Biography

Mark G. Bloom is the Manager of Technology Licensing and Chief Patent Counsel for Cleveland Clinic Foundation Innovations (CCFI).

Mr. Bloom received a Bachelor of Science Degree in Microbiology/Biochemistry from the Ohio State University and a Juris Doctor from Franklin Pierce Law Center. While at Franklin Pierce, he served as an Issue Editor of *IDEA: The Journal of Law and Technology*. Mr. Bloom is a member of three state bars and numerous federal courts and professional organizations and is registered to practice before the United States Patent and Trademark Office. Before attending law school, Mr. Bloom worked in sales and marketing for the pharmaceutical, medical device, and medical diagnostic software industries. After receiving his law degree, Mr. Bloom served as patent counsel for the Roswell Park Cancer Institute and as a marketing and legal consultant for Harvard Medical School's *Funds for Discovery Program* (a seed fund for biotech start-ups). Immediately prior to joining CCFI, Mr. Bloom was employed by the Wisconsin Alumni Research Foundation (WARF) as a Licensing Officer.

Mr. Bloom brings more than seventeen years of corporate sales, marketing, and intellectual property law and management experience to CCFI where his myriad responsibilities include overseeing the invention patenting process, facilitating industrially-sponsored research, and out-licensing CCF technologies.

CCFI is the Cleveland Clinic Foundation's comprehensive technology commercialization department. It is a one-stop shop for industry and CCF Staff with responsibility for all CCF activity related to technology transfer including invention disclosures, patenting, licensing, industrially sponsored research, spin-off companies, material transfer agreements and relations with federal, state and local technology development organizations. Its mission is to broadly and rapidly deploy CCF technology to expand and improve treatment of the sick.

University and Other Non-Profit Organization Licensing: An Insider's Perspective

Mark G. Bloom, Esq.
Manager of Technology Licensing
and
Chief Patent Counsel
CCF Innovations
The Cleveland Clinic Foundation
Cleveland, OH

Tenth Annual Advanced Licensing Institute
Franklin Pierce Law Center
Concord, NH

July 16, 2001

WHY SHOULD WE PROTECT INTELLECTUAL PROPERTY RIGHTS?

WHEN we come to weigh the rights of the several sorts of property which can be held by individuals, and in this judgment take into consideration only the absolute question of justice, leaving out the limitations of expedience and prejudice, it will be clearly seen that intellectual property is, after all, the only absolute possession in the world…

The person who brings out of the nothingness some child of their thought has rights therein which cannot belong to any other sort of property…

An inventor or author of a book or other contrivance of thought holds their property, as a god holds it, by right of creation…

Whatever tends to lower the protection given to intellectual property is so much taken from the forces which have been active in securing the advances of society during the last centuries.

Professor Nathaniel Shaler
Harvard University
c. 1936

University and Other Non-Profit Organization Licensing: An Insider's Perspective

Mark G. Bloom, Esq.
Manager of Technology Licensing
and Chief Patent Counsel
The Cleveland Clinic Foundation

Genesis of NPO/University TT

- Prior to 1968 - Section 8.2(b) Petition for Greater Rights (case-by-case basis)
- 1968-80 - Institutional Patent Agreements (IPAs)
  - University of California, WARF, Battelle Institute, Iowa State, and Research Corporation
- University and Small Business Patent Procedure Act (P.L. 96-517) - the "Bayh-Dole Act of 1980" or the "Bayh-Dole Act" or the "BDA"

US Institutions Having TT Programs

1972	30
1999	278

US Start-Up Companies Formed

FY 1980-FY1995	FY 1996	FY 1997	FY 1998	FY 1999	Total FY 1980 to FY 1999
1,633	248	333	364	314	2,922

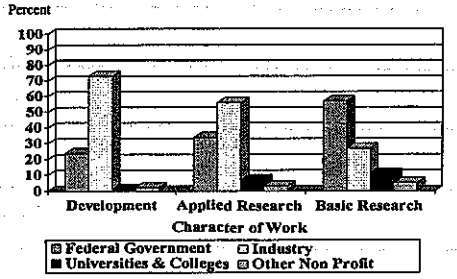
Federal Legislation Re: Cooperative Technology Programs

- **Stevenson-Wydler Technology Innovation Act--1980**
  - Facilitated Technology Transfer From Federal Labs
- **Bayh-Dole University and Small Business Patent Act--1980**
  - Ownership of Patents Vested in Universities
- **Small Business Innovation Development Act--1982**
  - Started SBIR Program

Federal Legislation Re: Cooperative Technology Programs

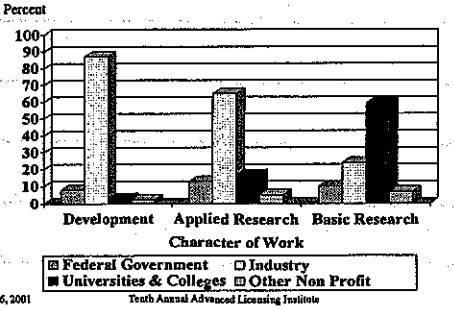
- **Federal Technology Transfer Act--1986**
  - Started CRADAs
- **Omnibus Trade and Competitiveness Act--1988**
  - Created NIST's Manufacturing Technology Center Programs
- **National Competitiveness Technology Transfer Act--1989**
  - Federal Labs Cooperative R&D Agreements
- **Defense Conversion, Reinvestment & Transition Assistance Act--1992**
  - Technology Reinvestment Project (TRP)

National R&D Expenditures by Source



Source: Science & Engineering Indicators--1996

National R&D Expenditures by User



Source: Science & Engineering Indicators--1996

Industry Technology Dependence on Academia by Percentage

Industry	Products	Processes
Pharmaceuticals	44	37
Information Processing	28	27
Metals	22	21
Instruments	21	3
Electrical	9	7
Chemical	8	6
Oil	2	2

Metrics for FY 1999

- 3,914 New Licenses (up 7% from FY1998)
- $862 Million in AGI from Royalties and Options (up 16% from FY1998)
- 344 New Companies Formed
- 2,922 New Companies Formed Since 1980 (1,934 still alive at 183 Institutions)
- Total Economic Impact - $40.9 Billion
- 12,324 Invention Disclosures Reported (up 5% from FY1998)
- 5,545 New US Patent Applications Filed (up 14% from FY1998)
- 3,661 US Patents Issued (up 14% from FY1998)
- Total US Patents Issued Since FY1993 – 16,935

Universities/NPOs are Different

- Politics are Alive and Well!
- Faculty vs. Administration Controlled
- TTO Separate Legal Entity vs. Internal
- TTO Resources (People and Funding)
- TTO Control over Faculty (Ego^{2})

Funding Agreement under BDA

Any contract, grant, or cooperative agreement entered into between any Federal agency and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government.

Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance or experimental, developmental, or research work under a funding agreement as herein defined.

Invention Definition under the BDA

Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act.

Subject Invention under the BDA

Any invention of the contractor conceived or first actually reduced to practice in the performance of work under the funding agreement.

Title Sequence under the BDA

What is sequence in right to title in an invention?

- University/NPO has right to retain title - interpreted to mean that title was with the University *ab initio.*
- If University/NPO declines, title will vest in government through the specific funding agency - 35 U.S.C. 202(d).
- Inventor(s) may petition the specific funding agency to obtain title to the invention, but must continue the patenting process.

Important BDA Preference (1)

Preference for Small Business licensees vs. Large Business licensees – Section 202(c)(7)(D)

Important BDA Preference (2)

Preference for US-based licensees vs. Non-US-based licensees – Section 204

Other Important BDA Terms

- ◆No assignment of rights without permission of federal funding agency – Section 202(c)(7)(A).
- ◆Inventor(s) must receive share of royalties – Section 202(c)(7)(B)
- ◆Technology must be developed by licensee – Sections 200 and 203(1)(a).

BDA Conclusions

Three things contributed to the success of the BDA and technology transfer under it:

- Certainty of title in the inventions;
- The inventor remains in the development picture;
- There is uniformity in the handling of intellectual property under the law.

Most Important TT Issues

- ◆Maintenance of Freedom to Publish
- ◆Proper Attribution
- ◆Equitable Recognition of University/NPO's Role in the Development of Technology
- ◆Equitable Sharing of Revenue Generated by Commercial Use of Licensed Technology

Biggest SR TT Mistake No. 1

Placing unreasonable restrictions on a researcher's right to publish research results, i.e., preventing the exercise of academic freedom.

- onerous confidentiality requirements are bad news
- short publication delay for patentability review is usually an acceptable compromise

Biggest SR TT Mistake No. 2

Requiring some level of control over researcher-based publications resulting from sponsored research ("SR") efforts.

- –requiring editorial control is bad news
- –requiring publication approval is bad news

Biggest SR TT Mistake No. 3

- Demanding a perpetual, worldwide, royalty-free license (with the ability to sublicense) to all IP developed using sponsored research dollars.
  - –viewed as demeaning and inequitable
  - –slow or prohibit SR contract negotiation

Typical Industry IP Clause

Without limitation, Sponsor shall own all discoveries, inventions, developments, know-how, trade secrets, techniques, methodologies, modifications, innovations, improvements, research materials, new uses, data and rights (whether or not protectable under state, federal or foreign patent, trademark, copyright or similar laws) that are conceived, discovered, invented, developed, created, made or reduced to practice by Institution (whether alone or jointly with others) during and in performance of the Research.

Typical Industry IP Clause (cont.)

As used in the foregoing sentence, research materials shall include, without limitation, RNA samples, cDNA libraries, genes, DNA sequences, polynucleotides, proteins, peptides, amino acid sequences, plasmids, vectors, expression systems, cells, cell lines, organisms, antibodies, biological substances, and any constituents, progeny, mutants, derivatives or replications thereon or therefrom.

CCF SR Position on IP Rights

Option for the first good-faith negotiation for a royalty-bearing license to a technology that has been:

- developed solely/jointly by CCF researcher(s); and
- which utilized specific SR monies (note that at most NPOs, SR monies are likely to be co-mingled with Federal research funds).

Licensee Due Diligence (1)

Has the University/NPO filed patent applications in all of the relevant markets for the technology?

- –domestic vs. foreign rights
- –filing costs are an issue at many Universities/NPOs

Licensee Due Diligence (2)

Have the University/NPO inventor(s)' published their ideas prior to the filing of appropriate patent applications?

– If yes, how long ago?

Licensee Due Diligence (3)

Has a validity analysis been conducted to determine whether the patents that have been applied for by the University/NPO are likely to issue?

– pre-filing by University/NPO

– pre-agreement by Licensee

Licensee Due Diligence (4)

Is the technology properly the subject of patent protection, or are there other forms of IP protection that would be more appropriate?

– trade secret

– copyright

– PVPA

– plant patent

Licensee Due Diligence (5)

Have all of the inventor(s) and institution(s) involved assigned all of their respective rights to the technology?

- joint inventorship issues
- Inter-Institutional Agreements (IIAs)
- deal only with the lead Institution

Licensee Due Diligence (6)

Does the project require access to materials or information not covered by the technology license?

- biological materials
- software
- know-how and/or show-how

Licensee Due Diligence (7)

Will the licensee exploit the technology in combination with other technologies, and how will that affect the distribution of royalties?

- royalty stacking
- ask for ability to sue infringers
- reduction in royalties if patent does not issue

Licensee Due Diligence (8)

Besides a consulting arrangement or institutional royalty-sharing policies, are there other financial incentives a licensee can offer an inventor?

- equity stake
- stock options
- be aware of conflict-of-interest ("COI") issues!
- fixed or annual fees are a better choice for compensation than variable payments, e.g., payments tied to outcome

Licensee Due Diligence (9)

Have the IP policies, SR guidelines, COI policies, etc., of the University/NPO been obtained and reviewed by licensee's counsel?

- request copies from the University/NPO
- Surf the Net!

Licensee Due Diligence (10)

Do you know the proper party with which you should be negotiating an agreement, i.e., are you dealing with a person or entity that can legally bind the university to a contractual arrangement?

- ask if a person has signatory authority (SA)
- assume that the faculty member does not have SA!

NDAs and MTAs

- Non-disclosure Agreements are a fact of life when dealing with industry.
  - be vigilant for IP "traps" buried in the language
- Material Transfer Agreements are a large part of TT practice.
  - watch out for "reach through" IP provisions
  - create master agreement templates
  - be aware of NIH Research Tool Guidelines

SBIR, STTR, and ATP Grants

- Small Business Innovation Research (All Big Feds)
  - Phase I (Feasibility) - up to $100K over 6 months (67/33)
  - Phase II (Full R/R&D) - up to $750K over 2 years (50/50)
- Small Business Technology Transfer (5 Big Feds)
  - Phase I (Feasibility) - up to $100K over 1 year (50/50)
  - Phase II (Full R/R&D) - up to $500K over 2 years (50/50)
- Advanced Technology Program (NIST)
  - funding for early-stage, speculative, high-risk research
  - very competitive proposal process

Final Words of Advice

- Direct your clients to look to Universities/NPOs as a rich source for cutting-edge technologies
- Explore all means of University/NPO TT
  - licenses, options, SR, JV/SA, SBIR & STTR programs
  - faculty and students
- Know University/NPOs' IP/TT/SR/COI policies
- Recognize University/NPO TT strengths and weaknesses
- Treat University/NPO as equitable TT partner

Feedback/More Information

Mark Bloom
bloomm@ccf.org
(216) 445-4010

Copyright © 2001 Mark G. Bloom, Esq.
All Rights Reserved

A Tutorial on Technology Transfer at U.S. Colleges and Universities

Prepared by Mark G. Bloom, Esq.
Manager of Technology Licensing
and Chief Patent Counsel
The Cleveland Clinic Foundation

INTRODUCTION

The Role of the University in The New 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 will take the country into the 21st century. As the 21st century begins, every industry is, or soon will be, affected by the major enabling technologies of biotechnology, information technology and advanced materials.

Professor Michael Porter[1] has shown 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 report by the Milken Institute[2] has concluded that the presence of a major research university is the most important factor in the success of a high-tech region.

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 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 funding for the conduct of scientific research in a wide range of areas. That research in turn leads to new knowledge which is published, and that shared knowledge leads to new products and processes for the marketplace, adding new jobs throughout the economy.

The university mission of teaching and research - of creating and disseminating knowledge - is its primary contribution to society as a whole and to the increasingly knowledge-based economy. But within this broad mission, the university has recognized that it can contribute more directly by playing an active role in working with the for-profit sector. It does so in a variety of ways such as traditional teaching and publishing and less traditionally, perhaps, by engaging in collaborative research with industrial companies, by exchanging personnel, materials, and equipment with profit-sector companies, and also by 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, with conflicts 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 activity that we now call "technology transfer" is not a new phenomenon. For many years it has been commonplace within the business sector of the economy to engage in transfers of information or manufactured devices, prototypes or materials, by means of a legal instrument, or through the provision of services, or through direct sales. Within the last twenty years, universities have picked up and adopted that label for certain of their own activities. 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. Perhaps the best-known and most widely used informal "transfer" mechanism is scholarly publication.

For purposes of this Tutorial, the term is used more narrowly to refer to the handing-off of intellectual property rights from the university to the for-profit sector for purposes of commercialization. This "passing over" or transfer is made possible through patenting of university-made inventions and assertion of copyright for university-developed software, multi media teaching tools and educational materials. University-owned biological materials developed in university laboratories and registration of university trademarks add to the general pool of transferable intellectual property. Unlike industry where transfer sometimes takes place as an actual sale of the information, article or service to be transferred, universities in almost all cases accomplish transfer of intellectual property through the licensing process. Biomaterials that are not captured as patents may be licensed or may be conditionally transferred as bailed property under contracts known as "material transfer agreements".

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. Since technology transfer can result in an income stream from royalties that is shared with inventors, that income may assist in retaining faculty who might otherwise leave the university to pursue more lucrative careers in the for-profit sector. And that income also benefits the university as it is reinvested in new research and teaching programs and provides financial support for students.

The reader is also asked to recognize that many universities are seeing a new brand of student. Engineering, biotechnology, computer science, and business students eager to participate in developing new technology, in learning the fundamentals of new company formation, and in working with faculty and industry to realize the potential of new business models often find that technology transfer activities give them a running start at careers that will build the economy in the 21st century.

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 and subsequent amendment Public Law 98-620, implemented at 37 CFR Part 401) provided recipients of federal research and development funds with the right to retain ownership of their patents and charged them with the responsibility to 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. While it is possible for a university to have different policies regarding the patenting and licensing of inventions which were not federally funded, in general, the university's interest in maintaining the flexibility to draw research funds from multiple sources, including the federal government, and the desire to avoid applying conflicting policies, favor constructing a single policy that is consistent with the requirements of federal law and regulation. 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.

B. Important Aspects of Bayh-Dole: Bayh-Dole permits universities, other nonprofits such as teaching hospitals, and, in most cases, commercial federal contractors 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 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 did not result 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, Bayh-Dole was amended to provide "big business" commercial contractors nearly the same rights to their inventions as the non-profits and small businesses had won 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;

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. They explain why 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.

D. The Government's Rights in University Inventions: Except 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 or does not elect 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 public use within a reasonable time; where health or safety

needs are not being met; or where the U.S. manufacturing requirement has not been met and has not been waived by the funding agency;

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 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.

IV. INTELLECTUAL PROPERTY: AN INDISPENSABLE COMPONENT OF TECHNOLOGY TRANSFER

While university policies are quite 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, universities with established technology transfer programs, nevertheless, have recognized that it is often important to protect intellectual property in order to attract the additional investment needed to develop ideas into useful products. As we have previously discussed, universities use intellectual property protection to provide the legal fabric of property ownership that makes technology transfer through licensing possible.

All major U.S. universities have developed fairly extensive policies to address various kinds of intellectual property: who owns it as between the university and 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.

We know from the section dealing with the Bayh-Dole Act, above, that 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 software, multi media works, and instructional materials. Works of authorship comprise a body of information protected by copyright. A very different structure of intellectual property protection from patents, copyrights may be every bit as challenging as patents in coaxing out those elements that are candidates for commercial licensing. A marketable copyrighted work is apt to be the endgame in a long process such as developing and programming computer software and documentation, or the weaving together 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. 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.

Two other university assets are worth noting. Trademarks are a third category of intellectual property that the university may consider protecting in order to increase value for a product or service to be commercialized. Biomaterials that may be transferred under bailment agreements constitute a fourth category. These four categories of intellectual property are the mainstays in the university's technology transfer portfolio.

The reader will find that 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 altogether dissimilar. However, as the reader will see, 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. Universities define their intellectual property activities through their policies. Each institution tailors its policy to meet institutional principles and objectives. This means that defining principles and objectives or goals is fundamental and must be the first step in the process. Because establishing intellectual property protection generally informs a series of events that will follow, an institution formulating a policy must decide when that outcome will serve the goals of the institution and when it will not. The following is a listing of factors that are generally considered in developing a sound policy for dealing with intellectual property and may prove useful to the reader.

- 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 procurement regulations 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. The complexity of university technology transfer activities makes it clear that universities must give considerable thought to a new phenomenon within the university - intellectual property management. The major research universities have addressed management by establishing technology transfer or licensing offices. Over the past 20 years since Bayh-Dole moved patent ownership from the federal government to the universities, technology transfer offices have worked diligently to develop the expertise necessary for managing the rapidly increasing number of university relationships with complicated intellectual property considerations. They have found that successful management demands sophisticated knowledge of intellectual property, licensing, and contract law, an in-depth understanding of current business realities, and the capability to predict new market trends. In addition, as part of the management process, the technology transfer office must develop and maintain elaborate database support systems for managing these activities and relationships. And, perhaps of greatest importance, the technology transfer office must understand the overall institutional policy context within which it works. It 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 a complex set of policies and procedures that are designed to manage a complex set of agreements and the intellectual property rights associated with these agreements. 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.

A major portion of the remainder of this Tutorial will describe in some depth how the academic technology transfer process transforms an idea into a product or service useful to people. The factors and circumstances that must align along the way are by no means pre-determined, nor can they be predicted with any degree of certainty. The U.S. university community, particularly over the last 20 years, has arrived at a consensus through trial and error as to certain practices that are more likely to result in desirable and successful transfer, despite the unknowns that plague all new discoveries looking to enter the marketplace.

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 that he or she believes may have potential for commercial development.

A. Submitting the Disclosure. The first formal step in the process occurs when an inventor or creator submits a "disclosure" form describing the innovation to the university office that has responsibility for university licensing activities (for convenience called the Technology Licensing Office or "TLO"). 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. 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.

When the Disclosure is an Invention

1. Evaluating a Disclosure for Patenting. If the disclosure is an invention, the TLO will further investigate the invention to determine whether it seems advisable to invest funds in patenting it. U.S. patents cost in the order of $10,000-30,000 each and filing for equivalent foreign protection can increase the ultimate cost several-fold. The decision whether to file a patent application generally is based on the answers to at least three questions:

(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). The first question is answered 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 it were patented, would the invention be likely to attract the commercial investment needed for development through a license? The second question is far more difficult to answer. 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? The answer to this question is one of practicality. Since a university TLO may receive a significant number of invention disclosures each year, it will not have the financial resources to investigate the commercial potential in detail for each invention or to invest in the costs of patenting for each invention. Consequently, all TLOs must make choices.

Other factors contribute to making the decision on patenting one of the most difficult a TLO must make. 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, patenting decisions must very often be made quickly. The TLO 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.

Some universities may use patent committees comprised of faculty or outside advisors to help with the patenting assessment. There are pros and cons to be considered when deciding to use outside committees or outside advisors. Two to consider are (i) the length of time that it may take to convene outsiders to evaluate patenting an invention and (ii) the accountability factor - the fact of outsiders making decisions on spending the limited financial resources of the TLO. There may be gain, 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 TLO 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, 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 TLO must have a good understanding of the patenting process as well as an understanding of the various strategies under current patent law for filing provisional and utility patents.

As we have learned under the section on Bayh-Dole requirements, if the invention was funded by a U.S. federal agency, a series of reporting requirements begins at the time of Invention Disclosure and escalates once the decision is made to file. And, what if the TLO decides that it will not file a patent application? The reader will recall that Bayh-Dole has requirements for reporting this situation as well. Under most university technology transfer policies, if the university decides it will not file, there is an opportunity for the inventors to decide whether they would like ownership waived to them. 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. A university will file a patent application on an invention only if it intends to license the invention for commercial development. The challenging basic premise with respect to university inventions is that most often they are of unproven market potential. Often additional research must be undertaken before the real work of product development can even begin. Few companies are willing to take the risk university inventions require, particularly where, as in the case of many medically related inventions, 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. Potentially, 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 if the product is successfully developed. Universities typically seek licensees as soon as the patent application is filed, rather than wait the 2-5 years until the patent is issued. The motivation for early licensing is to get industry investing in the technology as soon as possible. Additional motivation comes from the university's need to get its patent filing and prosecution costs reimbursed so that these funds can be recycled into patent filings on other inventions. If the patent fails to issue, the license is terminated since there is no protected intellectual property unless the license covers other types of intellectual property, such as trademarks or copyrighted software, which are not dependent upon valid patent protection.

(c) Identifying Potential Licensees. Most universities with successful licensing programs find that it is important to know a variety of companies in fields where the university is prolifically inventing and to focus on the technology plans and the unmet needs of those companies. At the same time, efforts are made to encourage companies and potential investors to get to know the university and its researchers. Then, when a new invention arises, the potential for a "customized" introduction is already in place. It is seldom that a university is able to find more than one potential licensee at a time for an invention. Those universities interested in "getting the technology moving" as quickly as possible (rather than holding it for years trying to find the optimal licensee), will usually begin negotiations for a license with the first qualified company or investor who wishes to negotiate for a license. It is important for successful technology transfer to emphasize the word "qualified". Before any serious effort at negotiations is begun, 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 might be the best choice because of its motivation to carry a "signature" product through to commercialization.

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 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 (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 company's development is successful.

Nonexclusive licenses are generally desirable when the invention is a broadly applicable process or has self-evident technological advantages that will be useful to many companies and so it is not necessary to "induce" investment. Nonexclusive licenses are highly preferable where the invention is a research tool, useful to both the commercial and academic communities and a high degree of access is important. In some cases, where 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, the university must 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 are a mandatory contractual commitment. If diligence provisions are not met, the university may cancel the license or, if the license was exclusive, rather than terminating the license altogether, 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. 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 deal 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: This fee may range from a very few thousand dollars to a quarter of a million or more. It is usually a fact-specific determination depending upon 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 the company secures sufficient investment capital.

(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 assures that the company shows an active interest in retaining the license as evidenced by its willingness to make a financial commitment to renew the license annually. Some 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; occasional licenses include royalties outside that range based on specific factors.

(v) Equity Shares: When a license is granted to a young privately held company, shares of stock in the company may be offered to the university as a form of royalty under the license. Often, other license fees and/or running royalty percentages may be lowered in consideration of the equity shares. 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 activity reporting requirements for the licensee; agreement (in the case of an exclusive license) as to which party will prosecute patent infringers and how damages will be shared; agreement on 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 those purposes. 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.

5. 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 the patenting costs of the invention if the license does not hold the licensee accountable for these 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 the Bayh-Dole Act, 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 (although allocating revenues to support the cost of the technology transfer process is permitted). 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. 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, computer software generally has some copyrightable elements, and may or may not in addition have 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 TLO is to determine whether to pursue patent protection in addition to copyright protection. While copyright protection will prevent the unlicensed copying, distribution, modification, adaptation, display 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 and the rights and obligations that are normally included in a software 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 TLO that will undertake end-use licensing or whether the department, laboratory or center that developed the software will do it.

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 candidates for software licensing. One is a start-up company. Universities are finding that graduate students, especially, 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. With the proliferation of dot com companies, 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, derivatize, 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, 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) or 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. These rights are broader than the rights retained by the government under Bayh-Dole for patented inventions. They are contained in Federal Acquisition Rules (FAR) Subpart 27.4, Rights in Data and Copyrights, Section 27.402 - Policy.

(c) The License Term. The term of the license is not generally an issue under a patent license. Patent life covers a relatively short 20 years from the date of filing (with extensions possible if the patent application is delayed in the U.S. Patent Office). 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. Another way to shorten a license term is for the university to retain a right to terminate the license if the licensee is no longer marketing the software.

(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. The current fee for registering a copyright in the U.S. is $30.00, and even this is not required to sustain the copyright. 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 are presumed to be less and therefore the software is worth more when it is turned over to the licensee by the university. 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. A final comment on software royalties reminds the reader that the 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 in Section B. 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. It makes little sense for a university to consider applying trade secret protection to source code in a license (by prohibiting disclosure by the licensee) if the software was developed under federal funding, due to the government's broad rights to release it, or if the university believes that students should be able to publish and otherwise disclose the code to third parties as part of their educational activities.

D. When the Disclosure is a Multimedia Work.

1. Identifying the Pieces of the Puzzle. Unlike patentable inventions, or computer software that 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 TLO may include a computer program, a video, a digital archive, text content, recorded music, film clips, still images, just to name some of the possibilities. Prior to considering whether a multimedia work is a viable candidate for commercialization, the TLO 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 TLO 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 out better rights than it has, the scope of rights licensed must fall to the lowest common denominator, or, at a minimum, must set the license terms accurately for that piece owned by the contributor setting the lowest common denominator. While one can always license lesser rights than one has, one cannot license better rights than one has. It is not unusual, then, to have some portions of a multimedia work licensed exclusively and some non-exclusively to the same licensee. Or, a licensing institution may decide that the least complicated path is simply to license an entire work non-exclusively. The downside in doing so is that the license may lose value as a whole, rather than lose value only with respect to certain pieces. 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. It should be obvious to the reader that the licensing of multimedia will often require 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) 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 (copyrighted and/or patented software, copyrighted text, images, film, new delivery technology that may be patented and more). 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" (i.e., the 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 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 will be used to identify goods. It will be used as an adjective to indicate origin of the goods or services to which it is applied and to denote standardized quality for the goods or services bearing the mark. 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, with no technology being transferred. 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 that will reach the marketplace pose a danger of liability for the university. Consequently, they are 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, has 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 the university no longer owns it. 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 ® or ™ symbols is also important. And, universities, especially those non-public institutions that may be susceptible to liability suits, 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. Most institutions involved in foreign trademark licensing use licensing agents. 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. A current issue that universities engaged in trademark licensing are beginning to address as a matter of university policy is that of Fair Labor standards worldwide for workers engaged in manufacturing for trademark licensees.

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 candidates for commercial licensing 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, 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.

C. Know How or Show How. The licensing of know how or show how (the unpatented "how to" information that accompanies any scientific discovery or innovation) is not altogether common for universities, but neither is it unknown. As a component of patent licensing, the licensing of know how 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 how 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. As the reader will appreciate, none of the activities described in this Tutorial takes place in a vacuum. The inter-relationship of all of the people and the diverse interests represented 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 apply some braking pressure in the form of 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.[3]

A. Managing Institutional Conflicts.

Institutional conflicts of interest occur when the university has a financial stake in the outcome of its research programs that goes beyond the procurement of research funding. The financial stake 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. Or, it may be a venture capital fund created by the university to aid university-derived spin-offs. 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 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; 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 is likely to threaten the objectivity of the research to be performed.

Current federal regulations require disclosure by anyone involved in the design, conduct or reporting of a federally funded research project. Significant financial interests in research are defined as equity interests that, when aggregated between the investigator and his/her family either exceed $10,000 in value; equal 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. For clinical trials, more stringent thresholds are established.[4] All universities have implemented some procedures to meet these federal standards and most universities apply those procedures not only to all federally funded research (including all agencies), but also to non-federally funded research projects.

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. Conflict of Commitment. The issues having to do with conflict 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 becomes 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 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. 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 the 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.

---

[1] Porter, Michael E., "Managing in the New Economy", pages 25-48. A Harvard Business Review Book, 1999.

[2] DeVol, Ross C., "America's High-Tech Economy Growth, Development, and Risks for Metropolitan Areas". Milken Institute, July 13, 1999.

[3] See 42 CFR Part 50, 45 CFR Part 94 and the National Science Foundation Grants Policy Manual 520, dated July 11, 1995.

[4] Food and Drug Administration: Guidance for IRB's and Clinical Investigation (21 CFR Parts 50 and 56).

MARK BLOOM'S FAVORITE INTELLECTUAL PROPERTY WEB SITES

General Intellectual Property Web Sites (Great Starting Points!)

Franklin Pierce Law Center's IP Mall: http://www.ipmall.fplc.edu

Jeff Kuester's Technology Law Resource Page: http://www.kuesterlaw.com

Law Journal Extra's IP Center: http://www.ipcenter.com

The U.S. House of Representatives' Internet Law Library: http://www.lawguru.com/ilawlib/index.html

Copyright Web Sites

The U.S. Copyright Office: http://lcweb.loc.gov/copyright/

The Copyright Web Site: http://www.benedict.com

University of Texas at Austin's Office of General Counsel's Crash Course on Copyright:
http://www.utsystem.edu/OGC/IntellectualProperty/cprindx.htm

Institute for Learning Technologies' Guide to Copyright:
http://www.ilt.columbia.edu/projects/copyright/index.html

American Communication Association's Copyright and IP Rights Resources Page:
http://www.uark.edu/depts/comminfo/www/copyright.html

Association of Research Libraries' Copyright & IP Resources Page:
http://arl.cni.org/scomm/copyright/copyright.html

Stanford's Copyright & Fair Use Home Page: http://fairuse.stanford.edu

A Visit to Copyright Bay: http://www.nmjc.cc.nm.us/copyrightbay/default.html

Law Girl: http://www.lawgirl.com

The Electronic Frontier Foundation Home Page: http://www.eff.org/

Copyright Management Center of Indiana University-Purdue University Indianapolis:
http://www.iupui.edu/it/copyinfo/home.html

Multimedia Law and Information Web Sites

International Entertainment, Multimedia and IP Network: http://www.medialawyer.com

Multimedia Authoring Web: http://www.mcli.dist.maricopa.edu/authoring/

WWW Multimedia Law: http://www.batnet.com/oikoumene/index.html

An IP Law Primer for Multimedia & Web Developers: http://www.eff.org/pub/CAF/law/ip-primer

Software Publishers Association (SPA): http://www.spa.org

Copyright Clearance Information Web Sites

Copyright Clearance Center Online (CCC): http://www.copyright.com

American Society of Composers, Authors and Publishers (ASCAP): http://ascap.com

Broadcast Music, Inc. (BMI): http://rep.edge.net/index.html

The Harry Fox Agency, Inc. (HFA): http://www.nmpa.org/hfa.html

Patent Law Web Sites

The U.S. Patent & Trademark Office (USPTO): http://www.uspto.gov

The World Intellectual Property Organization (WIPO): http://www.wipo.org/eng/index.htm

The Software Patent Institute (SPI): http://www.spi.org/

Directory of World Patent Offices: http://www.ip.lawnt.com/iplinks.html

Patent Search Sites

IBM's Patent Server: http://www.delphion.com

USPTO's Patent Search Site: http://patents.uspto.gov/access/search-bool.html

Community of Science's U.S. Patent Search Site: http://patents.cos.com/cgi-bin/search.main

Special Internet Launch Pad

1700+ Online Publishers: http://www.hku.hk/Internet/1700Pub.html

Trademark Search Site

USPTO's Trademark Database Search Site: http://www.uspto.gov/tmdb/index.html

Domain Name Search Site

Network Solutions, Inc.: http://www.networksolutions.com

Trade Secret Sites

R. Mark Halligan's Trade Secrets Home Page: http://www.execpc.com/~mhallign/

The Trade Secret Home Page: http://seamless.com/trade/index.html

University Technology Transfer Web Sites

Association of University Technology Managers' Home Page: http://www.autm.net

University of Texas at Austin's Office of General Counsel IP Home Page:
http://www.utsystem.edu/OGC/IntellectualProperty/index.htm

General Legal Research Sites

The Court of Appeals for the Federal Circuit Home Page: http://www.fedcir.gov

The FDA Home Page: http://www.fda.gov

Cornell Law School's Legal Information Institute: http://www.law.cornell.edu

Hieros Gamos: http://www.hg.org/hg.html

Courts on Line: http://www.legalonline.com/courts.htm

Meta-Index for US Legal Research: http://gsulaw.gsu.edu/metaindex/

Law Guru: http://www.lawguru.com/index.html

WWW Virtual Law Library: http://www.law.indiana.edu/law/v-lib/lawindex.html

FindLaw: http://lawcrawler.findlaw.com

ABA Law Links: http://www.abanet.org/lawlink/home.html