University Licensing: An Insider's Perspective

Mark G. Bloom

evassgaddiff uteiblert ralug densoll hyteraunut .

mosti e disti

Biography of Mark G. Bloom

Mark G. Bloom is the Wisconsin Alumni Research Foundation (WARF) Licensing Associate primarily responsible for protecting and marketing computer software and multimedia works developed at the University of Wisconsin-Madison.

Mark received his BS from the Ohio State University and his JD from the Franklin Pierce Law Center. While at Franklin Pierce, he served as Issue Editor of IDEA: The Journal of Law and Technology. Mark is a member of the State Bars of Wisconsin, New York, and Massachusetts, the Second Circuit Court of Appeals, the Seventh Circuit Court of Appeals, the Court of Appeals for the DC Circuit, the Court of Appeals for the Federal Circuit, the US Court of Federal Claims, the US Court of International Trade, the US Supreme Court, and is registered to practice before the United States Patent and Trademark Office. In addition, he is an active member of numerous professional organizations including the American Bar Association, the American and Wisconsin Intellectual Property Law Associations, the Licensing Executives Society, the Association of University Technology Managers, the Association for Computing Machinery, the Computer Society of the Institute of Electrical and Electronic Engineers, and the American Association for the Advancement of Science. Before attending law school, Mark worked in sales and marketing for the pharmaceutical, medical device, and medical diagnostic software industries. Immediately prior to joining WARF, Mark was a marketing and legal consultant to computer software and biotechnology-based start-up companies.

Mark brings more than fifteen years of corporate sales, marketing, and intellectual property law experience to WARF.

When not traveling in Cyberspace on business, Mark and his wife Becky reside in Madison.



University Licensing: An Insider's Perspective

CONTROL WAS NOT BE A SECOND OF SECOND

and become the all of the second of the second

e politik virgan pri i sendrok pominanak pala dali betapat barakan wali 5,700 (bi

and the second of the companies of the street of the second of the secon

Mark G. Bloom, Esq.

Franklin Pierce Law Center
Advanced Licensing Institute
Concord, NH

ant y togreg fruits. From <mark>box og</mark> fruikrær oplike ikkærgen Spoueto, fru i 19 km met het helfal i ståk

July 19-23, 1999

WHY SHOULD WE PROTECT INTELLECTUAL PROPERTY RIGHTS?

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

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

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

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

Professor Nathaniel Shaler Harvard University c. 1936

University Licensing: An Insider's Perspective

Mark G. Bloom, Esq.
Licensing Associate
Wisconsin Alumni Research Foundation

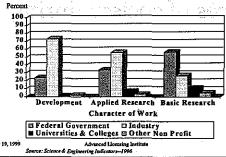
Genesis of University TT

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

July 19, 199

Advanced Licensing Institut

National R&D Expenditures by Source of Funds



National R&D Expenditures by Performing Sector Percent 100 90 80 100 100 Development Applied Research Basic Research Character of Work E Federal Government | Industry M Universities & Colleges | Other Non Profit July 19, 1999 Advanced Licensing Indiance 4

The University-Industry Connection in the United States

- A recognition within government circles that basic research conducted by the university sector provided a vehicle for enhancing the national economy by increasing the flow of knowledge to be used by industry.
- The establishment and success of several research-oriented agencies of the Federal government, in particular the National Institutes of Health and the National Science Foundation, the formation of which was stimulated by that recognition.
- The ultimate passage of legislation which gave the universities the first option to retain title to inventions conceived or made during the course of research conducted by university personnel with funds obtained from the Federal government through its various agencies.

July 19, 1999

Advanced Licensing Institute

Federal Legislation Re: Cooperative Technology Programs

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

July 19, 1999

Advanced Licensing Institut

Federal Legislation

Re: Cooperative Technology Programs

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

July 19, 199

Advanced Licensing Institute

Dependence of Industry on Academic Research By Percentage

Products	Processes		
28	27		
9	7		
8	6		
21	3		
44	37		
22	21		
2			
	28 9 8 21 44 22		

Source: Science & Engineering Indicators—1989 (Mensfield)
July 19, 1999 Advanced Licensing Instit

Institutions	Having	Technology	Transfer
Programs -			

1972

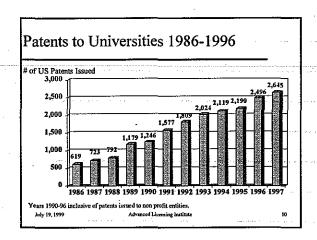
30

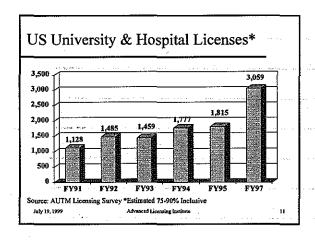
1997

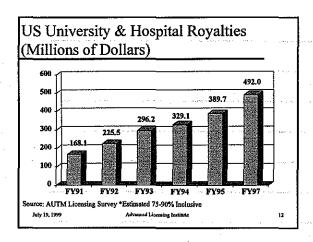
275°

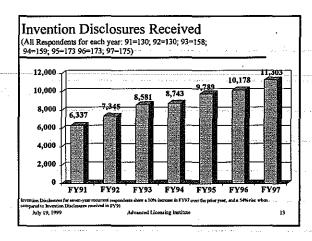
July 19, 1999

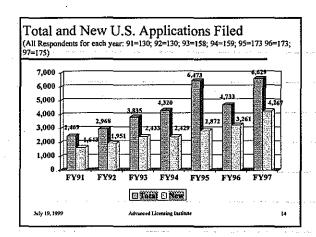
Advanced Licensing Institute



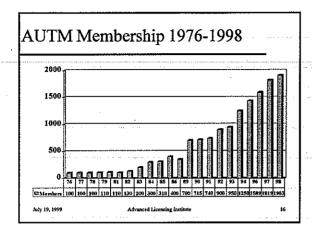








FY 1980- FY 1993 (N=154)	FY 1994 (N=156)	FY 1995 (N=172)	FY 1996 (N=168)	FY 1997 (N=171)	Total FY 1980 to FY 1997	
1,169	· 241	223	248	333	2,214	
						J



Universities are Different

- ◆ Politics are Alive and Well!
- ◆ Faculty Controlled v. Administration
- ◆ TTO Separate v. Integral
- ◆ TTO Resources
- ◆ TTO Control over Faculty (Ego2)

July 19, 1999

Advanced Licensing Institu

Funding Agreement under BDA

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

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

July 19, 1999

Advanced Licensing Institute

18

	A section of the market of the section of the secti
	enter en
:	Minima na nasa mananggala.
:	an a
	को जन १, १५ वर्ष के अने विकास प्रकार की बिजान के लोग के प्राप्त के प्राप्त कर है। अभिन्न के बार्ग के लोग के बीच के लिए
	- El Peris Manescen, capitalista (Nov. 1900) est esta platación (P Majorit, a hyll 2000) este esta persona (Novembra
	The state of an initial reports on the annual of
: .	
1	the surgestable system to the states

Invention Definition under the BDA

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

July 19, 1999

Advanced Licensing Institute

19

Subject Invention under the BDA

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

July 19, 1999

Advanced Licensing Institute

20

Title Sequence under the BDA

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

July 19, 1999

Advanced Licensing Institute

Exceptions to the BDA Requirement to Give Federal Agency Rights		E program and the Charles of Charles and the Charles of
35 U.S.C. 212 No scholarship, fellowship, training grant or other funding agreement made by a Federal agency primarily to an awarded		
for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.		
·		The second of th
July 19, 1999 Advanced Literating Institute 22		
· · · · · · · · · · · · · · · · · · ·		and the second of the second o
Important BDA Preference (1)		A MARTINE AND A SECTION AND AND AND AND AND AND AND AND AND AN
A CONTRACTOR OF THE CONTRACTOR		<u> </u>
◆ Preference for US-based licensees vs. Non-US-based licensees	no e o o	
A MANAGEMBER OF A STATE OF A STAT		To the property of the second second to the second
Suly 19, 1999 Advanced Licensing Institute 23		
	•	
Important BDA Preference (2)		eng jarah salah sa
◆ Preference for Small Business licensees vs. Large Business licensees		The state of the s
	e de la composición del composición de la compos	La company of the figure and the respect to the effective and the second of the second
July 19, 1999 Advanced Licensing Institute 24	**********	

Important BDA Preference (3) • Preference for Non-exclusive licenses vs. Exclusive licenses Other Important BDA Terms ◆ Inventor(s) must receive share of royalties ◆ No predetermination of royalty rates or royalty thresholds. ◆ Technology must be developed by licensee, i.e., "use it or lose it". **BDA Conclusions** ◆ Three things contributed to the success of the BDA and technology transfer under it: - Certainty of title in the inventions; - The inventor remains in the development picture; - There is uniformity in the handling of intellectual property under ◆ Keep in mind that success was achieved without cost to the taxpayer as occurs with other government programs.

Most Important TT Issues

- ◆ Maintenance of Academic Freedom
- ◆ Proper Attribution
- ◆ Equitable Recognition of University Role
- ◆ Equitable Sharing of Royalties

July 19, 1995

dvanced Licensine Institute

28

Biggest SR TT Mistake No. 1

- ◆ Placing unreasonable restrictions on a faculty member's right to publish research results, i.e., seriously impinging upon or outright preventing the exercise of academic freedom.
 - onerous confidentiality requirements are bad news
 - short publication delay for patentability review is usually an acceptable compromise

July 19, 1999

Advanced Licensing Institute

29

Biggest SR TT Mistake No. 2

- ◆ Requiring some level of control over facultybased publications resulting from sponsored research efforts.
 - requiring editorial control is bad news
 - requiring publication approval is bad news

July 19, 199

dvanced Licensing Institute

Biggest SR TT Mistake No. 3

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

July 19, 1999

Advanced Licensian Institut

31

WARF SR Position

- ◆ Right to the first good-faith negotiation for a royalty-bearing license to a technology:
 - developed solely by University researcher(s)
 - utilizing specific sponsored research monies.

July 19, 1999

Advanced Licensing Institute

32

Licensee Due Diligence (1)

- ◆ Has the University filed patent applications in all of the relevant markets for the technology?
 - domestic vs. foreign rights
 - filing costs are an issue

July 19, 199

Advanced Licensing Institute

	Licensee Due Diligence (2)		
	◆ Have the University inventor(s)' published their ideas prior to the filing of appropriate patent applications?	_	Selection State Street (12) when we had believed to be a selection of the control
	- If yes, how long ago?		
	and the second of the second o	<u></u>	
	and the second of the second o		
	July 19, 1999 Advanced Licensing Institute 34		
ı		1	
	Licensee Due Diligence (3)	-	The state of the s
	and the second s		
	◆ Has a validity analysis been conducted to		 In the Assemble operation of the participation.
- 1	determine whether the patents that have been applied for by the University are likely to issue?	l . –	
	- pre-filing by University		
ł	- pre-agreement by Licensee		
	And the second control of the second control	···	;
	July 19, 1999 Advanced Linearing Institute 35		
ı		7	and the state of t
	المنظمة المنظمين الم	en e	and the second of the second o
	Licensee Due Diligence (4)		the second secon
	A CAMPAGNA		ui non Nill Nerling (1944), and di li 1940 (1974).
	◆ Is the technology properly the subject of patent protection, or are there other forms of IP	· · —	
	protection that would be more appropriate?] <u> </u>	and the state of t
	- trade secret - copyright		Market Control (Market Control
	– PVPA		
. [- nlant natent	1	

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

July 19, 1999

Advanced Licensing Institute

37

Licensee Due Diligence (6)

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

July 19, 199

Advanced Licensing Institute

32

Licensee Due Diligence (7)

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

July 19, 1999

Advanced Licensing Institute

Licensee Due Diligence (8) ◆ Besides a consulting arrangement or institutional royalty-sharing policies, are there other financial incentives a licensee can offer an inventor? - equity stake - stock options July 19, 1999 Licensee Due Diligence (9) ◆ Have the IP policies, sponsored research guidelines, conflicts-of-interest policies, etc., of the university been obtained and reviewed by licensee's counsel? - Surf the Net! Licensee Due Diligence (10) ◆ Do you know the proper party with which you

42

should be negotiating an agreement, i.e., are you dealing with a person or entity that can legally bind the university to a contractual

arrangement?....

Spirit von Station Station

The (Infamous) Singer Case

- ◆ Singer vs. The Board of Regents of the University of California System
 - royalties vs. sponsored research dollars
 - university IP policies are key
 - places negotiation strategy under strict scrutiny
 - inventor(s) must be kept fully informed

July 19, 1999

Advanced Licensing Institute

43

Final Words of Advice

- ◆ Look to Universities as rich source for cuttingedge technologies
- ◆ Explore all means of University TT
 - licenses
 - faculty and students
- ◆ Know University IP/TT policies
- ◆ Recognize University TT strengths/weaknesses
- ◆ Treat University as equitable TT partner

July 19, 199

Advanced Licensing Institu

More Information

Mark Bloom 608.263.2830

mgbloom@facstaff.wisc.edu Internet: www.wisc.edu/warf

Copyright © 1999 WARF

July 19, 1999

Advanced Licensine Institute

University Technology Transfer: Evolution and Revolution

文字系数数 MS 20 字可可引擎解示的图 《元·安尔》是《美国

estimine i bac rejitari

upali pasaraji Wilas sah

by

Howard W. Bremer, Esq.

Revised and Updated by Mark G. Bloom, Esq.

राजे हैं। इंदेवरा नकी हमारी, जाकी हुए व बुदार का 👪 🧸 हैं।

University Technology Transfer: Evolution and Resolution

by

Howard W. Bremer, Esq.

Revised and Updated by Mark G. Bloom, Esq.

I.	Prologue	Theresia.	A BELLEVA BELLEVA	
II.	Technology Transfer De	fined		

Intellectual Property

- A. Constitutional Basis
- B. Nature of University Research
- C. The Government Sector
- D. Government Policy-Move Towards Uniformity
- E. Institutional Patent Agreements
- F. The Bayh-Dole Act
- IV. The Economic Climate
- V. Government Patent Policy Reshaped
- VI. The Impact of the Bayh-Dole Act
- VII. Heritage of the Bayh-Dole Act
- VIII. Commentary

III.

University Technology Transfer: Evolution and Revolution

Bar dan angula ga Marasig**i k**alalang salah dikebiji b

references that fagure each experience

"Upon this gifted age, In its dark hour,
Rains from the sky a meteoric shower
Of Facts - They lie unquestioned, uncombined Wisdom enough to leech us of our ill
Is daily spun, but there exists no loom
To weave it into fabric.

-- from a poem by Edna St. Vincent Millay

I. 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.

II. <u>Technology Transfer Defined</u>

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 the President Harry Truman in 1945 by Dr. Vannevar Bush¹ 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 a recognition of 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.

in and 1940 services in the millioning research in spaces principles on integral in presence with

and the artists of the second section of the second section is sectional.

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.

region was delegate pale grat accepting to protoners, est reporter plant, at all the costs, and the correct

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.

respirate interespirar calabra colori di calabra de calabra de la segli de pare la segli de calabra de la cola

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. Such ownership may be manifested by patents, copyrights, trademarks, trade secrets or a proprietary right in the tangible products of research.

III. Intellectual Property we have an include a continuous consequence where the interest of the continuous co

A. Constitutional Basis

As we all know, the Constitution was drafted in the context of a struggle with a government which 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 1, Section 8:

Described distribution of the content is a content of the content

"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 8, 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.

anis parimente vanos gritas as estos arecemos acisos. O temprio mais reternos enistes polícies e meigre con cad

dada, Barak izani sebi bar Barampazkan Barampan bah masali ya Birak Baramta di Baramas da ka

referentiation and sequence is the set of the research and similar of the sequence of the five

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:

and the lightest of a thrown in the contract of the early result is self-through the contract of the contract of

and first the course of the control of the control of a confict that are the control of the control over fi

Sinan Lina (Sina), in kalaman kenalagana produce kermi, kanalah s

"—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 at 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.

and the second of the second of the second

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.

aken dipara la mêjirin. Li sekom ji rajîn, îngala ni yewen embizî rek, îk nambi kende ni, inkêrerî.

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. 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 Sate University, Battelle Development Corporation, Research Corporation (which represented an 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.

There was not the control of the con

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.

in readoning as in the Independent of the days of the Depayler Alterday, including its species of

The Labertan transporter scheduler is to the region of the region of the region of the course of the region of

Johnston Commission (in Evolution)

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.

en les en este en la la companya de la companya de

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 which gave the

laren elika a teoritarre en talente late promite a ten elika applicata al ritogra esta en parti en escatigia e

agencies the right to hold patents or license technology. Such acts were viewed as objectives of the agency mission. Consequently, each governmental agency which 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, since to support a given research pursuit, funds from different agencies were often co-mingled, 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 nonuse. 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 which 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.

ally compliant to the relativistic political control or an interpolation of the expension of the project of the control of the

An interesting comparison along these lines was made by Harbridge House² in its 1968 study of Government-funded patents put into use between 1957 and 1962. It was found that contractorheld 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 effect 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. Kennedy⁴ 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. 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 governmentsponsored 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 design of the attributed to the Book of expression at an expect the two by the Propiets

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 which 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.

ídh

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. <u>Institutional Patent Agreements</u>

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 Agreement⁶ between the National Science Foundation and the University of Wisconsin-Madison (again, via WARF). The first ever of such agreements 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.

March 2 and in 2004, and an internal leaf of the first of a second record of the contraction

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 the Bayh-Dole Act). In fact, that law is often looked upon as a codification of the terms and provisions of the IPAs.

provide the paragraph of the color of the first only on the a force made \$1000 to the color of the paragraph.

F. The Bayh-Dole Act 7

The passage of the Bayh-Dole Act was the reward for almost 20 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:

Turk to the content of the property of the property of the property of the second and the solvest

a transfer of the second of the second and the second of t

- (1) that imagination and creativity are truly a national resource;
- that the patent system is the vehicle which permits us to deliver that resource to the public;
- (3) that 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) that 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 which 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 which actually controverted the law and its intention. As a consequence, much greater attention was given to the regulations by a university group which 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.

er frank i vila de komunitario e franksi e filologia e filologia e egitorrelik men kansen kan filologia.

vigat fig. (1) in the light of place, we introduce the first of the light of page and the first operation

IV. The Economic Climate and the problem from the state of the real management of the lightness

To more fully appreciate what has evolved through the sequence of events which 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);
- 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.

and tradition Annal Experience of a factor law takes in the relation of experience with the backets. See

Para di La Salanglia di Propinsi Nasa da Comeniación de

With the passage of the Bayh-Dole Act and, in the same year, the decision of the Supreme Court in the Chakrabarty Case, 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.

Strate Strates and periodic in the of recently of the region in the region of north of their court

raditi aneka labaran gadendan atradan gararan a langdalik pandangnan sebe

V. 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.

r de la colo de la colo

and the same of a common contraction in the contract of a section was

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 which 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;
- 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:

n transfering for the company between the company of the first for all the first of the company of the first

avor engels diesere Bedhalait a and 6 and 9 Eag

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. 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 Policy¹¹ 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.

to a blance ablancilares es miles millos

vid i i sufficie i kristitet. 2001 zan e 201 asaya di palek, swa za za ki

The fourth event was the amendment of the Bayh-Dole Act by Public Law 98-620¹² 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 which 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 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.

Architecture (C. A. Charletter, C. Barrier, C. Barrier

calle will grant as in the character of which is an inventor of the basis of the decision of the call

tionerges/auditer and reserve in a server and the compression of the server and a final service will be the com-

MESA - Effecti interesa in teleji pesa izerbite yritne vina sai - i i estave sa endrusava ovi a gelati neg

od dianagy ra**žubi**tom s tomnie (Deus ord en jos ii) sala verska koj vejda kara a silvi sredjel L

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.

VI. 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.

rak kaji mosta komining i tili mengala kata kanang mengalah katapan miningkah mengalagan pengalakan katapan

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 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 fiscal year 1996, the university sector reported almost 11,000 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 1997 reached 11,303. The number of total and new applications filed, as might be expected, have also increased year-to year to a total of 6,629 new applications in 1997.

n de grinn af ne dals altre francische staffen als appalaentent om beautre der der datalliken zu de Konina schiali

As a result of these patenting and licensing activities, universities and teaching hospitals have experienced growing royalty income which reached 492 million dollars in 1997. 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 fiscal 1996, the percent increase from the previous year was 8.4 percent for recurring correspondents in the AUTM survey. About 10.9 percent of the licenses or options granted were to start-up companies. 54.7 percent were to small businesses. Moreover, at the end of fiscal 1996, the university sector reported 10,487 active licenses or options, the latter being up by 12.9 percent over the previous year. The number of such licensees and options producing income increased by 16.1 percent over the previous year while the income of \$365.2 million generated by those activities in 1996 represented an increase of 22.1 percent over 1995.

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 AUTM Survey, more than 2,200 new university-technology-based start-up companies have been formed since 1981. 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.

generalise in generalise se de la financia de la compania de la compania de la compania de la configuración de

The impact of the Bayh-Dole Act is also seen in other indicators. For example, another excellent indicator which 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 approximately 2000. 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.

entre de la procesa de la comercia de la desta propera de la comercia de la procesa de la comercia de la colora

ANG BORD DE LES MAN BERTHER DE ALBERT DE LE SELECTION DE LE CONTRACT DE LE CONTRA

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 60.2% of all funding in 1995, 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:

da a contra a militar en la calenda grandiga de la conflictat de mandante, en la colonidad de frativo de saffe

o como o filografia de los comos estes de la comosta de acolo de este como como como como como como como este c

- (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.

ogas. Porabilismo son terrapa son å biggera plimomra operativa a norsomer klagset in sok 1996 och

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 economic benefits flowing from the universities' licensing activities adds about \$24.8 billion per year to the United States economy.

องได้รับเรียกที่ครอดักรู สมาบาร์ตา สองสมบาย ค.ศ.พมธ์ค.ศ.คระ 535 เคราะรักษณะเดิดสมบาท มาโดยที่เมาโทก เรื่

Significant as that dollar amount is, 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.

VII. 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, most have not. One piece of legislation which could be 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 act had been intended to promote the utilization of technology generated in government laboratories, but was singularly unsuccessful in accomplishing that goal.

Relateration from Mark (1995), and Markymon a March, all of the control of the co

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.

all thought to not unlike accountly through a real of the bow out business been countliked to 1.00

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.

e li purpo esplicar o recréa remener e con en propo e la filopo de le publica e que enpo depar

The second of Statement Company of Selection (1994) and selection

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.

na centra alla coma casa la stata coma tra il quentra traditoria di sua entra con contra con la cita di nato c

VIII. Commentary

The growth of technology transfer has taken place over the last 30 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. During that period we have seen a dramatic change in the attitude of the justice department and the interpretation of the anti-trust laws where patents and anti-trust are no longer viewed as antithetical. We have seen a move toward a favorable statutory basis under which we have much greater freedom to operate. We have had an active effort by various administrations to obtain equitable treatment for U.S. citizens in foreign venues, both in trade and intellectual property pursuits. We have had numerous and far-reaching changes in the patent laws of those foreign venues which have provided greater opportunities for technology transfer to these venues. We have also experienced extensive changes in our own patent laws and practices which have further expanded the opportunities to engage in technology transfer. We have had the benefit of a knowledgeable court in the Court of Appeals for the Federal Circuit which has slain many of the mythical dragons attached to intellectual property law to provide

uniformity of interpretation of those laws and before which we can expect equitable treatment.

We have obtained the attention of congress and, particularly, the attention in that body to the university sector's perspective on intellectual property law issues. We have seen the introduction and passage of legislation favorable to the universities and their technology transfer efforts. We have also seen developed, not only in the university sector, but in university-industry relationships and university-industry-government relationship, a greater awareness of technology transfer and a growing recognition of the possibilities which can be made available through creative technology transfer efforts and a much greater sophistication in handling those possibilities. Today we operate in a climate which recognizes the value of intellectual property and the technology transfer function. We 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.

However, a word of caution! We work in a very uncertain business where, on the average, it takes in excess of ten years and hundreds of thousands, even millions, of dollars to bring an invention to the marketplace. We must also remember that, as a licensor, we have very little actual control over the process by which an invention is brought to the market or how, ultimately, it is marketed. We are always vulnerable to the attacks of special interest groups, whether inside or outside government, which are based not on fact but on emotion or which may be waged for psychological reasons. As long as envy and jealously are part of the human condition such attacks are inevitable, only the intensity will rise and fall.

the comparison beautiful and the parties of the first behind the first of the comparison of the compar

Alary, which styles actuals in a secretary and following a second state and multi-

The emphasis today, 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 which made that contribution possible was the Bayh-Dole Act. Without doubt, the objectives 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;

detain and deute in the Contract and debet in the contract of the contract of the contract the contract of the

- (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.

an ing paramatan at at manggraphy ping talah banggraphy ang manggraphy ping panggraphy panggraphy ang ang ang

In recent years, we have been experiencing 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, pending legislation 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.

personal frainces and climical in the construction of the construction of the construction of weather from the

We must understand that no matter how much money we 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, we 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. The words of the poet Edna St. Vincent Millay seem to have been written especially for this situation.

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, we must remain alert.

in a character of the company of the contract of the contract

Massan i sikali fiziki diliki sebeli

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 is a rich field for cultivating political power. We must never forget that freedom demands a constant price and that vigilance is essential. To quote the classic comic strip character Pogo, "We have met the enemy and they is us."

In the struggle to obtain the passage of the Bayh-Dole Act as well as on other pieces of proposed legislation which impinged on the university sector, the universities, collectively, spoke with a loud and single voice. We must continue to do so in all circumstances which threaten the rights and opportunities which we have earned over many years by dint of perseverance, patience and hard work. This will require a unified, active and continuing participation by all members of the university sector.

起头 经数据分类的 海 人名英格兰人姓氏克斯特住所名词名 计分配的 电影克克克斯斯特

in the first set of the companies of the contraction of the contractio

o de la Grande Company de la company de Al company de la company d

o autorial du filipio de la come de 190 de mais particolos filmentes en la come autorio de come los comes de d

车载 到了她,一样都在一家,你就要要你的话,一个人的话,一点一点,一点,只是大家的话,这个女人的话,不是不不会,这是

DATE IN ANY CONTROL OF THE OF TWO YES APPLICATED AND ANY CONTRACTOR

gat nadje MANG (1886), in tolijene des jelenje, en nadalje ji najskom nemije, kasa let. Best Militaria se nastana izvirenskom sadenje letje i koje nemi najskom kom kom silen.

De tradition in infraerament were find to a molecular or earlier of the first demangement in the makened The original contribute and members that a product of the people of the first one contribute of the original

Control of the second of the second of the second of

e and the complete of the rest and in the application and application of the control of the cont

Out primarily will a status time of the calculation of an existing surface

Romania de la como de la Romania de la como d

North and complete again the second

garage a garage of the company of a first angles.

"THE HERITAGE OF THE PAST IS THE SEED
THAT BRINGS FORTH THE HARVEST OF THE
FUTURE."
17

医性神经病 化二烷基 经销售工厂 联络的战争

hanest dat betil harmon a stored to

S. 1888

Endnotes

² Harbridge House, Inc., Government patent Policy Study for the FCST Committee on Government Patent Policy, May 15, 1968 Vol. II, 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 (F.R. Vol. 28, No. 200, October 12, 1963).
- ⁵ Presidential Memorandum and Statement of Government Patent Policy (F.R. Vol. 66, No. 166, August 26, 1971).
- ⁶ For historical interest re 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 United States Code by adding Chapter 18, Sections 200-212.
- ⁸ Diamond, Commissioner of Patents v. Chakrabarty, 206 USPO 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 Unites 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 37CFR 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 (52FR8552) and subsequently codified at 37CFR Part 401.1-401.16.
- ¹⁴ The Association of University Technology Managers, Inc., report entitled "AUTM Licensing Survey, FY 1997: A Survey 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 See note 9.
- ¹⁷ From a tablet affixed to the front of the National Archives in Washington D.C.

¹ 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.

About the Authors

Howard W. Bremer is Special Patent and Legal Counsel to the Wisconsin Alumni Research Foundation (WARF), located in Madison, WI. Since joining WARF in 1960, Mr. Bremer has been instrumental in facilitating many of the key legal agreements and technology transfer-based legislation outlined in this paper. His untiring and ultimately successful efforts to obtain passage of the Bayh-Dole Act are especially noteworthy. A 1949 graduate of the University of Wisconsin School of Law, Mr. Bremer was also a founding member of both the Licensing Executives Society (LES) and the Association of University Technology Managers (AUTM).

Mark G. Bloom is a Licensing Associate with WARF and is a 1992 graduate of the Franklin Pierce Law Center.

in Franklika with source experimentation that is, which we also recovered the experimental contribution of the

HEATH CHECKER AND A SECRET RESIDENCE OF PRODUCTS ARE ARRESTED FOR THE PRODUCT OF A SECRET PRODUCT OF

ge in de proposition de la completa de la completa de la proposition de la completa de la completa de la propos La completa de la co La completa de la comp

e visioni insulta si tangensi mengenarah mengentah mengenjan inggan mengenjangan mengenjan mengenjan mengenjan

English Colonia da Koramana an Alba et

at range for positionable largest tight calculate committee

and the magazine for the state of the property of the more than the expension of the first of th

PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

35 U.S.C. Section

200	Policy and objective.
201	Definitions. The law one of the confidence is no curate limited in related the page of
202	Disposition of rights. Fig. 19 Canada and Fig. 19 Canada and Canad
203	March-in rights: after the telephone by allowing definitions by granding and it was a more and a sec-
204	Preference for United States industry. The grids, and it is said, when it is beginning the beginning the professional and the contract of the
205	Confidentiality. A location of which is a final property of the confidence of the co
206	Uniform clauses and regulations. The second research and the second regulations are second regulations.
207	Domestic and foreign protection of federally owned inventions.
208	Regulations governing Federal licensing.
209	Restrictions on licensing of federally owned inventions.
210	Precedence of chapter.
211	Relationship to antitrust laws.
212	Disposition of rights in educational awards.

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 which is or may be patentable or otherwise protectable under this title or any novel variety of plant which 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(l), 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.

- 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 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.
- 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 percent 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 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 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent 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 Law 98-620, 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 which 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 which 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.

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.

的复数使用的复数形式 医多种性性 医皮肤性 医皮肤性 医二氏性神经炎

- (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.)

ern amerika salakan di Telaka e darah

a miser vilke kieli sigen. Evil viole i se aterilie i selle kien ar kundi kien ili.

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.)

MARK BLOOM'S FAVORITE INTELLECTUAL PROPERTY WEB SITES

General Intellectual Property Web Sites (Great Starting Points!)

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

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

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

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

was a fight of all the ordinary and all the search of the fight was fally and being a fight

us in a sample of the other of the trace, in a function and the man date.

en la colorador de la comercia de la cominación de la palación de la colorada de la colorada de la colorada de

indisente a montación en la careacte de francia de carregra de la companyo de la finación de la careacte de la

The section of the contract of the first section with

THE ROLL OF BOTTO TO (ME AND THE BOTTO

report in the fit week where he sie so

The reserved and the second of the second

censia nel discolar nel aliavano e la libra de la compania de la compania de la compania de la compania de la c

Copyright Web Sites

The U.S. Copyright Office: http://lcweb.loc.gov/copyright/@produce@distable.com/windersearchean-com/winder

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

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

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

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

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

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

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

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

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

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

Multimedia Law and Information Web Sites

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

UW-Madison Dept. of Learning Technology & Distance Education's "Multimedia & Technology in Education" Resources Page: http://www.wisc.edu/learntech/grp/mtechres.html

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

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

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

ten succesii veisce in . Like birove A

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

Copyright Clearance Information Web Sites

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

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

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

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

Patent Law Web Sites

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

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

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

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

Patent Search Sites

IBM's Patent Server: http://www.patents.ibm.com/ibm.html

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

STO's Internet Patent Search System: http://sunsite.unc.edu/patents/intropat.html

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

Trademark Search Site

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

Trade Secret Sites

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

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

University Web Sites

Association of University Technology Managers' Home Page: http://autm.rice.edu/autm/index.html

the lighter to the first the first the property of the large of the first terms of the company of the property of the property

and the first term has been readened to be the first the first appearance of the

media arabi aty anagi awasa majesi 1945 (itahin arizeringa) ina esa itahan efiata bibelai ag

The contradition of the co

on south that there was to be a second of the year of a criber of a

the Property Common Section Complete Conference on the conference of

Note that with the conduction of the conduction of the end of the conduction of

อาเมริโดย เปิดสมวัน อริโดสิเมากรู การพระวิวัตถุล เพละเกรียก ซระ เมริโดสิติ

familion film the part of the glave of the film film that the period is

Francisco de la començación de exercicados (Abrazá de El combido de Aulta de El Combidade de Albara de El Combi

Problem complex considers on a policy of the property beautiful and the constant of the constant of the CVS.

and make the Beliffet promote extension to the first that and the second III of the first of the second test and

in die in de la company de

STEEL STATE OF STATE OF STATE OF

WARF Home Page: http://www.wisc.edu/warf/

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