entry into force of The Digital Millennium Copyright Act in late 1998.

At most universities copyright issues are handled by the university counsel, rather than the technology transfer office, with possible exceptions for some technologies, such as software, involving both copyright and utility patents for protection.

Further information. To learn more about obtaining copyrights or using copyrighted material, see the following Web sites:

- Cornell University, "The Copyright Information Center." www.copyright.cornell.edu
- Stanford University Libraries, "Copyright and Fair Use." fairuse.stanford.edu
- Indiana University and Purdue University Indianapolis, "Copyright Management Center." www.copyright.iupui.edu
- Library of Congress, United States Copyright Office. www.copyright.gov

6.5 *Trademark*

A *trademark* is essentially a brand name, which is used to identify or distinguish in the marketplace one company's goods from another's. A trademark includes any word, name, symbol, or device, or any combination of these. Many of the products we buy sport trademarks, from Sunkist oranges and Coke, to Levi Strauss jeans, Dell computers, and Intel microprocessors.

There are other types of "marks" as well. The *service mark* is similar to the trademark, but the service mark identifies a service or the source of a service, rather than goods or the source of goods (for example, a cleaning service, rather than mops and brooms). A *certification mark* identifies a "*regional or other geographic origin, material, mode of manufacture, quality, accuracy, or other characteristics of goods and services.*" A *collective mark* is a type of trademark or service mark used by the members of a collective group and indicates membership in the organization.

Trademarks, and the other types of marks, are handled by the U.S. Patent Office. Application involves filing a form, along with a drawing of the mark to be protected and specimens of the mark. (The specimen will be a prototype of the design, such as a label or tag, which incorporates the mark.) Before one files an application, it is advisable to run a search to check that the mark is not already registered. With proper maintenance (use, renewal, and so on) a trademark can be perpetual.

At most universities, the university counsel handles trademark and service mark applications. Properties that many universities protect by copyright, design patent, and perhaps trademark, are the university's name, logo, and other symbols, such as a mascot. Some universities—particularly those with well-known sports programs—earn considerable funds through the licensing of their protected names and logos for merchandise.

A department wanting to use the university logo, for example, on a T-shirt being designed for an upcoming symposium, must first obtain permission from the office that is responsible for trademarks and such.

Further information. To learn more about trademarks, see the Web site of the U.S. Patent and Trademark Office, "Basic Facts about Trademarks." www.uspto.gov/web/offices/tac/doc/basic/.

6.6 *Trade Secrets*

A *trade secret* is secret or confidential information that gives the company that possesses the information an advantage over companies that do not possess it. Trade secrets can protect any information that provides a competitive advantage. Examples include a process, method, composition, or recipe. The recipe for Coca-Cola syrup, and many other food and beverage products are protected as trade secrets. A trade secret has a far longer term of protection than a patent. A trade secret is in force as long as the secret information is kept secret and not made publicly available.

A trade secret protects information, quite simply, by keeping it secret. Trade secrecy laws make it illegal for someone to obtain the secret by misappropriation (for example, breaking into the vault in which the secret is kept). Of course, a product must be able to be used or marketed without revealing the secret to be protected as a trade secret (for example, the product must not be able to be reverse engineered). If someone innocently, independently discovers the same information, they can use it without infringement. Indeed, the second discoverer could in fact apply for a utility patent, in some instances.

By university policy, no secret research is conducted at the university, but an invention that results from research could, in some instances, be protected by trade secret at least temporarily,

pending an application for another form of IP protection.

6.7 *Bailment Law*

Some inventions can be marketed without the formal protection of a patent or other form of IP protection though the use of *bailment law*. Under this approach, control over use and dissemination of the invention is obtained by careful use of material transfer agreements and licenses. Where applicable, this method reduces paperwork and the costs of preparation and application for patents or other forms of protection. The method would require careful coordination with the technology transfer representative.

Further information. To learn more about bailment law, see PM Simpson, Jr. 1998. Use of Bailment in Transferring Technology from a University. *Journal of the AUTM*. www.autm.net/pubs/journal/98/simpson.html.

7. SUMMARY

Managing the IP issues that arise in the course of university research and teaching functions is important. Though sometimes the issues are complex, the management of these issues *can* be handled efficiently, reducing time commitment. The goal of this chapter is to provide basic information to enable university scientists/inventors to manage intellectual property and technology transfer issues. The university scientist need not be an IP expert. The ability to protect some forms of IP is fairly recent, having undergone or even still undergoing rapid changes in interpretation and strategy. Being knowledgeable and capable in these areas is the task of those university personnel in the technology transfer office and the outside legal experts who work with the university on IP and technology transfer. Researchers/inventors should consider how they want to handle IP issues during day-to-day work and know whom they should contact when they have new IP or technology transfer issues. They should not hesitate to use these resources whenever needed. ■

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1 This chapter provides many links in the text to important online resources. Pertinent additional resources are:

Braman SJ. 1996. Are Your Patent Rights Disappearing Over the Internet? *Journal of the AUTM*, pp. 29–31. www.autm.net/pubs/journal/96/4-96.html.

Cornell Center for Technology, Enterprise, and Commercialization. Invention Disclosure Process. www.cctec.cornell.edu/cctec/researchers/disclosures/index.cfm.

Cornell Center for Technology, Enterprise, and Commercialization. Lab Notebook Guidelines. www.cctec.cornell.edu/cctec/researchers/protocols/guidelines/index.cfm.

Cornell Center for Technology, Enterprise, and Commercialization. Material Transfer Agreements. www.cctec.cornell.edu/cctec/researchers/protocols/mta.cfm.

Cornell University. The Copyright Information Center. www.copyright.cornell.edu.

Stanford University Libraries. Copyright and Fair Use. fairuse.stanford.edu.

Council on Government Relations (COGR). 1999. The Bayh-Dole Act: A Guide to the Law and Implementing Regulations. www.cogr.edu/docs/Bayh_Dole.pdf.

Council on Government Relations (COGR). 2003. Material Transfer in Academia. www.cogr.edu/docs/MTA_Final.pdf.

Florida State University, Office of IP Development and Commercialization. Notebook Guidelines. www.techtransfer.fsu.edu/notebookguidelines.html.

Graff G, A Heiman, and D Zilberman. 2002. University Research and Offices of Technology Transfer, *California Management Review* 45, no. 1 (fall). are.berkeley.edu/~ggraff/Graff-Heiman-Zilberman-CMR-2002.pdf.

Indiana University and Purdue University Indianapolis. Copyright Management Center. www.copyright.iupui.edu.

Innes C, and CC Valauskas. 2000. Development and Deployment of Digital Works in Universities: A Guide for Authors and Licensing Officers, AUTM Educational Series, no. 5.

Leslie B. (1998) Material Transfer Agreements, AUTM Educational Series, No. 3.

Library of Congress. United States Copyright Office. www.copyright.gov.

Lieberstein SH. 1998. Relevant Concepts in Determining Difficult Disputes Over Ownership. *Journal of the AUTM*. www.autm.net/pubs/journal/98/lieberstein.html.

Malilay GP, AM Mueting, and AS Viksnins. 1997. Prior Art: Silent Time Bombs That Can Blow Away Your Licensing Deals. AUTM Educational Series, no. 2.

Northwestern University Technology Transfer Program. Maintaining Laboratory Notebooks. www.northwestern.edu/ttp/investigators/lab_notebooks.html.

Northwestern University, Technology Transfer Program. Material Transfer Agreements (MTAs). www.northwestern.edu/ttp/investigators/material_transfer.html.

Public Law 96-517, Patent and Trademark Act of 1980, 37 C.F.R. Part 401, reported in the Federal Register, vol. 52, no. 52, March 18, 1987, pp. 8552–8563.

Rockman HB. 2004. *Intellectual Property Law for Engineers and Scientists*. Wiley-IEEE Press: Hoboken, New Jersey.

Rogers EM, J Yin, and J Hoffmann. 2000 Assessing the Effectiveness of Technology Transfer Offices at U.S. Research Universities. *Journal of the AUTM*. www.autm.net/pubs/journal/00/assessing.html.

Simpson Jr, PM. 1998. Use of Bailment in Transferring Technology from a University. *Journal of the AUTM*. www.autm.net/pubs/journal/98/simpson.html.

United States Department of Agriculture. Plant Variety Protection Office. www.ams.usda.gov/science/PVPO/pvpindex.htm.

United States Patent and Trademark Office. Basic Facts about Trademarks. www.uspto.gov/web/offices/tac/doc/basic/.

United States Patent and Trademark Office. General Information about Plant Patents. www.uspto.gov/web/offices/pac/plant/.

University of California, Office of Technology Transfer. Disclosing an Invention. www.ucop.edu/ott/faculty/disclose.html.

Valauskas CC and C Innes. 1999. Copyright Protection of Software, Multimedia, and Other Works: An Authors Guide. AUTM Educational Series, No. 4.

Von Bargen Mueller L. 1995. An Inventor's Guide to Patents and Patenting. AUTM Educational Series, No. 1.