Tutorial on Technology Transfer Brochure

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Published Date: 10/18/2011

COUNCIL ON GOVERNMENTAL RELATIONS

A TUTORIAL ON TECHNOLOGY TRANSFER IN U.S. COLLEGES AND UNIVERSITIES

AUGUST 2011

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FOREWORD

This Tutorial has been compiled through the efforts of the Council on Governmental Relations (COGR) to help explain modern technology transfer practices of U.S. colleges and universities. It updates the version initially published in September 2000. The Tutorial begins with a broad discussion of the role technology transfer plays in adding value to the academic and research mission of universities and colleges. It describes the federal legislation that provides the launching platform for university technology transfer in the U.S. Those elements of intellectual property that make up the legal fabric of "transferable" technology or property are discussed and a closer look provided at the nuts and bolts of the process of technology transfer in a "how to" section. The Tutorial concludes with a consideration of certain of the indirect consequences of technology transfer, such as institutional and personal conflicts of interest, student involvement in outside activities and export controls, and how these issues are managed within the university. The Tutorial includes references to other documents on the COGR website (www.cogr.edu) which discuss certain topics in more detail. The Tutorial is provided as an educational tool with the understanding that COGR is not providing legal advice, and cannot and does not warrant the legal sufficiency of any of the information presented in the Tutorial.

INTRODUCTION

THE ROLE OF THE UNIVERSITY IN THE U.S. ECONOMY

The economy of the United States has moved in a series of startling progressions from an agricultural base in the 18th and 19th centuries, to a manufacturing base in the 20th century, to a technology/knowledge base that exists as the country has moved into the 21st century. Currently, every industry is, or soon will be, affected by the major enabling technologies that include biotechnology, information technology and advanced materials.

More than 10 years ago Porter[1] showed that technology-driven change occurs in regions dominated by specific industrial clusters. These clusters flourish in regions where specialized labor pools are prevalent, where capital and infrastructure are supportive, and where a major research university(s) is located. A recent report by the Brookings Institute revalidated this theory, with regional innovation clusters seen as a framework for structuring the nation's economic development activity.[2] A report by the Milken Institute[3] concluded that the presence of a major research university is the most important factor in the success of a high-tech region. This finding has been further confirmed by additional studies pertaining to US economic advancement.[4]

Universities contribute in many ways to the growing technology- and knowledge-based economy. They graduate the next generation of leaders for emerging industries. They train the

[1] Porter, Michael E., "Managing in the New Economy", pages 25 – 48. A Harvard Business Review Book, 1999.
[2] "The New Cluster Moment: How Regional Innovation Clusters Can Foster the Next Economy." Mark Muro & Bruce Katz. Brookings Institute. (September, 2010)
[3] DeVol, Ross C., "America's High-Tech Economy Growth, Development, and Risks for Metropolitan Areas". Milken Institute, July 13, 1999
[4] See e.g. "The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007. Final Report to the Biotechnology Industry Organization." (September 3, 2009). David Roessner, Jennifer Bond, Sumiye Okubo, & Mark Planting.; "Entrepreneurial Impact: The Role of MIT." Edward B. Roberts and Charles Eesley. Kauffman Foundation. (February, 2009).

specialized labor force — professionals and knowledge workers necessary for the operation of technology companies. They create a dynamic and intellectually stimulating society, which attracts and retains that work force. Universities also attract and concentrate significant amounts of capital that funds scientific research in a wide range of areas. The research leads to new knowledge which is published, and the shared knowledge leads to new products and processes for the marketplace and adds new jobs throughout the economy.

The university missions of research, teaching, creating and disseminating knowledge, and public service, contribute to society as a whole and to the increasingly knowledge-based economy. University knowledge transfer takes many forms, including training and employment of students, scholarly publications, conferences, and faculty consultations and collaborations. But within this broad mission and set of activities, universities have recognized that they can contribute more directly by actively working with the for- profit sector, particularly through licensing patented university inventions and other forms of new technology to industry for commercialization. This dynamic involvement with industry creates new demands on the university to manage these activities so that the institution's primary goals of education, research, and dissemination of knowledge are not compromised, but rather are augmented, and conflicts are minimized and managed. Generally, this is accomplished through the development and implementation of university policies governing such areas as scientific integrity, conflict of interest and intellectual property.

I. TECHNOLOGY TRANSFER: A DEFINITION

The phrase *technology transfer* in its broadest sense encompasses many activities at U.S. universities. The earliest of these were university agricultural and manufacturing extension programs, whose origins can be traced back to the U.S. Civil War era.

However, for purposes of this Tutorial, the term is used more narrowly to refer to the transfer of intellectual property rights from the university to the for-profit sector for purposes of commercialization. Unlike in industrial agreements, in which transfers sometimes take place as an actual sale of the information, article or service to be transferred, universities almost always transfer intellectual property through the *licensing process*.

Three forms of intellectual property are primarily implicated in technology transfer: patents; copyrights; and trademarks and servicemarks. A patent grants to the patentee for a limited period of time (a term of 20 years from the date on which a patent application was filed) the right to "exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." A copyright is a form of protection granted for original works of authorship fixed in a tangible medium of expression. A copyright is a bundle of rights that allows the copyright holder to control reproduction of the work, preparation of derivative works, distribution of copies of the work, public performances of the work and public display of the work. A trademark is any word, name, symbol, device, or combination of these that is used to identify the source of goods and to distinguish these from the goods of others. Most universities have licensing programs that regulate, promote and protect the use of the university's name and identifying marks, both on and off campus. A servicemark operates the same way as a trademark but identifies and distinguishes services rather than goods. In addition to these three forms of intellectual property, university-owned biological materials developed in university laboratories may comprise an additional component of university technology transfer. Biomaterials which are not patented may be licensed or conditionally transferred as *bailed property* under contracts known as Materials Transfer Agreements. (For more information see *Materials Transfer in Academia* on the COGR website (www.cogr.edu) under Educational Materials–Intellectual Property).

II. TECHNOLOGY TRANSFER: AN IMPORTANT CONTRIBUTION TO THE UNIVERSITY MISSION

The primary reason universities engage in technology transfer is to enhance the likelihood that new discoveries and innovations, new uses of physical materials, and new applications of science to solve industrial and medical problems, will actually lead to useful products, processes and services throughout the U.S. and world economies. Technology transfer also propels new research collaborations, exchanges of materials, information and personnel with industry, adding new dimensions to university research programs and, at the same time, offering unique research opportunities for faculty and students. Technology transfer can result in financial returns to the university from licensing revenues which are typically shared with inventors and their departments or schools. These revenues provide funds for new research and teaching programs or financial support for students and also may assist in retaining faculty who otherwise might leave the university to pursue more lucrative careers in the for -profit sector well. (For more general information on technology transfer and universities see *21 Questions About University Technology Transfer* on the COGR website under Educational Materials—Intellectual Property).

III. THE BAYH-DOLE ACT: PROVIDING THE PLATFORM FOR UNIVERSITY TECHNOLOGY TRANSFER

A. The Purpose and Effect of Bayh -Dole: The Bayh-Dole Act, passed by Congress in 1980 and named for its co-sponsors Senators Birch Bayh and Robert Dole, created a uniform patent policy among the U.S. federal agencies that fund research in the non-profit and small business sectors. The Act (Public Law 96- 517; 35 USC 200 *et. seq.* and subsequent amendment Public Law 98- 620, implemented at 37 CFR Part 401) provided recipients of federal research and development funds with the ability to retain ownership of their inventions and

charged them with the responsibility to pursue patents and ensure commercial use of inventions created with federal financial support.

Since a vast majority of university research (particularly in the sciences) is funded by the federal government, university policy regarding technology transfer must be consistent with federal law and policy as set forth in the Bayh-Dole Act. The underlying tenet of the Bayh-Dole Act is that federally funded inventions should be licensed for commercial development in the public interest. That principle is reflected in virtually all university policies whether or not the invention is federally funded. (The COGR website includes a *Guide to the Bayh-Dole Act and Implementing Regulations*).

B. Important Aspects of Bayh-Dole: Bayh-Dole permits small businesses, universities and other nonprofit institutions such as teaching hospitals to retain title to inventions that are conceived or first reduced to practice in the performance of a federal grant, contract, or cooperative agreement in exchange for certain obligations on the part of the contractor.

In considering Bayh-Dole's implications and requirements, it is important to keep in mind the objectives of the Act as established in its preamble. They are to:

- promote the utilization of inventions arising from federally supported research and development programs;
- encourage maximum participation of small business firms in federally supported research and development efforts;
- promote collaboration between commercial concerns and nonprofit organizations;
- ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise;

- promote the commercialization and public availability of inventions made in the U.S. by U.S. industry and labor;

- ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and

- minimize the costs of administering policies in this area.

In part, the Bayh-Dole Act stemmed from a realization that federal ownership of inventions made at nonprofit institutions and small businesses as part of federally funded research had not previously resulted in effective transfer of innovations to industry for commercialization. After considerable Congressional debate, it was concluded that incentives such as ownership and the right to income generated through licensing (or through commercial development in the case of small business) must be provided to nonprofits and small businesses so they would invest in patenting and licensing and in the commercial development of federally funded inventions. A few years after its passage by Congress, the federal government provided "big business" commercial contractors nearly the same rights to their inventions by Presidential Executive Orders as the non-profits and small businesses had received under the initial Act.

C. University (and other nonprofit) Obligations under Bayh-Dole: By accepting federal funds in support of a research project, recipient institutions assume responsibility for complying with the requirements of the Act. In general, the nonprofit institutions are required to:

- obtain written agreements from all employees (except clerical and non-technical personnel) recognizing their obligations to report inventions developed under federally funded programs to the appropriate university office and assign them to the institution (see D. below);

- disclose an invention to the federal agency supporting the applicable research program within two months after the inventor discloses an invention in writing to the institution;

- elect title to the invention within two years after disclosing the invention to the federal agency but no later than 60 days before the end of any statutory period in which valid patent protection can be obtained in the U.S.;

- file a patent application within one year after election of title, but no later than the end of any statutory period in which valid patent protection can be obtained in the U.S.;

- include at the beginning of the U.S. patent application and patent a statement that the U.S. Government has rights in the invention and identifying the sponsoring agency and the number of the funding award;

- submit to the funding agency a confirmatory license for each U.S. patent application;

- notify the funding agency within 10 months after filing the initial patent application whether and in which countries corresponding foreign applications will be filed;

- submit periodic reports, no more frequently than once a year, regarding the utilization of the invention as requested by the funding agency;

- notify the funding agency at least 30 days before statutory deadlines if a patent application or patent will be abandoned;

- give preference to issuing licenses to small business firms if they show they have the resources and capability to bring the invention to practical application;

- except with permission of the funding agency, not assign rights to inventions to third parties (except to patent management firms), including to the inventor;

- require any exclusive licensee to substantially manufacture in the U.S. any products that will be sold in the U.S., unless this requirement is waived by the funding agency;

- share with the inventor(s) of the invention a portion of any income the institution receives from the licensing of the invention;

- use the balance of income received from the licensing of the invention (after costs associated with patenting and licensing are reimbursed) to support education and scientific research.

These obligations are not trivial, and failure to comply with them could impact ownership[5]. Universities and non-profit institutions must make serious resource commitments to supporting the personnel and infrastructure required to comply with the federal regulations that implement the Bayh-Dole Act. To assist with the reporting requirements, the government has developed an electronic reporting system (iEdison) which is used by most federal research funding agencies.

D. Obtaining Assignments from University Inventors.

The Bayh-Dole implementing regulations (37 CFR 401) include a standard patent rights clause for use in federal funding agreements subject to the Bayh-Dole Act. The standard clause requires (401.14(f)(2)) that federal funding recipients obtain written agreements from employees (other than clerical and nontechnical employees) to disclose subject inventions and to execute all papers necessary to file patent applications and establish the government's rights. While it implies that inventors must assign subject inventions to the institution, it does not use the term nor specify a particular form of assignment.

In the case of Stanford v. Roche (Sup.Ct. 2011-No. 09-1159), the U.S. Supreme Court held that the Bayh-Dole Act does not

[5] In Campbell Plastics v. Brownlee, 398 F. 3d 1243 (Fed. Cir. 2004) the Federal Circuit Court of Appeals upheld forfeiture of a federal contractor's patent under the Bayh-Dole Act for failure to appropriately report an invention to the funding agency.

automatically vest title to federally funded inventions in federal contractors such as universities. The case involved a Stanford researcher who had signed a visiting scientist agreement with a small research company called Cetus (subsequently acquired by Roche). In that agreement the researcher agreed that he would assign and *"does hereby assign"* to Cetus all rights to any inventions made *as a consequence of his access to Cetus*. The researcher learned techniques at Cetus which he then used to develop federally-funded inventions at Stanford which Stanford patented. Stanford's standard patent agreement (which the researcher had signed prior to going to Cetus) provided that the researcher "agreed to assign" to Stanford his rights in inventions resulting from his employment. Cetus (Roche) subsequently commercialized the procedures that the researcher developed at Stanford. When sued for patent infringement by Stanford, Roche cited the Visiting Scientist agreement as giving it co-ownership of the procedures. The Federal Circuit Court of Appeals agreed with Roche.

According to the Supreme Court majority opinion, the Bayh-Dole Act addresses only the respective rights of the federal government and federal contractors in federally funded inventions, and does not affect the rights of the inventor. For Bayh-Dole to apply, federal funding recipients are expected to have an effective assignment from the inventor to the institution. The Federal Circuit's holding was based on its earlier decision in *FilmTec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568 (Fed.Cir.1991). In that case, the Federal Circuit had concluded that an agreement to "hereby assign" a future invention has priority over a previously executed "agree[ment] to assign" the same future invention. (The Federal Circuit's theory is that equitable title passes immediately to the assignee in such cases, which then is converted to legal title when an invention is made). The effect of Stanford v. Roche is for the Federal Circuit *FilmTec* doctrine to govern rights in inventions even when federally funded (although the Court's decision left the door open for a subsequent challenge to *FilmTec*).

The decision raises a number of serious compliance considerations for COGR institutions. One is the need to review polices and employment agreements to ensure that they incorporate the "hereby assign" or equivalent present assignment language, in order to assure the assignment is effective. There is a great variety of existing institutional policies and practices with regard to assignment language. For those institutions that previously have followed an approach of using future assignment language such as "agree to assign," obtaining more effective assignments through appointment or reappointment letters, new employment agreements, or affirmative statements in proposals submitted to research sponsors may be mechanisms to accomplish this. Institutions also may want to review existing license agreements to assure that the inventors have executed present assignments of invention rights (and obtain such assignments if they have not). It should be noted that the concept of and issues with obtaining effective assignments are true regardless of funding source, so long as the *FilmTec* doctrine remains the guiding authority.

While institutions can take actions to address the situation prospectively, this may not fully resolve the issue of potentially dueling assignment agreements in the future as researchers move among institutions and execute present assignment agreements with different employers over time. Additionally, it will be difficult if not impossible to resolve any previous assignments to third parties that a researcher may have already made. The result may be that title to inventions is clouded, and institutions are unable to warrant clear title. Institutions may want to consider negotiating more conditional warranty language (e.g. "no knowledge of" other ownership claims), which may complicate license negotiations. A high degree of due diligence will be necessary to assess whether there are potentially conflicting assignments, both with new and existing licenses. However, no amount of due diligence can fully solve the problem or avoid the possibility of other parties claiming invention rights, based on an agreement a researcher signed years ago. It seems likely that licensees will push for more

robust warranties, and that "hereby assign" or "hereby grant" language may start to appear in sponsored research, materials transfer, and other types of research-related agreements. Institutions also may want to consider reviewing third party agreements of faculty, including consulting agreements, to assure that faculty have not made present assignments of future invention rights and/or that faculty (and the institution) can fulfill any promises made in such agreements with regard to rights in inventions. There are obvious cost and burden implications for institutions. It should also be noted that the status of the government rights in inventions subject to Bayh-Dole, discussed in E. below, is uncertain. Under the logic of Stanford v. Roche, the government would not obtain any rights if an inventor had made a prior present assignment of his/her future invention rights to a third party even if a subsequent invention was federally funded and otherwise would be subject to Bayh-Dole.

E. The Government's Rights in University Inventions. Except as discussed in D. above and in the case of inventions resulting from federal funding awards made primarily for training (such as training grants and fellowships), the Government retains certain rights in all federally funded inventions made by universities and other non-profits. The Government's rights are the following:

- The right to a nonexclusive, nontransferable, irrevocable, paid-up license to the invention to practice it or have it practiced for or on its behalf throughout the world;

- The right to require the university to assign title to any invention to the Government if the university fails to report the invention, or fails to or does not elect to take title, or fails to file a patent application in the time periods required;

- The right, under limited circumstances, to require the university owning the invention to license it to third parties (including the right to require the canceling of an existing exclusive license) or the right of the Government to grant

those license(s) itself (referred to as Government "march-in" rights). The Government's right to do the foregoing is limited to situations where the invention has not been brought into practical application for public use within a reasonable time; where health or safety needs are not being met; where requirements for public use specified in federal regulations are not being met; or where the U.S. manufacturing requirement has not been met and has not been waived by the funding agency. Note that these march-in rights provide the government with the ability to require compulsory licensing; they do **not** confer ownership rights on the government. Although several march-in petitions have been submitted to the National Institutes of Health (NIH), NIH has denied all such requests and to date, the government has never exercised its march-in rights under the Bayh-Dole Act.

- The right of a federal agency to make a Determination of Exceptional Circumstances (this is sometimes called a "DEC") if there are compelling reasons why the right of the university to retain title to some or all inventions made under a particular funding program or activity should be restricted or eliminated. DECs require rigorous analysis by the declaring agency of why such action is necessary and will better carry out the intent of Bayh-Dole than leaving title to the invention(s) with the university. In addition, the declaring agency must file the DEC and a justification for using it with the Department of Commerce.[6] DECs were rare in the early years of implementation of the Bayh-Dole Act. However, in recent years, some federal agencies, in particular NIH, have issued DECs more frequently, primarily to provide preferential invention rights to industry collaborators in NIH-funded programs. Some NIH programs also have restricted the rights of funding recipients in program announcements or guidelines without following a formal DEC process. In addition to

[6] Commerce responsibilities for oversight of federal implementation of the Bayh-Dole Act were transferred to the National Institute of Standards and Technology (NIST) in 2007.

disadvantaging the university recipients of the NIH funding, these practices threaten to undermine the careful balancing of private and public interests provided by the Bayh-Dole framework.

IV. INTELLECTUAL PROPERTY: AN INDISPENSABLE COMPONENT OF TECHNOLOGY TRANSFER

University policies are clear that technology transfer must be conducted in ways which do not conflict with the university's mission of teaching, research and dissemination of knowledge. Nevertheless, universities with established technology transfer programs have recognized that the protection of intellectual property is sometimes necessary to attract the additional investment needed to develop ideas into useful products. Universities use patents and copyrights to provide the legal fabric of property ownership that makes technology transfer through licensing possible.

All major U.S. universities have developed policies to address various kinds of intellectual property: whether it is owned by the university or the individual inventors, authors and creators; how decisions on commercializing the intellectual property will be determined; and how any revenues earned as a result of licensing activity will be shared. However, there is some variation among U.S. universities with respect to the types of academic work product that the university seeks to protect and how it is protected.

As discussed in the section dealing with the Bayh-Dole Act, certain activities will follow from the disclosure of an invention with regard to *patenting*. Universities also make transfer determinations with respect to *works of authorship* including s*oftware*, *multi media work*s, and *instructional materials.*

Copyrights provide a different structure of intellectual property protection from patents. A marketable copyrighted work might

result from computer software and documentation, or the weaving together of the text, video, music, film and other components of a multimedia work, or the bringing together the curriculum, pedagogy and instructional tools of an educational program or course, although the university may elect not to claim ownership rights in some of those categories. Identifying the market-readiness of copyrighted works is very different from pinpointing the more specific activity that was the conception or reduction to practice of a patentable invention. Researching the provenance of an authored work, simply to establish whether or not the university has sufficient rights in the work to make it a viable candidate for commercialization, takes an in-depth knowledge of copyright law and the patience to trace scholarly and creative contributions back to their source.

Much of the detail that is described throughout the rest of the Tutorial is focused on the practice of technology transfer as it relates to patents. A discussion of the licensing of non-patented intellectual property, that is, copyrights, trademarks and so forth will also be found. Many of the factors leading to successful licensing of patents are also relevant to the licensing of non-patented materials. While the legal fundamentals of these different kinds of intellectual property are not alike, the steps in considering whether an intellectual property "product" is marketable, assessing its value, and finding a licensee are not dissimilar. However, the license terms will vary since the legal "metes and bounds" of patents, copyrights and trademarks are different. A successful university technology transfer organization will develop sufficient sophistication to handle this variation. We will see that an even greater challenge is presented by new technologies that are not defined solely as "a patent" or "a copyright" or "a trademark" but combine multiple kinds of intellectual property protection, such as a computer program that is comprised of a *patented* algorithm, a *copyrighted* computer code and a name or identifying logo that is *trademarked*.

A. Formulating an Intellectual Property Policy. The following factors are generally considered in developing a sound policy for dealing with intellectual property:

- Identifying the fundamental institutional principles, objectives and goals;
- Considering (not neglecting) the legal basis for ownership;
- Federal patent and copyright laws defining ownership;
- The employee-employer relationship creating the "work-for-hire" situation;
- State laws affecting intellectual property ownership in "public" institutions;
- The requirements of Federal regulations and terms attaching to federal grants and contracts;
- Federal and state tax consequences of intellectual property ownership and disposition;
- Academic custom with respect to scholarly publication;
- Types of intellectual property that will be protected and will be candidates for transfer;
- Royalty sharing with inventors and authors;
- Rights of the university to retain use rights in licensed or individually owned intellectual property; and
- Institutional responsibility for administration of the policy.

B. Managing the Intellectual Property Assets. Over the past 30 years since the enactment of Bayh-Dole, university technology transfer offices have become increasingly sophisticated and worked diligently to develop the expertise

necessary for managing the rapidly increasing number of university relationships with complicated intellectual property considerations. Experience has shown that successful management requires a highly developed knowledge of intellectual property, licensing, and contract law, as well as an in-depth understanding of current business realities, and the capability to predict new market trends. In addition, the technology transfer office must develop and maintain sophisticated database support systems for managing these activities and relationships. Perhaps of greatest importance, the technology transfer office also must understand the overall institutional policy context within which it works. The technology transfer office must recognize and successfully resolve conflicts, or the perception of conflicts, between its own activities and the broader university mission.

Faculty and technology managers must understand and operate within a complex set of policies and procedures that are designed to manage this process. As a consequence of the specialized knowledge and expertise developed in the technology transfer office in managing intellectual property, the technology transfer professional becomes an indispensable member of institutional teams that are framing policies and procedures for constructing a wide variety of university research relationships with industry. Closely related are the issues that arise when graduate students or faculty have equity interests in start-up companies or other ventures supporting research. Technology managers must become informed as to the potential conflict of interest that may occur on account of personal interests of those individuals involved in the research or corporate interests where companies are funding research programs. The important role of the technology transfer manager in helping to establish procedures where studies involve clinical trials, environmental studies or public safety to ensure that the apportionment of intellectual property rights do not undercut the credibility of the research results or the position of the university as an impartial source of scientific knowledge and information cannot be overstated.

V. TECHNOLOGY TRANSFER: HOW THE PROCESS WORKS

The technology transfer process begins in the university when the research investigator or creator identifies a discovery or innovation or completes a copyrightable work which he or she believes may have potential for commercial development. A thorough analysis of the funding source(s) contributing to the innovation is necessary, as agreements with the sponsor(s) may prescribe the future requirements for protecting and/or licensing the technology.

For example, the National Institutes of Health requires that all NIH applications that seek $500,000 or more in direct costs in any single year include a plan for data sharing or explain why sharing is not possible. NIH explained this position by stating that it believes "that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health." (Final NIH Statement On Sharing Research Data, February 26, 2003, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.) NIH recognizes that investigators may benefit from their initial exclusive use of the data, but specifies that data are to be released and shared no later than the acceptance for publication of the main findings from the final data set.

Besides requiring data sharing, NIH requires public access to and sharing of peer-reviewed research publications generated with NIH support. As of April 7, 2008 investigators that receive funding from NIH must submit copies of research manuscripts to PubMed Central (PMC) upon acceptance for publication. PMC will ensure these manuscripts are publicly available no later than 12 months after the publication date.

Like NIH, the National Science Foundation (NSF) believes that data sharing is beneficial to scientific development and innovations. NSF "expects investigators to share with other researchers, at no more than incremental cost and within a

reasonable time, the data, samples, physical collections and other supporting materials created or gathered in the course of the work." It also encourages awardees to share software and inventions or otherwise act to make them or their products widely available and usable." Beginning October, 2010, NSF also requires that all proposals include a data management plan that explains how the project will conform to the data sharing policy. The plan will be reviewed as part of the intellectual merit or broader impacts of the proposal, or both. See NSF Proposal and Award Policies and Procedures Guide, January 2011 available at www.nsf.gov.

Requirements such as these are agency specific and should be taken into account. Penalties for noncompliance vary in severity from agency to agency and are based on the specifics of a given violation.

A. Submitting the Disclosure. The first formal step in the process occurs when an inventor or creator submits a "disclosure" form describing the patentable or copyrightable innovation to the university technology transfer office ("TTO"). The disclosure briefly describes the idea of the new discovery or invention or, if software, multimedia or other informational product, describes the product, what it does, what platform(s) it has been developed to run on and so forth. Institutions also may want to consider reviewing any third party agreements of inventors, including consulting agreements, to assure that inventors have not made present assignments of future invention rights and/or that inventors (and the institution) can fulfill any promises made in such agreements with regard to rights in inventions (see Section III. D). Other types of information included on a disclosure form typically are:

- Names of the inventors or authors;

- The federal agency, industrial company or other organization sponsoring the research that spawned the discovery. In the case of an invention, if and when the invention has been published or whether publication is imminent;

- Potential commercial markets for the innovation;
- Companies that may be interested in licensing the discovery; and
- In the case of software, whether documentation has been written.

B. When the Disclosure is a Patentable Invention.

1. **Evaluating a Disclosure for Patenting** If the disclosure is an invention, the TTO will further investigate the invention to determine the advisability of investing funds to file a patent application. U.S. patents cost on average between $10,000-30,000 each and filing for equivalent foreign protection can increase the ultimate cost several-fold. The decision of whether or not to file a patent application generally is based at least on the following three issues:

   (a) Based on the state of publicly known information about the elements of the discovery (called "prior art"), is the invention likely to be patentable, and is the patent likely to be broad enough in scope to have commercial value (that is, to cover a substantial product or class of products, rather than just a minor variation on known and existing products).[7] This issue is addressed by a search of the literature and the past patents, often with the help of a professional search librarian, and sometimes by consulting a patent attorney and asking for a *patentability opinion* based on the patent attorney's search of all resources.

   (b) If the invention was patented, would it be likely to attract the commercial investment needed for development

[7] For most inventions utility is required; an invention must actually perform a function and not involve inoperable devices (or immoral consequences). However, non-utility patents may be granted for new varieties of asexually reproduced plants. The legal requirements for plant patents are basically similar to those for utility patents. See www.uspto.gov/web/offices/pac/plant/#1 for more information. For institutions involved in agricultural research, plant patents may constitute a significant source of intellectual property.

through a license? This issue is far more difficult to address than the first. It depends on the potential market for the product; the likely technological success of developing the invention into a practical product; the type of technology - and whether investors are currently interested in investing in such fields; what are the competitive technologies; and even the current state of the economy. The more innovative the technology, the more difficult it is to conduct market research in an efficient, meaningful manner, since the potential investors and customers may never have envisioned such a product.

(c) Are there funds available within the institution or from a prospective licensee to pay for the patenting costs? This consideration is one of practicality. A university TTO receives a significant number of invention disclosures each year. The decision to patent involves a determination of available financial resources, balanced with the likelihood the invention will generate commercial interest. Consequently, all TTOs must make choices.

Other factors contribute to making the patenting decision a difficult choice. Impending or actual scientific publication of the invention limits the time for decision making, since patents must be filed before publication if foreign patent coverage is not to be lost; and must be filed within one year after publication if only U.S. patent protection is sought. Since most universities, as a matter of policy, will not ask the investigator to delay publication for patenting purposes, very often patenting decisions must be made quickly. The TTO is forced, then, to make "educated guesses" based on its knowledge of the technology and the market, coupled with some cursory discussions with the inventor(s) and perhaps with a few potential licensees. The advent of provisional patent applications in 1994 has helped

TTO's by enabling filing of a low cost provisional application under such time constraints. Such filings must, however, fulfill the enablement requirements of Section 112 of the U.S. patent code (35 USC). Moreover, they must be converted into a regular or pCT application within one year of the initial provisional filing or result in a loss of the provisional priority date. The provisional filing date is not included within the 20-year patent lifespan. Universities tend to vary in the extent of their use of the provisional patent application process, but its importance may further increase under the changes to U.S. patent law that are currently being considered by the U.S. Congress.[8]

Some universities also may use patent committees comprised of faculty or outside advisors to help with the patenting assessment. There are important points to be considered when deciding whether or not to use outside committees or outside advisors. They include (i) the length of time that it may take to convene outsiders to evaluate patenting an invention and (ii) the accountability factor – the fact that outsiders are making decisions on spending the limited financial resources of the TTO without accountability for the funds being spent. There may be benefit, though, in having an invention evaluated by impartial experts who may understand the marketplace or who are able to judge how high the invention registers on the "innovation" scale.

2. **Filing the Patent Application.** If the decision is made to file an application, the TTO engages a patent attorney to work with the inventor(s) to write the patent application, file it in the U.S. Patent and Trademark Office (USPTO), and follow it through the patenting process. In order to comply with the procedural requirements imposed under U.S. patent law, licensing or staff professionals in the TTO must

[8] As of the date of publication of this document legislation was pending in the U.S. Congress that would change the standard for patenting from "first to invent" to "first inventor to file," in order to more fully harmonize U.S. patent practice with that followed elsewhere in the world.

understand the patenting process as well as the various options under the law for filing provisional and utility patents.

If the invention was funded by a U.S. federal agency, Bayh-Dole mandates a series of reporting requirements, beginning with the invention disclosure and continuing after the decision is made to file (see section III C.). This reporting continues through the licensing and development stages. If the TTO decides not to file a patent application, under Bayh-Dole the government may assert title to the invention, but the university may request that the federal funding agency waive title to the inventor if the inventor requests ownership. The process for requesting a waiver, or endorsing an inventor's request for waiver to the funding agency in the case of a federally-funded invention, should be well established within the university.

3. Marketing the Patent (finding a licensee)

(a) The challenge of licensing university inventions. Patents are filed when a university intends to market and license the invention for commercial development. However, university inventions are often embryonic in nature and of unproven market potential. Additional research must be conducted before product development can begin. Because of the resources required, finding companies willing to take the risk may be challenging. This is particularly true in the case of many medically-related inventions where it may take many years of research and development before it is known whether the product will be successful. A company or investor must have a long product-planning horizon before it will consider investing in university patents. For this reason, traditional methods of technology marketing, such as advertising the invention, publishing lists of technologies available for licensing, or using Internet listing services, meet with limited success in finding licensees for university patents.

(b) When licensing begins. A license to the patent—particularly if it is exclusive or partially exclusive—increases the incentive for the company to make the risky investment in development, since the patent can protect the company ("the licensee") from competition in the marketplace. Universities typically seek licensees as soon as the patent application is filed, to get industry participation and investment in the technology as soon a possible. The university also needs to have its patent filing and prosecution costs reimbursed so that these funds can be recycled into additional patent filings. If the patent fails to issue, the license can be terminated unless it covers other types of intellectual property protection, such as trademarks or copyrighted software.

(c) Identifying potential licensees. The identification of potential licensees for a patent often starts with information provided on the disclosure form and through discussions with the inventors. Further research is performed by the TTO to identify as many companies as possible that are working in the general area relating to the invention. Additionally the TTO will usually be able to leverage prior relationships with companies with whom they have licensed other technologies when seeking licensees for new inventions. Before serious negotiations begin, the potential licensee must demonstrate that it has the technical, financial and marketing capabilities to develop the invention into a product or service and to bring it to market.

(d) Selecting the licensee. In those rare cases where more than one qualified licensee has requested a license, the university will consider co-licensees, or may divide the license by *field of use* (see below). If neither of these alternatives is commercially practical, the university will make a judgment as to which is the better prospect for licensing, taking into consideration the financial and technical capabilities of the candidates

to develop and market the technology and the commitments each is willing to make to reach the marketplace. While royalties and license fees offered may tip the scales, all things being equal, greater weight will be given to the candidate most likely to succeed in the unpredictable business of turning university inventions into commercial products. It should be noted that although there is some risk that a small or start-up company may fail more often than a larger licensee, a small company licensee may be the best choice because of its motivation to carry a "signature" product through to commercialization. Often the inventor also may be able to play an active role in advising or perhaps even assuming a management role in a start-up company to facilitate further development and commercialization. The inventor's continued involvement is advisable even with large company licensees, which may employ the inventor in an advisory or consulting capacity. In any event, the TTO should keep the inventor informed of the status of the selection process.

4.Negotiating the License

(a) Field of the License. Some inventions cover multiple products in a number of different fields. A biological invention, for example, may have applications in research, in diagnostics, in vaccines, and in therapeutics. A chemical synthesis method may have applications in agriculture, polymer synthesis, and in pharmaceuticals. If the licensee is a large multi-divisional company with businesses in all fields of the invention and is willing to commit to product development in all fields, the license granted may be broad. If the company's business is limited to a single field, then a *field of use* may be specified in the license, and the company's rights to exploit the invention will be limited to that field. This will leave the invention licensable to companies working in other fields.

(b) Exclusive or Nonexclusive within a field (or in all fields). A license may be *nonexclusive* (that is, similar licenses may be granted to a number of companies) or *exclusive* (a license is granted to one company only). In the case of federally funded inventions, under Bayh-Dole, all licenses must acknowledge that the federal government also has a license for government purposes. Exclusive licenses are generally desirable when the licensee must make a large, high-risk investment to bring the product to market. Few companies will be willing to undertake such an investment if licensing rights are available to other companies once the original licensee has successfully developed the technology.

Nonexclusive licenses are generally desirable when the invention is a broadly applicable process or has self-evident technological advantages which will be useful to many companies and so it is not necessary to grant exclusivity to "induce" investment. Nonexclusive licenses are highly preferable when the invention is a research tool, useful to both the commercial and academic communities and a high degree of access is important (NIH has polices and funding conditions with regard to research tools which encourage nonexclusive licensing; see 64 *FedReg*72090; 12/23/99). In some cases (e.g., when the development cycle is relatively short), an exclusive license may be granted for a limited period of time - long enough for the original licensee to recoup its development investment from the marketplace - after which the license becomes nonexclusive and licenses may be granted to other companies.

(c) Diligence requirements. If an exclusive license is granted to a company, Bayh-Dole requires that the university assure that the company is working diligently to develop the invention. Neither federal nor university

policies allow a patent to be licensed in order to "put it on the shelf" – a circumstance that might be attractive to some licensees if the invention threatens to compete with an existing product. Consequently, an important part of any license negotiation is the *diligence provisions*. These requirements may include, for example, specifying the number of people assigned to develop the invention within the company, the amount of funding a company will commit to development, or in the case of a small company, the amount of investment capital that will be raised to fund development. Where the development of the product is sufficiently predictable at the time of licensing, the diligence provisions may specify a date by which a working prototype of the product is made, a date by which the first commercial product must be sold, and sales levels that must be achieved by certain dates. Diligence provisions or milestone dates are a mandatory contractual commitment. If diligence provisions are not met, the university may terminate the license or, if the license was exclusive, the university may make it nonexclusive, thereby regaining the option to grant licenses to others.

(d) Royalties and other financial considerations. The financial considerations for a license involve a balancing of risks and rewards. Since many university inventions tend to be at an early stage of development at the time of licensing, royalty rates and license fees are typically lower than those between commercial companies licensing one another where the technology is closer to being an actual product. At the same time, universities are usually unwilling to "cap" royalties at a pre-determined dollar value in the license. Since the university is sharing the "downside" with lower license fees and royalty percentages, it is reasonable to share in the "upside" if the product is very successful and value received by the licensee is greater than

anticipated. The financial components of the license are negotiated between the university and the licensee and typically include:

(i) **Reimbursement of the university's patent costs:** This is required, almost without exception, for exclusive licenses.

(ii) **License issue fee:** The range of this fee may vary from a very few thousand dollars to a quarter of a million or more depending upon a fact-specific determination which takes into account the stage of development of the invention (well developed as a result of significant investment by the university, or less well-developed requiring considerable investment by the licensee), the size and breadth of the patent package, whether any patents have issued or whether all are still pending, the size of the potential market and so forth. These are factors contributing to the "value" of the invention. For small companies and start-ups, the license issue fee may be partially postponed until sufficient investment capital is secured by the company.

(iii) **Annual license maintenance fees:** Many universities use these as a way of sharing the risk with the licensee. An annual license maintenance fee allows the university to charge a lower license issue fee upfront, and helps assure that the company is interested in developing the technology as evidenced by its willingness to make a financial commitment to renew the license annually. Sometimes universities allow annual maintenance fees to be treated as "minimum royalties" so that if the company is paying significant running royalties, no additional annual maintenance fee is required.

(iv) Running royalties: These are usually specified as a percent of sales of the product or service covered by the patent. The rate depends on many factors, including the profitability (margin) of the class of product covered by the invention; the size of the market; the stage of development of the technology when licensed; whether the product also falls under patents owned by others; and whether the university's technology is the key enabling technology for the product or just a minor component.

Typically, university patents command royalties in the range of 1 to 6 percent of product sales; occasionally licenses include royalties outside that range based on specific factors.

(v) Equity shares: When a license is granted to a start-up company, shares of stock in the company may be taken by the university as a form of compensation. Universities may take the equity in lieu of an upfront fee, allowing the start-up to conserve cash for development of the technology. Other license fees and/or running royalty percentages may be lowered in consideration of the equity shares. The arrangements may be negotiated so that the company "buys out" the university's equity interest over time, which is converted to a higher royalty percentage as product sales increase. Not all universities have policies allowing them to accept equity in lieu of royalties and some state institutions do not have the requisite legal authority to accept equity.

(e) Additional License Terms. Licenses also commonly include terms specifying certain reporting requirements for the licensee; which party will prosecute patent infringers and how damages will be shared; which party

will have responsibility for prosecuting and maintaining patents and in which countries; circumstances under which, and procedures for, terminating the license; and the administrative and legal processes for handling disputes between the parties.

Finally, and very important for the university, provisions are placed in licenses for protecting the university as licensor. To protect the university's ongoing research and educational programs, under any exclusive license grant, the university usually retains the right to use the licensed technology for continuing teaching and research efforts as well as the right to grant such licenses to other nonprofit institutions. Most universities will insist on a *Non-Use of Names* provision prohibiting the use of the university's name to promote the company or the products made under the license. Universities will also require *Indemnification and Insurance* provisions. Since in virtually all university licensing situations the licensee has complete control over product development, it must also assume all responsibility for any product liability arising from the company's use of the invention. Many universities require evidence that a company has obtained sufficient insurance to honor its obligations to protect the university against any such legal actions.

5. **Socially Responsible Licensing.** In recent years a great deal of attention has been given by universities and other groups including non-profit foundations and public advocacy groups on ways to encourage the use of university research innovations to provide the broadest possible public benefit, particular in areas related to global health and neglected diseases. A large number of universities and university groups have endorsed a statement of *Nine Points to Consider in Licensing University Technology in the Public Interest.* Point 9 discusses the need to include provisions in license

agreements that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world. The discussion points to the social compact that universities have with society, and their responsibility to try to alleviate the suffering and dying of people around the world from preventable or curable diseases. This includes finding ways to share the fruits of the global knowledge gained by universities for the benefit of the world's poor. The statement points to the increased awareness of university licensing professionals that responsible licensing includes consideration of the needs of people in developing countries and members of other underserved populations. While the details and application in particular cases may vary, universities should strive to construct licensing arrangements in ways to ensure that under-privileged populations have low or no-cost access to adequate quantities of medical innovations. For additional information and a copy of the statement see www.autm.net/Nine_Points_to_Consider.htm.

Non-traditional approaches to develop and distribute therapeutics and diagnostics to the developing world also are emerging through novel partnerships that merge philanthropic and humanitarian goals with product development. Organizations like MIHR (Center for the Management of Intellectual Property in Health), the TB Alliance, PIPRA (Public Intellectual Property Resource for Agriculture) and others have approached specific segments of global health, but the vast resources of the Bill and Melinda Gates Foundation have focused the attention of policy makers and the public more generally on global health research. While some initiatives have looked broadly at the problems, issues, and needs to bring therapeutics or diagnostics to the developing world, many efforts have focused on the earliest stages of the commercialization ecosystem – such as university research and licensing.

The Association of University Technology Managers (AUTM) Better World Project provides numerous examples of university licensing that have an impact on global health (see www.autm.net) and AUTM recently established a Global Health Initiative

6. **Distribution of Patent Licensing Revenues.** All U.S. research universities have instituted policies governing the disposition of revenues earned from technology transfer activities. Most commonly, the first revenues received from a license are used to repay the university for any unreimbursed patenting costs. Thereafter, revenues are generally distributed according to a formula that has been adopted by the university. In most cases, inventors will receive approximately one-third of revenues earned from the licensing of their patents ("inventors' share"), although the percentage is higher in some institutions and lower in others. Some universities implement a sliding scale, with the inventor's share higher in the early years of a license when the royalty return tends to be lower. The remaining revenues are distributed within the institution ("institutional share") in proportions that vary widely from university to university between the inventor(s)' laboratories, the inventor(s)' departments, and the university's general fund. In some universities, a portion of the institutional share will be used to "seed" inventions or new technology developments that will benefit from some maturation in the university before they are ready for licensing.

   Under Bayh-Dole, the institutional share from federally funded inventions, regardless of where within the institution it is distributed, must be used wholly for research and educational purposes. Word often reaches the public on a university technology transfer "success" as a result of a company in which the university took equity going public, or in the case of a product which has found large acceptance in the marketplace (the AUTM *Better World* reports provide numerous examples). While these situations

are relatively rare, they give universities an opportunity to put funds to good use as in endowing academic chairs, underwriting new technology developments and providing an endowment for student scholarships.

C. When the Disclosure is Computer Software

1. **Choosing the Best Form of Protection.** Unlike subject matter that qualifies only for a single form of intellectual property protection, nearly all computer software qualifies for copyright protection, and some software may also contain elements that are patentable. Most often, the patentable element of a computer program will be an algorithm that is used for a novel purpose. The challenge for a university TTO is to determine whether to pursue patent protection in addition to copyright protection. While copyright protection will prevent the unlicensed copying, distribution, adaptation, display and performance of the computer code and is immediately available at virtually no cost, patenting will require a commitment of time, effort and money, as previously discussed. The advantage of patenting, however, is that it protects against independent discovery and is generally considered a stronger form of protection than copyright. Since patent protection covers different elements than copyright protection, it is altogether possible, and may be commercially advantageous, to seek both kinds of protections. It must be pointed out that where a software product is both patented and copyrighted, the license will be drafted to include rights and obligations that are normally included in a patent license in addition to provisions that are normally included in a copyright license (as further described below). These licenses are complex and require detailed knowledge of both patent and copyright licensing.

2. **Choosing the Best Form of Licensing.** Making decisions as to whether software is best commercialized under an exclusive license or by licensing multiple end

users is often determined by the nature of the software and its intended use. If the software is complex, requires continuous maintenance and updating, then, unless a university has an interest in acting as a software distributor, the best choice may be licensing it exclusively to a licensee that has the capability, financial resources and interest to staff itself with programmers to maintain the software for end users and to continue developing and enhancing it. While some universities have made these capabilities a part of their normal activities, most have not and prefer to look for a licensee interested in undertaking this type of business.

Often software programs developed at a university are in the nature of educational, mathematical, design or other types of software tools. If the software program is not complex, it may be licensed directly by the university, on a non-exclusive basis, to end-users. Setting up a software end-use licensing capability is not difficult. Most often a standard, pro forma license will be drafted and used for all transactions. In the case of direct distribution, a decision will have to be made whether it is the TTO that will undertake end- use licensing or whether the department, laboratory or center that developed the software will do it. Software commercialization and use licenses are often single payment (fully paid up) licenses without running royalties on copies sold.

A further consideration for software licensing is whether or not to license it via an 'open source' model. In the creation of computer software, the source code is readable by programmers and can be adapted and expanded upon. Executable code or object code is the machine readable version of code that users purchase to install on their computers and it is not readily adaptable. Many commercial software vendors choose to keep their source code proprietary and only make executable code available to users. The open source movement arose in the software programming community to encourage programmers to

freely share their source code so that anyone could adapt and enhance the code and share their improvements with the community without the restrictions typically imposed by commercial software vendors. This is a successful model and is preferred by a number of academic software developers over a traditional licensing model.

There are many established formats for open source licenses. Typically these licenses are without fees and free of restrictions on downstream uses of the code other than to make adaptations available in an open source manner. Some variations on open source licenses allow users to charge for their improvements and others require that improvements be offered without fees. It is important to understand the pedigree of the code you intend to license and whether or not it includes any code subject to an open source license. Commercial licensing to companies wishing to create a proprietary code base may only be possible if the open source components are removed.

3. **Finding a Licensee.** There are fewer commercial candidates for software licensing than for patent licensing. Many commercial software developers market their own proprietary products and may have less interest in marketing university-developed software unless it is truly unique and the market for it is either a large one, or the software, itself, is of such complexity that it will (i) command a high price in the marketplace as one-of-a -kind, or (ii) require maintenance and updating which, itself, may be profitable and therefore appealing to a developer/distributor.

There are two other potential categories of candidates for software licensing. One category includes start-up companies. Universities are finding that graduate students especially those who have been involved in developing a unique software program as part of their graduate studies are sometimes interested in starting a company to market,

support and enhance the software. Software spin-outs from universities are providing a relatively low cost opportunity for student entrepreneurs to get into a high stakes marketplace as opposed to developing a product from an early-stage patent. The other category of candidates for software licensing not to be overlooked includes established companies that are interested in finding new process, computational, or design software to reduce manufacturing time and costs, but do not have the capability to develop the software themselves.

4. Constructing the Software Copyright License.

(a) Identifying the Licensed Program. Because computer programs are often subject to revision, "bug-fixing", or enhancement, it is important to accurately identify and define the version of the software that is the subject of the license. If the licensed "program" is too vaguely defined, the licensee may claim it is entitled to updated versions when that is not the intention of the university. It is also important to identify the specific platform or platforms the license will cover. It is prudent to always keep an exact duplicate of the software delivered in case a question arises at a later time as to what was licensed and what was not. It is also elementary that the license identify whether source code or object code, or both, are being licensed.

(b) The Grant of Rights. Software protected by copyright may be licensed to permit the licensee to utilize the entire *bundle* of rights that comprise copyright protection (rights to copy, distribute copies, create derivatives, display publicly, perform publicly) or a subset of them. It is clear that a software developer/distributor would need the right to copy and distribute. The right that requires the most consideration is the right to *prepare a derivative work*. A derivative work includes any modification, adaptation, abridgement and

so forth, including writing the software program in another programming language.

Under copyright law, unless expressly done as a work for hire, a derivative work is owned by the author who derivatizes it. This means that a licensee, derivatizing software under a license that permits it, will own the derivatized software. The university, as the original owner of the software program retains all rights to the program as it was delivered to the licensee, but will not own or have rights to use the new pieces of code added by the licensee. In some cases, it may be possible for the university to negotiate a right to use derivatized code, but most licensees will not be willing to let modified or enhanced versions of the software go back to the university. To some extent, the university loses control over its software when it is licensed out with a right to derivatize. However, most licensees, if they are developers, will argue that they need access to the source code and the right to modify, if they are to keep up with the changing needs of their customers. On the other hand, if the software is licensed only for end use, generally only under an object code license, then the end user needs neither the rights to copy and distribute (unless licensed to a site where multiple copies will be made and used throughout the site) nor the right to derivatize.

The *granting* clause is also the clause that will contain the scope of the license; whether it is exclusive or non-exclusive; whether the right to issue sublicenses is granted and other limitations such as territory or field of use. There are two kinds of sublicenses - one that permits the licensee to issue sublicenses for end use and one that would permit the licensee to sublicense all of its rights to a third party. Since universities often develop software under federally funded programs, licensing professionals must be aware of the retained rights of the government. For federal contracts, these rights are broader than the rights retained by the

government under Bayh-Dole for patented inventions. They are contained in FAR Subpart 27.4, Rights in Data and Copyrights (see Rights in and Responsiblities for Technical Data and Computer Software Under Federal Awards on the COGR website). While universities generally are permitted to copyright federally funded software, in many cases the government may also have unlimited rights, including the ability to exercise all the rights of the copyright owner. In situations where universities are working with companies in a federally funded program, copyright may not be permitted. Contracts from the Department of Defense are subject to separate requirements. Under federal grants and cooperative agreements, universities generally have rights similar to rights to inventions under Bayh-Dole, with the government receiving limited license rights.

(c) The License Term. The term of the license is not generally an issue under a patent license. Patent life covers a relatively short twenty (20) years from the date of filing (with extensions possible if the patent application is delayed in the USPTO). Conversely, the term of copyright is exceedingly long. Assuming the university is the copyright holder, the term of copyright protection extends for a period of approximately 95 years. It is incomprehensible to think of a computer software program as having an effective life of 95 years. Universities commonly license software for the life of the copyright, meaning effectively, in perpetuity, particularly if an exclusive license is being granted. However, some consideration should be given to a reasonable license term if for no other reason than to get the license off the books of both the university and the licensee at a point in time when the software will most likely be out-of-date. Typically, software is completely rewritten within five years. Another way to shorten a license term is for the university to retain a right to terminate the license if the software is no longer being marketed by the licensee.

(d) Software Royalties. Royalty strategies applied to software licensing generally follow the same strategies as those used for patent licensing with a few significant differences. First, unless the software has been patented, there will not be a "reimbursement" for the costs associated with seeking protection. Copyrights exist for an original work fixed in a tangible medium from the moment they are created and there is no need to register a copyright except to pursue an infringement action in the US. The current fee for registering a copyright in the U.S. is $20.00. There is no registration requirement in other countries. Second, software royalty rates tend to be higher than patent royalty rates. This is generally because the licensee's development costs prior to getting software to market generally are less and profit margins are higher thus justifying the higher royalty rate. Third, because of the nature of software and copyright protection, licensees often receive peripheral rights that they would not receive if they were licensing a patent.

The right to derivatize the software has already been discussed. This is an extremely valuable right that permits the licensee to develop the software for multiple markets. It is completely appropriate for the university to get a royalty return on a "derivatized" software product, but the university, when licensing, must remember that the derivative product will belong to the licensee, and therefore specific language should be carefully constructed to ensure a continuing stream of royalties to the university even if with the passage of time the software product being marketed by the licensee no longer contains any code belonging to the university. Additionally, fees earned by a software licensee from maintaining and updating the software are also income categories to which royalties may be applied.

(e) Other Terms. Other license terms are similar to those discussed for patent licenses. An issue not previously discussed but which should be considered by a university licensor is whether to apply *trade secret* protection for software as well as copyright protection. This question arises generally under *source code* licenses, rather than *object code* licenses. As long as the source code is not disclosed to third parties except under a non-disclosure agreement, source code can be protected as a trade secret. Unlike a patent, which is published to the world when the patent issues, copyrighted code is not necessarily published.

D. When the Disclosure is Multimedia

1. **Identifying the Pieces of the Puzzle.** Unlike patentable inventions, or computer software which have fairly distinguishable elements, a *multimedia* work is generally a collage of separately identifiable and often independent contributions. For example, a multimedia work disclosed to a university TTO may include a computer program, a video, a digital archive, text content, recorded music, film clips, and still images. Prior to considering whether a multimedia work is a viable candidate for commercialization, the TTO must assemble all of the components and then determine whether the university has ownership in all, some, or none of the pieces. Unless the answer to the question of university ownership is "yes" to all elements of the work, the TTO must determine from the non-university owners whether it is possible to acquire sufficient rights to enable the entire work to be licensed into the marketplace.

2. **Choosing a Distribution Vehicle.** Similar to the case of some computer programs, the university will be faced with making a decision as to whether the multimedia product, especially if it is an educational or learning tool, will be best distributed by a commercial publisher or software house, whether the university's technology transfer operation is in

a position to distribute the product directly to users, whether the department that developed it wishes to undertake distribution or whether the creator of the multimedia work will elect to take a license from the institution and start his/her own company. Perhaps the only new consideration to be added in the case of educational multimedia is an assessment of whether the licensee has the requisite technical expertise and reputation in the educational marketplace to effectively enhance and market the work. Since the marketable value of an educational tool is often dependent upon whether it has something new to offer, an assessment of the licensee's capability to add "bells and whistles" may become an important consideration in choosing a licensee.

3. **The Licensing Process.** If we consider a multimedia work often to be a collage or "collection" of separate elements or components, it follows that the various copyright holders or "authors" of the separate components may have different ideas as to the scope of rights they may be willing to grant to the licensing institution. Since the institution cannot license rights that it does not have, the scope of rights licensed must accurately reflect only those owned by the contributor. It is not unusual, then, to have some portions of a multimedia work licensed exclusively and some non-exclusively to the same licensee or simply to license an entire work non-exclusively. Rights to the various components not owned by the institution may be gained through an assignment from the owner to some or all of the copyrights, through a release (a promise not to sue) to the institution, or through a license from the owner to the institution which is broad enough in scope to permit the institution to issue one or more tiers of sublicenses to third parties and beyond.

4. **Managing the Licensing of a Multimedia Work.** The licensing of multimedia works requires employing a different set of considerations than other intellectual property products. Since the ability to license a product in

its entirety depends upon gaining sufficient rights, there are most likely component licensing negotiations that will need to be held with the component owners (who may be faculty, students or third party contributors) before licensing of the entire work can be considered. Determining the cost of securing the component rights may result in a complicated formula based on a predicted return on the sale of the entire work, divided by the "agreed upon" value of the component; or, it may be a percentage based on sales price; or it may be a flat fee assessed on each unit sold; or it may be based on any number of different strategies. The point to bear in mind is that the licensing in to the institution must be the pre-cursor to the licensing out. The licensing professional must ensure that all of the separate pieces line up so that a licensing out deal can be accomplished on better than a revenue neutral basis.

E. When the Disclosure is a Web-Based Product. The licensing of web-based (or Internet-based) products such as digital archives, databases, learning tools, courseware and web pages intended for distributed learning environments is much like the licensing of multimedia products in that there is apt to be a tangle of separately protected elements (e.g., copyrighted and/or patented software, copyrighted text, images, film, new delivery technology that may be patented). And, there are additional considerations because the product will be distributed over the Internet.

1. Factors to Consider in Web-Based Licensing. The following is a sampling of factors that must be considered prior to distributing web-based material or products, either by direct institutionally-initiated distribution or by license to a third party.

- Ownership of the various components of the product;

- Whether content is libelous, defamatory, infringing, or violates rights of privacy or rights of publicity;

- Accuracy of the materials and whether it will be important to keep the content current;

- Distribution method, either openly accessible or controlled access;

- Consideration of risk that the institution may inadvertently become liable for infringing materials under the No Electronic Theft Act (P.L. 106-160) or the Digital Millennium Copyright Act (P.L. 105-304);

- What rights will be granted to users – rights to copy by downloading to computers and/or to print - rights to incorporate into published works - rights to modify - rights to archive; and

- If it is a web-based interactive course, rights to display student contributions.

2. **Use of the Institution's Name.** Both web-based and multimedia educational materials may derive significant market value from using the name of the university as a *branding* designation. While the use of the institutional name as a "brand" is a form of trademark licensing, it is distinct from sports indicia licensing or straight trademark licensing for non-educational products. The traditional product liability aspects that make straight trademark licensing a matter of balancing income versus risk become less important, while the overall "good will," integrity and reputation associated with the institution's name become more important. Before beginning the licensing of educational products which inevitably raises the question of the use of the university's name at some point, it will be wise for the institutional academic leaders in conjunction with licensing professionals to consider when and how the institution's name will be used and who is the proper authority to approve its use.

VI. TRADEMARK LICENSING

A different type of intellectual property licensed by universities is *trademarks*. These may include the name of the university, a well-known university symbol (such as the university dome or tower), the university mascot, and the names and nicknames of its athletic teams. Trademarks may also include certain technical or product identifying names and symbols which relate to new technologies or innovations developed by the university which will become known in the marketplace by their trademarked names. It is important to recognize that a trademark is a word or abbreviation that is used to identify goods. *Trademarks* and *service marks* are subject to the same rules and regulations, with the former applying to goods and the latter to services. Ownership rights for trademarks and service marks emerge when the mark is used on goods or services that are placed "in commerce." Trademarks and service marks are federally registered under The Lanham Act (15 USC §501 et.seq.). They may also be registered under state law and/or may be protected under common law.

A. Insignia licensing. Frequently, the university and athletic team names and logos are licensed out to be used as insignia on clothing, gifts, and other consumer objects. In this case, the university license will be concerned simply with proper use of the trademark on appropriate objects, suitable royalties payable to the university, and indemnification obligations. The risk to the university of a properly run insignia program is relatively slight, and the royalty rewards for those universities with well-known and winning athletic teams can be substantial. Even for those universities whose income from insignia licensing is quite small, the program can be important in controlling the proper use of the name and preserving it from "trademark dilution" arising from unlicensed use by others.

B. Licensing of Technology-Related Trademarks. Trademarks licensed in conjunction with products or services can increase the liability for the university and therefore need to be more

carefully managed. By law, a trademarked good implies that the owner of the trademark is responsible for the quality of the goods. A university generally will not license trademarks for technology goods unless it can assure itself of the quality of the goods or has assurance that it, and its licensee, have suitable insurance protection if something goes wrong. In many circumstances universities will either refuse to license a trademark or will choose to transfer the trademark outright to the technology licensee so it is no longer owned by the university. Like software licensing, trademark licensing has its own peculiar considerations. The most important of these are the quality control, packaging and advertising obligations and restrictions that must be followed by the licensee. The requirement to mark licensed products with the appropriate ® (when the trademark is registered in the USPTO) or ™ symbols is also important. Additionally universities must ensure that licensees maintain adequate insurance policies. Royalties most often are negotiated as a percentage of sales and a license maintenance fee may be imposed.

C. Foreign Licensing. Some universities with significant name recognition earn substantial revenues from the foreign licensing of their trademarks. As in the U.S., in order to get sufficient protection for trademarks in foreign countries to carry on a trademark licensing program, the marks must be registered. Trying to administer a foreign trademark program without the protection of foreign registration would be difficult. Many institutions involved in foreign trademark licensing use foreign-based licensing agents to try to increase use of the marks and monitor use of the marks in those countries. Additionally, there are several large companies that serve as trademark agents for licensing in the U.S. as well as in foreign countries. Generally, royalties earned are split with the agent on a negotiated percentage basis. Agents provide the benefit of having established contacts in the countries where they do business. They handle the direct licensing with manufacturers and offer some assistance in policing use of licensed marks.

VII. LICENSING OTHER RESEARCH PRODUCTS

This Tutorial focuses on patent, copyright and trademark licensing as the most commonly practiced forms of technology transfer by licensing at universities. However, universities are not restricted to these traditional forms. Other types of intellectual property that may be commercially licensed include:

A. Maskworks: Semiconductor masks (or chips) are protected by a special type of intellectual property. Registration is inexpensive and protection is similar to copyright although of much shorter duration.

B. Biomaterials: Certain types of reproducing biological materials may have significant commercial value either in product development research or in manufacture. These include transgenic animals, pieces of DNA, cell lines especially adapted for manufacturing proteins, stem cells, and many others. As has been pointed out in the section on Patenting, these materials may or may not be patentable. If patentable the university may choose to patent or not to patent them depending upon a number of circumstances that have already been discussed. Perhaps the most important consideration for those materials which are not patented but are useful as research tools is to weigh the importance of easy access for scientific research against the financial benefit from restricted access licensing, and make decisions which best fulfill the stated mission of the university. The *Nine Points* document discussed previously includes a section on research tools. Also as noted earlier if funded by NIH they are subject to the NIH *Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*, December, 1999 (64*FR*72090).

C. Know how: The licensing of *know how* (the unpatented "how to" information that accompanies any scientific discovery or innovation) is not common for universities, but it is utilized as a component of patent licensing, where it can be an important

source of revenue for a university. If a discovery is unpatentable, or perhaps is not patented worldwide because of a publication restriction, permitting a licensee access to the unpublished information that provided the roadmap for the discovery or innovation may be of sufficient value so as to warrant licensing consideration. The challenge for the licensing professional in deciding whether *know h*ow is actually licensable is to consider whether its value to a licensee can be maintained. Once *know how* becomes published, whether as part of conference proceedings or in a scholarly article or through delivery in a report to the government in the case of federally funded research projects, the value is diminished because accessibility is no longer restricted. The propriety of maintaining confidentiality of *know how* in order to protect its licensing value should be considered as a matter of policy or in practice by universities in light of their overall missions.

VIII. MANAGING CONFLICTS OF INTEREST

In activities that involve the *balancing* of interests of multiple constituencies within an academic institution such as inventors and authors, students, corporate research sponsors, technology transfer professionals, and faculty principal investigators *with* the university's traditional missions of education, research, and public service, there are bound to be areas of overlap in which conflicts arise. None of the activities described in this Tutorial takes place in a vacuum. The inter-relationship of the diverse interests represented in the technology transfer process creates an environment where conflict is inevitable. The principles, which academic institutions must protect most carefully, are: academic freedom, excellence in education, open and timely communication and dissemination of knowledge, and their reputation for integrity of research and service. It is to the credit of the U.S. universities that the potential for conflict has not put an abrupt stop to the commercialization of university research. Rather, universities have become conscious of the need to adopt conflict

management procedures, disclosure requirements, and new policies and guidelines intended to achieve an acceptable balance of interests. The federal government has also played a part in introducing certain requirements intended to ensure that scientific integrity is maintained in federally funded research.[9]

A. Managing Institutional Conflicts. Institutional conflicts of interest occur when the university or institutional leaders have a financial interest in the outcome of research programs, and the financial interest may compromise or appear to compromise the integrity of institutional research. The financial interest may be in the nature of royalties to be earned from licensing; it may be an equity interest in a start-up company that holds licenses to the university's technology; it may be a subsidiary of the university itself, organized to carry on a commercial business; it may be a venture capital fund created by the university to aid university-derived spin-offs; or it may be a university holding equity in a company but also participating in clinical trials of that company's drug because the faculty/physician company founders want to be the first to take the drug to trial.

Many universities, as part of their governing policy, will limit official university involvement or representation in start-up companies or subsidiaries in order to keep a bright line between the university and commercial activities in which the university may have an interest. Some universities will not permit a university licensee, in which the university holds an equity interest, to provide research funding back to the university. Others will require a disclosure of the university's interest in publications.

Several options exist for management on a case-by-case basis. If a university conflict of interest is perceived, but the activity is allowed to continue under university policy, oversight is generally assigned to an appropriate university official or group to ensure the project is managed in the best interests of education and scientific advancement. Management of equity interests is usually

[9] See 42 CFR Part 50, 45 CFR Part 94 for Public Health Service Policy (including National Institutes of Health) and National Science Foundation Award and Administration Guide, Chapter IV.A.

separated from technology transfer and research activities. Insider information that may be known to the technology transfer unit in the university must, by law, be withheld from the unit managing the equity interest. In all cases, institutions may consider it advisable to require faculty to disclose to graduate students faculty interests in outside companies that may be perceived to benefit from the students' research.

Virtually all universities adhere to the traditional values of investigator-led research, freedom of publication and arm's length dealing with all corporate research sponsors and licensees, regardless of whether or not the university has a financial interest in the company with which it is doing business.

B. Managing the Personal Conflicts. Conflicts of interest involving individuals most often arise in two areas. These are *financial conflicts of interest* that an investigator may have and *conflicts of commitment* that may occur between an individual and his/her institution.

1. **Financial Conflicts of Interest.** Like the institutional conflict described above, personal conflicts arise when an individual investigator (whether faculty, student or staff) stands to benefit financially from the outcome of his or her scientific investigation. The financial benefit may be derived from owning stock in a company providing the research funding; from an ownership interest or employment in a company that may benefit if it becomes the licensee of a university invention; or from the existence or expectation of entering into a consulting arrangement with a company sponsoring research. In none of these cases does an investigator necessarily do anything to jeopardize the accuracy or outcome of a scientific investigation, but in all of them there is a *perception* that this *could* happen. In order to eliminate this perception, federal and university procedures for dealing with individual conflicts of interest require a two-step process. Initial faculty disclosure of financial relationships is followed by subsequent objective

institutional review of these disclosures, to ascertain that none of the respective relationships or holdings are likely to threaten the objectivity of the research to be performed.

Some federal regulations require disclosure by anyone involved in the design, conduct or reporting of a federally funded research project of significant financial interests. Significant financial interests are defined differently by federal research funding agencies. For the U.S. Public Health Service (PHS) including the National Institutes of Health, regulations announced on August 25, 2011 (76FR53256) define such interests as those related to the investigator's institutional responsibilities that when aggregated between the investigator and his/her family exceed $5,000 in value for services or equity interests in a publicly traded company ($0 de minimus for disclosure of equity in non-public companies). For the National Science Foundation, the term includes interests that do not represent 5% or more in ownership in any single entity; or payments from an outside source that exceed $10,000 or more in any twelve-month period and would reasonably appear to be affected by the NSF-funded activities. If institution review finds that a financial conflict exists, related to PHS-funded reserarch, the PHS regulations require that the conflict must be reported to the PHS funding agency with a plan to manage the conflict. The institution also must post information about the conflict on a publicly accessible website or respond to written requests for information about it (NSF does not require similar reporting). All institutions have implemented procedures to meet the federal requirements (in the case of PHS, institutions must be in compliance by August 24, 2012). Many universities apply these procedures not only to federally funded research but also to non-federally funded research activities. Some institutions may have more stringent standards than the federal rules (in which case the PHS regulations provide that the institution's standards will apply). More stringent institutional requirements also may apply to clinical trials.

Some institutions have gone further and prohibited certain activities viewed as too "sensitive." In some cases, investigators may not conduct research for a company in which they own an equity interest. In others, an oversight authority will be established to monitor the conduct of the research program. This may involve review of the research protocol and/or monitoring of the research by independent reviewers. It may involve modification of the research plan or disqualification of an individual from direct participation in or supervision of some or all of the research. Or, commencement of research may be delayed until a significant financial interest has been divested or an individual has severed a relationship that creates the conflict. Some universities have taken the position that certain fields, such as medical research, raise greater concerns about conflict situations and have placed more rigorous requirements in these fields than in others. Many academic journals also require disclosure of any applicable financial interests by an investigator who wishes to publish research findings.

2. **Conflicts of Commitment.** The issues having to do with conflicts of commitment are an outgrowth of the faculty *consulting* privilege that is commonly recognized in major research universities. Most U.S. universities accept that faculty consulting is a benefit to the institution, the individual faculty member and to students. By gaining experience working closely with companies, faculty become finely tuned to the new technical directions and innovations that are occurring daily in industry laboratories. They also become privy to the kind of workforce that companies will be searching for in the future. Bringing this information and experience back to the classroom and university laboratory enriches the environment for students and scientists, alike. Faculty consulting has played a large role in defining the university-industry partnership. Recognizing that conflicts may arise between individual commitment to the university as the primary employer and

commitment to a company, universities generally pay strict attention to faculty time spent outside the university classroom or research laboratory, and many require annual disclosures of all faculty consulting activities.

Conflict of commitment also raises an issue when faculty inventors with an entrepreneurial interest wish to become involved in a start-up company. Universities may see this activity, if it is being carried on simultaneously with a faculty member's teaching and research obligations, as a conflict of commitment. It will be managed differently at different institutions, but it is not unusual for an institution to require a faculty member who is active in a new company to take a leave of absence from the university.

Conflict of commitment has recently found new importance in determining university policy with respect to faculty developing and teaching courses for organizations other than their home institution. Some institutions are formulating new policies limiting the scope of these activities as an element of conflict of commitment.

3. **Protecting Students.** An unintended consequence of faculty consulting and empowering faculty inventors to start their own companies is the potential for distracting students from their focus on education by offering them simultaneous working opportunities within a faculty-led company. Or, the direction of a faculty-led research program in which a student is participating may be influenced (or perceived to be influenced) by the faculty member's interest in an outside company. Establishing mandates prohibiting student participation in outside companies is probably not appropriate for universities. However, providing students with appropriate guidance, ensuring they have choices, and supporting them in their choices is a very appropriate role for the university. Likewise, providing strict guidance to faculty on proper and responsible conduct toward students is also appropriate for the university.

IX. EXPORT CONTROLS

University TTO's need to be mindful of the export control laws and regulations in their technology licensing activities. Currently these laws are implemented by the U.S. Department of Commerce through the Export Administration Regulations (EAR) and Commodity Control List (CCL—"dual use" items); the Department of State through the International Traffic in Arms Regulations (ITAR) and the U.S. Munitions List (USML—defense articles and services) and the Department of Treasury through the Office of Foreign Assets Controls (OFAC—trade embargoes).

The export control laws and regulations have several purposes: to restrict exports of goods and technologies that could contribute to the military potential of U.S. international adversaries; to prevent proliferation of weapons of mass destruction; to advance U.S. foreign policy goals; and to protect the U.S. economy and promote trade goals.

The EAR and ITAR apply to the transfer of specific physical items on one of the control lists and information and the provision of specific services related to those items to persons and entities outside the U.S. (exports). An important concept for universities is "deemed exports." Transmission or disclosure of technologies or information controlled under the export control regulations to foreign nationals inside the U.S.is deemed to be an export to the foreign national's country. There are a number of exceptions and exemptions but the basic principle is that export or deemed export of controlled items or information requires government permission via a license from the cognizant federal agency. Violations may result in substantial criminal penalties (including fines and/or prison sentences for individuals) as well as civil penalties.

Among the exceptions is technical information that is publicly available (EAR) or in the public domain (ITAR). Both the EAR and ITAR contain definitions and categories of publicly available or public domain information. Very importantly for universities,

under the publicly available or public domain exceptions, fundamental research performed by universities is excluded from export controls so long as that research is carried out openly and without restrictions on publication or access to and publication of the research results. For these purposes fundamental research is basic or applied research in science and engineering performed or conducted at accredited institutions of higher learning in the U.S. where the resulting information is ordinarily published and shared broadly in the scientific community. It is distinct from research that results in information restricted for proprietary reasons or funded by the federal government and subject to specific access and dissemination controls. This fundamental research exclusion from export controls applies particularly to deemed exports. Note that it does not apply to transfers of information to foreign campuses of U.S. universities, or to foreign research collaborators abroad.

A detailed discussion of the export control regulations is beyond the scope of this Tutorial. However, university technology licensing officers need to be mindful of the export control regulations. Licensing proprietary or confidential information may affect the fundamental research exclusion. Also while patents and patent applications are exempt from export controls, disclosure of controlled technologies or information in licensing activities may give rise to export control issues. Most universities have export control compliance offices or individuals. The TTO should coordinate with those officials to assure that disclosures do not lead to inadvertent export control violations. The COGR and AUTM websites both have extensive materials on export controls.

X. CONCLUSION

In spite of the complexities of university technology transfer, the success of U.S. colleges and universities and their faculty, research scientists and students has had a demonstrable effect upon the U.S. and global economies. While policies for each university or college will reflect the institution's unique faculty,

student body, curriculum and institutional priorities, the principles, methods and goals underlying academic technology transfer are generally held in common. This commonality has permitted U.S. universities to become a forceful catalyst for new industries, new company formation, new products on a global scale and new jobs for the U.S. economy. Pressures for universities to engage in even greater commercialization of research results are increasing. It is important that the implications and requirements be understood by all involved.

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