Non-Profit Organization Licensing: Agreement Basics

Mark G. Bloom, Esq.

Associate General Counsel
and
Chief Intellectual Property Counsel

The Cleveland Clinic Foundation
Cleveland, OH

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

July 14, 2003

Non-Profit Organization
Liaoning
Agricultural Society

Table of Contents

Biography

Mark G. Bloom, Esq. is Associate General Counsel and Chief Intellectual Property Counsel for The Cleveland Clinic Foundation (CCF).

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 four 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 CCF, Mr. Bloom was employed as a Licensing Officer and Patent Counsel for the Wisconsin Alumni Research Foundation (WARF).

Mr. Bloom brings more than eighteen years of corporate sales, marketing, and intellectual property law and management experience to CCF where his myriad responsibilities include overseeing the invention patenting process, facilitating industrially-sponsored research, out-licensing of CCF technologies, and serving as Special Counsel to The Cleveland Clinic Press.

The Cleveland Clinic Foundation, founded in 1921, integrates clinical and hospital care with research and education in a private, not-for-profit group practice. It is consistently ranked in the top four hospitals in America. Approximately 1,100 full-time salaried physicians at The Cleveland Clinic and Cleveland Clinic Florida represent more than 100 medical specialties and subspecialties. In 2002, there were more than 2.2 million outpatient visits to The Cleveland Clinic. Patients came for treatment from every state and from more than 80 countries. There were nearly 52,000 hospital admissions to The Cleveland Clinic in 2002. The Cleveland Clinic website address is www.clevelandclinic.org.

MARK BLOOM'S FAVORITES QUOTES

WHAT IS A WORD?

"A word is not a crystal, transparent and unchanged; it is the skin of a living thought... and may vary greatly in color and content according to the circumstances and time in which it is used."

Oliver Wendell Holmes, Jr.

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 that have been active in securing the advances of society during the last centuries."

Professor Nathaniel Shaler

FREE TRADE IN IDEAS

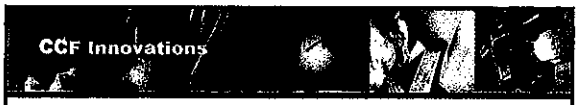
"The ultimate good is better reached by free trade in ideas. The best test of truth is the power of the thought to get itself accepted in the competition of the market."

Oliver Wendell Holmes, Jr.

TRANSPLANTATION OF IDEAS

"Many ideas grow better when transplanted into another mind than in the one where they sprang up."

Oliver Wendell Holmes, Jr.



Non-Profit Organization Licensing: Agreement Basics

Mark G. Bloom, Esq.

Franklin Pierce Law Center

Twelfth Annual Advanced Licensing Institute

THE CLEVELAND CLINIC

THE CLEVELAND CLINIC

Genesis of NPO TT

- Prior to 1968: Section 8.2(b) Petition for Greater Rights (case-by-case basis).
- 1968-1980: Institutional Patent Agreement (IPAs) negotiated by Univ. of CA, WARF, Battelle Institute, Iowa State, and Research Corp.
- 1981 to present: University and Small Business Patent Procedure Act (P.L. 96-517) – the "Bayh-Dole Act of 1980".

THE CLEVELAND CLINIC

NPO TT Metrics for FY2001

- 4,058 New Licenses (down 7% from FY2000).
- 9,707 Licenses/Options Yielding Income (up 7% from FY2000)
- $1.071 Billion in AGI from Royalties and Options.
- 494 New Companies Formed.
- 3,870 New Companies Formed Since 1980 (2,514 still alive at 159 NPOs).
- 13,569 Invention Disclosures Reported (up 6.9% from FY2000).
- 6,812 New US Patent Applications Filed (up 6.9% from FY2000).
- 3,721 US Patents Issued (even with FY2000).
- Total US Patents Issued Since FY1993 – 24,420.

THE CLEVELAND CLINIC

NPOs are All Different

- Politics are very much alive and well!
- Faculty versus Administration controlled.
- TTO separate legal entity versus internal.
- TTO resources vary tremendously.
- TTO control over faculty varies from a lot to practically none.

THE CLEVELAND CLINIC

Most Important TT Issues

- Maintenance of "Academic Freedom," also known as the "Freedom-to-Publish."
- Proper attribution.
- Equitable recognition of NPO's role in the development of a technology.
- Equitable sharing of revenue generated by commercial exploitation of technology.

THE CLEVELAND CLINIC

Licensee Due Diligence (1)

- Has the NPO filed patent applications in all of the relevant markets for the technology?
  - –domestic vs. foreign rights
  - –filing costs are an issue at many NPOs

THE CLEVELAND CLINIC

Licensee Due Diligence (2)

- Have the NPO inventor(s)' published their ideas prior to the filing of appropriate patent applications?
  - –If yes, how long ago?

THE CLEVELAND CLINIC

Licensee Due Diligence (3)

- Has a validity analysis been conducted to determine whether the patents that have been applied for by the NPO are likely to issue?
  - –pre-filing by NPO
  - –pre-agreement by Licensee

THE CLEVELAND CLINIC

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, or plant patent.

THE CLEVELAND CLINIC

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

THE CLEVELAND CLINIC

Licensee Due Diligence (6)

- Does the practice of the technology require access to materials or information not covered by the license?
  - –biological materials
  - –software
  - –know-how and/or show-how

THE CLEVELAND CLINIC

Licensee Due Diligence (7)

- Will the licensee exploit the technology in combination with other technologies, and how will that affect the distribution of royalties (i.e., royalty "stacking")?
  - –ask for ability to sue infringers
  - –reduction in royalties if patent does not issue

THE CLEVELAND CLINIC

Licensee Due Diligence (8)

- Besides a consulting arrangement or NPO-based 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

THE CLEVELAND CLINIC

Licensee Due Diligence (9)

- Have the IP policies, SR guidelines, COI policies, etc., of the NPO been obtained and reviewed by licensee's counsel?
  - –request copies from the NPO
  - –use the Internet!

THE CLEVELAND CLINIC

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 NPO to a contractual arrangement?
  - –ask if a person has signatory authority (SA)
  - –assume that the faculty member does not have SA!

THE CLEVELAND CLINIC

Types of Available IP

- Patentable subject matter.
- Copyrightable subject matter (usually software).
- Know-how (knowledge) and show-how (techniques).
- "Tangible Research Property" – unpatented biological materials.

THE CLEVELAND CLINIC

Most Common NPO TT Agreements

- Sponsored Research Agreements.
- Clinical Trial Agreements.
- Material Transfer Agreements.
- Fee-for-Service Agreements.
- Consulting Agreements.
- Confidentiality Agreements.

THE CLEVELAND CLINIC

Sponsored Research Agreements

- Nature of the Agreement – "basic" or "directed".
- Treatment of IP developed during research usually the basis for most of the negotiation between the parties.
- Confidentiality issues and post-termination cost issues run a close second.

THE CLEVELAND CLINIC

Clinical Trial Agreements

- The "phase" of the trial usually determines whether or not new IP is likely to be developed.
- More akin to a fee-for-service arrangement than "true" sponsored research.
- Data ownership/publication rights and patient confidentiality issues are of paramount concern.

THE CLEVELAND CLINIC

Materials Transfer Agreements

- Academic licensee versus industry licensee.
- Use of the UBMTA encouraged for academic requesters.
- "Reach-through" IP clauses are the most contentious issue with industry.

THE CLEVELAND CLINIC

Fee-for-Service Agreements

- Production of test data for sponsor.
- Usually, NPO does not request IP rights.
- Publication rights are requested.

THE CLEVELAND CLINIC

Consulting Agreements

- Nearly all consulting arrangements have a requirement to assign all IP created pursuant to the consultancy to the sponsor.
- Requirement to assign IP may conflict with consultant's duties to their NPO.

THE CLEVELAND CLINIC

Non-Disclosure Agreements

- Academic party versus industry party.
- "Cracker Jack" phenomenon biggest problem.
- Length of term and duties attendant to identify what is to be deemed confidential are usually the key issues.

THE CLEVELAND CLINIC

Inventorship at an NPO

- "An author does not necessarily an inventor make!"

Mark Bloom

THE CLEVELAND CLINIC

Public Disclosures at an NPO

- A premature "public disclosure" can have a materially adverse effect on one's ability to obtain patent protection for an invention, especially outside of the U.S.
- "Premature" means *any time* before a patent application is filed.

THE CLEVELAND CLINIC

IP Due Diligence (1)

- If possible, research agreements should be reviewed on a case-by-case basis, with IP disposition being guided by the research to be performed *per se*.
- Master or template research agreements might be useful, but they are usually not overly so (and may even be damaging).

THE CLEVELAND CLINIC

IP Due Diligence (2)

- How vigorously you contest a sponsor's IP clause should, in no small part, depend upon the nature of the research work that is to be performed.
- Likelihood of valuable IP being developed is high – negotiate very vigorously.
- Likelihood of valuable IP being developed is low – negotiate much less vigorously or not at all.

THE CLEVELAND CLINIC

IP Rules of Thumb (1)

- Basic research provides more IP opportunities than clinical research.

THE CLEVELAND CLINIC

IP Rules of Thumb (2)

- Early-stage clinical trial research provides more IP opportunities than later-stage clinical trial research.
- The same could be said about "clinical" research in general.

THE CLEVELAND CLINIC

IP Rules of Thumb (3)

- Since "new uses" for "old" drugs can be very valuable, consider the likelihood of their creation in a clinical trial and, if appropriate, do not give up rights to them in the clinical trial agreement.
- Review the clinical trial protocol!

THE CLEVELAND CLINIC

IP Rules of Thumb (4)

- "Fee-for-service" projects provide fewer or no IP opportunities as compared to basic research or clinical research.

THE CLEVELAND CLINIC

IP Rules of Thumb (5)

- Compromise positions on the ownership, protection, and commercialization of IP rights and the responsibilities attendant thereto are *always* available.

THE CLEVELAND CLINIC

Important IP Guide Post (1)

- If you are producing the research agreement at issue, you will, of course, have more initial control over the IP terms.

- Volunteer to draft the research agreement if the option to do so is available.

THE CLEVELAND CLINIC

Important IP Guide Post (2)

- Is the allocation of IP ownership in accordance with U.S. Patent Law?

THE CLEVELAND CLINIC

Patent Ownership Position

- U.S. Patent Law basically says that "if you invent it, you own it, if the sponsor invents it, the sponsor owns it, and if you and the sponsor invent it (joint inventorship), then you and the sponsor own it."

THE CLEVELAND CLINIC

Important IP Guide Post (3)

- Does the IP clause grant the sponsor (i) an outright license or (ii) a first right to negotiate a royalty-bearing license to commercialize new inventions?

THE CLEVELAND CLINIC

IP License Option Recommendations

- An outright license grant is usually not appropriate in a basic research agreement.
- You should offer a first negotiation right (to obtain a license).
- The negotiation is to be completed within a set period of time, e.g., 6 months.

THE CLEVELAND CLINIC

Tax-exempt Status Issues

- Use of tax-exempt, municipal bond-financed facilities for the conduct of research:
  - No pre-assignment of future IP (licenses only);
  - No royalty-free commercial use rights to future IP; and
  - No pre-establishment of value of future IP (must be FMV at the time of license).

THE CLEVELAND CLINIC

Tax-exempt Status Issues

- The Private Inurement/Private Use Equation
- The Bayh-Dole Act "Paradox"

THE CLEVELAND CLINIC

IP License Format Recommendation

- The IP license should be royalty-bearing, and, in most every case, exclusive.

THE CLEVELAND CLINIC

Negotiation Period Recommendations

- Periods in the range of 90 to 180 days are typical for the negotiation of the license.
- Longer periods are acceptable on a case-by-case basis, guided by reasonable business judgment.

THE CLEVELAND CLINIC

Patent Costs Recommendation

- I would strongly recommend that you make the right to negotiate (a license) contingent upon the sponsor's payment (or reimbursement) of all patent costs associated with protecting the relevant invention. Of course, there should be other consideration flowing back to the NPO as well!

THE CLEVELAND CLINIC

"Ancillary" Requirements Recommendations

- ◆License agreements should always have strong progress reporting, auditing, and termination provisions.
- ◆Reasonable development milestones should also be seriously considered.
- ◆"Most-favored-licensee" clauses should be avoided.

THE CLEVELAND CLINIC

Favorite Sample MFL Clause

- ◆See Handout

THE CLEVELAND CLINIC

Key Cases – Singer et al. v. UC

- ◆Substituted a court's judgment as to "market reasonableness" of license terms in place of good-faith negotiation of the relevant technology transfer officials.
- ◆Legal "second-guessing" always an option for dissatisfied academic inventors.

THE CLEVELAND CLINIC

Key Cases – Madey v. Duke University

- Arguably eliminated the "experimental use defense" to patent infringement.
- Forever altered the landscape for academic technology transfer.
- Will likely open the litigation floodgates (NPOs will need a lot more IP litigation counseling).

THE CLEVELAND CLINIC

Key Cases – OddzOn Products

- Resulted in the hindrance of the flow of information between research collaborators.
- Section 102(f) or (g) in view of Section 103(c) – non-public information and no common ownership of the information.
- Proposed "Collaborative Research Promotion Act of 2003" – potential congressional fix.

THE CLEVELAND CLINIC

Key Cases – *Florida Prepaid* Cases

- US Supreme Court ruled that state agencies cannot be sued in *federal* court for patent, trademark (or copyright) infringement.
- Re-enforced Eleventh Amendment immunity against suit of states agencies.

THE CLEVELAND CLINIC

Key Cases – *Hypotheticals*

- Would *Madey* have been decided differently if the non-profit entity was UNC-Chapel Hill (a state university), rather than Duke University (a private university)?
- Is *Madey* in conflict with the *Florida Prepaid* cases?

THE CLEVELAND CLINIC

Final Comments

- The commercialization of IP rights can be a valuable source of additional revenue for an NPO. However, like a tree, IP must be protected and nurtured to "bear fruit."

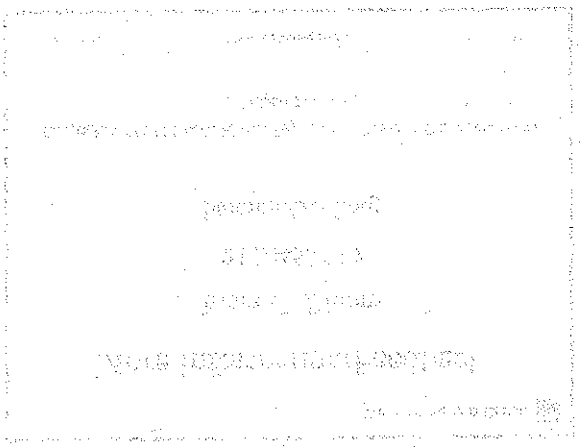
THE CLEVELAND CLINIC

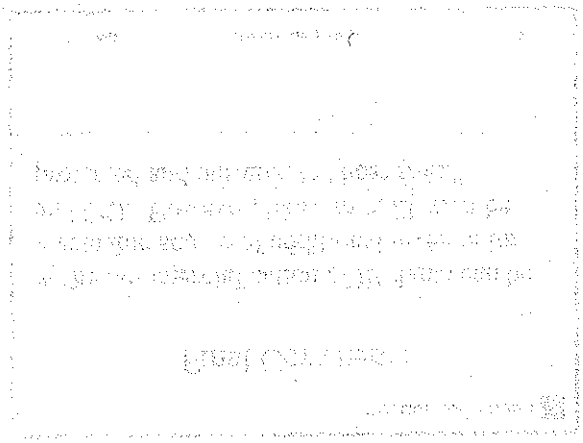
More Information/Feedback

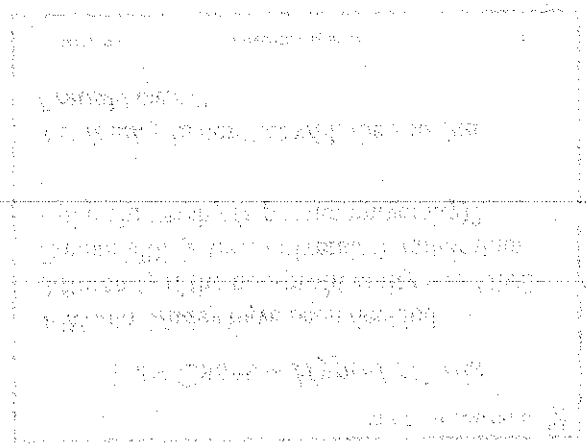
Mark G. Bloom

216.445.4010

bloomm@ccf.org







Sample "Most Favored Licensee" Clause

"4.2. CCF shall negotiate in good faith exclusively with COMPANY X for a period of up to six- (6) months for the acquisition of such license under or other rights to (including outright acquisition of ownership of) each Invention by COMPANY X. If the parties are unable to agree on the terms of such acquisition, and CCF receives a *bona fide* offer from a third party to acquire rights in the Invention, CCF shall give COMPANY X prompt notice of such **third party offer** including the identity of the offeror and all material terms of the offer, and COMPANY X shall have **a right of first refusal** for a period of ninety- (90) days thereafter or such shorter period as the offer is open to acquire such rights in the same term as are set forth in the notice. If COMPANY X fails to make such acquisition within that period, CCF thereupon shall have a period of one hundred and twenty- (120) days within which to reach a definitive agreement with the identified offeror for such acquisition on terms not materially more favorable to the offeror than those specified in the notice to COMPANY X, failing which CCF shall give COMPANY X prompt notice of such failure and COMPANY X's **right of first refusal** shall be reinstated and the subsequent provisions of this Section 4.2 shall reapply, *ad infinitum.*"

COMPANY X's attorney's response to my objection to the inclusion of a MFL clause in the subject Sponsored Research Agreement:

"It seems that CCF's attorney has misinterpreted the provisions of Section 4.2. There is no call for a most favored licensee arrangement, or anything else along the lines the attorney is questioning - CCF's attorney should consider attending a few more CLE seminars to stay current on such matters. It should be understood that Company X has a vested interest in the technology with all of the investigators/institutions that it enters into sponsorship of research. CCF has the best of all worlds with this arrangement. If it cannot reach agreement with Company X, it has the opportunity to reach agreement with a third party. The third party's offer establishes the value of the technology, assuming that Company X hasn't made a better offer in the previous negotiations with CCF."

Case and Statutory Citations

Case Citations

Singer et al. v. The Regents of the University of California; and Does 1 through 50
No. 950381 (Cal. Superior Court for the City and County of San Francisco 1996)
40 U.S.P.Q.2d 1035

Singer et al. v. The Regents of the University of California
No. A076331 (Cal. App. 1 Dist. 1997) (unpublished)

Singer et al. v. The Regents of the University of California
No. S066620 (Cal. Supreme Court 1998)
Petition for Review Denied

Madey v. Duke University
307 F. 3d 1351 (Fed. Cir. 2002)

OddzOn Products, Inc. v. Just Toys Inc., Lisco, Inc., and Spaulding and Evenflo
122 F. 3d 1396 (Fed. Cir. 1997)

Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank
527 U.S. 627 (1999) (The Court ruled that the Patent Remedy Act violated the Eleventh and Fourteenth Amendments of the U.S. Constitution and thereby affirmed the Third Circuit holding that College Savings Bank's patent infringement claims were barred by Eleventh Amendment immunity.)

College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board
527 U.S. 666 (1999) (The Court affirmed the Third Circuit decision holding that College Savings Bank's Lanham Act (trademark infringement) claims were barred by Eleventh Amendment immunity.)

NB: The Eleventh Amendment generally provides that state governments cannot be sued in *federal* court by the citizens of another state. The Fourteenth Amendment empowers Congress to deter or remedy Constitutional violations. Accordingly, Congress can authorize actions against state governments in federal courts as an exercise of its remedial powers under Section 5 of the Fourteenth Amendment.

35 U.S.C. Section 102 states that:

A person shall be entitled to a patent unless:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one- (1) year prior to the date of the application for patent in the United States, or

(c) the applicant for patent has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or their legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve- (12) months before the filing of the application in the United States, or

(e) the invention was described in:

(1) an application for patent, published under Section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in Section 351(a) shall have the effect under this subsection of a national application published under Section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in Section 351(a), or

(f) the applicant for patent did not invent the subject matter sought to be patented, or

(g)

(1) during the course of an interference conducted under Section 135 or Section 291, another inventor involved therein establishes, to the extent permitted in Section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or

(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

35 U.S.C. Section 103(c) states that:

"Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of Section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

MARK BLOOM'S FAVORITE INTELLECTUAL PROPERTY WEB SITES

General Intellectual Property Web Sites (Great Starting Points!)

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

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

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

Copyright Web Sites

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

The Copyright Web Site: www.benedict.com

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

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

Law Girl: www.lawgirl.com

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

Copyright Management Center of Indiana University-Purdue University Indianapolis: www.copyright.iupui.edu

Multimedia Law and Information Web Sites

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

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

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

Software and Information Industry Association: www.spa.org

Copyright Clearance Information Web Sites

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

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

Broadcast Music, Inc. (BMI): www.bmi.com

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

Patent Law Web Sites

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

The World Intellectual Property Organization (WIPO): www.wipo.org

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

Patent Search Sites

USPTO's Patent Search Site: www.uspto.gov/patft/index.html

PCT and EPO Search Site: //ep.espacenet.com

Trademark Search Site

USPTO's Trademark Search Site: //tess.uspto.gov/bin/gate.exe?f=tess&state=5he8hm.1.1

Domain Name Search Site

Network Solutions, Inc.: www.networksolutions.com

Trade Secret Sites

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

University Technology Transfer Web Sites

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

General Legal Research Sites

U.S. Government's Official Web Portal: www.firstgov.gov

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

FDA Home Page: www.fda.gov

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

Hieros Gamos: www.hg.org

Meta-Index for U.S. Legal Research: //gsulaw.gsu.edu/metaindex

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

FindLaw: www.findlaw.com

UNIVERSITY LICENSING: PAST, PRESENT AND INTO THE FUTURE

Prepared by Mark G. Bloom, Esq.
Associate General Counsel and
Chief Intellectual Property Counsel, CCF Innovations
The Cleveland Clinic Foundation
Cleveland, OH

Table of Contents

B. **NIH Guidelines for the Licensing of Biomedical Research Tools (or Cell Lines and TIGRs and Bayh-Dole, Oh My!)**
Background
Cause and Effect
Impact on Private Investment
Ultra Vires
Conclusions

C. **The Florida Prepaid Case and UTT**
A Brief History of Eleventh Amendment Immunity
The Florida Prepaid Decision
Implications of Florida Prepaid
Alternative Potential Forms of Relief
State Law Cause of Action
Ex Parte Young
Waiving Immunity
Actors within the Scope of Immunity
Conclusions
Impact of Florida Prepaid on UTT

X. **Summary**

Special Thanks

The author would like to thank Howard E. Bremer, Esq. for his input and inspiration in preparing and updating this subchapter. Mr. Bremer, a 1949 graduate of the University of Wisconsin Law School, is widely regarded as the "Father" of University Technology Transfer due to his nearly twenty-year effort to obtain the passage of what was to become the Bayh-Dole Act of 1980. Mr. Bremer was the chief architect and proponent of this groundbreaking legislation, as well as being a founding member of the Association of University Technology Managers (AUTM), the Licensing Executives Society (LES), and the Council on Government Relations (COGR). Mr. Bremer joined the Wisconsin Alumni Research Foundation (WARF) in 1960 and is currently Emeritus Patent Counsel.

I. Introduction

Activities reported in the first three years of the New Millennium indicate that the field of University Technology Transfer ("UTT") is entering what may be deemed its Golden Age. The number of technology disclosures, patent applications filed, patents issued, technology licenses signed, and new company start-ups created, are still increasing over prior years, with no signs of abatement. However, the best way to gauge how far UTT will truly go in the future is to first review UTT's past and present.

II. Prologue

Appropriate to the basic research function at universities, it is suggested that the loom for weaving into a substantive fabric the wisdom derived from the conduct of research lies in the enlightened cooperation between the universities, industry and the federal government which, through voluntary acts and legislative initiatives, has permitted and continues to permit the transfer of that wisdom to the public for its use and benefit.

III. Technology Transfer Defined

The concept of technology transfer—the transfer of the results of research from universities to the commercial sector - is said to have had its origins in a report made to then President Harry Truman in 1945 by Dr. Vannevar Bush[1] entitled "Science - The Endless Frontier." Having witnessed the importance of university research to the national defense for its role in the successful Manhattan Project, Dr. Bush projected that experience to recognize the value of university research as a vehicle for enhancing the economy by increasing the pool of knowledge for use by industry through the support of basic science by the federal government. The report stimulated substantial and increasing funding of research by the federal government leading to the establishment of several research-oriented governmental agencies, e.g. the National Institutes of Health, the National Science

Foundation, the office of Naval Research, and, ultimately, to the acceptance of the funding of basic research as a vital activity of the federal government.

Long before the Vannevar Bush concept, but absent federal support in their research endeavors, the universities have been engaged in the transfer of the technology, although that specific term may not have been applied to their activities.

Their greatest technology transfer efforts have probably been expended in preparing papers on research results for publication in scientific journals. Another area involves the activities of the Extension Services, particularly the Agricultural Extension Services, which communicates a great variety of useful information, largely technical, but also in social and economic fields, to many users, both rural and urban.

Another area of communication of information lies in the continuing education programs, e.g. in law, medicine, pharmacy, engineering, to keep professionals in those fields abreast of the latest developments.

Technical consultantships provide technology transfer in both directions—the consultant imparts information to whomever is engaging them while the consultant, in turn, can expect some professional enrichment from that activity.

Still another means for transferring technology is by making a tangible product of research available to others with or without a view toward commercialization. For example, seedling plants for propagation by others, appropriate fragments of tissue for tissue culture, cell lines, hybridomas, and transgenic seeds or animals as well as mechanical or electronic prototypes and computer software programs.

Thus, technology transfer occurs in many ways - through the simple spoken word, through the physical transfer of a tangible product of research, through the hiring of students or faculty consultants, or through the relative complexity of an intellectual property-licensing program.

Although all of these forms of technology transfer have been and are being practiced today the focus of this paper is upon the transfer of technology as represented by the transfer of a property right as the result of ownership of the intellectual property generated during the conduct of research. Patents, copyrights, trademarks, trade secrets or a proprietary right in the tangible products of research may manifest such ownership.

IV. Intellectual Property

A. Constitutional Basis

As we all know, the Constitution was drafted in the context of a struggle with a government that had abused its obligations to defend the rights of its citizens. It was no accident, therefore, that the salient portion of the Constitution drafted for the purpose of protecting your liberties, the Fifth Amendment, made the Government the servant and protector and not the master of your individual rights. The Fifth Amendment of the Bill of Rights provides that:

> "No person shall...be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use without just compensation."

Thus, the Fifth Amendment provides generic protection for individual property. Since there is little doubt that the term "property" as used in the Fifth Amendment includes intellectual property, it would seem that the protection afforded the individual by that amendment would be adequate. Yet, the framers of the Constitution felt compelled to be even more explicit about intellectual property and provided the following language in Article I, Section VIII:

> "The Congress shall have Power - To promote the Progress of Science and useful arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

Why this special handling of intellectual property?

There was no recorded debate in the Constitutional Convention on September 5, 1787, when Article I, Section VIII, was presented and it was approved unanimously. That intellectual property, the products of the mind, should prospectively receive legal protection, even from a centralized Government to be formed, was a principle upon which no one disagreed.

The power given under this clause is not general. Hence, it expressly appears that Congress is not empowered by the Constitution to pass laws for the benefit of protection of authors and inventors except as a means to "promote the Progress of Science and useful arts."

Under this specific power the present patent statute, Title 35 of the United States Code, (35 U.S.C.) was enacted. It is significant that the face of the patent document contains the following statement:

> "...these Letters Patent are to grant unto the said claimant(s)...the right to exclude others from making, using, or selling the said invention throughout the United States."

and that 35 U.S.C. 261 characterizes this right to exclude as a property right. The technology transfer function is in great part based upon the recognition of and the specific provision for that very special property right.

B. Nature of University Research

During the prevalence of the "Ivory Tower" concept of universities and the research that was carried out in them, little thought or impetus was given to the transfer of the results of that research to the public other than through the accepted and acceptable route of scientific publication. In fact, under that "Ivory Tower" concept, a researcher who accepted a corporate subsidy aroused the suspicion among his colleagues that he had been diverted from their basic research and had become a tool of vested interests. They had accepted "tainted money."

When, in 1924, it was suggested at the University of Wisconsin-Madison that a plan be developed to make use of patentable inventions generated by faculty members which would:

1. protect the individual taking out the patent;
2. insure proper use of the patent; and, at the same time;
3. bring financial help to the University to further its research effort,

the purists quickly applied the "tainted money" theory to the plan. It was feared that any such arrangement would divert the scientist from basic research to work only on those ideas which appeared to have commercial potential. In other words, the research function would no longer be driven by the seeking of new knowledge but by the dollar-driven need to solve current problems in the real world, even to the development of products and processes to market-ready condition.

The fears propounded by the purists then, and which are still embraced in academia by some, did not materialize. There was no great rush toward patenting. There was no evident movement among university researchers toward applied research tied directly to actual product development. Nor was there any observable change in the research scientists' attitude. In fact, University research then, even as now, remained essentially basic in character.

The generation of inventions is almost never the main objective of basic research. If inventions do flow from that research activity, it is a largely fortuitous happening that takes place because the researcher, or perhaps, an associate, has the ability to see some special relationship between their scholarly work product and the public need. It is from the recognition of this connection, which can convert a discovery or invention into patentable invention, that innovation arises.

It was not too many years ago that there was little appreciation of the value of intellectual property generated during the course of research being conducted on the university campus or of the value of that intellectual property to the university if properly transferred to the private sector for development and marketing through appropriate arrangements. In fact, on many campuses those

activities would have even been unwelcome as an incursion into academic pursuits as was the early experience at the University of Wisconsin-Madison. Nevertheless, prior to the legislative initiatives under which, today, most universities engage in the protection and licensing of intellectual property, several universities and organizations carried out such practices with the attendant opportunity to generate funds to aid in supporting research efforts. Prominent among such institutions were the University of California, Iowa State University, Battelle Development Corporation, Research Corporation (which represented a number of universities), and the University of Wisconsin-Madison through its patent management organization - the Wisconsin Alumni Research Foundation (WARF).

C. The Government Sector

During the early history of the United States very little technical development work was done by the Government and therefore, as a practical matter, the question of the Government owning a patent never arose. Gradually, federal agencies begun to undertake the practical kind of development work which led to inventions. Prior to World War II, when almost all Government-financed research and development work was conducted in federal laboratories by full-time Government employees, there was a small but recurring problem of what to do with inventions resulting from such work - inventions which, if made by private parties, would have become the subject of patent applications. This situation changed rapidly during and after World War II when the technological demands imposed by more and more sophisticated military requirements, as well as the increasing complexity of support services, made it quickly evident that there were not sufficient resources within the Government to undertake all the scientific projects necessary to a winning war effort. The absolute necessity to utilize the best technical ability available, regardless of its locus, spawned a rapid proliferation of Government-sponsored and government-funded research and development contracts.

The proper disposition of rights to patents resulting from this work was theoretically as important then as now but was never seriously addressed as a major problem because of the exigencies of wartime needs.

The basic issue was whether the Government should always take the commercial rights to patentable inventions generated under a Government sponsored contract or from Government-funded research or whether such rights would be better left with the contractor or grant recipient to permit utilizing the patent system for transferring the technology developed to the public sector for its use and benefit.

Following the end of World War II, the rapid technological strides made under the impetus of a wartime footing and the obvious necessity for continuing technological superiority, at least in defense-oriented efforts, made it imperative to continue to provide public support for science. Nor was this support limited to the military. For example, in 1950 Congress finally provided an annual budget of $15 million for the National Science Foundation to conduct basic scientific research at universities.

During this same period, hundreds of millions of dollars were appropriated by the Government in the area of medical research in the beginnings of an all-out attack on disease.

With the rapid expansion of scientific projects being undertaken and supported by the Government, the same shortage of technical ability and facilities continued to prevail as had been experienced under the pressures of World War II. Since the Government could not do all the necessary work in its own facilities, qualified private companies, universities and nonprofit organizations were sought out to perform many of the programs through contractual arrangements. In each arrangement, the same old problem of ownership of patent rights existed but was seldom, if ever, directly addressed. In the case of universities and other non-profit organizations, few were engaged at the time in patenting the results of research and in technology transfer activities. Since one of the prime

objectives of such an institution was to support its respective research efforts and since the government was a ready source of funds for supporting such efforts, the prevailing attitude was simply to "take the money and run" with little thought being given to the underlying property rights and the value of those rights in the long term.

The Government itself had not developed a uniform patent policy for all of its agencies regarding the disposition of rights in intellectual property generated during the course of research supported by those agencies. In fact, there was no existing statutory authority that gave the agencies the right to hold patents or license technology. Such acts were viewed as objectives of the agency mission. Consequently, each governmental agency that supported a research and/or development effort, through either or both of contractual or grant arrangements developed its own policy. The ultimate result was that many and varied policies evolved to the point that the university sector was faced with the prospect of having to deal with some 26 different agency policies. Also, to support a given research pursuit, funds from different agencies were often co-mingled; hence, more than a single agency policy had to be considered with the most restrictive policy becoming the controlling policy. Operating under the various agency policies, the Government had accumulated in its patent portfolio about 30,000 patents of which only about 5% had been licensed and the inventions of which had found their way into commercial use in an even smaller percentage. Thus, with the Government, as represented by its agencies, espousing, in the main, a non-exclusive licensing policy the experience of licensing Government-owned patent had been irrefutably one of non-use. For example, in 1978 NASA reported that through 1978 it had had 31,357 contractor inventions reported to it. Of those, title had been waived to the contractor in 1,254 cases, or less than 4%. The results of NASA's own licensing program were said to have been disappointment representing a commercialization rate of less than 1%. In contrast, the rate of commercialization of the waived inventions was consistently in the 18-20% range. Therefore, the intended benefits that were to flow

to the public in the form of new products and processes as a result of federal support of research both intramurally and in the university sector and stimulated through use of the patent system were left unrealized.

Harbridge House[2] made an interesting comparison along these lines in its 1968 study of Government-funded patents put into use between 1957 and 1962. It was found that contractor-held inventions were 10.7 times as likely as Government-held inventions to be utilized in products or processes employed in the private sector for the benefit of the public.

Moreover, under the agency policies then in place, Government ownership of a patent was in a sense an anomaly. The patent system was created as an incentive to invent, develop, and exploit new technology to promote science and useful arts for the benefit of the public. When the government held title to those many inventions under the aegis that the inventions should be freely available to all, much the same as if the invention had been disclosed in a publication, the patent system could not operate in the manner in which it was intended. The incentive inherent in the right to exclude conferred upon the private owner of the patent, and which is the inducement to development efforts necessary to the marketing of new products or the use of new processes, was simply not available. What is available to everyone is of interest to no one.

The ineffectiveness and inadvisability of such agency policies and their adverse effect on the public benefit should have been apparent.[3]

D. Government Policy-Move Towards Uniformity

In 1963, Dr. Jerome Weisner, President Kennedy's Science Advisor and later Dean of MIT's School of Engineering, recognized a need for some guidelines to affect a more uniform Government policy toward inventions and patents on a Government-wide basis. The results of Dr. Weisner's study culminated in the Policy Statement issued on October 10, 1963 by President John F. Kennedy[4] to establish Government-wide objectives and criteria, subject to existing statutory requirements, for the

allocation of rights to inventions as between the Government and its contractors, which would best serve the overall public interest while encouraging development and utilization of the inventions. Since the policy, as promulgated, would most likely have to be revised after experience had been gained in operating under it, a Patent Advisory Panel was established under the Federal Council for Science and Technology to assist the Agencies in implementing the Policy, acquiring data on the Agencies' operations under the policy, and making recommendations regarding the utilization of Government-owned patents. In December 1965, the Federal Council established the Committee on Government Patent Policy to assess how the Policy was working.

The studies and experience of the Committee and the Panel culminated in the issuance of a revised Statement of Government Patent Policy by President Richard M. Nixon on August 23, 1971.[5] The changes effected in the Nixon Policy Statement were made as a result of analysis of the effects of the Policy on the public interest over the seven years from the Kennedy Policy Statement. The fundamental thrust of that statement was:

> A single presumption of ownership of patent rights to government-sponsored inventions either in the government or its contractors is not a satisfactory basis for government patent policy and, that a flexible, government-wide policy best serves the public interest.

The considerations basic to the Statement of Government Patent Policy were the following:

(a) The Government expends large sums for the conduct of research and development that results in a considerable number of inventions and discoveries.

(b) The inventions in scientific and technological fields resulting from work performed under Government contracts constitute a valuable national resource.

(c) The use and practice of these inventions and discoveries should stimulate inventors, meet the needs of the government, recognize the equities of the contractor, and serve the public interest.

(d) The public interest in a dynamic and efficient economy requires that efforts be made to encourage the expeditious development and civilian use of these inventions. Both the need for incentives to draw forth private initiatives to this end, and the need to promote healthy competition in industry must be weighed in the disposition of patent rights under government contracts. Where the contractor acquires exclusive rights, he remains subject to the provisions of the antitrust laws.

(e) The public interest is also served by sharing of benefits of Government-financed research and development with foreign countries to a degree consistent with our international programs and with the objectives of U.S. foreign policy.

(f) There is growing importance attaching to the acquisition of foreign patent rights in furtherance of the interest of U.S. industry and the Government.

(g) The prudent administration of Government research and development calls for a Government-wide policy on the disposition of inventions made under Government contracts reflecting common principles and objectives, to the extent consistent with the missions of the respective agencies. The policy must recognize the need for flexibility to accommodate special situations.

Although there is evidence that the guidelines did bring the patent practices of the Agencies into greater harmony, divergent policies still existed and there was a strong presumption, if not evidence, in terms of the transfer of technology to the public sector, that the more restrictive the policy of the Agency, i.e. the more "title" oriented the Agency was toward inventions and patents generated under

its funding i.e. the Agency generally took title to most if not all inventions made with the use of the funds, the less was the likelihood that the technology would be transferred for the public benefit.

E. Institutional Patent Agreements

During the period from 1963 to 1971, while experience with the Weisner-Kennedy effort was being gained, further efforts were being made to persuade several federal agencies, specifically the Department of Health, Education and Welfare (now Health and Human Services or HHS) and the National Science Foundation, to enter into Institutional Patent Agreements, (IPAs) with universities. The policies of both of these agencies permitted a waiver of rights to the inventions made with their funds (referred to as an 8.2(b) petition for grant of greater rights). However, on the very few occasions where such a waiver was granted, it was so fraught with restrictive provisions that it presented an unworkable basis for transferring technology to the private sector. No commercial firm was willing, under the conditions imposed under many of the waivers, to risk the expenditure of the necessary development funds.

Subsequently, after five years of negotiation, the then Department of Health, Education and Welfare, in 1968, issued its first new IPA to the University of Wisconsin-Madison (via WARF). This was followed in 1973, after another five years of effort, by an Institutional Patent Agreement[6] between the National Science Foundation and the University of Wisconsin-Madison (again, via WARF). This was the first IPA with that agency.

That evidence of not only the availability of an IPA, but that those two agencies would actually grant them, appeared to provide some impetus to universities to engage in the technology transfer business. Nevertheless, some of the provisions of the IPAs available form those two agencies were unacceptable under some universities' policies, while many other governmental agencies still clung tenaciously to the policy of taking title to all inventions made with funds they had supplied.

Fundamental to the success of technology transfer under the IPAs was the vestment of certainty of title to inventions held by the universities under those agreements. That factor and, in addition, the ability of universities to grant exclusive licenses were instrumental in the subsequent willingness of private sector industry to engage in licensing arrangements with universities that had IPAs. Although limited to two agencies, the IPAs were not only important as manifesting a change in the attitude of those agencies and potential licensees but, more importantly, as establishing, through negotiation, terms and provisions which were carried into and set the tone for the legislative effort which culminated in the passage of Public Law 96-517, the Small Business and University Patent Protection Act, in 1980 (better known as simply the Bayh-Dole Act). In fact, that law is often looked upon as a codification of the terms and provisions of the IPAs.

F. The Bayh-Dole Act[7]

The passage of the Bayh-Dole Act was the reward for almost twenty years of effort by the non-profit sector to stimulate the transfer of technology through the vehicle of the patent system. It was the culmination of the many pieces of legislation introduced over many years that had sought to establish a uniform patent policy within the government. It should be considered a landmark piece of legislation in that, after many false starts and unsuccessful efforts, it was, finally, a recognition by Congress that:

(1) imagination and creativity are truly a national resource;

(2) the patent system is the vehicle which permits us to deliver that resource to the public;

(3) placing the stewardship of the results of basic research in the hands of universities and small business is in the public interest; and, significantly,

(4) the existing federal patent policy was placing the nation on peril during a time when intellectual property rights and innovation were becoming the preferred currency in foreign affairs.

The most significant feature of the Act was that it changed the presumption of title to any invention made by small business, universities and other non-profit entities through the use, in whole or in part, of government funds from the government to the contractor-grantee. Another factor, often overlooked, is that the Act did away with the distinction between grants and contracts, which agencies had often made when dealing with universities, a distinction which a number of agencies rigorously applied in their zeal to retain rights to intellectual property as a contractual obligation. It is also not universally recognized that the Act provided, for the very first time, statutory authority for the Government to apply for, obtain and maintain patents on inventions in both the United States and foreign countries and to license those inventions on a non-exclusive, partially exclusive or exclusive basis. The passage of the law was not, however, the end of the battle. It took over a year to settle the controversy that arose over the drafting of the regulations under the law. During the course of the legislative effort, an almost adversarial relationship had developed as between the University sector on the one hand and the Departments of Energy, Defense, and NASA on the other hand. The nature of that relationship became very clear when those agencies combined to voluntarily draft regulations that actually controverted the law and its intention. As a consequence, much greater attention was given to the regulations by a university group that promulgated regulations that afforded protection against both arbitrary exemptions to the law at agency discretion and to the exercise of march-in rights by the Government.

The Bayh-Dole Act represented the first cautious step into a new relationship between the Government, as represented by its agencies, and the universities. It also presaged a new and closer relationship with industry. The certainty of title in the universities to inventions made with government funds afforded by the Bayh-Dole Act, which was the stimulus to successful technology transfer under the Institutional Patent Agreements, provided the major impetus to new and expanding university-industry relationships. Inasmuch as the Government always receives and

irrevocable royalty-free license under any of such inventions, and because of other provisions of the Bayh-Dole Act and the ensuing regulations under that Act, the relationship is, in reality, a university-industry-government relationship.

V. The Economic Climate

To more fully appreciate what has evolved through the sequence of events that has been enumerated, it must be kept in mind that through this period, the economy of the country as a whole, as well as the economy of each state, was and still is in transition. Today, universities operate in an economic climate which:

(1) is knowledge based - not capital based (although, without question, availability of capital is a necessity);

(2) is entrepreneurially based - witness the large numbers of new companies created in recent years;

(3) involves world markets - the international aspect of protection for intellectual property generated through the research function must be a consideration;

(4) reflects continuous and often radical technology changes;

(5) is becoming more decentralized - making state and local options and initiatives more significant;

(6) is an economy of appropriateness not one of scale - i.e., merely increasing the size of a production plant will not necessarily reduce the cost of product or increase its quality;

(7) is increasingly competitive on a global scale - witness the advent of the European economic community and other geographic economic blocks.

In view of this continually evolving economic climate, and since new products arise from new fundamental ideas as well as from new applications of existing technology, the necessity for supporting research is evident. However, support of research is not enough. That support must be

coupled with a creative technology transfer capability. Invention without innovation has little economic value.

With the passage of the Bayh-Dole Act and, in the same year, the decision of the Supreme Court in the Chakrabarty Case[8], which stood for the proposition that merely because something was alive (in that case a bacterium) it was not precluded form being patentable, along with the evolution of genetic engineering concepts, the universities were literally propelled into an awareness of the potential economic value of the technology that was being generated in their research programs. That fact made it self-evident that steps had to be taken to make innovation follow invention since invention alone holds little hope for generating needed revenues to support an expanding research effort. Because the government has been and still is the primary source of the funds supporting the research effort at universities, the passage of the Bayh-Dole Act permitted the universities to position themselves, through the establishment or expansion of technology transfer capabilities, to better insure that innovation would follow invention.

VI. Government Patent Policy Reshaped

At the outset it must be presumed that Government research dollars are made available in the expectation of not only developing basic knowledge, but also in the expectation that the funded research will lead to products, processes and techniques which will be useful and acceptable in all or part of our society to improve the well-being of society in general.

In the face of this presumption it is apparent that inventions, whether made through the expenditure of private or governmental funds, are of little value to society unless and until they are utilized by society. In order to achieve such utilization it is essential that the invention be placed in a form or condition that will be acceptable and beneficial to the public. In other words, the technology must somehow be transferred to the public sector. To quote Thomas Edison: "The value of an idea lies in the using of it."

In a free enterprise system such transfer is normally accomplished as the result of pertinent and appropriate activities of private enterprise. Since such activities obviously entail the commitment and expenditure of substantial monies - many times the amount needed to make the invention - adequate and appropriate incentives to such commitment and expenditures must be afforded. Consequently, and since the patent system provides such incentives and is the most viable vehicle for accomplishing the transfer of technology, full and careful consideration must be given to the making of any policy which will affect the transfer of technology that has been generated in whole or in part by Government-funded research. In addition, careful consideration must also be given to proposed changes in the patent laws, including proposed treaty accommodations, which could adversely affect the technology transfer capabilities.

One would not disagree that the primary objectives of a Government patent policy should be to:

(1) promote further development and utilization of inventions made in whole or in part with government funds;

(2) ensure that the Government's interest in practicing inventions resulting from its support is protected;

(3) ensure that the intellectual property rights in Government sponsored inventions are not used for unfair, anti-competitive or suppressive purposes;

(4) minimize the cost of administering patent policies through uniform principles; and

(5) attract the best qualified contractors.

However, of all of the considerations attendant upon the establishment of a governmental patent policy, only one consideration should be paramount:

> In whose hands will the vestiture of primary rights to inventions serve to transfer the inventive technology most quickly to the public for its use and benefit?

The passage of the Bayh-Dole Act was the beginning of the reshaping of Federal Patent Policy. Subsequent events between 1981 and 1985 further shaped that policy. The Bayh-Dole Act, the first event, became effective on July 1, 1981. The Congressional intent in its passage is abundantly clear from the recitation of the Policy and Objectives portion of the Act 35 U.S.C. 200.[9]

The second event was the issuance in 1982 by the Office of Management and Budget policy guidance to federal agencies for implementing the Bayh-Dole Act in the form of OMB Circular A-124.[10] This Circular clarified provisions in the Bayh-Dole Act regarding:

(1) standard patent rights clauses for use in federal funding agreements;

(2) reporting requirements for universities electing title; and

(3) special federal rights in inventions.

A third event was the issuance of a Presidential Memorandum on Government Policy[11] under which federal agencies were directed to extend the terms and provisions of the Bayh-Dole Act to all government contractors with a follow on amendment to the Federal Acquisition Regulations (FAR) to assure that all federal R&D agencies would implement the Bayh-Dole Act and the Presidential Memorandum.

The fourth event was the amendment of the Bayh-Dole Act by Public Law 98-620[12] to remove some politically-motivated restrictions on exclusive licensing placed in the original Bayh-Dole Act. That law, in essence, made the Department of Commerce the lead Agency in administration of the Bayh-Dole Act as amended.

The fifth event, which did not occur until 1987, comprised publication of rulemaking[13] by the Department of Commerce that finalized the provisions of the Bayh-Dole Act, P.L. 98-620, the OMB Circular A-124 and the Presidential Memorandum.

Also, in this same period the establishment of the Court of Appeals for the Federal Circuit, under the able leadership of Chief Judge Howard T. Markey, gave further impetus to the value of patents and a uniformity to their interpretation which put to rest the disparities which existed among the Judicial Circuits and had led to forum shopping in patent litigation. The paraphrase Chief Judge Markey - no institution has done so much for so many with so little understanding as the United States Patent System.

The government patent policy, as reshaped by the events noted, presented a charge and a challenge - a charge to show, through performance, that the confidence which was placed in the hands of the universities by Congress to transfer technology for the public benefit was not misplaced - a challenge to maximize the benefits which can be derived from the opportunity offered through that patent policy to aid in maintaining the United States as the world leader in innovation.

These events, led by the passage of the Bayh-Dole Act created the revolution in university technology transfer.

VII. The Impact of the Bayh-Dole Act

How can the practical impact on universities of the Bayh-Dole Act and the reshaped Government patent policy be measured? Since we are dealing for the most part with the transfer of technology from a protected base, i.e., patents and other forms of intellectual property protection, an obvious answer is to look at the change in the number of patents issued to universities and other non-profit entities, e.g. teaching hospitals, since the effective date of the Bayh-Dole Act in 1981. The growth and trend lines are evident. The university sector now receives about 3% of all United States origin patents issued.

If the total count of patents issued is inclusive of non-profit entities in addition to the universities, the observable impact of the Bayh-Dole Act is even greater. In addition, because more institutions have technology transfer programs, a greater number of institutions are receiving patents. The real measure of technology transfer is not, of course, the number of patents which the university sector holds, but the amount of technology represented in and by those patents which has been transferred to the private sector for further development into products and processes useful to mankind. In a study conducted in 1989 among executives in various industries, it was shown that a number of industries, especially pharmaceuticals, relied heavily on research conducted at universities for new products or for shortening the time necessary to bring a product or process into commercial use. What has been the licensing experience? The most recent licensing survey by the Association of University Technology Managers (the "AUTM Survey")[14] shows a continuing growth in patenting and licensing activities by the university sector. The data presented in the FY1997 AUTM Survey was utilized by the General Accounting Office (GAO) in part in formulating its required periodic review of the administration of the Bayh-Dole Act.[15]

According to the AUTM Survey, at the end of FY2001, the university sector reported 22,937 total active licenses or options. The patenting and licensing activities are, of course, based upon the number of invention disclosures received and the patent applications filed. The invention disclosures received have been increasing every year and in FY2001 reached 13,569. The number of patent applications filed and number of issued U.S. patents, as might be expected, have also increased year-to-year to a total of 10,533 in FY2001 (6,812 and 3,721, respectively).

As a result of these patenting and licensing activities, universities and teaching hospitals have experienced growing royalty income that, for the second consecutive year, exceeded one *billion* dollars (FY2001). For the most part, these monies, after sharing with the invention or inventor group, are utilized to support further research within the university or teaching hospital. Licenses

and options executed have increased steadily since the passage of the Bayh-Dole Act, representing both an increase in the number of universities engaging in patenting and technology transfer activities and in the increasing activities of those universities already engaged in those functions. In accordance with the GAO report for FY1996, the percent increase from the previous year was 8.4% for recurring correspondents in the AUTM survey. About 10.9% of the licenses or options granted were to start-up companies. 54.7% were to small businesses, i.e., companies with less than 500 employees (including start-ups) (rising to 67% in FY2001). Moreover, at the end of FY1996, the university sector reported 10,487 active licenses and options, the latter being up by 12.9% over the previous year (note that the FY2001 total of 4,058 licenses and options was down 7% from FY2000). The number of such licenses and options producing income increased by 16.1% over the previous year while the income of $365.2 million generated by those activities in FY1996 represented an increase of 22.1% over FY1995.

Another significant outgrowth of the university technology transfer programs are the number of new start-up companies which have been formed that find their basis in the technology generated during the course of basic research. According to the FY2001 AUTM Survey, more than 3,870 new university-technology-based start-up companies have been formed since 1980 (including 494 in FY2001 alone) and that nearly 65% were still in operation. The most visible example of this phenomenon has been in the field of biotechnology. In fact, the biotechnology industry arguably evolved from basic university research.

The impact of the Bayh-Dole Act is also seen in other indicators. For example, another excellent indicator that parallels the growth of the technology transfer function in the university sector is the growth of the membership in AUTM. After the passage of the Bayh-Dole Act, and particularly after the effective date of that Act in 1981, there has been a dramatic increase in the number of AUTM members to the current level of over 3,200. Growth in non-US-based AUTM membership has also

dramatically increased as other countries recognize the contributions which their universities can make as modeled on the United States experience.

Although, the foregoing figures represent the effect of all licensing activities and not only those attributable directly to operation under the Bayh-Dole Act, it is submitted that because of the overwhelming support of research and development in the university sector by government funding, for example being 62.8% (equal to $19.9 billion) of all funding in FY2001, and the traditional co-mingling of funding by the universities it is legitimate to conclude that the bulk of patenting and licensing activity in the university sector is government-fund driven and falls within the ambit of the Bayh-Dole Act.

In sum, several factors have contributed to the success of the Bayh-Dole Act and the transfer of technology under it. They are:

(1) The continuing support for basic research by the federal government,

(2) the ownership of the inventions by the universities as opposed to the government,

(3) the inventor remains in the development picture, and

(4) the uniformity of handling intellectual property generated with federal support regardless of the federal agency from which the support funds were obtained.

One important factor, which is often overlooked, is that the success was achieved without cost to the taxpayer. In other words, no separate appropriation of government funds was needed to establish or manage the effort. In fact, it has been estimated that the current (FY2001) economic benefits flowing from the universities' licensing activities adds more than $40 billion dollars per year to the United States economy and supports over 260,000 jobs.

Recently, the National Institutes of Health (NIH) recently conducted a major study of the university technology transfer process.[16] While the report, which was delivered to Congress in August 2001, focused solely upon biomedical research in the United States, it testified to the dramatic impact of

university technology transfer upon this singular sector of the U.S. economy. Similar impact of university research upon other segments of the U.S. and Canadian economy may be inferred from the FY2001 AUTM survey data reported above. The NIH report concludes that:

"Current practices in technology transfer have yielded a dramatic return to the taxpayer through the discovery of new technologies that extend life and improve the quality of life and through the development of products that, without the successful public-private relationship, might not be available. The transfer of federally funded technology has also resulted in financial returns from licensing activity, and such funds are used to buttress the biomedical research enterprise that has made the U.S. the world leader in this field...[I]t is impossible to overstate the achievements or the global macroeconomic impact of taxpayer-supported biomedical research. Federally funded biomedical research, aided by the economic incentives of Bayh-Dole, has created the scientific capital of knowledge that fuels medical and biotechnology development. American taxpayers, whose lives have improved and extended, have been the beneficiaries of the remarkable medical advances that come from this enterprise."

Finally, it should not be overlooked that university inventions, arising, as most of them do, from basic research, have led to many products which have or exhibit the capability of saving lives or of improving the lives, safety and health of the citizens of the United States and around the world. In that context, their contribution to society is immeasurable.

VIII. The Heritage of the Bayh-Dole Act

The Bayh-Dole Act can be given credit for focusing congressional interest on intellectual property-oriented legislation. With that focus established, the years since have seen many pieces of such legislation introduced. Some have become law but most have not. One piece of legislation that is considered to have been almost directly spawned because of or as the result of the Bayh-Dole Act is

the Federal Technology Transfer Act of 1986 (FTTA). That act was introduced as an amendment to the Stevenson-Wydler Act of 1980, which had been intended to promote the utilization of technology generated in government laboratories, but was singularly unsuccessful in accomplishing that goal.

The FTTA was largely a response to the increasingly tough international competition facing the United States and the prevalent complaint that "the US wins Nobel Prizes while other countries walk off with the market." The designers of the FTTA built the act under certain fundamental principles:

(1) The federal government will continue to underwrite the cost of much important basic research in scientifically promising areas that takes place in the United States.

(2) Transferring this research from the laboratory to the marketplace is primarily the job of the private sector, with which the federal government should not compete.

(3) The federal government can encourage the private sector to undertake this by judicious reliance on market-oriented incentives and protection of proprietary interests.

The principles enumerated were first tested through experience with the Bayh-Dole Act and the FTTA responded to the lessons learned from that law, perhaps the most important of which was its success in promoting university-industry cooperation.

The FTTA is, clearly, a direct highly beneficial legacy of the Bayh-Dole Act, as has been additional legislation designed to expand the use of the results of research carried out within government-owned government operated laboratories by expanding the licensing opportunities for those laboratories.

IX. Storm Clouds on the UTT Horizon?

A. Singer et al. v. The Regents of the University of California System

The Players - The plaintiffs in this case were former University of California (UC) Professors Jerome R. Singer and Lawrence E. Crooks, who joined UC in 1956 and 1976, respectively. Singer and Crooks were involved in the development of magnetic resonance imaging (MRI) technology while associated with UC's Radiological Imaging Laboratory (RIL), which was located at UC San Francisco. Each had executed UC's standard Patent Agreement, which, among other things, required that they assign to UC any patentable technology developed while working in UC facilities on UC time. In return, the Patent Agreement guaranteed them a portion of royalties and fees received by UC when (and if) it commercially exploited that technology. Further, UC's Patent Policy stipulated that inventors would receive 50% of the *net* royalties and fees generated from the licensing of their patented inventions. The defendants (as represented by the Regents of the University of California) were the RIL and the UC Technology Transfer Office (TTO) (collectively "UC"), which were involved in the development and licensing activities surrounding the patented MRI technology. UC's MRI technology portfolio contained over 100 patents that named more than 20 different inventors. Furthermore, the development of MRI technology at the RIL was spurred by research funding provided exclusively (and sequentially) by three companies: Pfizer Medical Systems, Inc. (Pfizer), Diasonics, Inc. (Diasonics), and Toshiba America Medical Systems, Inc. (Toshiba). These three companies are also the only three entities that received licenses to UC's patented MRI technology.

Background - Pfizer began funding the RIL in 1976. In exchange for being the exclusive source of research funds on MRI, UC promised Pfizer that it would be first in line for the opportunity to negotiate an exclusive license for any MRI technology developed by the RIL and later patented by UC. UC eventually obtained patents on certain MRI technology, and in 1980 Pfizer obtained an

exclusive license to exploit that technology. Although a royalty rate as high as 5% (later reduced to 3.89%) may have been contemplated by UC and Pfizer, the final *executed* royalty rate on the license was set at 0.56% of the net selling price of all licensed MRI inventions sold to third parties. The preamble, i.e., the "whereas" clauses, of the Pfizer License Agreement contained a reference to research funding, but the substantive terms of the contract did not require Pfizer to continue to fund research in exchange for continuing rights to an exclusive license. Nonetheless, Pfizer entered into a separate research funding agreement with the RIL and continued funding research until 1981, when it decided to exit the medical imaging market.

When Pfizer left the MRI industry, Diasonics assumed the Pfizer license via a new, albeit substantively identical, agreement with UC. In essence, Diasonics stepped into the shoes of Pfizer as licensee. Like the Pfizer license, the new license did not require that Diasonics fund research. Diasonics also entered into a separate research funding agreement with UC.

In 1983, Diasonics marketed its first MRI product based on the RIL-developed patented technology. That year, in recognition that the MRI technology had become commercially marketable, UC and Diasonics modified the License Agreement to provide for a "triggered" variable royalty rate that ranged from a low of 0.56% to a high of 6%. It is important to note that the MRI technology development "trigger" to raise the royalty rate above 0.56% was never attained. The substantive sections of the modified agreement remained the same, however, and contained no express requirement of continued research funding. Diasonics continued to fund MRI research at the RIL until 1989, when Toshiba bought out Diasonics' MRI division and took over as licensee.

When Toshiba purchased Diasonics' assets, Toshiba entered into yet another new license agreement with UC. This license was substantially similar to the Diasonics and Pfizer agreements, but did contain some variations. The most significant variation was that the Toshiba agreement required Toshiba to fund research at the RIL. Toshiba's separate research funding agreement with UC, while

mandated by the license agreement, was substantially identical to the prior funding agreements between UC, Pfizer, and Diasonics.

As a result of the combination of research funding and royalties paid to UC by Pfizer, Diasonics, and Toshiba, UC received a gross sum of approximately $22 million. Of that, approximately $2 million was considered by UC to be "royalties," while approximately $20 million was considered by UC to be "research funds." Singer and Crooks received $103,543 and $235,648, respectively, of net royalties. Singer and Crooks argued that those combined revenues, i.e., royalties plus research funds, represented a "package deal" that UC had obtained in consideration of its commercial exploitation of the assigned patent rights. Singer and Crooks further asserted that UC's failure to share all of the "financial proceeds" derived from this "package deal" constituted a breach of UC's Patent Agreement.

Initial Legal Salvo - The primary gravamen of Singer and Crooks' legal complaint against UC was that they believed UC should have treated research funds provided by Pfizer, Diasonics, and Toshiba as shared royalties rather than non-shared research funds. In other words, it was Singer and Crooks' position that they were entitled to share not only in the 0.56% patent license royalty, but also in research grants collected by UC for scientific research. UC firmly believed that Pfizer and its successors-in-interest provided these research funds for the dedicated purpose of conducting further scientific investigation into the (then) embryonic field of MRI technology. As evidence, UC had provided documentation showing that these funds were spent by UC to pay salaries of researchers and others pursuing the specific research goals set by Pfizer and UC, to construct and maintain research facilities, and to offset related overhead expenses. It is interesting to note that the research funds at issue covered nearly 18 years' worth of Professor Crooks' salary.

Singer and Crooks filed suit in the Superior Court of the State of California for the City and County of San Francisco against UC for breach of contract, seeking monetary damages, a declaration of

their rights under the UC Patent Agreement, and a rescission of their assignment of patent rights to UC. Additionally, Singer and Crooks asserted that (1) UC had a contractual duty to sue alleged infringers of its patents; (2) UC had a contractual duty to maximize the royalty rate it charges its licensees; (3) UC had a contractual duty to require its licensees to mark their products with patent numbers to preserve claims for damages against third parties; (4) UC wrongfully impounded gross royalty proceeds to pay the costs of litigation against Singer and Crooks; and (5) UC wrongfully allocated the inventor's share of licensing royalties among Singer and other inventors named on the licensed patents. All of Singer and Crooks' claims rested upon the argument that UC's Patent Agreement incorporated UC's Patent Policy, including a 50% sharing of net licensing royalties provision, and thereby created contractual constraints on UC's subsequent patent licensing and enforcement decisions.

Trial Court Jury Finds for Plaintiffs - After a trial on the merits, the jury found that UC had breached its Patent Agreement/Patent Policy obligations to pay Singer and Crooks 50% of the true amount of the royalties derived from the licensing of the patents at issue. The "true" amount was determined to be a percentage of the generated patent license royalties, as well as a portion of the research funds received by UC from Pfizer, Diasonics, and Toshiba. In total, $714,716 and $1,628,572 was awarded to Singer and Crooks, respectively, as damages.

Trial Court Judge Grants JNOV - In response to the trial jury's verdict, California Superior Court Judge James L. Warren granted UC a Judgment Notwithstanding the Verdict (JNOV).[17] In a concise and well-reasoned opinion, Judge Warren ruled that UC had no duty to share research funding as a royalty, no duty to dispense royalties to inventors if in defense of patent rights, no duty to negotiate royalties in accordance with individual inventor's demands, no duty to mark patented inventions licensed to others, and no duty to pursue infringers of the inventions at issue. Judge Warren also felt

strongly that substantial deference must be given to UC licensing and patent enforcement decisions. In other words, Judge Warren repudiated each and every one of the plaintiffs' accusations.

California Court of Appeal Reverses - Unfortunately for UC, the California State Court of Appeal for the First Appellate District (Division Five) reversed Judge Warren's JNOV.[18] The Court of Appeal ruled in an unpublished decision that the jury's verdict was supported by substantial evidence and that, among other things, UC had breached its Patent Agreement with Singer and Crooks by "renaming" royalties as research funds. The Court of Appeal felt that there were at least three critical findings that supported its decision. They were the "whereas" clause in the patent license agreements which mentioned sponsored research, the 0.56% royalty rate in the patent license agreements when accepted in lieu of the 3.89% royalty rate (that was never agreed upon), and the 6% royalty rate trigger (that was never attained).

In sum, the Court of Appeal believed that "under these circumstances, the jury could reasonably determine that the 'research fees' were, in fact, compensation for the use of the licensed technology and, therefore, were royalties which UC was required to share equally with the inventors." Obviously, the implication was that UC had granted an artificially low (shared) royalty rate to Pfizer, Diasonics, and Toshiba as a quid pro quo to their providing significant (non-shared) research funds.

Appeal to the California State Supreme Court - Following the reversal by the California State Court of Appeal, an appeal was filed by the defendants in the California State Supreme Court that asked for a review of the Court of Appeal's decision. In addition, *amicus* letters were sent from the American Council on Education, the Council on Governmental Relations, MIT, the University of Southern California, the University of Washington, and a number of corporations who sponsor research at Universities, including Toshiba, one of the licensees in this case. All *amicus* letters supported review. However, on March 18, 1998, the California State Supreme Court decided not to hear the appeal,

effectively making Singer et al. v. The Regents of the University of California System legal precedent in the State of California.[19]

Impact of Singer on UTT Activities - It still remains premature to speculate on the impact that *Singer* might have on University technology transfer activities in states other than California. However, many UTT professionals are still concerned that being subjected to inconsistent liabilities or, at the very least increased potential liabilities, will jeopardize the financial integrity of their Universities, and that there will be a corresponding reduction in corporate-sponsored research. It is also likely that Universities will continue to review and perhaps revise their patent and/or employment agreements and policies to address any future *Singer* situations. Furthermore, open communication between a University's TTO and other campus offices may be shown to have been negatively affected. Finally, many more University TTO's may consider becoming an independent entity like WARF, i.e., a 501(c)(3) non-profit corporation, in an effort to completely separate the patenting and licensing function from the sponsored research function.

B. NIH Guidelines for the Licensing of Biomedical Research Tools (or Cell Lines and TIGRs and Bayh-Dole, Oh My!)

Background - Concerns among scientists regarding the ever decreasing access to critical research tools prompted the NIH to establish a "Working Group on Research Tools." The "specific charge" of the NIH Working Group was to device solutions to the problem of access to research tools on the part of the NIH-funded scientists.[20] However, the recommendations of the NIH Working Group, which was chaired by University of Michigan law professor Rebecca Eisenberg, went far beyond this limited scope - the NIH Working Group recommended that NIH use it formidable economic clout to significantly limit the enforcement of intellectual property rights on research tools as a means for private financial gain. The NIH Working Group recommendations were molded into a manifesto

entitled "NIH Proposed Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources" (the "Guidelines").[21]

Cause and Effect - The Guidelines are based on the premise that licensing restrictions on inventions used as biomedical research tools generally are not an "appropriate" means for implementing the Bayh-Dole Act.[22] Namely, that "restrictive" licensing of research tools is particularly "inappropriate" where "employed primarily for financial gain."[23] This far reaching principle would apply to all research tools developed with NIH funding.[24] The NIH would seriously curtail the terms on which grant recipients may transfer research tools to commercial partners. Exclusive licenses covering the use of a tool in scientific research would be prohibited. NIH grantees would be obligated to ensure that the tools are widely available to scientists at little or no cost. The NIH would expect its grantees to abide by the Guidelines in their own transactions, and to contractually require their corporate partners to do so as well.

Where research tools are not patented, licenses would be required to substantially conform to the Uniform Biological Materials Transfer Agreement (UBMTA), which provides for the transfer of technology at no cost or, at most, for a fee limited to reimbursement of the provider's "preparation and distribution costs."[25]

As to patented materials, licenses granting rights to results achieved by the use of the licensed research tool would be expressly prohibited. The scope of prohibited licensing terms applicable to such results includes rights of first refusal, options to purchase or license, and automatic grants of exclusive or non-exclusive licenses. Additionally, the NIH would prohibit licenses that "reach through" to base royalties or other remuneration to the licensor on product sales or other results derived from using the licensed tool.

Major pharmaceutical companies and other commercial users of biomedical research tools would benefit most from the Guidelines, which would apply to licenses to commercial firms as well as non-

profit and academic scientists.[26] The imposition of profit-maximizing license fees, royalties, or commercial options on transfers of NIH-funded research tools to firms would be contrary to the Guidelines. Hence, the Guidelines extend far beyond merely ensuring that NIH-funded scientists have access to research tools previously invented with NIH funds - the NIH is arguably trying to use its influence to address the issue of whether patents on research tools should be enforced. This broader policy objective distorts the NIH's core mission of providing public support for biomedical research.

Impact on Private Investment - If there were no money to be made in licensing NIH-funded research tools, then why would any third party invest in their development and commercial exploitation? According to the Guidelines, commercial development is simply not required. The Guidelines state that "utilization, commercialization and public availability of technologies that are useful primarily as research tools rarely require patent protection."[27] The NIH's rationale being that "further research, development and private investment are not needed to realize their usefulness as research tools."[28] There are innumerable instances where such a claim would not be supportable. DNA chip technology and automated gene sequencers such as those used by Dr. Craig Ventner at The Institute for Genomic Research (TIGR) are but two that come to mind.

Ultra Vires - As discussed more fully above, the Bayh-Dole Act was based on a Congressional determination that private ownership, motivated by the prospect of financial gain, ultimately would lead to more efficient commercialization and distribution of federally funded technological innovations. In contravention of this ideal, the NIH concludes that the pursuit of private gain is not appropriate for research tool inventions. The NIH's authority to partially reverse the Bayh-Dole Act for a specific class of federally funded inventions is highly questionable and, it is submitted, only Congress has the ability legislate such an outcome.

The Guidelines also run counter to Congressional restrictions on the ability of funding agencies (such as the NIH) to exercise "march-in-rights" over federally funded inventions that have passed into private ownership.[29] Under the Bayh-Dole Act, that power may be exercised only after an agency has made certain case-specific findings.[30] Further, such findings cannot be made in regulations or guidelines that apply to broad categories of inventions. Clearly, Congress wanted to ensure that federal agencies did not exercise control over the licensing of federally funded inventions to which title has been elected under the Bayh-Dole Act by any means other than the exercise of warranted march-in-rights. The Guidelines appear to violate this legislative intent.

Conclusions - As was and is the case with Singer, the ongoing or future impact of the Guidelines on UTT licensing practices remains uncertain. However, it is clear that the Guidelines may prevent universities from garnering significant revenue from patented research tools; however, it might also have an effect opposite to that intended - knowing that price restrictions might be placed on their non-academic sales, companies might become even less willing to provide patented research materials to academic scientists. Such an outcome would be detrimental to academic biomedical research. In any event, continued scrutiny of the impact of the NIH Guidelines would certainly be warranted.

C. The Florida Prepaid Case and UTT

On June 23, 1999, the U.S. Supreme Court ruled in Florida Prepaid Postsecondary Educational Expense Board v. College Savings Bank[31] ("Florida Prepaid") that the Patent Remedy Act violated the Eleventh and Fourteenth Amendments of the U.S. Constitution. This important ruling requires reconsideration of the viability of intangible property actions against state actors in federal court.

A Brief History of Eleventh Amendment Immunity - The Eleventh Amendment generally provides that state governments cannot be sued in federal court by the citizens of another state. In Seminole Tribe of Florida v. Florida[32], the Court made it clear that Congress could not circumvent the

Eleventh Amendment restriction on the Article III power of federal courts by relying solely on Congress' Article I power. However, the Fourteenth Amendment empowers Congress to deter or remedy Constitutional violations. Accordingly, Congress can authorize actions against state governments in federal courts as an exercise of its remedial powers under Section 5 of the Fourteenth Amendment.

In City of Boerne v. Flores[33], the Court set forth a two-part test for determining the validity under the Fourteenth Amendment of legislation authorizing actions against state governments. First, the legislation must be congruent with the ends sought - the remedy or prevention of a perceived Constitutional violation. Second, legislation must be proportional to a remedial or preventative purpose; otherwise it is an attempt at a substantive change in the Constitutional protections. Only by meeting both of these measures, congruence and proportionality, can a congressional act be remedial in nature and a proper exercise of congressional authority.

The Florida Prepaid Decision - Because the Patent Clause is an Article I power, that clause is an inadequate basis for creating jurisdiction of federal courts for infringement by state actors. Thus, the validity of the Patent Remedy Act, which subjects states to federal court jurisdiction for patent infringement, turns on whether it is a proper exercise under Section 5 of the Fourteenth Amendment. The Supreme Court addressed this precise question in Florida Prepaid.

The Court analyzed the Patent Remedy Act under the standards set forth in City of Boerne. It found neither congruence nor proportionality in the congressional record supporting the Patent Remedy Act.

Congressional findings in the passage of the Patent Remedy Act included little if any evidence that patent infringement by state actors was a common or intentional activity. In determining the remedial nature of the Patent Remedy Act, the Court judged "with reference to the historical experience." The Court noted that even the Federal Circuit, in upholding the Patent Remedy Act,

only cited eight patent infringement actions against state actors in a 100-year period - an inadequate basis for the sweeping legislation of the Patent Remedy Act.

Moreover, Congress made no findings concerning a lack of state law remedies. That state actors infringed was in and of itself inadequate; a taking without due process of law is the critical issue. In other words, patent infringement alone does not violate the Constitution - only violation without any or adequate state law remedies could result in a deprivation of property without due process. Significantly, Congress also neglected to consider the element of intention. Negligent injury to property does not support a "deprivation" as understood from the Due Process Clause.[34]

Thus, the lack of historical violation of patent rights and the overbroad scope of congressional coverage under the Patent Remedy Act made it clear that the Act could not stand as a valid exercise of the Fourteenth Amendment's Section 5 power.

Implications of Florida Prepaid - The Court's reasoning with respect to the Patent Remedy Act appears likely to apply with equal force to Section 511 of the Copyright Act, which permits infringement actions against the states. However, Florida Prepaid likely does not mean that state governments can infringe patents, copyrights, and trademarks with impunity.

Alternative Potential Forms of Relief - Despite the elimination of patent infringement actions against state actors under Florida Prepaid, several other avenues for relief still appear to exist for patent holders. These avenues include proceeding under a state law cause of action or seeking prospective injunctive relief in federal court under the doctrine of Ex parte Young[35]. While both courses of action appear available, each has limitations and potential difficulties.

State Law Cause of Action - In Florida Prepaid, the Court suggested patentees might advance a takings or conversion claim in state court. This, of course, depends upon the availability of such actions under state law. While patents are property, it is not clear that takings or conversion actions would provide relief.

The Fifth Amendment Takings Clause applies to the states. Infringement of a patent by a state actor, however, might not rise to a level cognizable under current takings law to support compensation. Even if such an infringement is deemed a taking, state actors are only held to payment of "just compensation." The patent law remedies of enhanced damages and attorneys' fees would likely not apply. By way of example, infringement in the federal government context equates to an eminent domain action.

State laws vary in the law of conversion, and in many instances conversion or trespass to chattels is not recognized under common law for intangible property.[36] Frequently, for such actions to lie, the intangible rights must be incorporated into some tangible form. The Restatement (Second) of Torts §242 specifically addresses conversion of intangible rights. This section, however, limits its coverage to the kind of rights that are represented by and merged into a document, such as a debenture or mortgage note.[37] Moreover, many states have common law holding that federal law preempts actions based on patents or copyrights. Such decisions would require rethinking in light of Florida Prepaid in the case of state actors.

One open question of significance in any state court action relating to a patent would be the propriety of patent claim construction and arguments for non-infringement and invalidity.

Ex parte Young - The doctrine of Ex parte Young remains viable after Seminole Tribe but must be applied on a case-by-case basis. Under this doctrine, state officials can be enjoined from actions that violate the federal constitution. The Ex parte Young Court reaffirmed the doctrine "that a suit against individuals, for the purpose of preventing them, as officers of the state, from enforcing an unconstitutional enactment, to the injury of the rights of the plaintiff, is not a suit against the state within the meaning of [the Eleventh] Amendment." However, this exception does not extend to financial liability for past violations. The important distinction is "between prospective relief on one hand and retrospective relief on the other."[38] Thus, a patentee would bring an action for

prospective injunctive relief against the state official responsible for infringement. This, of course, would not allow for any money damages.

Waiving Immunity - Justice Scalia stated in College Savings[39] that a state could waive immunity by consenting to suit. Consent must be explicit, as College Savings expressly overruled the theory of constructive waiver from Parden[40], which was already weakened by subsequent decisions.

Actors within the Scope of Immunity - Not all governmental and public bodies are within the scope of Eleventh Amendment immunity, as this immunity is limited to states and state instrumentalities. Political subdivisions of states, such as counties, municipalities, school boards, and other types of municipal boards, do not receive the benefit of immunity. Thus, while Florida Prepaid may affect the liability of state universities for patent and copyright infringement, it should not affect the liability of primary schools and public libraries. Moreover, the Eleventh Amendment provides no immunity from an action against a state actor in the courts of another state if an adequate basis for personal jurisdiction exists under International Shoe[41] and its progeny.

Conclusion - In Florida Prepaid the Court invalidated the Patent Remedy Act, making state actors immune from patent infringement actions in federal court. While the Court did not directly address the Copyright Remedy Act, the same standards will likely apply, and that act may well also be invalidated. Rights holders still have recourse under state law, but this alternative relief probably is limited. For example, under Ex parte Young, the state official can be sued only for injunctive relief in his individual capacity.

Impact of Florida Prepaid on UTT - According to reports by the ABA Section of Intellectual Property Law[42], Congress was working behind the scenes and with the private sector to fashion mechanisms for re-establishing remedies for alleged victims of State-based intellectual property infringement in view of Florida Prepaid. It appears that these efforts may move to center stage as this edition of the Licensing Update goes to press. On November 1, 2001, Senate Judiciary Chairman Patrick Leahy

(D-Vermont) submitted a bill to the United States Senate entitled the "Intellectual Property Protection Restoration Act of 2001" (the "IPPRA")[43]. The stated purposes of the IPPRA are to: (1) help eliminate the unfair commercial advantage that States and their instrumentalities now hold in the Federal intellectual property system because of their ability to obtain protection under the United States patent, copyright, and trademark laws while remaining exempt from liability for infringing the rights of others; (2) promote technological innovation and artistic creation in furtherance of the policies underlying Federal laws and international treaties relating to intellectual property; (3) reaffirm the availability of prospective relief against State officials who are violating or who threaten to violate Federal intellectual property laws (see Ex parte Young discussion *infra*); and (4) abrogate State immunity in cases where States or their instrumentalities, officers, or employees violate the United States Constitution by infringing Federal intellectual property. The language of the IPPRA contains provisions by which the previously described purposes are implemented – such provisions being based primarily on a "waiver of immunity resulting in a denial of monetary and/or injunctive relief" paradigm. It is interesting to note that more than a decade ago, at the recommendation of the ABA Section of Intellectual Property Law, the ABA House of Delegates approved a policy statement opposing State exemption from liability for damages and equitable relief in actions for infringement of federal patent, copyright, or trademark laws. Harking back to that decade-old policy statement, the ABA Section of Intellectual Property Law was (again) acting as a proponent for the legislation submitted by Senator Leahy as it advocated the position that States should not be immune from suit for acts of infringement of intellectual property rights, while also including the denial of both monetary damages and injunctive relief to States seeking such remedies for infringement of State-based intellectual property rights when those States had not waived sovereign immunity[44].

In view of these developments as a response to Florida Prepaid, it is unclear how such legislation, if it became law, would impact UTT at this time.

X. Summary

The growth of technology transfer has taken place over the last thirty years in an environment that slowly progressed from hostile to favorable. That progression was given major impetus by the passage of the Bayh-Dole Act in 1980. During this period, there has been a dramatic change in the attitude of the U.S. Justice Department and the interpretation of the antitrust laws where patents and anti-trust are no longer viewed as antithetical. There has been a move toward a favorable statutory basis under which there is much greater freedom to operate. There has been an active effort by various administrations to obtain equitable treatment for U.S. citizens in foreign venues, both in trade and intellectual property pursuits. Numerous and far-reaching changes in the patent laws of those foreign venues have provided greater opportunities for technology transfer to these venues, while extensive changes in the U.S. patent laws and practices have further expanded the opportunities to engage in technology transfer. A knowledgeable Court of Appeals for the Federal Circuit has slain many of the mythical dragons attached to intellectual property law to provide uniformity of interpretation of those laws and before which patentees can expect equitable treatment. UTT has obtained the attention of Congress and, particularly, the attention in that body to the university sector's perspective on intellectual property law issues. The introduction and passage of legislation favorable to the universities and their technology transfer efforts has taken place. UTT has seen developed, not only in the university sector, but also in university-industry relationships and in the university-industry-government relationship, a greater awareness of technology transfer and a growing recognition of the possibilities that can be made available through creative technology transfer efforts and a much greater sophistication in handling those possibilities. Today, UTT licensing professionals operate in a climate that recognizes the value of intellectual

property and the technology transfer function. Many in the UTT licensing field would like to think that much of this has come about because the universities, as a source of fundamental discoveries and inventions, have been the source of enlightenment for a recognition of the value of innovation. The current emphasis, especially in our nation's capital, is "global competitiveness." That the university sector has made a tangible contribution to the competitiveness of the United States in a global market through the technology transfer function cannot be denied. The seminal piece of legislation that made that contribution possible was the Bayh-Dole Act. Without doubt, the objectives[45] of the Act has been realized. Through operation under that Act:

(1) Small business, which is frequently the test bed for embryonic university technologies, has benefited to a very large extent;

(2) the government is comforted in knowing that taxpayer dollars, which support the bulk of basic research in the university sector, have lead to the development of products and the use of processes that have advanced the quality of life for its citizens.

(3) industry can rely on a source of technology, data and information and a pipeline of manpower which fulfills its needs and feeds the production processes.

In sum, all sections of society enjoy both the protection and benefits afforded under the Bayh-Dole Act and its progeny.

In recent years, there has been an increasing incidence of efforts to restrict or curtail the technology transfer capabilities of the University sector under the Bayh-Dole Act through government agency actions, agency programs and legislative activities and through agency-industry consortiums. For example, NIH Guidelines regarding the licensing of patentable/patented biomedical research tools would disenfranchise the universities, as well as other non-manufacturing entities utilizing the patent system, from exercising the constitutional-based right vested in the patentee to exclude others from practicing the invention patented.

All licensing professionals understand that no matter how much money is spend on research and development the findings are not going to benefit the public unless there are suitable incentives to invest in commercialization. And because no one knows which venture will succeed, one must strive for a society and an environment ruled by the faith that the guarantee of reasonable profits from risk-taking will call forth the endless stream of inventions, enterprise and art necessary to resolve society's problems.

We have already passed through an era where science was being made subservient to politics. In today's technologically intense atmosphere, where the maximum protection for intellectual property is more than ever necessary to provide protection for the heavy investment necessary to technology development, the entire licensing profession must remain alert.

Even in the current favorable climate for university technology transfer as the heritage of the Bayh-Dole Act, views on the issues in the control of intellectual property, whether by government or special interests, can lend themselves to emotional molding. Outspoken claims to the guardianship of the public interest or welfare are a rich field for cultivating political power. In the struggle to obtain the passage of the Bayh-Dole Act as well as on other pieces of proposed legislation that impacted the university sector, the universities, collectively, spoke with a loud and single voice. Universities will likely continue to do so in all circumstances that threaten the rights and opportunities that they have earned over many years by dint of perseverance, patience and hard work. In sum, technologies licensed from academia have been instrumental in spawning entire new industries, improving the productivity and competitiveness of companies, and creating new companies and jobs. Hence, by all measures, UTT will be an important part of technology-driven economic prosperity well into the next century and perhaps beyond.

Footnotes

1. Dr. Vannevar Bush held the following positions in government: Chairman, National Defense Research Committee 1940; Director - Office of Scientific Research and Development 1941; Chairman - Joint Research and Development Board 1946-47; Member - Research and Development Board of National Military Establishment 1944-48.

2. Harbridge House, Inc., Government Patent Policy Study for the FCST Committee on Government Patent Policy, May 15, 1968 Vol. 11, Parts II and III.

3. See Resume of U.S. Technology Policies - Dr. Betsy Ancker-Johnson - *Les Nouvelles* (Journal of the Licensing Executives Society) Dec. 1976, Vol. XI, No. 4, p. 186; Statement before the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Dec. 11, 1976. (This latter document also contrasts the experience of universities in licensing patents owned by them some or most of which may have resulted from research supported in whole or part by Federal monies.)

4. Presidential Memorandum and Statement of Government Patent Policy (Fed. Reg. Vol. 28, No. 200, October 12, 1963).

5. Presidential Memorandum and Statement of Government Patent Policy (Fed. Reg. Vol. 66, No. 166, August 26, 1971).

6. For historical interest regarding Institutional Patent Agreements and early DHEW practice see Report to the Congress on "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry" by the Comptroller General of the United States, August 12, 1968.

7. P.L. 96-517, Patent and Trademark Amendments Act of 1980. This law amended Title 35 of the United States Code by adding Chapter 18, Sections 200-212.

8. Diamond, Commissioner of Patents v. Chakrabarty, 206 USPQ 193, U.S. Supreme Court.

9. §200. Policy and Objective. "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that 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 to minimize the costs of administering policies in this area."

10. OMB Circular A-124 was subsequently codified as 37 CFR Part 401.

11. The Presidential Memorandum was incorporated into the text of OMB Circular A-124 on March 24, 1984.

12. PL-98-620, The Trademark Clarification Act amended Chapter 18 of Title 25 U.S.C.

13. Final rules were published on March 18, 1987 (52 Fed. Reg. 8552) and subsequently codified at 37 CFR Parts 401.1-401.16.

14. The Association of University Technology Managers, Inc., report entitled "AUTM Licensing Survey, Fiscal Year 2001: A Survey Summary of Technology Licensing (and Related) Performance for U.S. and Canadian Academic and Nonprofit Institutions, and Patent Management Firms."

15. Technology Transfer - Administration of the Bayh-Dole Act by Research Universities, GAO, Report to Congressional Committees May 7, 1998.

16. Department of Health and Human Services, National Institutes of Health, report entitled "NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected"; July, 2001. Link to www.nih.gov to view full report.

17. Singer et al. v. The Regents of the University of California System; and Does 1 Through 50; No. 950381 (Cal. Superior Court for the City and County of San Francisco 1996); 40 USPQ2d 1035.

18. Singer et al. v. The Regents of the University of California System; No. A076331 (Cal Court of Appeal 1st District 1997) (unpublished).

19. Singer et al. v. The Regents of the University of California System; No. S066620 (Cal. Supreme Court 1998) Petition for review denied (without opinion).

20. Report of the NIH Working Group on Research Tools, p. 4, June 4, 1998.

21. See NIH Proposed Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical research Resources; request for Comments, 64 Fed. Reg., No. 100, May 25, 1999, pp. 28205-28209.

22. Id. at 28206.

23. Id.

24. Id. at 28205, footnote 1.

25. Id. at 28207.

26. Id.

27. Id. at 28206.

28. Id.

29. 35 U.S.C. §203.

30. 35 U.S.C.§203(1)(a)-(d).

31. 119 S. Ct. 2199 (1999). Also note that in a companion case, College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board, 119 S. Ct. 2219 (1999) ("College Savings"), the Court affirmed the Third Circuit decision holding that College Savings' Lanham Act claims were barred by Eleventh Amendment immunity.

32. 517 U.S. 44 (1996).

33. 117 S. Ct. 2157 (1997).

34. See Florida Prepaid, at Footnote 30 (quoting Daniels v. Williams, 474 U.S. 327, 328 (1986)).

35. 209 U.S. 123 (1908).

36. See, e.g., Yost v. Early, 87 Md. App. 364, 388 (Md. Ct. Spec. App. 1991) (stating that Maryland conversion law requires the "exercise of unauthorized dominion and control to the complete exclusion of the rightful possessor," and thus not applying to intangible property actions); Miles, Inc. v. Scripps Clinic & Research Foundation, 810 F. Supp. 1091, 1098 (S.D. Cal. 1993) (holding no action for conversion of the right to commercialize a cell line under a three-part test: (1) an interest capable of precise definition, (2) an interest capable of exclusive possession, and (3) a legitimate claim to exclusive ownership) (quoting S.S. Rasmussen & Associates v. Kalitta Flying Service, 958 F.2d 896, 903 (9th Cir. 1992)).

37. See §242 Restatement (Second) of Torts. The rights in patents and copyrights have not been addressed in respect of this document merger requirement and may not qualify for conversion actions under the Restatement view.

38. Quern v. Jordan, 440 U.S. 332, 337 (1979) (holding that the district court remedy constituted impermissible retrospective relief against a state).

39. See Footnote 30.

40. Parden v. Terminal Rail Company of Alabama Docks Department, 377 U.S. 184 (1964).

41. International Shoe v. State of Washington, 326 U.S. 310 (1945).

42. ABA Section of Intellectual Property Law, Chair's Bulletin, Vol. 6, No. 1, Page 4, September 2001.

43. S.1611 – "Intellectual Property Protection Restoration Act of 2001." Introduced by Senator Patrick Leahy (D-Vermont) to the United States Senate (107th Congress (1st Session)) on November 1, 2001.

44. See letter from Mr. Charles P. Baker, (then) Chair, ABA Section on Intellectual Property Law to The Honorable Patrick Leahy (February 22, 2002). Available online at http://www.abanet.org/intelprop/107legis/honleahyletter161.html

45. See Footnote 9.

PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

35 U.S.C. Sections 200-212

35 U.S.C. 200 Policy and objective.

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to 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 to minimize the costs of administering policies in this area.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3019, "The Bayh-Dole Act")

35 U.S.C. 201 Definitions.

As used in this chapter:

(a) The term "Federal agency" means any executive agency as defined in section 105 of Title 5, United States Code, and the military departments as defined by section 102 of Title 5, United States Code.

(b) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, 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

of experimental, developmental, or research work under a funding agreement as herein defined.

(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) **The term "invention" means any invention or discovery that is or may be patentable or otherwise protectable under this title or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.).**

(e) The term "subject invention" means any invention of the contractor **conceived or first actually reduced to practice in the performance of work under a funding agreement:** *Provided,* That in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(g) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) The term "small business firm" means a small business concern as defined at Section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(i) **The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.**

(Subsection (d) amended Nov.8, 1984, Public Law 98-620, sec. 501(1), 98 Stat. 3364.)
(Subsection (e) amended Nov. 8, 1984, Public Law 98-620, sec. 501(2), 98 Stat. 3364.)
(Subsection (i) added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3019.)

35 U.S.C. 202 Disposition of rights.

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided, however,* That a funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter, (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities, or (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's

right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

(b) (1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in clauses (i) through (iii) of subsection (a) exists. Except in the case of subsection (a)(iii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses.

(3) At least once every five (5) years, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

(4) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the last paragraph of section 203(2).

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided*, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: And *provided further*, That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in

other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights; including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreements relating to weapons development and production.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided*, That any such information, as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of Title 5 of the United States Code.

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with the inventor; (C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research, or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operator facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100% of the balance of any royalties or income earned and retained by the contractor during any fiscal year, up to an amount equal to five percent (5%) of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility provided that if said balance exceeds five percent of the annual budget of the facility, that 75% of such excess shall be paid to the Treasury of the United States and the remaining 25% shall be used for the same purposes as described above in this clause

(D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(8) The requirements of sections 203 and 204 of this chapter.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) in any case when a Federal employee is a co-inventor of any invention made under a funding agreement with a nonprofit organization or small business firm, the Federal agency employing such co -inventor is authorized to transfer or assign whatever rights it may acquire in the subject invention from its employee to the contractor subject to the conditions set forth in this chapter.

(f) (1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

(Subsection (a) amended Nov. 8, 1984, Public Law 98-602, sec. 501(3), 98 Stat. 3364.)
(Subsection (b)(2) amended Nov. 8, 1984, Public Law 98-620, sec. 501(4), 98 Stat. 3365.)
(Subsection (b)(4) added Nov.8, 1984, Public Law98-620, sec. 501(4A), 98 Stat. 3365.)
(Subsection (c)(4) amended Nov. 8, 1984, Public Law 98-620, sec. 501(5), 98 Stat. 3365.)
(Subsection (c)(5) amended Nov. 8, 1984, Public Law 98-620, sec. 501(6), 98 Stat. 3365.)
(Subsection (c)(7) amended Nov. 8, 1984, Public Law 98-620, sec. 501(7), (8), 98 Stat. 3366.)
(Subsection (f)(2) added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3020.)
(Subsection (b)(3) amended Dec. 10, 1991, Public Law 102-204, sec. 10, 105 Stat. 1641.)

35 U.S.C.203 March-in-rights.

(1) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder, to require the contractor, an assignee, or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such:

(a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(c) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(d) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

(2) A determination pursuant to this section or section 202(b)(4) shall not be subject to the Contract Disputes Act (41 U.S.C. 601 et seq.). An administrative appeals procedure shall be established by regulations promulgated in accordance with section 206. Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, as appropriate, the determination of the Federal agency. In cases described in paragraphs (a) and (c), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3022; amended Nov. 8, 1984, Public Law 98-620, sec. 501(9), 98 Stat. 3367.)

35 U.S.C. 204 Preference for United States industry.

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3023.)

35 U.S.C. 205 Confidentiality.

Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of

any document that is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3023.)

35 U.S.C. 206 Uniform clauses and regulations.

The Secretary of Commerce may issue regulations that may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance.

(Amended Nov. 8, 1984, Public Law 98-620, sec. 501(10), 98 Stat. 3367.)

35 U.S.C. 207 Domestic and foreign protection of federally owned inventions.

(a) Each Federal agency is authorized to:

(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of Chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract; and

(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce authorized to:

(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3023; amended Nov. 8, 1984, Public Law 98-620, sec. 501(11) 98 Stat. 3367.)

35 U.S.C. 208 Regulations governing Federal licensing.

The Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned

by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3024; amended Nov. 8, 1984, Public Law 98-620, sec. 501(12), 98 Stat. 3367.)

35 U.S.C. 209 Restrictions on licensing of federally owned inventions.

(a) No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention, except that any such plan may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under Section 552 of Title 5 of the United States Code.

(b) A Federal agency shall normally grant the right to use or sell any federally owned invention in the United States only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

(c) (1) Each Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a federally owned domestic patent or patent application only if, after public notice and opportunity for filing written objections, it is determined that:

(A) the interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public;

(B) the desired practical application has not been achieved, or is not likely expeditiously to be achieved, under any nonexclusive license which has been granted, or which may be granted, on the invention;

(C) exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment of risk capital and expenditures to bring the invention to practical application or otherwise promote the invention's utilization by the public; and

(D) the proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention's utilization by the public.

(2) A Federal agency shall not grant such exclusive or partially exclusive license under paragraph (1) of this subsection if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with the antitrust laws.

(3) First preference in the exclusive or partially exclusive licensing of federally owned inventions shall go to small business firms submitting plans that are determined by the agency to be within the capabilities of the firms and equally likely, if executed, to bring the invention to practical application as any plans submitted by applicants that are not small business firms.

(d) After consideration of whether the interests of the Federal Government or United States industry in foreign commerce will be enhanced, any Federal agency may grant

exclusive or partially exclusive licenses in any invention covered by a foreign patent application or patent, after public notice and opportunity for filing written objections, except that a Federal agency shall not grant such exclusive or partially exclusive license if it determines that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the United States in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with antitrust laws.

(e) The Federal agency shall maintain a record of determinations to grant exclusive or partially exclusive licenses.

(f) Any grant of a license shall contain such terms and conditions as the Federal agency determines appropriate for the protection of the interests of the Federal Government and the public, including provisions for the following:

(1) periodic reporting on the utilization or efforts at obtaining utilization that are being made by the licensee with particular reference to the plan submitted: *Provided* That any such information may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under Section 552 of Title 5 of the United States Code;

(2) the right of the Federal agency to terminate such license in whole or in part if it determines that the licensee is not executing the plan submitted with its request for a license and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

(3) the right of the Federal agency to terminate such license in whole or in part if the licensee is in breach of an agreement obtained pursuant to paragraph (b) of this Section; and

(4) the right of the Federal agency to terminate the license in whole or in part if the agency determines that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by the licensee.

(Added Dec. 12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3024.)

35 U.S.C. 210 Precedence of chapter.

(a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following:

(1) Section 10(a) of the Act of June 29, 1935, as added by title 1 of the Act of August 14, 1946 (7 U.S.C. 427i(a); 60 Stat. 1085);

(2) Section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624(a); 60 Stat. 1090);

(3) Section 501(c) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951(c); 83 Stat. 742);

(4) Section 106(c) of the National Traffic and Motor Vehicle Safety Act of 1966 (15 U.S.C. 1395(c); 80 Stat. 721);

(5) Section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871(a); 82 Stat. 360);

(6) Section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943);

(7) Section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457);

(8) Section 6 of the Coal Research Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337);

(9) Section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920);

(10) Section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634);

(11) Subsection (e) of section 302 of the Appalachian Regional Development Act of 1965 (40 U.S.C. App. 302(e); 79 Stat. 5);

(12) Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5901; 88 Stat. 1878);

(13) Section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 86 Stat. 1211);

(14) Section 3 of the Act of April 5, 1944 (30U.S.C. 323; 58 Stat. 191);

(15) Section 8001(c)(3) of the Solid Waste Disposal Act (42 U.S.C. 6981(c); 90 Stat. 2829);

(16) Section 219 of the Foreign Assistance Act of 1961 (22 U.S.C. 2179; 83 Stat. 806);

(17) Section 427(b) of the Federal Mine Health and Safety Act of 1977 (30 U.S.C. 937(b); 86 Stat. 155);

(18) Section 306(d) of the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1226(d); 91 Stat. 455);

(19) Section 21(d) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2218(d); 88 Stat. 1548);

(20) Section 6(b) of the Solar Photovoltaic Energy Research Development and Demonstration Act of 1978 (42 U.S.C. 5585(b); 92 Stat. 2516);

(21) Section 12 of the Native Latex Commercialization and Economic Development Act of 1978 (7 U.S.C. 1780); 92 Stat. 2533); and

(22) Section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360).

The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act.

(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the performance of funding agreements with persons other than nonprofit organizations or small business firms.

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of

agencies to allow such persons to retain ownership of inventions, except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in Paragraph 202(c)(4) and Section 203 of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized.

(d) Nothing in this chapter shall be construed to the require the disclosure of intelligence sources or methods or to otherwise affect the authority granted to the Director of Central Intelligence by statute or Executive order for the protection of intelligence sources or methods.

(Subsection (c) amended Nov. 8,1984, Public Law 98-620, sec. 501(13), 98 Stat. 3367.)
(Subsection (d) added Dec. 12,1980, Public Law 96-517, sec. 6(a), 94 Stat. 3026.)

35 U.S.C. 211 Relationship to antitrust laws.

Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or create any defenses to actions, under any antitrust law.

(Added Dec.12, 1980, Public Law 96-517, sec. 6(a), 94 Stat. 3027.)

35 U.S.C. 212 Disposition of rights in educational awards.

No scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(Added Nov. 8, 1984, Public Law 98-620, sec. 501(14), 98 Stat. 3368.)