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Commercialization of Research Results in the United States

An Overview of Federal and Academic Technology Transfer

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SWEDISH INSTITUTE FOR GROWTH POLICY STUDIES

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Foreword

The United States is often used as a benchmark in the Swedish research policy debate. The scope and quality of American research, the ability to commercialize research results and the entrepreneurial spirit are some reasons for this.

Against this background the Swedish government commissioned the Institute for Growth Policy Studies (ITPS) to undertake a study on the science system and policies in the United States. The ITPS Office at the Swedish Embassy in Washington D.C. was assigned to conduct the study. The results of the project will serve as an input to the next Bill on Research that will be presented to the Swedish Parliament 2004–2005. The results are presented in this report and three others*.

This study covers federal and academic technology transfer in the United States. It includes university-industry relationships, licensing and patent activities, business incubators, funding of technology transfer, intellectual property policy, entrepreneurship and education, small business policy and other government initiatives relevant for the transfer of technology.

Stockholm, March 2004

Sture Öberg,
Director-General

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- "American Science – the Envy of the World? An Overview of the Science System and Policies in the United States", by Kerstin Eliasson.
- "From Doctoral Student to Professor – The Academic Career Path in the United States", by Eva Karlsson.
- "The Structure and Financing of Medical Research in the United States – An Overview", by Eva Ohlin.

Content

Summary

The United States has a history of successfully turning research results and new technologies into commercially viable products and services. Commercialization of new technologies has contributed to economic development and growth. Technology transfer activities started to become institutionalized in academia and government after World War II and have grown significantly in the last two decades, triggered largely by political reforms.

This report provides an overview of the extent and nature of technology transfer and the underlying reforms and enablers in the U.S. The purpose is to identify U.S. strengths that are relevant for Swedish challenges related to the commercialization of research results. Special attention is given to commercialization at universities. Five important areas enabling technology transfer are pointed out and discussed. Examples and figures have an emphasis on medical and biotechnology R&D.

Federal and academic technology transfer

- In 2002, the federal government invested 81 billion dollars in R&D and universities and colleges performed 37 billion dollars worth of R&D (of a total of 292 billion dollars). Industry is by far the largest investor and performer of R&D and accounted for about 70 percent of the total R&D enterprise. This share is similar in Sweden.
- Federal applied R&D (not counting federal basic research and defense-specific R&D) amounted to 32 billion dollars and can be considered "candidates for technology transfer". The Department of Health and Human Services (HHS) is dominating this area and life science is by far the leading research discipline.
- Federal agencies disclosed over 4200 inventions, made over 2100 patent applications and more than 1400 patents were issued in 2000. HHS accounted for around 10 percent of these numbers. However, HHS is the leading agency when it comes to the number of licenses and licenses revenues.
- The National Institutes of Health (NIH) accounts for most of HHS R&D. About 85 percent of it is performed by external entities, such as universities and hospitals. The NIH technology transfer program is the most successful of the U.S. government's programs based on generated royalty income (52 million dollars from over 1700 licenses in 2000). It is widely recognized that federal support (particularly through the NIH) has been instrumental in creating the successful U.S. biotechnology industry.

- Federal legislation has been important for supporting technology transfer, for example by allowing federal entities to enter Cooperative Research and Development Agreements (CRADAs) with private industry (currently about 3000 active agreements), by giving the performing company the right to retain title of inventions and by requiring that all federal laboratories establish an office of technology transfer.
- Of the total R&D expenditures by universities and colleges (33 billion dollars in 2001), the medical sciences accounted for the largest share (30 percent). The largest medical institution in terms of R&D spending is the University of California.
- Direct industry sponsorship is the most frequent form of university-industry relationship. There has been a steady trend of increasing industry support during recent years but its share of total academic R&D has remained between six and eight percent. It is a similar percentage in Sweden. Industry financing amounted to 2.2 billion dollars in 2001. Duke University and MIT received the most industry support.
- Universities and colleges collected about 830 million dollars in royalties and other payments from licenses on inventions in 2001. This was no more than two to three percent of the total academic R&D effort. Columbia University ranked highest with an income of 130 million dollars. Most revenues came from a few “blockbuster” licenses. Of about 23,000 active licenses reported in 2001, only 131 generated more than one million dollars in yearly income. Most university licensing offices barely break-even.
- Universities reported a total of 11,259 inventions disclosures during 2001. They filed 9400 applications for U.S. patents, signed over 3300 licenses and created 402 start-up companies. Over 3800 new companies have been formed on the basis of a license from an academic institution since 1980. 2100 of them were still in operation in 2001. The trend is that universities take equity positions with their start-ups (in about 70 percent of the companies in 2001).
- Regional clusters of innovation are important for the commercialization of research. “High-tech” clusters make up about 2.5 percent of total U.S. employment. The New York City area accommodates by far the largest bio/pharmaceutical cluster. Nine major biotechnology centers (including the dominant Boston and San Francisco areas) received more than 4.4 billion dollars in NIH R&D funding in 2000. About 9 billion dollars of venture capital investments and 10 billion dollars worth of contracts with major pharmaceutical firms were made between 1995 and 2001.
- There is an increasing number of business incubator programs operating in North America. In 2001, there were 950 incubators, assisting more than 35,000 start-up companies that provided full-time employment for nearly 82,000 workers and generated annual earnings of more than 7 billion dollars.

- Incubators with a biotech/biomedical focus raised more money, obtained more research support, held more patents and licensed more technology than other kinds of incubators. On the other hand, they had slower revenue and employment growth.

Commercialization at universities

- Largely as a result of the Bayh-Dole Act, academic institutions across the U.S. have established a strong national technology-licensing infrastructure (over 200 technology transfer offices, TTOs). Some of the most successful institutions are Stanford University, MIT, Columbia University and the University of California System.
- Patent and licensing offices have been supplemented by offices for sponsored research and industry liaison offices to cover a wide range of university-industry interactions. Activities are typically governed by a set of policies, including guidelines for patenting, licensing, equity ownership, copyright, consulting and contracts with industry. Policies have been developed to protect the rights of researchers and to preserve core academic values as well as to protect the university from conflicts of commitment and conflicts of interest.
- Mandatory assignment of inventions is an important policy at universities. Employees at the University of California, for example, are required to sign a Patent Agreement in which they agree to disclose all potentially patentable inventions and to assign all rights to inventions to the university.
- Public universities, including the University of California, have a public service mission to ensure that research results are made available for public benefit. Industry involvement is encouraged and it is becoming more and more recognized that such contacts actually benefit academic research activities.
- Private universities seem to pursue commercialization more aggressively than public institutions. They are also more flexible when it comes to, for example, financial compensation to inventors and rules for owning equity in start-up firms.
- The major drivers for the researcher to be involved in technology transfer are the possibility of getting a share of licensing revenues and becoming engaged in well-paid consulting work.
- Researchers at Stanford University receive one third of the net royalties from the licensing of their inventions. At the University of California, inventors receive 35 percent of net income.

- A critical issue is how to get researchers to disclose inventions. It is estimated that less than half of the developed technologies are disclosed. According to some studies, it seems as if the "best faculty" is the least likely to bother with pursuing commercialization. One explanation is that most inventions require further R&D in a more applied direction than the original researcher may wish to engage in.
- A challenge for the TTO system is to find skilled personnel. Deals are getting more and more complex and office staff must master many competencies. Apart from knowledge of the science behind the invention, they must have marketing, legal and negotiation skills.

Important factors enabling technology transfer

1. Funding technology transfer

- Industry and individual private equity investors ("business angels") are the most important funding sources for early-stage technology development (not venture capital). Angel investing has increased rapidly in past years – there are at least 170 angel groups in the U.S. Several tax reforms have been instrumental in creating incentives for private investments.
- Venture capitalists have played an important role in the formation of new high-tech companies. Small business policy in the 1950s, pension fund regulations and policies facilitating acquisitions were important federal initiatives that helped to create this market. Investments have declined radically from 94 billion dollars the peak year of 2000, to 19 billion dollars in 2002. Focus has turned to less risky, later-stage investments.
- Furthermore, securities, banking and bankruptcy laws favor the individual creditor in a way that the entrepreneur does not risk losing house and home if the business fails. These regulations make possible the widespread view that business failures are acceptable.

2. Intellectual property policy

- The foundation for intellectual property protection is the U.S. patent law. Since the 1950s, a series of amendments and court decisions have significantly strengthened patent protection, for example by providing the right to patent modified living organisms in 1980.
- The federal government's principal way for promoting technology transfer is to grant intellectual property rights to the performing institution of federally funded R&D, such as universities, federal laboratories and private firms (the Bayh-Dole and Stevenson-Wydler Acts). Institutions are free to commercialize the results but must share the benefits with the inventors.

- It is widely recognized that Bayh-Dole is successful and has helped establish new businesses, create new industries and open new markets. Since 1980, it is estimated that licensing of innovations has contributed to the establishment of 2200 firms, created between 250,000 and 300,000 jobs and have added 30–40 billon dollars annually to the U.S. economy.

3. Entrepreneurship and education

- Entrepreneurship is a widespread activity in the United States. About six percent of all adults are engaged in starting new firms.
- Entrepreneurship education has helped to create the necessary skills and mind-set. More than 1500 universities and colleges offer some form of training. Nearly 500 million dollars are invested in more than 250 endowed professorships and chairs in entrepreneurship. Babson College runs the largest and highest-ranking program.

4. Small business policy and programs

- Since the 1950s, the U.S. Small Business Administration (SBA) has provided financial, technical and management assistance to small companies. SBA is the largest single financial supporter of small businesses with a portfolio of business loans, loan guarantees and disaster loans, worth more than 45 billion dollars and a venture capital portfolio of 13 billion dollars (2002).
- The Small Business Investment Company (SBIC) program provides equity capital, long-term loans and management assistance to small firms, particularly in their growth stages. In 2002, SBICs assisted 2853 companies with 2.3 billion dollars (down 50 percent from 4.7 billion dollars in the peak year 1999). SBICs venture capital-type financing represented about 11 percent of all venture capital funding in 2002.
- The Small Business Innovation Research (SBIR) program provides support to firms to compete for federal R&D awards. The Small Business Technology Transfer (STTR) program supports firms that collaborate with non-profit research institutions to compete for such projects. Through these programs, a specific percentage of federal R&D funds are reserved for small businesses. The SBIR program has experienced rapid growth since 1983.

5. Other government initiatives and programs

- Industry-University Cooperative Research Centers (IUCRCs) and Engineering Research Centers (ERCs) are administered by the National Science Foundation (NSF). Currently, there are about 50 IUCRCs and 20 ERCs. The NSF investment is intended to support partnered approaches to new and emerging research areas. The majority of the funding comes from industrial firms. The intention is that the centers gradually will become self-sustaining (usually within a 10-year period).

- The Advanced Technology Program (ATP) was established in 1990 by the Department of Commerce. This public-private partnership program funds high-risk research to develop enabling technologies that promise significant commercial payoffs. The program may be phased out by the Bush Administration.
- Project BioShield is an example of a recent government initiative to use R&D procurement to stimulate innovation. According to the proposal by the Administration, 6 billion dollars will be invested over 10 years to develop and make available modern, effective drugs and vaccines to protect against biological and chemical terrorist attacks. The idea is that the government should guarantee a market for innovative counter-terrorism technologies.

Technology transfer issues

Issues and concerns include the possible negative effects of the commercialization of research at universities and colleges (such as increased secrecy, possible conflicts of interest and barriers to access to research tools), how to deal with the funding of early-stage technology development, problems experienced with Bayh-Dole and the current intellectual property protection regime and, ways to improve technology transfer practices within the current legal framework

U.S. strengths and Swedish challenges

In conclusion, five crucial factors (within the areas above) for the success of technology transfer in the U.S. have been selected and discussed in relation to Swedish challenges related to the commercialization of research results. The factors are (1) availability of private capital, (2) ownership of research results, (3) entrepreneurial skills, (4) small business involvement and (5) government programs.

1 Introduction

1.1 Technology Transfer on the Political Agenda

In a comparative perspective, the United States has been successful in creating and developing new technologies and turning them into competitive businesses. The transfer of research results from government funded R&D at federal and academic institutions to the private sector has grown significantly in the past two decades in the U.S. Today it represents an increasingly important part of the overall industrial commercialization of technologies. Federal Reserve Chairman Alan Greenspan recently noted, "In a global environment in which prospects for economic growth now depend importantly on a country's capacity to develop and apply new technologies, our universities are envied around the world. The payoffs – in terms of the flow of expertise, new products and start-up companies, for example – have been impressive" (BHEF 2001). This is demonstrated by the fact that the rate of start-up formation is between three and four times higher in North America compared to most other OECD countries (OECD 2002a).

A number of factors have contributed to this development. The Massachusetts Institute of Technology (MIT) and Stanford University pioneered technology transfer efforts at universities in the 1940s and a number of federally funded R&D labs were created to meet the needs of World War II. In the 1950s, the government started to support small businesses with growth capital. The ambitious space program during the 1960s supplied more federal funding for R&D and required cooperation between government and industry to succeed. In the early 1980s, federal technology transfer became widely regarded as a means of addressing concerns about U.S. industrial strength and competitiveness. The "threat" from Germany and Japan contributed to the reforms that make up the foundations of today's technology transfer environment: a uniform patent policy, the access to venture capital and increased participation of small businesses in R&D and technology transfer.

In the 1990s, we saw the development of comprehensive educational programs on entrepreneurship and innovation at many universities as well as the success of technology transfer resulting from the intense focus on biotechnology and medical R&D. Today, technology transfer is still on the science and technology policy agenda in the U.S. During the spring of 2003, the President's Council of Advisors on Science and Technology (PCAST) prepared and presented a report to the President on ways to improve the transfer of technologies (PCAST 2003). For historical accounts of technology transfer in the U.S., see for example NRC 2003 and the report by Howard W. Bremer (undated).

The drivers behind technology transfer initiatives are similar in many countries: to increase national competitiveness, to generate funds for more R&D, to optimize the return on taxpayer's investments and to use R&D to fulfill political and societal goals. Industry benefits include access to research experts and students as potential employees as well as expanding pre-competitive research, both with universities and with other companies. Universities are motivated by getting access to external sources of funding and expertise, by identifying relevant research issues and by broadening the experience of students and faculty, among other things.

1.2 What is Technology Transfer?

Generally, technology transfer is the movement of an idea, practice or object resulting from research, into a setting where it can improve a product, service or process in any way (see for example RAND 2003 p. 26). Another common definition states that technology transfer is "the formal transfer of new discoveries and innovations resulting from scientific research conducted at universities and non-profit research institutions to the commercial sector for public benefit" (Association of University Technology Managers, AUTM). The concept of technology transfer is said to have its origins in the famous report to the President in 1945 by Vannevar Bush, entitled "Science – The Endless Frontier". In this report, the term technology transfer and the commercialization of research results will be used with the same meaning.

The technology transfer process typically includes a set of components, starting with investment in R&D, the actual R&D performance, decision how to handle intellectual property, building a prototype to demonstrate the technology, the further development needed for commercialization and finally resulting in the successful introduction of a product or service on the market (see for example the model in Table 1-1). It is important to point out that in real life; innovation is a complex, often non-linear process and shows a lot of iteration between these stages. Depending on perspective, the starting point may be a specific technology coming out of the research lab or the process can start with defining a particular user need or market segment. Usually, we think of technology transfer as a process from the public to the private sector. However, there are also examples of technologies flowing from firms to government and universities, including transfer of patent rights from firms to universities for further development in exchange for tax benefits.

TABLE 1-1
An idealized sequential model of technology development

Stage	Activity	Outcome
1	Basic research	Patent
2	Proof of concept/invention	Invention (functional)
3	Early-stage technology development	Business validation
4	Product development	Innovation: new firm or program
5	Production/marketing	Viable business

Source: NIST 2002

The process involves a variety of players such as federal funding agencies, universities, research and transfer organizations, venture capitalists and private companies as well as individual scientists, entrepreneurs and business angels. The success of technology transfer depends on the interaction between these actors and their ability to tackle a number of challenges along the way. They must prove that the technology or concept works, decide when to patent, negotiate licensing terms, secure necessary capital investment in several stages, put together a skilled management team, identify the value or utility to the user/customer and create a business plan and a strategy for going to market. A number of mechanisms to support technology transfer have been identified in the literature, including licensing, cooperative R&D agreements, technical assistance, use of facilities, exchange programs, networking, publications and conferences.

The success of technology transfer can be measured and evaluated from a number of perspectives. Economic growth and competitiveness are expected at the national level, firms look at profit and market share, venture capitalists focus on return on investments, consumers want new and useful products and R&D performing institutions value revenues from patents and licenses. Consequently, there are a number of metrics that can be used for measuring success. Such metrics include the number of patents applied for and granted, the number of licenses and the revenue being generated, the number of public-private cooperative R&D agreements, etc. Measuring technology transfer and developing reliable metrics is an important input to the policy-making process and is necessary to achieve the goal of a learning technology transfer policy. See RAND 2003 (including appendix C) for a discussion on measuring technology transfer and a summary of promising research directions in this field and OECD 2002a for methods for evaluating industry-science linkages.

1.3 Overview of R&D in the United States

In 2002, the United States invested an estimated 292 billion dollars in R&D, which represented 2.8 percent of its Gross Domestic Product. The largest share of money came from industrial firms (66 percent) and the federal government invested about 81 billion dollars (28 percent). See Table 1-2. The main federal R&D funding sources are the Department of Defense (DoD), the Department of Health and Human Services (HHS), the National Aeronautics and Space Administration (NASA), the Department of Energy (DoE) and the National Science Foundation (NSF). Together these top-five funders account for 95 percent of the annual federal investment in R&D.

TABLE 1-2
U.S. expenditures of R&D, by performing sector and source of funding 2002 (preliminary).

Performers	Sources of funds (billion dollars)				
	Federal government	Colleges & universities *	Non-profit institutions	Industry	**Total**
Federal government	22				**22**
Colleges & universities	23	9.9	2.7	2.3	**37**
FFRDCs	10				**10**
Non-profit institutions	5.5		4.6	1.2	**11**
Total, excl. industry	60	9.9	7.3	4	**81**
Industry	21			190	**211**
Total	**81**	**9.9**	**7.3**	**193**	**292**

*Note: * Including Non-Federal Government funding*

Source: NSF 2003a

When it comes to performing R&D, industry also account for the largest share (72 percent) while the remaining portion is performed by the federal government (7 percent), universities and colleges (13 percent), Federally Funded Research and Development Centers (FFRDCs) (4 percent) and non-profit organizations (4 percent). In absolute figures, industry invested 193 billion dollars and performed R&D for 211 billion dollars in 2002 (NSF 2003a).

1.4 Focus and Outline of the Report

This report provides an overview of the extent and nature of the commercialization of research results and the underlying reforms and enablers in the U.S. The purpose is to identify U.S. strengths that are relevant for Swedish challenges related to the commercialization of research results.

The starting point will be the outline of technology transfer activities from two perspectives: (a) Federal technology transfer: the transfer of results originating from R&D funded by the federal government (section 2) and (b) Academic technology transfer: the transfer of results originating from R&D performed by universities and colleges (section 3). The center section of the report will focus on how leading U.S. universities are working with commercialization and how researchers are involved in the technology transfer process (section 4).

Next, five important areas enabling technology transfer are discussed: the funding of technology transfer (section 5), intellectual property policy (section 6), entrepreneurship and education (section 7), small business policy and programs (section 8), and other government initiatives and programs (section 9). A set of current technology transfer issues and challenges on the U.S. political agenda will be discussed in section 10. In the concluding section, U.S. strengths and Swedish challenges will be summarized (section11).

The discussion and examples in the text will have an emphasis on medical and biotechnology R&D. The report will not discuss international technology transfer, commercialization efforts at state and local government levels, commercial technology alliances and industry consortia, government-to-government cooperation or technology transfer originating from private sector firms. The Swedish system for technology transfer will not be described in detail in this report. This has been done in a number of earlier reports, including in Henrekson et al. (2000), VINNOVA (2002a), (2002b) and (2003).

The report is part of an assignment from the Swedish Government to study the American science system (U2001/4567/F). In June 2002, the Ministry of Education and Science commissioned the Swedish Institute for Growth Policy Studies (ITPS) and its office in Washington DC to carry out the study. The assignment was presented to the Government in November 2003. Apart from this report, the deliverables consist of the following three reports:

1. "American Science – the Envy of the World? An Overview of the Science System and Policies in the United States" by Kerstin Eliasson.
2. "From Doctoral Student to Professor – The Academic Career Path in the United States" by Eva Karlsson.
3. "The Structure and Financing of Medical Research in the United States – An Overview" by Eva Ohlin.

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2 Federal Technology Transfer

2.1 Technology Transfer Expectations

The concept of federal technology transfer was introduced in the 1950s with the 1958 Space Act authorizing the National Aeronautics and Space Administration (NASA) to enter into public-private partnerships to achieve its goals. No uniform government policy was in place before the Bayh-Dole Act of 1980. However, many agencies, including the Department of Defense (DoD), the National Institutes of Health (NIH) and the National Science Foundation (NSF) allowed contractors to retain patent rights to their inventions before 1980. The focus of federal policy in this field is mainly on the initial stages of technology transfer: federal R&D investment, performing R&D and intellectual property rights.

The federal government support different types of R&D. Of the 81 billion dollars invested in FY (fiscal year) 2002, about 30 percent is funding for basic research and another 30 percent is related to the development and weapons and defense-related systems. Both basic research and defense R&D (dual-use technologies) may lead to technology transfer, but the highest expectations for technology transfer apply to the remaining 40 percent of the federally funded R&D portfolio (Table 2-1). This portion of applied research and other development amounted to about 32 billion dollars for FY 2002. The Department of Health and Human Services (HHS) is the dominating source (34 percent) of federal funding in this area followed by the Department of Defense (24 percent). Apart from various development activities, life science is by far the leading research discipline (30 percent) followed by engineering (16 percent) (RAND 2003, NSF 2002b).

TABLE 2-1

Federally funded applied R&D – prime candidates for technology transfer – per discipline and main sources of funding for FY 2002

Applied research	**Amount in billion dollars**	**Percent of total**	**Main sources of funding**
- Life sciences	9.67	30%	HHS/NIH (80%)
- Engineering	5.01	16%	DoD (40%), NASA (25%)
- Mathematics and computer science	1.69	5%	DoE (42%), DoD (41%)
- Environmental science	1.59	5%	DoC (24%), DoI (20%), NASA (19%)
- Physical sciences	1.31	4%	DoE (37%), HHS/NIH (29%)
- Psychology	1.03	3%	HHS/NIH (87%)
- Social sciences	0.92	3%	HHS/NIH (28%)
- Other applied research	0.72	2%	
Systems development	**10.1**	**31%**	DoD (39%), NASA (28%)
TOTAL	**32.0**	**100%**	

Source: NSF 2002b

2.2 The U.S. Federal Lab System

Federal labs are government owned or leased facilities for performing research, development and engineering activities relevant to the missions and interests of a department or agency. The federal lab system consists of more than 700 facilities including the government-owned but contractor-operated (GOCO) labs and the Federally Funded R&D Centers (FFRDCs). From the 81 billion dollars of federal R&D investment in FY 2002, resources for the federal lab system accounted for 25 billion dollars (31 percent). Department of Defense (DoD) received 35 percent of the total for federal labs, and the Department of Energy (DoE) and the Department of Health and Human Services (HHS) received about 18 percent each. DoD is dominating intramural R&D while DoE has a focus on funding FFRDCs. The obligation for federal labs under HHS was 4.5 billion dollars; only 19 percent of its total obligations while DoE rely heavily on federal labs – over 70 percent of its total R&D resources (Table 2-2).

TABLE 2-2

Budget resources (preliminary) for federal lab R&D spending in relation to total obligations FY 2002. Intramural costs include the administration of intramural and extramural programs as well as the actual intramural R&D performance

	Total obligations (billion dollars)	Obligations - federal labs (billion dollars)		
		Intramural R&D	FFRDCs	Total
Department of Defense	34.2	7.90	0.88	**8.78**
Department of Energy	6.32	0.51	4.03	**4.54**
Department of Health and Human Services	23.8	4.13	0.38	**4.51**
National Aeronautics and Space Administration	7.26	1.81	1.20	**3.01**
Department of Agriculture	1.80	1.27	0	**1.27**
Other department and agencies	7.22	2.68	0.24	**2.89**
Total	**80.6**	**18.3**	**6.73**	**25.0**

Source: NSF 2002b

The Federally Funded Research and Development Centers (FFRDCs) have evolved from the research facilities established to meet the needs of World War II. The basic criteria for their operation were set in 1967. An FFRDC receives its major financial support (70 percent or more) from federal sources (usually from one agency) and performs R&D producing results that are directly monitored by the government. 36 FFRDC were registered under 8 departments and agencies in FY 2003 and they are organized in three categories: (1) university and college, (2) non-profit organization or (3) industry-administered. Most of them (26) are R&D laboratories and the others are focusing on systems engineering and integration, and study and analysis (see NSF 2002c for a master list of all laboratories).

In FY 2002, it was estimated that FFRDCs performed federally funded R&D for about 7 billion dollars. Centers administered by universities and colleges accounted for the majority of this budget (63 percent). FFRDCs administered by universities and colleges also accounted for the majority of basic and applied research (NSF 2002b). The National Institutes of Health under the Department of Health and Human Services have one industry administered FFRDC, a part of the National Cancer Institute (NCI) located at Frederick, Maryland.

2.3 R&D Joint Ventures and Agreements

The National Cooperative Research Act of 1984 encouraged U.S. firms to collaborate on generic, pre-competitive research. A database was established to track Research Joint Ventures (RJV) mainly for antitrust reasons. Over 800 RJVs were registered between 1984 and 2000. In total, these joint ventures involved over 4200 businesses and organizations. Of the about 3000 U.S. based participants, 88 percent were for-profit firms, 9 percent were non-profit organizations (including universities) and 3 percent were government entities. A majority of the joint ventures during this time involved companies in the electronics, communications and transportation industries. The number of new RJVs peaked in 1995 with 115 joint ventures registered. Between 1997 and 2000, this number was down to between 30 and 50 (NSF 2002a).

The Federal Technology Transfer Act of 1986 authorized federally owned and operated laboratories to enter into Cooperative Research and Development Agreements (CRADAs) with private industries and at the same time gave all companies the right to retain title to inventions. A total of around 3500 CRADAs involving 10 federal agencies and their laboratories were active in year 2000. The largest participants were the Department of Defense (47 percent of the total number of active agreements) and the Department of Energy (23 percent). The Department of Health and Human Services was involved in forming 50 new CRADAs during FY 2000 resulting in a total of 244 active agreements. The number of active CRADAs increased steadily and peaked in FY 1996 with over 3500 agreements and has since then stabilized at around 3000 active agreements (NSF 2002a).

2.4 Inventions, Patents and Licenses

A number of indicators on federal technology transfer are reported to the Department of Commerce (as stipulated by the Federal Technology Transfer Act of 1986) and include new inventions disclosed, patent applications, federally owned patents, licenses of patented inventions and revenues from these licenses (DoC 2002). Federal agencies involved in R&D and technology transfer reported over 4200 invention disclosures, over 2100 patent applications and more than 1400 patents issued during FY 2000. The Department of Health and Human Services (HHS) accounted for around 10 percent of these numbers. Between FY 1997 and FY 2000, a total of 5655 patents were issued to federal agencies (635 to HHS). See Table 2-3.

TABLE 2-3
Indicators of federal technology transfer – for all federal agencies and for the Department of Health and Human Services FY 1996 – FY 2000

TOTAL (HHS)	1996	1997	1998	1999	2000
Inventions disclosed	4153 (305)	3842 (268)	3503 (287)	4851 (328)	4209 (375)
Patent applications	1666 (147)	1789 (148)	1844 (132)	2258 (241)	2159 (263)
Patents issued	- (-)	1243 (152)	1446 (171)	1480 (180)	1486 (132)

Source: NSF 2002a, appendix table 4-35

The Department of Health and Human Services (HHS) is the leading agency when it comes to the number of licenses of patented inventions and even more dominating when it comes to the revenues generated by these licenses. HHS accounted for more than 40 percent of the total 3007 active federal licenses in FY 2000 and 70 percent of the total 69.5 million dollars income generated (Table 2-4).

TABLE 2-4
Indicators of federal technology transfer – licenses and revenues for selected agencies FY 2000

	Number of active licenses (percent of total)	**Income from licenses (million dollars) (percent of total)**
Department of Health and Human Services	1222 (41%)	48.6 (70%)
Department of Energy	1094 (36%)	12.7 (18%)
Other agencies	691 (23%)	8.2 (12%)
Total	**3007**	**69.5**

Source: NSF 2002a, appendix table 4–35

2.5 Organizations Supporting Federal Technology Transfer

There are a great number of technology transfer organizations and offices supporting the commercialization of federal R&D. At the federal-wide level, there are the Federal Laboratory Consortium (FLC) and the National Technology Transfer Center (NTTC). FLC was established to serve as a liaison between individual federal laboratories and nonfederal entities interested in developing technologies with the purpose to strengthen technology transfer nationwide. The Consortium was established in 1974 and was assigned a formal role by the Federal Technology Transfer Act of 1986. The NTTC was created to help business and industry gain access to marketable technologies, expertise, and facilities located within NASA and other federal laboratories with the purpose to strengthen the competitiveness of U.S. industry. The Center also promotes collaborations between U.S. companies and federal laboratories to commercialize technologies.

Each government department and agency has one or several offices for technology transfer (see Table 2-5). Moreover, the Technology Innovation Act of 1980 required each federal laboratory (with 200 or more R&D employees) to establish an Office of Research and Technology Applications (ORTA). The role of these offices is to assess R&D projects for commercial applications and make information on federal technologies available to local governments and private industry. At the regional level, states have established Technology Councils with the aim to support linkages among industry, government and higher education institutions.

TABLE 2-5
Selected technology transfer offices at government departments and agencies with WEB SITES on the Internet

Department of Defense, Office of Technology Transit	http://www.dtic.mil/techtransit/
Department of Energy, Office of Industrial Technologies	http://www.oit.doe.gov/
Department of Transportation, Technology Transfer	http://t2.dot.gov/
Department of Commerce, National Institute of Standards and Technology, Office of Technology Partnership	http://patapsco.nist.gov/ts/220/external/index.htm
National Aeronautics and Space Administration, Commercial Technology Network	http://nctn.hq.nasa.gov/index.html
Department of Health and Human Services, NIH Office of Technology Transfer	http://ott.od.nih.gov/
Public Health Service Technology Development Coordinators	http://ott.od.nih.gov/NewPages/tdc.html
Food and Drug Administration (FDA) Technology Transfer	http://www.fda.gov/oc/ofacs/partnership/techtran/1stpg.htm
Centers for Disease Control and Prevention (CDC) Technology Transfer Office	http://www.cdc.gov/od/ads/techtran/index.htm

2.6 Technology Transfer at the National Institutes of Health

R&D conducted by the public health components of the Department of Health and Human Services (HHS) – particularly the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control – generally has a large potential for producing new technologies. The 27 institutes and centers of the NIH accounted for 22 billion dollars (92 percent) of the Department's total obligations for R&D in FY 2002. Each year, the NIH conducts around 2000 projects in its own laboratories and funds about 35,000 research grants to universities, hospitals and other research institutions throughout the U.S. and abroad. Most of its budget it used for external R&D activities (85 percent); the smaller part supports intramural research. Most of the NIH inventions are drugs, vaccines, medical instruments and diagnostic tests. The institutes rely on industrial partners to provide for post-discovery activities such as drug development, scale-up, clinical testing, marketing and distribution.

The NIH Office of Technology Transfer (OTT) is the lead agency at HHS for supporting industry collaboration and the building of public-private partnerships. The office evaluates, protects, markets, licenses and monitors the intellectual property originating from researchers at NIH labs. See Table 2-6 for a list of technology development offices at some NIH entities. All technology transfer deals pass through the OTT but licensing revenues goes back to the originating institute after paying a cost-based fee to the central office. Inventors are compensated less generously compared to many universities. They typically receive between 15 and 25 percent of licensing income and there is a maximum annual income of 150,000 dollars. The scope of biomedical technology transfer includes therapeutics, diagnostics, vaccines, devices and research tools. The process is characterized by extensive regulatory requirements, long time to market and important ethical considerations. The NIH technology transfer program is the most successful in the U.S. government in terms of generated royalty income (52 million dollars from over 1700 licenses in FY 2000). See Table 2-7. In 2002, NIH technologies were part of over 200 products on the market, including 15 therapeutic drugs and vaccines (DoC 2002, Freire 2002, personal communication with Theodore Roumel).

TABLE 2-6
Selected technology Development offices at the NIH with WEB SITES on the Internet

National Cancer Institute (NCI), Technology Transfer Branch	http://ttb.nci.nih.gov/
National Heart, Lung, and Blood Institute (NHLBI), Office of Technology Transfer and Development	http://www.nhlbi.nih.gov/tt/index.htm
National Human Genome Research Institute (NHGRI), Technology Transfer Office	http://www.genome.gov/10001152
National Institute of Allergy and Infectious Diseases (NIAID), Office of Technology Development	http://www.niaid.nih.gov/ttb/ttb.htm
National Institute of Dental and Craniofacial Research (NIDCR), Technology Transfer	http://www.nidcr.nih.gov/research/transf.asp
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Office of Technology Transfer and Development	http://www.niddk.nih.gov/intram/techdev/otd1.htm
National Institute of Environment Health Sciences (NIEHS), Technology Transfer	http://www.niehs.nih.gov/techxfer/home.htm
National Institute of Mental Health (NIMH), Technology Transfer	http://intramural.nimh.nih.gov/techtran/

It is widely recognized that federal government support was a key factor in the creation of the thriving biotechnology sector in the USA. Today, there are more than 1200 biotech companies with a combined market capitalization of over 90 billion dollars. The NIH has been instrumental in creating this industry by supporting biomedical R&D and by the direct funding of industry R&D. First, many of the leading discoveries in molecular biology were originally made through NIH supported research. The NIH is by far the largest federal funder of academic research in the U.S. Second, the NIH became an aggressive actor in transferring research results to the private sector already in the late 1970s. The NIH is by far the largest federal licensor of new technologies (NCE 2002b).

TABLE 2-7
NIH invention disclosures, patent applications, total number of executed licenses and total income from all active licenses from FY 1990 to FY 2000

	1990	**1992**	**1994**	**1996**	**1998**	**2000**
Invention disclosures	212	262	259	196	287	330
Patent applications	184	202	143	136	132	189
Executed licenses	230	353	553	897	1320	1709
Royalties (million dollars)	5.80	10.0	18.5	27.0	39.6	52.0
Active CRADAs	109	165	237	313	388	470

Source: Freire 2002

3 Academic Technology Transfer

3.1 University-Industry Relationships

Starting with the Morrill Act of 1862 establishing the land-grant college system, cooperation between universities and industry has a long history in the U.S. with defense related R&D during World War II and the rivalry with the Soviet Union in the Cold War as major drivers. A new era of collaboration started in 1980 with passage of the Bayh-Dole Act that clarified the roles between industry, government and universities. The Act accelerated technology transfer and is considered instrumental in the creation of the biotechnology industry and commercial advances in other technology intensive industries. Other forces supporting collaboration are the growth of science-based industries and the need for American companies to seek ways to improve their competitiveness through alliances with universities.

During the 1920s, the MIT decided to take patents on inventions made by its faculty and students. The previous practice allowed entrepreneurs to search the university for ideas and to commercialize them without charge. The decision by MIT transformed the institute from a passive to an active actor in university-industry relations and the entrepreneurial university was created. During the 1940s, MIT realized that a more systematic support structure was required to deliver the full potential of commercializing academic knowledge. As a result, the institute established a venture capital instrument with close links to the Harvard Business School and Boston financial interests. Similar developments occurred at Stanford University. This new approach later developed a set of key elements: the technology transfer and licensing office, the incubator facility and the venture firm (Etzkowitz 2002). The changing role of universities and the emerging "academic capitalism" is also described in Slaughter et al. (1997), in Henrekson et al. (2000) and in Bok (2003).

The closer research ties between academia and industry have created many forms of collaborative R&D. There are more than a thousand university-industry R&D centers in the U.S. For example, at the Stanford University Center for Integrated Systems (CIS), company researchers from several firms participate in formulating and carrying out joint research activities with academic researchers. Company researchers participate directly in the research activities on a rotating basis.

Some of these R&D centers, called Industry-University Cooperative Research Centers, receive support from the National Science Foundation. The government also provides direct funding to universities through other types of alliances with industry with the purpose to enhance national competitiveness. The Advanced Technology Program (ATP), the dual use program of the Department of Defense, various small business programs managed by the Small Business Administration (SBA) and NASA's Centers for the Commercial Development of Space are examples of federally sponsored programs that mandate university-industry collaboration (see the description of some of these programs below). The presence of government funding of centers and programs is usually seen as increasing the status of research activities and may provide the needed signals to attract additional private investments (NRC 2003).

Other types of university-industry relationships include industry-sponsored research, technology licensing, regional clusters and startup companies (see for example COGR 1996 and BHEF 2001).

3.2 Total and Industry Sponsored R&D at Universities

The total R&D effort by universities and colleges in FY 2001 amounted to 33 billion dollars. A total of 585 universities and colleges reported R&D expenditures but the top-40 institutions accounted for 50 percent of the total amount. As discussed above, this R&D is mainly financed by the federal government and by institutional funds, but also, to a much lesser extent, by state and local governments and by industry. Medical sciences account for the largest share by far of the total R&D expenditures by universities and colleges. In FY 2001, 10 billion dollars (30 percent of the total amount) was invested in the medical sciences while bio- and biomedical engineering received a smaller amount of 211 million dollars. The largest institutions in terms of expenditures in medical sciences were the San Francisco and Los Angeles campuses of the University of California with 487 and 462 million dollars in R&D spending respectively. Johns Hopkins University ranked third and spent 299 million dollars.

In FY 2001, industry financing of universities and colleges amounted to 2.2 billion dollars (up from 240 million dollars in 1980) or about seven percent of total academic R&D expenditures. There has been a steady increase of industry financing during the last couple of years but their share of the total funding has remained between six and eight percent. This percentage is similar for industry sponsored R&D at universities in Sweden. Duke University received the largest industry support in absolute terms of all R&D institutions. Its industry contribution was 104 million dollars, which accounted for 28 percent of overall R&D at the university. MIT and Pennsylvania State University ranked second and third in the list (see Table 3-1). The Industrial Research Institute and others project that industry funding of university research will more than double in absolute terms between 2000 and 2010 (BHEF 2001). Direct sponsorship of university research by industry is the most frequent form of university-industry relationship. Typically, the corporate sponsors provide funding for a specific research project and generally have the right to exploit intellectual property resulting from the funded research.

TABLE 3-1
Industry-sponsored R&D expenditures at universities and colleges for FY 2001

Rank in FY 2001	University	Industry sponsored R&D (million dollars)	Percent of total R&D effort
1	Duke University	104	28%
2	MA Institute of Technology	97	22%
3	Pennsylvania State University	68	15%
4	Georgia Institute of Technology	60	20%
5	Ohio State University	55	14%

Source: NSF 2003b

3.3 Licensing and Patents Activities

Universities and colleges collected about 830 million dollars in FY 2001 in royalties and other payments from licenses on inventions, according to a survey of 143 U.S. institutions by the Association of University Technology Managers (AUTM). This was between two and three percent of the total R&D effort conducted at universities and colleges that year. About 15 percent of all revenues went to a single institution – Columbia University – that reported royalties of almost 130 million dollars. The major part of this income came from licenses on patents that the university held for a genetic-engineering technique used by a number of biotechnology companies. MIT ranked second with 74 million dollars in revenues. About half of that came from cashed-in equity from two of the institute's companies – the Internet-company Akamai and the biotechnology firm Pracecis Pharmaceuticals. MIT had received stocks in the companies as payment for rights to use the MIT inventions (see Table 3-2). It is important to note that this ranking is highly dependent on a few "blockbuster" licenses, which generate most of the revenues.

TABLE 3-2
Licensing revenues collected by universities and colleges in FY 2001

Rank in FY 2001	University	Licensing revenues (million dollars)	Percent of total R&D effort
1	Columbia University	130	37%
2	MIT	74	17%
3	University of California system	67	2%
4	Florida State University	62	54%
5	Stanford University	39	8%

Sources: AUTM 2003 and NSF 2003b

Revenue from technology transfer was not a large portion of overall R&D expenditures at universities and colleges. Only ten institutions reported royalties in excess of 20 million dollars and 17 institutions reported over 10 million dollars. Of approximately 23,000 active licenses reported in FY 2001, only 131 generated more than one million dollars in income that year. The overall revenues were lower in FY 2001 compared to 2000, but technology transfer activities appeared to be on the rise. Licensing offices that participated in the survey reported that a total of 11,259 inventions were disclosed during FY 2001, up four percent from the year before. Participants filed more than 9400 applications for U.S. patents (up 12 percent), signed over 3300 licenses and created 402 start-up companies (AUTM 2003 and CHE 2003).

Table 3-3 shows the number of U.S. patents issued to specific institutions during 2002. The entire University of California system ranked first with 431 issued patents, followed by MIT with 135. To put these figures in perspective, the IBM Corporation received 3288 patents in 2002, more than any other private sector organization, for the tenth consecutive year (USPTO 2003). In a recent study of over 100 U.S. research universities, the average number of invention disclosures during the 1990s was 67 with a mean annual license income per disclosure of 43,000 dollars (Lach et al. 2003).

TABLE 3-3
Top-five U.S. universities receiving the most patents (preliminary number) for innovations during 2002

Rank in 2002	University	Number of patents
1	University of California system	431
2	MIT	135
3	California Institute of Technology	109
4	Stanford University	104
5	University of Texas	93

Source: USPTO 2003

3.4 Regional Clusters of Innovation

The connection between innovative research and regional economic development has led to the establishment of science and technology parks, innovation networks and “clusters”, often around a national laboratory or research facility. Examples are the high-tech companies that emerged around the government laboratories and major universities in the Boston area and Silicon Valley where multiple private industries interacted with a major university combined with substantial federal funding (see for example Saxenian 1994). According to the OECD, the most successful industry-science partnerships involve links between publicly financed research organizations and a cluster of local industries. This means that resources are focused around existing regional centers of excellence working within specific academic-industrial sectors (OECD 2002a).

One of the most successful planned science parks, the Research Triangle Park (RTP) in North Carolina is defined by three universities: the North Carolina State University in Raleigh (NCSU), the University of North Carolina at Chapel Hill (UNC-Chapel Hill) and Duke University in Durham. Together they form the foundation of the region’s knowledge-based economy by providing research facilities and a critical mass of scientists, researchers and technicians. The entire park encompasses about 150 organizations employing more than 45,000 people in two significant and successful clusters: telecommunications and biotech/pharmaceuticals.

The biotech/pharmaceuticals cluster includes a number of key institutes such as the North Carolina Biotechnology Center (NCBC), the National Institute for Environmental Health Sciences (NIEHS) and part of the U.S. Environmental Protection Agency (EPA), and major private firms such as BASF, Bayer Biotechnology, Biogen, DuPont and GlaxoSmithKline (CII 2001). The RTP biotech cluster has been studied in more detail by ITPS (ITPS 2003).

Clusters referred to as "high-tech" make up 2.5 percent of total U.S. employment and biotech/pharmaceutical clusters employed about 260,000 people in 1999 (0.23 percent of total U.S. employment). The RTP biotech/pharmaceuticals cluster rank number nine of the top economic areas in terms of the number of people working in the field. The New York area is by far the largest cluster with more than 80,000 employees in 2001 (see Table 3-4) (CII 2001).

TABLE 3-4
Top-five economic areas by employment in bio/pharmaceuticals clusters and the number of patents for each area

Rank in 2001	Economic area	Total employment 2001	Number of patents 1998
1	New York – Northern New Jersey – Long Island	82,300	542
2	Los Angeles – Riverside – Orange County	20,700	148
3	Philadelphia – Wilmington – Atlantic City	13,600	238
4	Indianapolis	9,600	89
5	Grand Rapids – Muskegon – Holland, MI	9,100	19

Sources: CMP 2003, CII 2001

When it comes to the particular field of biotechnology, nine metropolitan areas show the highest concentration of activities (see Table 3-5). The Boston area and San Francisco (Bay Area) pioneered the industry in the 1970s and are still the dominant centers. Philadelphia and New York have developed biotech activities related chiefly to the historical presence of large pharmaceutical manufacturers. Based on their medical research establishment, San Diego, Seattle and Raleigh-Durham have emerged as significant centers of biotech industry. Washington/Baltimore is home to the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and several firms related to the mapping of the human genome, and finally Los Angeles is home to the largest biotech firm in the U.S., Amgen. These areas demonstrate a strong research capacity and the ability to convert research into successful commercial activity. Together they account for three fourths of the nation's largest biotechnology firms.

Taken together, these nine centers received more than 4.4 billion dollars in NIH R&D funding in 2000, acquired over 23,000 biotechnology-related patents during the 1990s and had almost 900 venture capital investments, amounting to 8.6 billion dollars between 1995 and 2001. 63 IPOs (initial public offerings) were made between 1998 and 2001 in these centers with San Francisco (Bay Area) as the leader with 31 IPOs. An indicator of commercialization activities in the field is the number and value of research contracts extended to biotechnology firms by major pharmaceutical companies. Boston has been the most successful center to establish this kind of R&D alliances. Between 1996 and 2001, the area enjoyed such contracts with a total value of 3.9 billion dollars. The total amount for all nine areas was 9.8 billion dollars (Brookings 2002).

TABLE 3-5
The nine U.S. economic areas with a high concentration of biotechnology industries with NIH R&D, patents and investment indicators

Biotechnology center	NIH funding for R&D institutions year 2000 (million dollars)	Number of patents 1990–1999	Venture capital investments 1995–2001	
			Number of investments	Amount (million dollars)
Boston – Worcester – Lawrence	500	3007	211	1916
San Francisco – Oakland – San Jose (Bay Area)	473	3991	261	3029
Philadelphia – Wilmington – Atlantic City	432	3214	51	458
New York – Northern New Jersey – Long Island	763	6800	63	639
San Diego	379	1632	169	1506
Seattle – Tacoma – Bremerton	379	770	44	420
Raleigh – Durham – Chapel Hill	367	796	54	380
Washington – Baltimore	679	2162	20	85
Los Angeles – Riverside – Orange County	433	1399	26	181

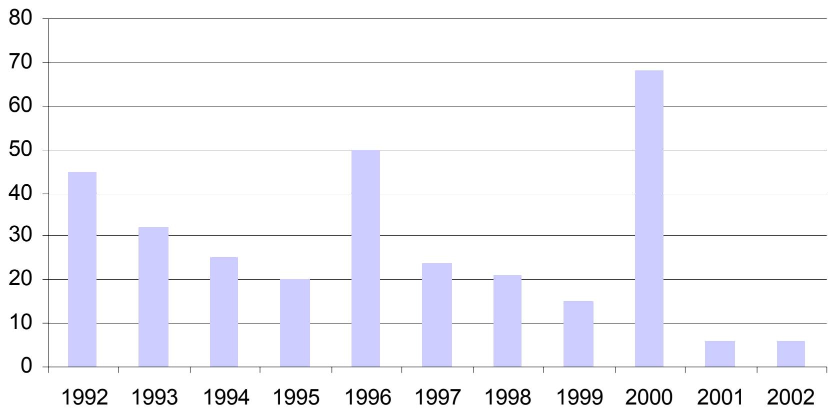
Source: Brookings 2002

3.5 Start-Up Companies and Business Incubators

New companies are established around major universities to commercialize research results and technologies. The rights to results are obtained through a license agreement and the university may take an equity position in the start-up company. According to the AUTM Survey, including both U.S. and Canadian research institutions, at least 494 new companies were created based on academic discoveries during FY 2001. 84 percent of them were established in the same state/province of the academic institution that created the technology. Since 1980, more than 3800 new companies have been formed based on a license from an academic institution, of which about 2100 were still in operation as of FY 2001. AUTM also found universities more often taking equity positions with their start-ups. Academic institutions received an equity interest in 70 percent of their start-ups in FY 2001, compared to 56 percent the year before (AUTM 2003).

The United States has by far the largest number of biotechnology companies in the world: almost 1500 companies in 2001 (up from about 1200 in the early 1990s) followed by Canada, Germany and the UK with between 300 and 400 companies each. Sweden ranks number seven with slightly less than 200 companies (Ernst&Young 2003). Diagram 3-1 shows the number of new biotech companies (IPOs) during the last ten years with clear peaks in 1992, 1996 and 2000.

DIAGRAM 3-1
Number of biotechnology IPOs (Initial Public Offerings) between 1992 and 2002



Source: Biotechnology Industry Organization

To support the process of starting and growing companies, the U.S. has a well-developed business incubation industry. In 2001, there were 950 business incubator programs operating in North America, up from about 590 in 1998. Half of these programs accepted a variety of clients and more than a third focused on assisting technology companies. Academic institutions are the most common incubation program sponsors. Apart from the more traditional services such as mentoring, access to office space, research facilities and manufacturing equipment, some incubators also offer entrepreneurs access to in-house investment funds, assistance with product designs and loaned executives to manage their companies. According to the National Business Incubation Association (NBIA), in 2001 alone, North American incubators assisted more than 35,000 start-up companies that provided full-time employment for nearly 82,000 workers and generated annual earnings of more than 7 billion dollars (NBIA 2003).

A recent study of 79 selected technology incubators in the U.S. found that the clients of incubators with greater biotech/biomedical focus had raised more money, obtained more research support, held more patents and licensed more technology than their peers. On the other hand, these incubators' clients had slower revenue and employment growth compared to mixed technology incubators. The 17 "best-in-class" incubators based on employment and revenue growth identified by the study, had a strong relationship with a research-intensive university or medical research institution, or were located in an area with a high concentration of technology-based companies. Most of the leading incubators focused on IT and electronics and five focused particularly on biotechnology and biomedical applications (see Table 3-6) (DoC 2003).

TABLE 3-6
Top-ten business incubators in the U.S. (not focusing exclusively on IT/electronics)

Biotech/biomedical focus	**Mixed technology focus**
Audubon Business and Technology Center, New York, NY	Business Technology Center of Los Angeles County, Altadena, CA
Association for Entrepreneurial Science, Rockville, MD	Ceramics Corridor Innovation Center, Painted Post, NY
Center for Emerging Technologies, St. Louis, MO	Long Island High Technology Incubator, Stony Brook, NY
MGE Innovation Center, Madison, WI	Purdue Technology Centers, West Lafayette, IN
Sid Martin Biotechnology Development Center, Alachua, FL	University of Central Florida Technology Incubator, Orlando, FL

Source: DoC 2003

4 Commercialization at Universities

4.1 Offices for Technology Transfer

As a direct result of the Bayh-Dole Act, academic institutions across the U.S. have established a strong national technology-licensing infrastructure to support the commercialization of research results. Since the 1980s, the number of Technology Transfer Offices (TTOs) in universities has grown from 25 to well over 200. Their responsibility is to implement the Act by facilitating and managing the disclosure and licensing of inventions with commercial potential. University technology transfer is mainly a system of inventions disclosure, patenting, licensing and enforcement of patents and licenses. The resources are almost entirely on the patenting process, where offices usually rely on external patent law firms, while considerably less is set aside for marketing the patents that result. In general, institutions market their intellectual properties primarily through web-based posting services (at the university or at the Association of University Technology Managers website).

Most TTOs have developed policies and guidelines for their activities that are available through web sites etc. and the Council on Governmental Relations, an association of research universities, publish guidelines and tutorials (see COGR 1999). As noted above, the direct economic impact of technology licensing on the universities themselves has been relatively small, with a few exceptions. It takes several years, typically between 5 to 10 years, to establish a new university licensing office and most offices barely break-even (Allan 2001, see also Sandelin 2003 for an account of best practices for university technology transfer including policies, procedures and resources).

Although, it is generally regarded that the TTO system works well, a recent study found that it is hard to convince faculty researchers to disclose their inventions. The study shows that the "higher quality" or "most productive" faculty are most often the least likely to bother with the distraction of pursuing commercialization. It is estimated that substantially less than half of the research results and developed technologies are disclosed for potential commercialization. A possible explanation is the fact that about 70 percent of university inventions require further R&D in a more applied direction than the original scientist or engineer may wish to engage in. In addition, the disclosure process itself is time-consuming, according to the study (Jensen et al. 2003).

Another challenge for the TTO system is to find skilled personnel. As the number of cases is increasing at most universities, the technology transfer offices also have to grow. Moreover, the cases the offices have to deal with are getting more and more complex, according to Javed Afzal, licensing officer at the University of California at Berkeley. Apart from solid knowledge in the specific scientific field, office staff must have legal and economic competence to judge whether the inventions is patentable or not, marketing and business skills in order to find commercial partners and finally, negotiation and social skills to be able to finalize a good agreement (personal communication with Javed Afzal).

It is widely recognized that university researchers need individual incentives to participate in the licensing process. For example, researchers at Stanford University receive one third of the net royalties from the licensing of their inventions. A recent study concluded that economic incentives, such as royalty sharing agreements, affect the number of inventions produced and the licensing income generated by universities. Universities that provide higher royalties to researchers trigger more inventions and higher license incomes. The study also found that researchers at private universities were four times more responsive to economic incentives than their colleagues in public institutions. Moreover, technology licensing offices in private institutions tend to have more effective, commercially oriented technology transfer activities and they are better at identifying and capture innovations for licensing to industry (Lach et al. 2003).

According to Jon Sandelin, a technology transfer expert at Stanford University, the inventor's active participation in the licensing process is crucial for a successful outcome. For example, the inventor may help to identify people in industry who should be interested in the invention. Such contacts are extremely valuable and it is key to licensing success that a person within the company acts as an invention advocate, according to Sandelin. The potential benefits to the inventor to participate in the process, apart from a share of net royalties, include additional research funding by the licensee directly to the lab of the inventor, paid consulting work, employment by the licensee (this is common when students are inventors/co-inventors) and payment for serving on scientific advisory boards (this is relatively common when the licensee is a start-up company) (Sandelin 2003 and personal communication with Jon Sandelin 2002).

Stanford University, MIT, Columbia University and University of California (UC) are among those established institutions considered most successful at university technology transfer. As a major public university, the UC is often considered a model that set standards for other universities. One interesting example of a university trying to leap-frog established technology transfer offices and create a new generation of technology venturing enterprise, is Arizona State University (ASU). The new president, recruited from Columbia University, has advocated a new general approach for the young university, including a focus on entrepreneurship. One of the initiatives is converting the old Office of Technology Collaborations and Licensing into a new entity called the Arizona Technology Enterprises, a technology development and commercialization company. The new program started in April 2003 with a director recruited from the private sector. Another example is the launch of the Arizona Biodesign Institute, an interdisciplinary research program and facility that will be fully operational by the end of 2004. The institute will serve as a prototype for the building of a new entrepreneurial research spirit at ASU. Moreover, it is expected to lay the foundation for new economic activity and contribute to the potential for a biosciences cluster in metropolitan Phoenix (Crow 2002, Kress 2003, personal communication with Michael Crow 2003).

4.2 Stanford University Technology Transfer

Stanford University, a private university, has long been a leader and benchmark institution in technology transfer through patenting and licensing. The Stanford's Office of Technology Licensing (OTL) was established in 1969, 11 years before most other universities took the same step because of the Bayh-Dole Act (for example, the Office of Science and Technology Development at Columbia University was established is 1982). The office reports to the Office of the Dean of Research and has about 25 employees and six full-time licensing associates that manage almost 2000 active cases. Each associate has an area of technical expertise and is responsible for a portfolio of cases from "cradle to grave". Over time, the office has executed 1956 licenses from a total of 4850 disclosures.

OTL pioneered the "marketing approach" to technology transfer by actively looking for licensees for those inventions with the highest potential. One result of this approach was the patenting of recombinant DNA or "gene splicing" in 1980, a program that returned 255 million dollars over the life of the patent. Stanford's technology transfer program has followed the pattern of most other programs: most income come from a limited number of "blockbuster" technologies. In FY 2002, Stanford earned about 50 million dollars in royalties from 385 technologies, seven of those produced royalties of more than one million dollars each. During that year, OTL concluded 112 new license agreements (down from 137 the year before) totaling 1.4 million dollars (down from 3 million dollars) in up-front license fees. The number of disclosures during the calendar year 2002 was a record 315 (up 9 percent from last year). Approximately 48 percent were in the life sciences and the rest in the physical and computer sciences. The rate of licensing of inventions is thus about 30 percent.

OTL retains 15 percent of the gross license income and the remaining 85 percent is split between the inventors, their departments and schools and colleges. In FY 2002, inventors received personal income of 11.3 million dollars, departments received 13.5 million dollars and schools received 13.1 million dollars. The School of Medicine received by far the most royalty payments of all Stanford schools (8.2 million dollars or 62 percent of total payments). The total patent expenses amount to about 5 million dollars per year for OTL with a cost for a U.S. patent being between 25,000 and 35,000 dollars over the life of the patent. A patent with broad foreign coverage usually reaches a cost of 200,000 dollars.

Stanford does not have a policy to give preference to local licensees. However, a strong regional market exists for new inventions with the rich ties between Stanford faculty and students and local businesses and venture entrepreneurs. Despite the fact that the economic downturn has negatively affected Silicon Valley, OTL licensed and received equity in 13 companies in 2002. Over the OTL lifetime, Stanford has held equity in 117 companies and earned approximately 21 million dollars. Stanford Management Company manages the equity, which is generally sold as soon as a public market exists.

Stanford OTL also administers a Birdseed Fund to provide small amounts of money (typically up to 25,000 dollars) for prototype development. Twenty-one projects have been funded to date. The Gap Fund was established in 2000 to support development efforts up to 250,000 dollars for unlicensed technologies. The purpose is to advance the technology to a point where it will be more attractive to potential licensees. Two projects were approved in 2002. Although licensing activities constitute the majority of OTL's work, the office also handles copyright (software), trademark licensing, Tangible Research Property (TRP) and outgoing Material Transfer Agreements for biological materials (Sandelin 2003, OTL 2002 and 2003).

To improve relations with industry, the Industrial Contracts Office (ICO) was established in 1997 under the OTL. The office negotiated over 500 university-industry contracts and worked with more than 100 companies during 2002. Stanford University has historically encouraged active involvement with industry. The relationships created have been very important for technology transfer and for the formation of university-linked start-up companies as well as for bringing in funds. Apart from 50 million dollars in royalties from licensing, industry-sponsored research projects collected 39 million dollars in FY 2002. This research focused on "basic inquiry" rather than on product or invention development. In its industry contacts, Stanford is committed to the principle that researchers must have the right to publish their work. The university allows a short delay in publication (not to exceed 90 days) for the corporate sponsor to review preprints and to request the filing of patent applications. In addition, Stanford prohibits any program of research that requires secrecy and do not wish to acquire confidential information from a sponsor.

Other sources of income include the Stanford Center for Professional Development. This initiative by the School of Engineering delivers Stanford academic programs to over 450 member companies and government organizations, and reaches more than 5000 students annually via broadcast television, videotapes, and the Internet. The university runs Industry Affiliate Programs where companies pay annual fees for networking and information. Stanford also enjoys generous corporate contributions towards buildings, endowed professorships or contributions to Interdisciplinary Research Centers. Another important university-industry link is industry advisory boards, something that is common among Stanford's more than 100 research centers.

Apart from running the technology licensing office, Stanford has taken a number of measures to support entrepreneurship and foster an innovative environment. The Stanford Entrepreneurship Task Force is an effort to coordinate such activities on campus and with the members of the Silicon Valley entrepreneurial community. The task force provides a vehicle for venture capitalists, attorneys and others to stay in touch with activities in Stanford's laboratories. The network also includes alumni entrepreneurs, faculty consultants and student-workers. Important support for the task force has been provided by the Technology Ventures Program, a teaching and research effort by the School of Engineering to train engineers and scientists in entrepreneurship skills.

A number of funding organizations have approached Stanford in search of ideas to convert into new ventures. One example is Concept2Company (C2C) that assists university researchers develop their ideas, typically when the inventor is not interested in leaving the university job. C2C has helped to turn business and technology concepts into companies at Stanford and other leading universities. The firm has raised more than 200 million dollars in venture capital since 1997. Stanford also has an industrial park that is now the home of some 300 companies that wish to be in close proximity to Stanford and Silicon Valley (SGPB 2002a, Sandelin 2001 and 2003).

4.3 University of California (UC) Technology Transfer

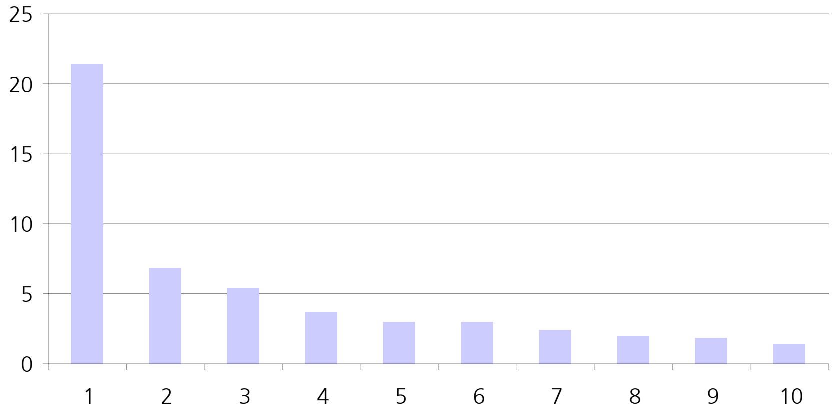
According to its mission statement, an important aspect of the University of California's public service mission is to "ensure that the results of its research are made available for public use and benefit". To achieve this objective, the university has maintained an active patenting and patent licensing program for over 40 years. As a result, the UC with its ten campuses is the leading university system in the U.S. in terms of number of patents and in the number of successfully commercialized inventions. The UC has received more patents than any other university in the world, which includes successful inventions such as the human growth hormone.

UC holds an active portfolio of almost 5500 inventions, holds more than 3000 U.S. patents and well over 200 companies have been founded to bring licensed technologies to the marketplace. UC San Diego (UCSD) and UC San Francisco (UCSF) are the most active in technology transfer. In FY 2002 (the year ending June 30, 2002), a record number of 973 inventions were disclosed from all campuses. Inventions in life sciences, including medicine and biotechnology, accounted for over 70 percent of new inventions, while those in physical sciences and engineering accounted for most of the remaining 30 percent.

The total licensing revenue reached 100 million dollars in FY 2002. UCSF alone, generated more than one third (34 million dollars) of that amount. Of the total licensing revenue, 88 million dollars (up 21 percent from FY 2001) came from royalties and fees derived from 980 technologies. The top-5 commercialized inventions earned royalties exceeding 40 million dollars. The top-earning invention was the Hepatitis-B Vaccine (21 million dollars), invented by UCSF in 1979 and 1981 (see Diagram 4-1).

DIAGRAM 4-1

The ten top-earning inventions at the University of California in million dollars for FY 2002. The average income per invention was 90,000 dollars



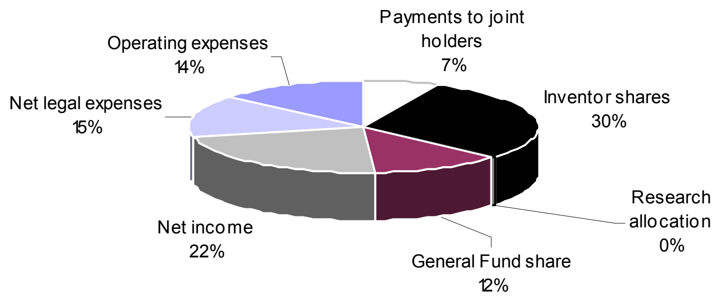
Source: UCOP 2002

According to the UC policy, inventors have the right to receive a portion of the total invention earnings. When there are two or more inventors, each shares equally in the income unless the inventors agree on an alternative distribution. Under current policy, inventors receive 35 percent of net invention income. Royalty payments are made to the inventors in November and their shares in any given year are calculated based on invention income and expense activity of the prior fiscal year. In FY 2002, a total of 1129 inventors received 26 million dollars based on the financial activity of their inventions through June 2001. There has been a steady increase in the number of inventors receiving distributions during the last five years (FY 1998 to FY 2002). However, the total amount they have received has been more stable between 24 and 33 million dollars during that period.

Over 30 million dollars was returned to the UC system for reinvestment in research and education during FY 2002. This amount includes three types of income distributions. First, current UC policy requires that 15 percent of net royalty and fee income from each invention be designated for research-related purposes at the inventor's institution or laboratory. The research allocation only totaled 406,000 dollars in FY 2002. Second, a portion of technology transfer income is allocated to the UC General Fund, which is part of the State-approved budget. It is calculated as 25 percent of the amount remaining after deducting direct expenses and payments to joint holders and inventors from the total licensing revenue. This mandatory distribution totaled 10.6 million dollars in FY 2002. Finally, the remaining portion of income, after expenses and other distributions, is available to be distributed to campuses to support ongoing research and education programs. The net income amounted to 19.6 million dollars in FY 2002.

The technology transfer financial activity also includes payments to joint patent holders (inventions resulting from collaboration between UC and non-UC researchers) as well as legal and operating expenses. Most technology transfer legal expenses are associated with patent prosecution, including payments for drafting patent applications. Operating expenses include funds spent for administration of the technology transfer program at the different UC licensing offices. Net legal and operating expenses amounted to 13.4 and 12.1 million dollars respectively in FY 2002. Operating expenses were 12 percent of total licensing revenues (see Diagram 4-2).

DIAGRAM 4-2
The financial distribution of technology transfer activities at the University of California system in FY 2002. The total income from royalties and fees was 88.1 million dollars



Source: UCOP 2002

At a public university such as UC, the main mission for technology transfer activities is the “public good” according to documents and statements. However, the fact that commercialization activities and university-industry interaction actually have demonstrated that it benefits research activities at the university may be a more important driver in the end, according to Suzanne Quick at UC. Even if it is not the first priority goal, she also points out that it is very important to be able to show that the technology transfer activities generate revenues for the university that can be invested in further research. In line with its public services mission, the UC is also expected to get fair compensation for making research results available to the private sector.

The UC technology transfer program is headed by the system wide Office of Technology Transfer (OTT). The office has the responsibility for policy development, legal oversight and other coordinating services. In addition to the campuses that have their own offices for technology transfer and sponsored research, offices at three UC-managed Department of Energy laboratories are included in the overall program (see Table 4-1). Each campus and laboratory develop and shape technology licensing programs that is suitable to their particular needs under a memorandum of understanding negotiated with the UC Office of the President. General oversight of the UC technology transfer program is provided by the Technology Transfer Advisory Committee (TTAC). This standing committee advice the UC president on technology transfer policy and guide the direction of the overall program (UCOP 1997 & 2002, personal communication with Suzanne Quick and Kelly Dinglasan).

TABLE 4-1
Technology transfer and sponsored projects offices at the University of California with WEB SITES on the Internet

UC Office of the President: Office of Technology Transfer (OTT)	http://www.ucop.edu/ott/
UC Berkeley: Office of Technology Licensing (OTL)	http://otl.berkeley.edu/
UC Davis: Technology Transfer Center (TTC)	http://ovcr.ucdavis.edu/TTC/
UC Irvine: Office of Technology Alliances (OTA)	http://www.ota.uci.edu/
UC Los Angeles: Office of Intellectual Property Administration (OIPA)	http://www.research.ucla.edu/oipa/
UC Riverside: Intellectual Property Services	http://www.ora.ucr.edu/
UC Santa Barbara: Sponsored Projects Office	http://research.ucsb.edu/
UC Santa Cruz: Office of Sponsored Projects	http://www.ucsc.edu/osp/industry.html
UC San Diego: Technology Transfer and Intellectual Property Services (TTIPS)	http://invent.ucsd.edu/
UC San Francisco: Office of Technology Management (OTM)	http://www.otm.ucsf.edu/
Los Alamos National Laboratory: Industrial Business Development Program Office	http://www.lanl.gov/partnerships/
Lawrence Berkeley National Laboratory: Technology Transfer Office	http://www.lbl.gov/Tech-Transfer/
Lawrence Livermore National Laboratory: Industrial Partnerships and Commercialization Office	http://www.llnl.gov/IPandC/

4.4 UC Patent Policy and Process

The UC patent policy recognizes the need for encouraging the broad utilization of the results of university research. The primary purpose of developing a licensing strategy for an invention should be to benefit the public, according to the policy. The main objectives for the UC patenting and patent licensing program are to:

1. Disseminate new and useful knowledge through the patent system.
2. License patents to industry to promote the development of inventions toward practical application.
3. Provide income for the use in further research and education, with a share of the income going to the inventor.

In addition, the Bayh-Dole Act of 1980 requires the university 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."*

The current UC patent policy was put in place in 1997 and it stipulates that the university obtains title to inventions or discoveries developed in the course of university employment, with the use of university research facilities or with university-controlled funds. Researchers involved in activities under these conditions are required to sign a contract called University Patent Acknowledgement. In the contract, they agree to disclose promptly the conception or development of potentially patentable inventions and to assign all rights to all inventions to the university. This means that the researcher does not have the option to take his or her invention to another institution for commercialization. The patent agreement does not cover results from permissible consulting activities without the use of university facilities. Graduate and undergraduate students are required to sign the agreement if they are also employees or if they participate in extramurally supported research projects.

The process of invention disclosure, patenting and licensing can be described by the following steps or phases:

1. The technology transfer process starts with a disclosure of an invention. It is the responsibility of the researcher to submit, as soon as possible, a Record of Inventions Form to the campus or laboratory patent coordinator. This information is confidential and researchers must not report inventions directly to research sponsors.
2. A preliminary evaluation is made by the university licensing officers. Factors such as patentability, commercial potential and patent rights of outside parties are considered in selecting cases to pursue further. The cost of patent prosecution, any impending publication bar dates and patent obligations to research sponsors also influence the desirability of obtaining patent coverage. The inventor is typically not involved in this phase of the process. The preliminary evaluation normally takes about 30 days.

3. As a next step, inventions that qualify are marketed to find a relevant licensee. If there is sufficient, commercial interest in the invention the case may be referred to a patent attorney. A prior art search in the U.S. Patent and Trademark Office (USPTO) is conducted and the attorney submit a preliminary opinion on patentability. This process usually takes 60 to 120 days.
4. If it is decided to proceed, the university licensing office authorizes and coordinates the process of filing a patent. A patent attorney is engaged to draft the patent application with close participation by the inventor. The application is submitted to the USPTO in the name of the inventor. At the same time, the inventor signs another agreement assigning the patent to the university. In some cases, the OTT decides that it is not financially desirable to file a patent. If the invention cannot be licensed or used by the university in any other way, it will be “returned” to the government. In this case, the inventor can ask to have the rights released from the government and be assigned directly to him or her (this is not very common, according to the OTL at UC Berkeley).
5. The process at the USPTO normally requires a series of communications with the patent examiner. The patent attorney, the licensing office and the inventor work together to respond to the examiner’s requests and to seek the broadest possible protection for the invention. The whole process normally takes at least two years. When it comes to foreign patents, the licensing office only recommends filing a patent when the cost is likely to be recovered from a licensee.
6. In order to find a licensee of an invention, the university licensing office contacts appropriate companies to assess their interest. Information by the inventor about possible companies is particularly important in this phase. If a private firm contacts the inventor directly, he or she should refer the firm to the licensing office. In many cases, licensing occurs before the patent is issued. Potential licensees may evaluate an invention during this period through the use of a secrecy agreement between the university and the commercial partner. If the research was performed with corporate financial support, the license is first offered to that sponsor before it is offered in the marketplace. Most biotechnology inventions are licensed to small businesses at UC Berkeley. They are more diligent in getting the technologies to the market, according to Javed Afzal. In some cases, the inventor may have the option to form a start-up company to develop the invention. This happens only in 10–20 percent of the cases in the area of biotechnology at UC Berkeley.

7. When a commercial partner has been identified, the licensing office is negotiating a license agreement on behalf of the university. The terms and conditions vary between agreements and they are negotiated on a case-by-case basis. Royalty rates are negotiated as part of the agreement. Under certain conditions, the university may accept equity in a company as partial compensation for technology licensing. An exclusive license may be granted when all of the funding was provided by one commercial sponsor or if it is deemed the best way to assure the development of the invention. If the invention was conceived in whole or in part with support from a federal agency, the U.S. government also receives a royalty-free license for government use, according to the Bayh-Dole Act. When no overriding sponsor rights exist, patent rights may be released to the inventor when the university elects not to file a patent application or commercialize an invention. Even if outside sponsorship is involved, including from federal agencies, the inventor may be able to obtain rights.
8. In some cases, a licensee wants to engage the university inventor as an independent consultant to assist in transferring the technology from the academic to the private sector. Consulting agreements are normally made between the inventor and the company without the university becoming a party. However, university policies on faculty and employee consulting apply to this situation and all consulting agreements must contain the phrase “subject to prior obligations to the University of California”. Earning money from consultancy work is also an incentive for the inventor. This income can be enjoyed earlier than the licensing revenues that may take as long as five to six years to reach the inventor.

This patenting and licensing process is slightly different depending on the nature of the research on the different UC campuses. For example, compared to research at a medical school (UCSF), the inventions from UC Berkeley in the area of biotechnology are more basic in nature. As a result, they typically take longer and are more risky to develop. This means that few research results are “ready to license” and it is common (in up to 90 percent of all cases) to negotiate an “option to license” agreements to compensate for this uncertainty. Under these agreements, companies get a one-year period to further investigate if they want to license the invention (UCOP 1997, 2001a & 2001b, personal communication with Javed Afzal).

Clinical trials are handled somewhat different from research contracts. Clinical trials are less uncertain and there is a specified method (protocol) and an anticipated outcome. The sponsor is granted the right of this outcome but not to any “unexpected” inventions that might occur during the trial. This does not happen very often, according to Kelly Dinglasan, Industry Contracts Division, UCSF, but it is included in the agreement just in case. At UCSF, there are two types of clinical trials: sponsored authored protocols, which is the most common type, and UCSF authored protocols. Clinical trials are more frequent but industry sponsored research amounts to more money. The trend is that both types are increasing at UCSF. The UC publication policy is that the investigators have an absolute right to publish results. The sponsor can review the content and may delay publication for up to 60 days (to allow for patent application), but cannot edit anything (UCSF, personal communication with Kelly Dinglasan).

4.5 Other UC Policies

Apart from the patent policy, there are a number of system-wide policies relevant for technology transfer at the University of California. Suzanne Quick at the UC Office of Technology Transfer (Office of the President) also points out the copyright and equity policies as well as the guidelines for faculty consulting and the so called principles policy, as particularly important. The copyright policy is fairly traditional but the equity policy has been more controversial.

The equity policy was created in 1996 to make official the practice of accepting equity as partial compensation for technology licensing-related transactions. This practice is now accepted at most universities but it is generally easier for private universities to take stakes in companies than it is for public universities. It is difficult to become part in managing a firm since it can create conflicts of interest and may compromise the public service responsibilities of a public university, according to Suzanne Quick. The policy allows the university to accept equity up to ten percent in a company as a last resort. This is mostly the case with smaller companies (UCOP 1996, personal communication with Suzanne Quick).

To clarify further the issue of faculty consulting and intellectual property, the UC Office of the President issued a new set of guidelines during 2003. The purpose was to make clear that university employees are responsible for ensuring that their personal consulting agreements do not conflict with their employment obligations regarding disclosure and assignment of inventions to the university. The general guiding principle is that the UC encourages faculty to participate in outside professional activities that contribute to their profession and to the broader community, including the university's public service mission. Three potential problem-areas are of particular interest in the document.

First, the guidelines point out that disclosure is a legal obligation of employment at the university and that all inventions must be disclosed, including inventions made on free time, at home or during paid or unpaid consulting work. If it is necessary to disclose company proprietary information to the university when disclosing an invention, this information may be protected by a non-disclosure agreement between the company and the university.

Second, the university regulates the permitted consulting time but not the amount of compensation. Full-time faculty members on a nine-month or fiscal-year appointment may engage in compensated consulting activities for 39 or 48 days respectively during the year. Faculty members may consult full-time during the summer months in which there is no other salary compensation from the university. The UC has a specific policy on conflict of commitment, which requires faculty members to submit annual reports on outside professional activities, including consulting, to their department chairs.

Finally, faculty members and researchers must disclose any financial interests with a company, such as consulting activities, when accepting research funding at the university from that company. In addition, the National Science Foundation (NSF) and the Public Health Service (PHS) require all researchers to report any financial interests in entities that may be affected by the work performed under the sponsored project. Thus, both State law and NSF/PHS regulations stipulates the disclosure of existing or prior consulting activities, which might require that a university grant be reviewed and approved by a campus Independent Substantive Review Committee (ISRC) as to conflict of interest concerns (UCOP 2003).

The principles policy was developed in 1999 to address issues regarding rights to future research results in university agreements with external parties. Following increasing interaction with industry during the last decade, agreements have become more complex and the number of different types of agreements has increased. However, there are a set of common values at the university that should be preserved and they must be agreed upon, articulated and communicated, according to Suzanne Quick.

The principles offer a basic framework that enables the UC to maintain consistency in managing research results across the campuses while providing a greater flexibility in the local administration of agreements. In addition, the principles were designed to provide university negotiators with a basis to support positions taken during often challenging contract negotiations. The policy stipulated the following eight principles:

- Open dissemination of research results and information. Agreements with external parties shall not abridge the ability of university researchers to disseminate their research methods and results in a timely manner. The most fundamental tenet of the UC is the freedom to interpret and publish or otherwise disseminate research results in order to support the transfer of knowledge to others and maintain an open academic environment that fosters intellectual creativity.
- Commitment to students. Agreements for research relationships with external parties shall respect the university's primary commitment to the education of its students.
- Accessibility for research purposes. Agreements with external parties shall ensure the ability of university researchers to utilize the results of their research to perform future research.
- Public benefit. Agreements with external parties shall support the ability of the university to make available for the public benefit in a diligent and timely manner any resulting innovations and works of authorship.
- Informed participation. All individuals involved in research governed by a university agreement with an external party shall have the right and responsibility to understand the rights and obligations related to future research results embodied within the agreement.

- Legal integrity and consistency. Commitments concerning future research results made in agreements with external parties shall be consistent with all applicable laws and regulations and the university's contractual obligations to others.
- Fair consideration for university research results. Agreements with external parties shall provide fair consideration to the university and the general public for granting commercial access to future university research results.
- Objective decision-making. When establishing or conducting university relationships with external parties, decisions made about rights to future research results shall be based upon legitimate institutional academic and business considerations and not upon matters related to the personal financial gain of any individual.

These principles should apply to all university agreements with external parties, including contracts and grants, which affect rights to research results, according to the policy. According to Suzanne Quick, the UC was one of the first universities to develop a principles policy and it has generated a lot of interest from other universities (UCOP 1999, personal communication with Suzanne Quick).

4.6 Technology Transfer Support at Two UC Campuses

The UC San Francisco (UCSF) is one of the world's largest health-sciences institutions, a prominent actor in biomedical research, patient care and higher education. With 18,000 employees and an annual budget of about 1.9 billion dollars, UCSF is San Francisco's second-largest employer. UCSF scientists have been responsible for launching over 70 California biotechnology companies, including industry giants Genentech and Chiron, since the 1970s.

According to a Business Week article, its achievements and culture has attracted both faculty and funding on a large scale. Starting in 1969, UCSF institutionalized the practice of collaborative research by grouping researchers with a common interest instead of creating specialized departments. This strategy established a cross-disciplinary "hothouse" – an innovation machine, according to the article (Business Week 2003). One result is that UCSF has by far the largest patent and license agreement portfolio of all UC campuses.

The entrepreneurial environment at UCSF includes the Entrepreneur Discussion Group (EDG) that provides an informal environment for getting feedback on early-stage ideas and the UCSF Center for BioEntrepreneurship (CBE), which was established in 2001 to introduce students and faculty to the business skills needed for success in the life science industry. In addition, the UCSF Innovation Accelerator (IA) supports the growing entrepreneurial spirit by establishing a network of Bay Area scientists and business professionals interested in life science entrepreneurship and by helping entrepreneurs develop their innovative ideas into viable businesses.

A new type of consortium called PharmaSTART, led by SRI International was announced in August 2003. Apart from UCSF, three other leading California research organizations were founding members: Stanford University, UC San Diego and the UCSF campus of the California Institute for Quantitative Biomedical Research (QB3). PharmaSTART will help accelerate the translation of breakthrough new drugs from discovery into clinical use. The consortium will address this innovation gap by offering drug development and consultation services, create new collaborations, start drug development initiatives and find new funding sources, according to the press release (SRI 2003).

The UC San Diego (UCSD) also has a strong position in biomedical sciences. Among all medical schools, UCSD School of Medicine ranks first in the U.S. in federal research funding per faculty member, and six departments are in the top-10 in National Institutes of Health (NIH) funding in their areas. The health sciences attract nearly 42 percent of UCSD's total research funding. In the 1980s, the university started to develop close university-industry linkages and has become a significant player in entrepreneurial development in the San Diego area.

The university has maintained a regional orientation toward licensing and many licensees are in the San Diego/Orange County/Los Angeles area. UCSD has spun off 150 San Diego companies, including 63 in the biomedical industry. To help speed up the commercialization process, the Technology Transfer and Intellectual Property Services (TTIPS) has established a License and Entrepreneur Assistance Program (LEAP) that helps small companies in the community as well as entrepreneurial faculty researchers to access and commercialize UCSD technologies.

The most famous technology transfer initiative is the CONNECT program. Established in 1985, it is primarily an economic development organization focused on regional high-technology entrepreneurship. According to the organization itself, UCSD CONNECT is widely regarded as the most successful regional program in the U.S. linking high-technology and life science entrepreneurs with the resources they need, such as technology, funding, markets, management, partners and support services. The program has assisted more than 800 technology companies since it was established. The program is entirely self-supporting and receives income from members, events and grants but does not get university funding. Nearly 1000 companies support the program in one way or another. The model has been replicated in other cities and countries, including Sweden.

CONNECT has a wide range of activities on its agenda, including networking activities, events, courses and assisting entrepreneurs. One example is a program called Springboard, which has a focus on early stage entrepreneurs. Participants receive coaching in business plan development by experienced technology executives. When ready, participants make a presentation to a feedback panel of investors, lawyers and industry representatives. Springboard has helped over 150 companies to raise more than 200 million dollars in capital.

Finally, CONNECT also hosts an annual Biotechnology Corporate Partnership Forum. The forum provides an opportunity for San Diego biotech companies to introduce their technologies to pharmaceutical companies, venture capitalists and larger biomedical firms. A related networking activity is the Biotech Business Development CONNECT (SBA 2000, CII 2001, SGPB 2002b). CONNECT networks have also been established outside the U.S., including Sweden.

5 Funding Technology Transfer

A fundamental contribution to the U.S. entrepreneurial economy was making capital more accessible to innovation enterprises. Technology transfer funding comes from a variety of sources including the federal government, such as the Small Business Innovation Research (SBIR) program (see below), as well from private sources such as individual investors ("business angels") and venture capital firms. Funding possibilities vary in design depending on the stage in the technology development process; from basic research to a viable business (see Table 5-1). The capital needs also range widely depending on stage of development: start-up (stage 2): up to about 300,000 dollars, early-stage (stage 3): between about 300,000 dollars to 3 million dollars and the venture capital phase (stage 4 and 5): over 3 million dollars (see also ITPS 2002 about funding start-ups and small companies).

TABLE 5-1
An idealized model of technology development and funding. X means source frequently funds this stage and (X) means that source occationally funds this stage

		Potential funding sources			
Stage	**Activity**	Federal R&D funding (i.e. NSF, NIH), corporate research, SBIR phase I	Angel investors, corporations, technology labs, SBIR phase II	Venture capital	Corporate venture funds, commercial debt
1	Basic research	X			
2	Proof of concept/invention	X	(X)		
3	Early-stage development	(X)	(X)	(X)	
4	Product development		(X)	X	(X)
5	Production/marketing			X	X

Source: NIST 2002

Start-up funding includes the entrepreneurs' own private savings, investments by family members and friends, credit cards and a second house mortgage. Federal public policy has played a major role in making these types of start-up financing possible. For example, securities laws provided broad exemption from securities registration requirements for investments by friends and family, which reduces the cost of selling stock to such investors. Moreover, banking laws allow for access to an abundance of credit card funds. Changes to the bankruptcy laws starting in 1978 favor the individual creditor in such a way that the entrepreneur does not risk loosing house and home if the business fails. These regulations support the wide-spread view that a business failure is acceptable – experiences not to be ashamed of, but learned from – according to a report from the National Commission on Entrepreneurship (NCE 2002a).

5.1 Early-Stage Funding

Entrepreneurs use a wide variety of funding options to keep early-stage technology projects alive, such as successive rounds of equity offerings, contract work, income from licensing patents, sale of spin-off firms as well as angel funds, angel investment backed by bank debt, university and corporate equity investments, seed investments by university, corporate venture capital programs, the Small Business Administration's basic loan program and certain other experimental R&D programs run by federal and state agencies.

It is difficult to estimate how much money flow into early-stage technology development activities. A recent study from Harvard University made two estimates based on one restrictive and one inclusive definition of this activity. It concluded that between 5 and 37 billion dollars out of the overall R&D spending in 1998 was devoted to early-stage technology development. Most funding came from industry (32 percent with restrictive definition and 48 percent with inclusive definition), individual private equity investors – "business angels" (28 and 24 percent) and the federal government (25 and 20 percent). Only small portions came from venture capital (8 and 2 percent), state governments and universities. The study estimated that corporate spending on early-stage technology development was about 13 billion dollars annually or around 10 percent of total corporate R&D spending. Industry support levels vary widely by industry and by companies within industries. Investments in the computer software industry are essentially zero while the rate is about 13 percent for the biopharmaceutical industry. The range within the biopharmaceutical industry was between 0 and 30 percent of R&D at the companies participating in the study (NIST 2002).

Angel investors provide the most significant source of funding for individual technology entrepreneurs and small technology start-ups while venture capitalists prefer to support firms that have at least proceeded beyond the product development stage. Angel investing has increased rapidly in past years in parallel to the dramatic growth of venture capital investments. For example, in 1999, private investments by individuals were estimated to more than 63 billion dollars compared to 49 billion dollars invested by venture capitalists.

Apart from individual and ad hoc angel investors, it is estimated that there are at least 170 formal and informal angel groups across the U.S., up from about 50 in 1997. These groups have part-time or full-time management, standardized investment procedures and a public face in the form of a web site and public relations activities. Angels do not only provide financial means to a start-up firm, they may also bring entrepreneurial and industrial expertise, as they serve as active advisors and provide additional relationships to aid business growth. Angel groups, which usually vary in size from a few members up to about 80 people, operate with different structures and there is not yet a leading candidate for an optimal model. Example of angel groups in California are Pasadena Angels, Tech Coast Angels and The Angels' Forum, and in New England: Angel Healthcare Investors, Common Angels, Hub Angels and Launch Pad (see EMKF 2002a for further information on angel groups).

The growth of the individual investor market was supported by legal reforms in 1978, which significantly reduced the capital gains tax compared to tax on ordinary income. This change was instrumental in changing the attitudes of potential investors, creating a mind-set that successful investments in entrepreneurial companies offered extraordinary returns, according to an NCE report. Moreover, the Tax Reform Act of 1986 drastically reduced the number of tax shelter schemes available to individual investors and as a result, investment money looked for other high-return opportunities, such as venture funds and direct equity investments in start-up companies (NCE 2002a).

It is important to note that the availability of funding is strongly concentrated in a few geographical regions and in a few industries. Early-stage technology development is strong in regions that invest heavily in R&D and that possess well-developed risk-capital networks and related complementary infrastructure (such as Boston Route 128 and Silicon Valley). State governments play a critical role in establishing regional environments that help bridge the gap between invention and innovation (see the section about clusters above). According to the Harvard study, angel investments are even more locally focused than venture capital. This indicates the importance of innovator-investor proximity and social networks supporting people and institutions (NIST 2002).

5.2 Venture Capital Investments

The U.S. venture capital market is the largest and most developed in the world and has played a crucial role in the formation of new high-technology companies. Over 80 percent of the entire world's venture capital is invested in the U.S. Federal policy changes in 1979 and 1980 encouraged the growth in venture capital. Less than a total of 700 million dollars invested before 1978 increased to almost 100 billion dollars invested during the peak year 2000 alone. Even during the current economic situation (2003), the venture capital investment rate is higher than any year before 1999. Healthcare investment made a comeback in 2002 with 27 percent of total investments, up from 17 percent in 2001. Although investments in healthcare companies declined in absolute terms from 6 billion dollars in 2001 to 5.2 billion dollars, this 14 percent drop is much smaller than the 48 percent decline in the IT sector (see Table 5-2).

TABLE 5-2
Investments made by venture capitalists or venture capital-type investors in U.S. companies – total and healthcare industry

Calendar year	Total VC investment (billion dollars)	Investments in healthcare (billion dollars)	Percentage of healthcare investment
1998	17.71	3.51	20%
1999	48.96	4.86	10%
2000	93.75	9.38	10%
2001	34.57	6.04	17%
2002	19.43	5.17	27%

Source: VentureOne 2003

During the past few years, venture capital funds have grown in size and they tend to fund less risky, and more later-stage investments. Some of the firms still do seed funding but the average company deal was about 15 million dollars in 2001 (and half of deals were below the 7 million dollars size). Venture companies are also focusing on existing companies and make later rounds of funding and restarts instead of seed and first round investments. First round venture investments fell from 37 percent of the deals in 2001 to 30 percent in 2002 (NIST 2002, VentureOne 2003).

Several steps of public policy reform have supported the growth of venture capital funds. First, the Small Business Investment Companies (SBICs) program was created in 1958 under the Small Business Administration. This meant that banks were allowed to form subsidiaries that could make equity investments in entrepreneurial companies (see the related section below). One important implication of this reform was that the program started to build the human capital infrastructure for the venture capital industry, creating people skilled at the art of risk capital intermediation. Second, new regulation in 1979 allowed public pension funds to invest a small portion of their assets in high-risk ventures, a change that had immediate and enormous impact on venture capital funds. Most of the money raised during the high-growth period came from public pension funds. Finally, the Small Business Investment Incentive Act of 1980 established that venture capital funds were business development companies and therefore not subject to registration and regulation under the Investment Advisers Act.

A number of other mechanisms were important to support the venture capital market, such as the establishment of NASDAQ in 1971 that provided a vehicle for making Initial Public Offerings (IPOs) and a set of regulations that facilitated acquisitions, making entrepreneurial companies attractive to buy for large companies. On a more fundamental level, even despite the recent corporate scandals, it can be argued that the American securities and financial disclosure system (established in the 1930s) created an atmosphere of confidence and trust that has been essential for opening up capital markets for entrepreneurs (NCE 2002a).

Apart from pension funds, endowment funds at universities are also a source of venture capital. The percentage of holdings in venture capital assets increases as total investment pool assets increase. The forty largest institutions with investment pool assets greater than one billion dollars had on average 4 percent of holdings in venture capital in 2002 (total of 4.5 billion dollars – my calculation) (NACUBO 2002).

As mentioned above, the regional concentration of venture capital investments is very strong. When looking at investments by state during 2002, California is by far the leading region. Almost half (about 9 billion dollars or 45 percent) of all investments that year were made in California (SSTI 2003).

6 Intellectual Property Policy

Protection and ownership of intellectual property is a fundamental factor in facilitating technology transfer and for creating incentives to commercialize research results. With clarified ownership, crucial capital investments are more secure and the risk of lost investments reduced. This is particularly important in areas such as biotechnology when there are long development times (sometimes up to 10 years) and large investments required.

The federal government's principal means for promoting technology transfer is to grant intellectual property rights to non-federal performers of federally funded R&D, such as universities, private firms and other entities. With these rights, the performers of R&D are free to commercialize the results and reap the economic benefits. There are a number of laws governing technology transfer related to federally funded research. The major ones are the Bayh-Dole Act and the Stevenson-Wydler Act (Table 6-1).

TABLE 6-1
Overview of major laws facilitating technology transfer of federally funded R&D (see also RAND 2003, FLC 2002 and appendix A)

"Bayh-Dole" Act	University and Small Business Patent Procedures Act (1980) Trademark Clarification Act (1984) Executive Order 12591 (1987)
"Stevenson-Wydler" Act	Technology Innovation Act (1980) Federal Technology Transfer Act (1986) National Competitiveness Technology Transfer Act (1989)
Other legislation	(NASA) National Aeronautics and Space Act (1958) (Department of Energy) Atomic Energy Act (1954), Non-Nuclear Energy Research Act (1974)

Bayh-Dole is relevant for technology transfer of the majority of federally funded R&D. Of the 81 billion dollars of federally funded R&D in FY 2002, Bayh-Dole governed 77 percent, Stevenson-Wydler 20 percent, the Space Act 2 percent and the Energy Acts one percent (RAND 2003).

The foundation for intellectual property protection is the U.S. patent law. Its basic structure was adopted in 1952 and a series of amendments and court decisions have significantly strengthened patent protection since then. Reforms included decisions that:

- declared that modified bacterium or "anything made by man under the sun" could be patented (1980),
- established a single court for patent appeals (1982),
- set a term of 14 years for all design patents (1982),
- allowed extension of patent terms due to delays by the Federal Drug Administration (FDA) (1984 and 1988),
- created a single Board of Patent Appeals (1984),
- defined infringement to include acts committed in outer space (1990),
- extended patent term to 20 years (1994),
- extended protection for biotechnology processes (1995), and
- extended protection to business processes in 1998.

A similar catalog of developments can be made for American copyright statutes (NCE 2002a).

6.1 The Bayh-Dole and Stevenson-Wydler Acts

What is usually referred to as "Bayh-Dole" is a set of laws and amendments including the University and Small Business Patent Procedures Act (1980), the Trademark Clarification Act (1984) and Executive Order 12591 (1987). The original Bayh-Dole Act of 1980 created a uniform patent policy that allowed universities, non-profit organizations and small businesses to keep ownership of intellectual property developed under federally funded research programs. The purpose was to encourage R&D performers to collaborate with commercial actors to promote the utilization of research results.

Under the Act, academics receiving federal funds are obliged to report their research results with potential commercial use to the university administration. Universities are expected to file patents on innovations they elect to own and they are expected to give licensing preference to small businesses. The government retains a non-exclusive license to practice the patent throughout the world. Government also keeps the right to withdraw a license if a company fails to commercialize an invention within a reasonable period of time. The "march-in" right was created to prevent companies from licensing academic inventions with the only purpose of blocking rival firms from doing so.

The Trademark Clarification Act of 1984 extended the force of these provisions to federal laboratories that are owned by the federal government but operated under contract by non-federal entities. The Executive Order 12591 further extended Bayh-Dole to include also large businesses conducting R&D with federal funds.

The "Stevenson-Wydler" Act also consists of several parts, including the Technology Innovation Act (1980), the Federal Technology Transfer Act (1986) and the National Competitiveness Technology Transfer Act (1989). These acts govern technologies resulting from R&D performed by federally operated laboratories. Federal agencies were given the continuing responsibility for technology transfer to non-federal entities and each agency was required to establish an Office of Research and Technology Applications (ORTA).

The Federal Technology Transfer Act of 1986 allowed federally operated laboratories to license their innovations and to keep all the royalties generated from the licensees after sharing at least 15 percent with the inventor or team of inventors. The provisions of Bayh-Dole governed the specific procedures for patenting and licensing.

R&D performed by NASA and the Department of Energy was not covered by the Stevenson-Wydler Act. Both agencies had legal authorities in place before 1980: the National Aeronautics and Space Act (1958), the Atomic Energy Act (1954) and the Non-Nuclear Energy Research Act (1974) (FLC 202, RAND 2003). See appendix A for a summary of technology transfer legislation.

6.2 Effects of Patent Policy Reforms

Before Bayh-Dole, all rights belonged strictly to the government and nobody could exploit research results without tedious negotiations with the federal agency concerned. Only 5 percent of the 28,000 patents owned by the government in 1980 had been licensed to industry. In addition, before 1980 fewer than 250 patents were issued to universities each year.

During the 1990s (FY 1991–1999) the growth in the number of new U.S. patent applications from universities was 198 percent and the number of licenses 133 percent. Since 1993, more than 1600 – and in some years as much as 2000 – patents have been issued annually to U.S. universities. Based on the survey by the Association of University Technology Managers (AUTM), more than 200 universities are engaged in technology transfer activities. This is eight times more than in 1980 (AUTM 2003).

Technology transfer activities through Bayh-Dole have helped establish new businesses, create new industries and open new markets. Since 1980, it is estimated that technology transfer activities (licensing of innovations) have contributed to establish 2200 firms, created between 250,000 and 300,000 jobs and have added 30–40 billon dollars annually to the U.S. economy. For example, companies like Genentech and Amgen based their first biotech products on research funded by federal government sources.

The Economist recently called the Bayh-Dole Act "possibly the most inspiring piece of legislation to be enacted in America over the past half-century". The journal argued that this single policy measure, more than anything helped the U.S. economy to regain its strength in the early 1980s and onwards (Economist 2002). The National Institutes of Health concluded in 2001, that two decades after the inception of Bayh-Dole, the nation's system of biomedical discovery and technology transfer is working well and that taxpayers are realizing significant returns under the current system (NIH 2001). It is widely recognized that the success of Bayh-Dole confirms that early-stage technology needs the security of law, the potential for reward and the active promotional and negotiating skills of technology transfer professionals to attract investment and finally reach the market.

It is important to note that most academic research was not affected by this legislation. Bayh-Dole has brought no or little change to the fields of physics, astronomy, evolutionary biology, the social sciences or the humanities. Inventing at any university is concentrated in a small number of fields, such as medicine, engineering, chemistry and telecommunications. Moreover, it has been argued that other factors, independent of the Bayh-Dole reform, help explain the increased patenting and licensing activity. For example, the growth in federal financial support for basic biomedical research in universities that begun in the late 1960s, along with the related rise of research in biotechnology that begun in the early 1970s, contributed to the growth of university patents and licenses (Mowey et al. 2002).

7 Entrepreneurship and Education

Entrepreneurship is a widespread activity in the United States. About six percent of all adults are engaged in trying to start new firms. That means that 10 million people are trying to create a new business at any given time. About half of all new ventures are started by teams of people, which mean that this start-up activity represents about 5.6 million potential new businesses. According to the statistics, men are twice as likely to be starting new businesses as are women. Men between 25 and 34 years old are most active. In general, those with higher education and with higher income are more likely to be involved in starting a business (EMKF 2002b).

The United States is one of the strongest entrepreneurial countries in the world, according to the Global Entrepreneurship Monitor (GEM). In terms of opportunity-driven (versus necessity-driven) entrepreneurship, the U.S. ranked number four of 29 nations surveyed in 2001. Compared to other countries, the U.S. has a greater percentage of older entrepreneurs and a higher ratio of women to men. Moreover, there is a more widespread perception that the government is supportive of entrepreneurship, a general belief that there is sufficient equity and debt financing, and cultural and social norms that support self-sufficiency, including the acceptance of job mobility and income disparity. Finally, compared to other countries, the U.S. has a training and educational system that better fosters creativity and personal initiative as well as explicit and established entrepreneurship education, according to the study (GEM 2002).

7.1 Entrepreneurial Education Programs

Entrepreneurship education has contributed to technology transfer activities. Educational programs can provide a diverse set of skills that increases the odds for success.

Harvard University started entrepreneurial education in 1947 but most of the growth has occurred during the last three decades. In 1970, a national survey of business schools found only 16 courses in entrepreneurship. Since then, entrepreneurial education has taken off and a similar study in 1997 found more than 400 schools offering at least one course in entrepreneurship. More than 50 schools gave four or more courses. Today, it is estimated that more than 1500 colleges and universities offer some form of entrepreneurship training. Nearly 500 million dollars is invested in more than 250 endowed professorships and chairs in entrepreneurship. The National Consortium of Entrepreneurship Centers has over 100 entrepreneurship centers among its members. Today, students can major or minor in entrepreneurship, get an MBA or a doctorate degree. Along with the degree programs, many schools hold student business plan competitions, sponsor research centers and host venture capital forums.

One factor behind the growth of the number of programs is that institutions want to tap into donations from wealthy alumni. Another explanation is the increased visibility of entrepreneurs in business during the last 30 years. The publicized connection between innovation and personal wealth, especially in the technology sector, created an interest in start-up businesses and the risk-taking mind-set that defines the entrepreneur.

The highest-ranking schools from a recent survey (using more than 30 criteria, including evaluations from peers and alumni) of over 700 U.S. entrepreneurship programs are shown in Table 7-1. Only the programs at MIT and the University of Maryland, College Park, were rated in the top-ten by both alumni and peers (Newton et al. 2003).

There is initial evidence that entrepreneurial programs are effective. In a study conducted in 1999, graduates from the Berger Entrepreneurship Program at University of Arizona were compared with other business school graduates from the university. It was concluded that entrepreneurship program alumni were three times more likely to start new businesses, three times more likely to be self-employed, had annual incomes that were 27 percent higher and owned 62 percent more assets. There was also evidence that their firms had higher growth rates and that they gravitated more towards high-tech companies. In addition, these alumni were more satisfied with their jobs than their peers were, according to the study.

TABLE 7-1
Top-tier national universities and colleges offering educational entrepreneurship programs in 2002

University/college	Program	Established	Number of faculty/courses
University of Arizona	Karl Eller Center, Berger Entrepreneurship Program	1984	12/23
Babson College	Arthur M Blank Center for Entrepreneurship	1967	35/33
Baylor University	Center for Entrepreneurial Studies	1971	7/10
University of California, Berkeley		1991	20/23
Harvard University		1947	5/8
Indiana University, Bloomington	The Johanson Center for Entrepreneurship and Innovation	1958	12/22
Louisiana State University, Baton Rouge	Institute for Entrepreneurial Education and Family Business Studies	1996	12/22
University of Maryland, College Park	Dingman Center for Entrepreneurship	1986	12/17
MIT	MIT Entrepreneurship Center	1961	18/21
University of Pennsylvania (Wharton)		1958	NA/24
Stanford University		1949	NA/NA
Wake Forest University	Angell Center for Entrepreneurship	1998	38/12

Source: Newton et al. 2003

Since the start in 1984, the Berger Entrepreneurship Program had trained 339 undergraduates and 200 graduate students in 2002. The program includes courses in competitive advantage, venture financing, market research and business plan development. A combination of tenure-track and business-adjunct faculty teaches the course offerings. About 70 students are accepted annually. All students participate in the internal business plan competition, where they must present and defend their plans. The winning plan receives 10,000 dollars in award money. Of the 289 business plans created as part of the program, at least 81 ventures have been launched (Charney et al. 2002). A comprehensive description of entrepreneurship in higher education can be found in KCEL 2001.

8 Small Business Policy and Programs

More than 99 percent of all U.S. firms are small (with 500 or fewer employees). There are about 23 million small businesses, employing half of the private workforce and generating more than half of the total GDP. Small firms provide 55 percent of innovations and they are the principle source (about 75 percent) of net new jobs added to the economy (see for example SBA 2003a and SBA 2001 for small business indicators).

Small firms are effective innovators and vital to economic development in the USA, according to a recent study. On average, small firms produce more highly cited and technically important patents than larger firms do. The small firm share of U.S. patenting is about 41 percent and small patenting firms produce 13–14 times more patents per employee than do large firms. Patenting is particularly strong in health technologies. Finally, small firm innovation is twice as closely linked to scientific research compared to large firm innovation and substantially more high-tech and leading edge (CHI 2003).

The President's Small Business Agenda is designed to create an environment where entrepreneurship can flourish. Key priorities are low taxes, clear and sensible regulations, open competition to government contracts as well as access to health care and reliable pensions. The U.S. Small Business Administration (SBA) is leading the implementation of the Administration's agenda.

8.1 The Small Business Administration

The U.S. Small Business Administration (SBA) was established in 1953 with the purpose to provide financial, technical and management assistance to small companies. SBA is the largest single financial backer of small businesses with a portfolio of business loans, loan guarantees and disaster loans worth more than 45 billion dollars and a venture capital portfolio of 13 billion dollars. One million businesses received assistance in 2001. The SBA programs relevant to technology transfer fall into three main categories: financing, government contracting and management assistance (SBA 2002).

1. SBA provides a basic loan program to help small businesses obtain financing when they might not be eligible for loans through normal channels. Several other loan programs are available for cyclical working capital needs, defense-dependent companies, export assistance, stimulating energy conservation, pollution control among other things. SBA also facilitates access to financing for start-up companies through simplified and fast loan procedures and indirect micro loans. For example, the Small Business Investment Company (SBIC) program provides equity capital, long-term loans and management assistance to small firms, particularly in their growth stages.

2. A number of SBA programs are designed to ensure small businesses a fair proportion of government contracts. Federal government contracting assistance includes procurement marketing support (Pro-net), contract assistance for Women Business Owners (CAWBO) and the HUBZone program that encourages economic development in underutilized business zones. The R&D assistance programs are the most relevant for the commercialization of new technologies. The Small Business Innovation Research (SBIR) program provides support for firms to compete for federal R&D awards and the program for Small Business Technology Transfer (STTR) supports firms that collaborate with non-profit research institutions to compete for such projects. Other programs support federal and state technology partnerships (FAST), small technology-based firms in underserved states (Rural Outreach) and networking activities (Tech-Net) for federal agencies, venture capitalists and others seeking to do business with small, high-tech companies under all the R&D assistance programs. Through these programs, mandated by the Small Business Innovation Development Act of 1982, the Small Business Research and Development Enhancement Act of 1992, and the Small Business Innovation Research Program Reauthorization Act of 2000, the SBA Office of Technology assist in achieving the commercialization of results from federal R&D programs and promotes public-private cooperation.
3. The programs for management assistance, business counseling and training include the Small Business Development Center (SBDC) and the Business Information Center (BIC), both with a focus on pre-business and start-up firms. Other SBA programs include public information and advocacy (Office of Advocacy), disaster assistance, support for exporters, assistance for Native Americans, veterans and women (see SBA 2002 for overview of all SBA programs).

8.2 The SBIC Program

The Investment Company Act of 1958 established the Small Business Investment Company (SBIC) Program. SBICs are privately owned and managed investment firms, licensed and regulated by the Small Business Administration (SBA). With their own capital and federal government funds borrowed at favorable rates, they provide venture capital to small independent businesses, new or already established. SBICs can be owned by small groups of local investors, commercial banks or have publicly traded stock. They have great flexibility in terms of financing options, which means that financing can be tailored to the needs of each small business. SBICs can make long-term loans, provide capital by purchasing equity securities but are not allowed to become a general partner. To be considered for an SBA license, the investment firm must have a qualified management team and sufficient private capital (minimum 5 or 10 million dollars if participating securities are utilized). An SBIC may receive government leverage equal to 300 percent of its private capital.

SBICs have provided approximately 27 billion dollars in long-term debt and equity growth capital to nearly 90,000 small companies since 1959. In 2002, SBICs financed 2853 companies (with debt securities and pure equity instruments) with the amount of 2.3 billion dollars, down 50 percent from 4.7 billion dollars in the peak year 1999 (see Table 8-1 and Table 8-2). SBICs venture capital-type financing represented about 11 percent of all venture capital funding in 2002 compared to about 5 percent during the dot.com peak in 2000. About 41 percent of SBIC money (1.1 billion dollars) were invested in high-tech companies during FY 2002. The largest investments were made in computer systems, software and semiconductor industries (over 25 percent). Less than 8 percent of all financing went to the medical sector (SBA 2003b, VentureOne 2003).

TABLE 8-1
Number of venture capital financings (excluding pure debt financings by SBICs)

Calendar year	SBICs	Other VC sources	Total	Percent of total by SBICs
1998	1614	2504	4118	39
1999	2306	4472	6778	34
2000	2946	6101	9047	33
2001	3306	3034	6340	52
2002	2853	2056	4909	58

Sources: SBA 2003b, VentureOne 2003

A number of well-known companies, including Apple, FedEx and Intel, where financed by the program during their initial growth period. (See the success stories published by the National Association of Small Business Investment Companies on the web site www.nasbic.org/success.cfm.) The tax revenues generated each year from successful SBIC investments more than covers the cost of the program.

TABLE 8-2
Amount of venture capital financing (excluding pure debt financings by SBICs)

Calendar year	SBICs (billion dollars)	Other VC sources (billion dollars)	Total (billion dollars)	Percent of total by SBICs
1998	3.01	17.71	20.72	15
1999	4.72	48.96	53.68	8
2000	4.56	93.75	98.31	5
2001	4.02	34.57	38.59	10
2002	2.28	19.43	21.71	11

Sources: SBA 2003b, VentureOne 2003

8.3 The SBIR and STTR Programs

The Small Business Innovation Research (SBIR) program was established as part of the Small Business Innovation Development Act of 1982. Through the program, a specific percentage of federal R&D funds are reserved for small businesses. Federal agencies with external R&D obligations above 100 million dollars must set aside 2.5 percent for SBIR projects. Ten agencies participated in FY 1999. Each year, the departments and agencies required to participate, designate R&D topics and accept proposals. They are responsible for releasing solicitations, evaluating proposals and awarding SBIR funding agreements on a competitive basis. Proposals are typically evaluated along three dimensions. (1) Agency importance – the ability to meet federal R&D needs, (2) Commercial importance – the ability to transform R&D into commercially viable products and (3) Technology Leadership – the science and technology capacity of the applying firm (such as expertise, facilities and experience). Innovations that have been patented or have patents pending will not be considered under the program – the focus is entirely on new innovations.

TABLE 8-3
Main departments and agencies participating in the SBIR program FY 1999

	FY 1999 (million dollars)	Cumulative FY 1983–99 (million dollars)
Department of Defense	514	4908
Department of Health and Human Services	314	2092
National Aeronautics and Space Administration	89	1164
Department of Energy	81	755
National Science Foundation	60	468
Other agencies	39	323
Total	**1097**	**9710**

Source: NSF 2002a, appendix 4-36

The program funds the start-up and development stages of small high-tech companies with the purpose to encourage the commercialization of technologies, products and services. According to Etzkowitz et al., the program informally provides start-up capital for high-tech spin-off firms from large corporations and universities (Etzkowitz et al. 2001). To participate, firms must be American-owned (at least 51 percent owned/controlled), independently operated, for-profit companies of no more than 500 employees. The principal researcher must be employed by the business. Firms that receive awards begin a three-phase program. (1) Start-up phase – explore the technical merit or feasibility of the idea (awards up to 100,000 dollars for up to 6 months), (2) Expand results from first phase – R&D work and evaluation of economic potential (awards up to 750,000 dollars for up to 2 years), (3) From laboratory to the marketplace (no SBIR support – the firm must find support from the private sector or from other non-SBIR federal agency funding).

The SBIR program has experienced rapid growth since 1983. In FY 2001, the program granted 3215 Phase one and 1533 Phase two awards for about 1.5 billion dollars. Between 1983 and 1999, the SBIR program awarded 9.7 billion dollars to over 55,000 projects. The Department of Defense was the largest participant in FY 1999 with 514 million dollars (47 percent), followed by Department of Health and Humans Services with 314 million dollars (29 percent) (see Table 8-3). The geographic distribution of SBIR awards reflects the overall concentration of federal R&D funding (NSF 2002a).

The Small Business Technology Transfer (STTR) program also reserves a specific percentage of federal R&D funding for awards to small businesses and non-profit research institution partners. The program seeks to combine entrepreneurial skills with high-tech research efforts by creating joint-venture opportunities for small firms and research institutions. Federal agencies with external R&D obligations above one billion dollars must set aside 0.15 percent for STTR projects. Five agencies participated in FY 1999 (see Table 8-4). Each year, the departments and agencies required to participate, designate R&D topics and accept proposals. The program started to make awards in FY 1994 and is based on the structure of SBIR.

TABLE 8-4
Departments and agencies participating in the STTR program FY 1999

	FY 1999 (million dollars)	**Cumulative FY 1994–99 (million dollars)**
Department of Defense	31	154
Department of Health and Human Services	20	82
National Aeronautics and Space Administration	6	38
Department of Energy	5	26
National Science Foundation	3	15
Total	**65**	**316**

Source: NSF 2002a, appendix 4-37

To participate, firms must be American-owned, independently operated, for-profit companies of no more than 500 employees. In this program, the principal researcher need not be employed by the small business. The non-profit research institution must be located in the U.S. and can be a university, college, research organization or federally funded R&D center. Similar to the SBIR program, joint ventures that receive awards begin a three-phase program: (1) Start-up phase (awards up to 100,000 dollars for up to one year), (2) R&D work phase (awards up to 500,000 dollars for up to 2 years), (3) Transfer to marketplace (no STTR funding).

In FY 2001, the STTR program awarded 224 Phase one and 113 Phase two awards totaling over 78 million dollars. The majority of the participating research organizations were universities (about 85 percent). The other institutions were federally funded R&D centers, hospitals and other non-profit organizations (NSF 2002a).

9 Government Initiatives and Programs

There are a number of other government programs and initiatives designed to support R&D and technology transfer of research results to the private sector and to promote public-private collaboration. Three selected initiatives and programs are described below: Industry-University Cooperative Research Centers, the Advanced Technology Program and Project BioShield.

Other government initiatives include the Defense Advanced Research Projects Agency (DARPA) – the central R&D organization for the Department of Defense (DoD) – that provides funding for high risk, high payoff research and works with industry to create innovative solutions, mainly for military purposes. DoD also runs a Dual Use Science and Technology Program for technologies that have both a military utility and a commercial potential. The program partner with industry to jointly fund technology development. The Experimental Program to Stimulate Competitive Research (EPSCoR) is a joint program of the National Science Foundation (NSF) and several U.S. states and territories. The program promotes the development of science and technology resources through partnerships involving a state's universities, industry, and government. Another NSF program, Grant Opportunities for Academic Liaison with Industry (GOALI), supports the mobility of researchers between academia and industry as well as interdisciplinary university-industry teams to conduct long-term projects.

9.1 Industry-University Cooperative Research Centers

Federal support for collaborative research between industry and academia was specified in the Federal Technology Transfer Act of 1986. One of the activities was the establishment of Industry-University Cooperative Research Centers (IUCRCs) administered by the National Sciences Foundation.

There are about 50 IUCRCs administered by NSF with more than 750 faculty researchers, some 750 graduate students and 200 undergraduates. Five of the centers are in the area of biotechnology and biomedicine (see Table 9-1). NSF's financial support to the centers is relatively small – about 5.2 million dollars in FY 2000. The majority of the funding (68 million dollars) comes from other sources, mainly from industrial firms. The centers currently have over 700 partners and 90 percent of these are companies. In addition, the majority of the universities also provide direct or indirect support to the centers. The NSF investment in an IUCRC is intended to seed partnered approaches to new and emerging research areas. If a prospective center can demonstrate strong scientific skills and strong support from industry, NSF may make an initial five-year award of 70,000 dollars annually to the center team. Funding can be extended for another five years at a lower level of 35,000 dollars annually. The NSF intention is that the centers gradually will become fully supported by university, industry and other funding. The target is to maintain at least 300,000 dollars of industrial support from at least six industrial members. The partnership is formalized through the center's Industrial Advisory Board (IAB) and faculty members and firm representatives decide jointly on the research agenda. A sign of success according to NSF is the large amount of "follow-on" R&D funding by member firms. This additional company funding amounted to 75 million dollars in FY 2000 (NSF 2002d).

A new kind of IUCRC was created in 1990. The State/Industry-University Cooperative Research Centers (S/IUCRCs) program was established following an understanding reached between NSF and the National Governors' Association Science and Technology Council of the States. An S/IUCRC is a university-based research center that receives base funding of an equal amount from NSF and the state government. 12 centers were established between 1991 and 1996.

A third type of government supported university-industry collaboration is the Engineering Research Centers (ERCs) program. They are similar to IUCRCs but have a focus on systems engineering, cross-disciplinary and systems-oriented research. Each ERC is established as a three-way partnership involving universities, industry, and NSF. Total annual funding for each center ranges from 3.1 to 19.4 million dollars, with NSF's contribution ranging from 2 to 3 million dollars annually, averaging 2.5 million dollars per year. There are currently 20 centers receiving support from NSF and since 1985 an additional 16 centers that are now self-sustaining. Eight of these centers are in the bioengineering field (see Table 9-1).

TABLE 9-1
Government supported Industry-University Cooperative Research Centers in the biotechnology and bioengineering field

Industry-University Cooperative Research Centers (IUCRCs) in the biotechnology and biomedicine field	**Industry/University Center for Biosurfaces (IUCB)** [The University at Buffalo, The University of Memphis, New York State College of Ceramics at Alfred University, University of Miami] **Biomolecular Interaction Technologies Center (BITC)** [University of New Hampshire] **Tree Genetic Engineering Research Cooperative** [Oregon State University] **Center for Biocatalysis and Bioprocessing of Macromolecules (CBBM)** [Polytechnic University] **Center for Intelligent Biomedical Devices and Musculoskeletal Systems (IBDMS)** [Colorado School of Mines and Rocky Mountain Musculoskeletal Research Laboratories]
Engineering Research Centers (ERCs) in the bioengineering field	**Georgia Tech/Emory Center for the Engineering of Living Tissues** [Georgia Institute of Technology, Atlanta, GA (lead institution) in partnership with Emory University] **Marine Bioproducts Engineering Center** [University of Hawaii at Manoa, Honolulu, HI (lead institution) in partnership with the University of California at Berkeley] **Computer-Integrated Surgical Systems and Technology ERC** [The Johns Hopkins University, Baltimore, MD (lead institution) in partnership with the Brigham and Women's Hospital, Carnegie Mellon University, Johns Hopkins Medical Institutions, MIT, and Shadyside Hospital] **Biotechnology Process Engineering Center** [Massachusetts Institute of Technology, Cambridge, MA] **VaNTH ERC in Bioengineering Educational Technologies** [Vanderbilt University, Nashville, TN (lead institution) in partnership with the Harvard University-MIT Division of Health Sciences and Technology, Northwestern University, and the University of Texas at Austin] **Engineered Biomaterials Engineering Research Center** [University of Washington, Seattle, WA]
Self-sustaining ERCs in the bioengineering field	**ERC for Emerging Cardiovascular Technologies** [Duke University and other North Carolina Institutions] **Center for Biofilm Engineering** [Montana State University]

Source: National Science Foundation

A study including both IUCRCs and ERCs concluded that the NSF funded centers had successfully supported technology transfer and increased knowledge spillovers between member firms and universities. Patent activity as well as co-authorship with faculty and hiring of graduate students to corporate R&D laboratories increased according to the evaluation (Adams et al. 2001).

9.2 The Advanced Technology Program

The Advanced Technology Program (ATP) was established in 1990 by the National Institute of Standards and Technology, Department of Commerce. The program is a public-private partnership that provides industry with a mechanism to extend its research and technological reach. The program funds high-risk research to develop enabling technologies that promise significant commercial payoffs. Awards are made on a cost-share basis after proposals have passed a peer review process. In FY 2003, 13 individual companies and three joint venture partnerships were selected for ATP awards, representing a total of 35 million dollars in ATP funding and an industry share of up to 22 million dollars.

TABLE 9-2
The number of ATP awards, participants and funding FY 1995 – 2000

	1995	1996	1997	1998	1999	2000
Number of awards	103	8	64	79	37	54
Number of participants	318	12	101	168	57	95
Total award funding (million dollars)	827	37	304	460	212	274
ATP funding share (million dollars)	414	19	162	235	110	144

Source: NSF 2002a, appendix 4-38

Between 1990 and 2000, over 1 100 companies, non-profit institutions and universities participated in the program and received 3.3 billion dollars in R&D funding (contributed equally from industry and federal funds). 522 projects were performed in biotechnology, electronics, information technology, materials, chemistry and manufacturing. Most projects were single-company projects (67 percent) and the rest were joint ventures (NSF 2002a).

The number of awards has fluctuated dramatically, for example down from a record high in FY 1995 to a record low in FY 1996 (see Table 9-2). This can be explained by the ongoing debate over the goals and merits of the program and there are currently signs that the program may be phased out or shut down by the Bush Administration. The program has been evaluated a number of times and some of the findings were that ATP funding supplemented rather than displaced private capital, the program have had a good reputation (the "Halo Effect") that increased the success of award recipients in attracting additional funding from other sources, and that firms selected tended to be more collaborative in new technical areas and to form new R&D partnerships (high spillover potential) (STEP 2001, NRC 2003).

9.3 Project BioShield

Project BioShield is one example of a recent government initiative to use R&D procurement to stimulate innovation in the area of counter terrorism. The anthrax attacks in the fall of 2001 emphasized the vulnerability to biological terrorism in the U.S. Effective countermeasures do not exist for many of the biological threats deemed most dangerous by the Centers for Disease Control and Prevention (CDC). In his State of the Union Address at the end of January 2003, President Bush announced Project BioShield to address these issues. According to the proposal, 6 billion dollars will be invested over 10 years to develop and make available modern, effective drugs and vaccines to protect against biological and chemical attacks. The idea behind the proposal is that the government should guarantee a market for innovative counter terrorism technologies, which are not likely to have a viable commercial market on their own.

The plan consists of three basic parts: (1) The creation of a permanent funding authority to stimulate the development of "next generation" medical countermeasures to allow the government to buy vaccines and drugs for smallpox, anthrax, botulinum toxin and other dangerous pathogens such as Ebola and plague. The Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS) will collaborate to identify critical countermeasures by evaluating likely threats and new opportunities in biomedical R&D. (2) Speeding up NIH development capabilities by giving the Director of the National Institute of Allergy and Infectious Diseases (NIAID) increased flexibility to award contracts and more rapid hiring of technical experts. (3) Giving the Food and Drug Administration (FDA) the ability to make promising, but yet unlicensed, treatments quickly available in emergency situations.

It is expected that the proposed investment into American biotechnology and pharmaceutical R&D for counter terrorism will have consequences for other civilian R&D carried out by the same organizations: "the breakthroughs resulting from Project BioShield are likely to have important spillover benefits in diagnosing and treating other diseases, and in strengthening our overall biotechnology infrastructure" (White House 2003). Some parts of the proposal are controversial. Critics say that biotech and pharmaceutical companies will require even more incentives than contained in the proposal. Other incentives being considered include the protection from litigation, tax and intellectual property incentives (CRS 2003).

10 Technology Transfer Issues

A number of issues and concerns relating to technology transfer and the commercialization of research results are debated in the U.S. and some have reached the political agenda. For example, the recent focus on homeland security has made technology transfer a matter of “life and death”. National security issues create an immediate and pressing need for rapid and efficient technology transfer and special attention is given to the development of technology transfer policies for the new Department of Homeland Security. Other issues debated are the possible negative effects of the commercialization of research, how to deal with the funding gap for early-stage technology development, problems experienced with Bayh-Dole and the current intellectual property protection regime, and ways to improve technology transfer practices within the current legal framework.

10.1 The Commercialization of Research

There is an ongoing discussion regarding the commercialization of research and higher education at universities. Critics have pointed out the potential negative effects of increasing commercial practices and the blurring boundaries between the corporate and academic worlds. This trend includes industry-funded research, technology licensing, industry-endowed chairs and professors starting their own firms, earning consulting fees and marketing their lectures on the Internet. Moreover, following the economic downturn with cutbacks in higher education, universities are under increased pressure of becoming more entrepreneurial.

According to one author, the former President of Harvard University, Derek Bok, the increasing commercialization of universities threatens to change the character of the university in ways that limits its freedom, its culture of openness and its tradition of sharing results. By compromising these core academic values, the university as an institution might loose its high standing in society and create barriers to further research and progress. While mentioning medical schools and biotechnology research as being particularly affected, Bok points out that this is not a recent phenomenon. The money poured into athletics programs is the worst example of how commercialization can erode the values and goals of the institution (Bok 2003, see also BHEF 2001). On the other hand, it can be argued that success in athletics, and enhanced public support, has led some state legislatures to increase funding for research and educational infrastructures at state universities, according to Henry Etzkowitz, Professor at State University of New York.

Three issue-areas have been pointed out to be particularly relevant for biomedical research. First, the increased secrecy in corporate funded research. Corporate sponsors want to protect their investments by making research results confidential. Reasonable publication delays to secure intellectual property protection are usually acceptable to universities. The “standard” delay is between 60 and 90 days but universities are under increased pressure to extend such delays. In a study from the mid-1990s, more than half of the corporate sponsors asked, admitted to insisting regularly on delays of more than 6 months. Moreover, one fifth of the life science professors surveyed admitted that they had delayed publication by more than six months for commercial reasons (Blumenthal et al. 1997). There is also occasional evidence of companies trying to suppress unfavorable findings.

Second, the increased possibility of conflicts of interest. Conflicts of interest arise in situations when financial or other personal considerations may question the researcher's ability to make unbiased decisions related to his or her work. Conflict of commitment can be anything that interferes with a faculty member's full-time duties. Most universities now have policies in place aimed at monitoring and managing such conflicts. Since 1995, universities receiving funds from the National Institutes of Health or the National Science Foundation have been required to have appropriate policies and procedures in place to handle these conflicts. Sound policies are particularly important in clinical trials when lives are at stake. Only a few percent of medical schools surveyed required that researchers disclose their financial conflicts to patients participating in experiments or to scientific journals publishing their results (McCrary et al. 2000).

Finally, the increasing barriers to access research tools. By allowing genetic information to be patented, researchers may not have free access to the information and materials necessary to perform further research. According to a recent report by the President's Council of Advisors on Science and Technology (PCAST), the availability of research tools that result from federally funded research should be monitored to assure a balance between protection and access. This balance is especially important where biological material is critical for continued research and at the same time has a commercial value (PCAST 2003). The National Institutes of Health provided guidelines in this respect in 1999 that are pointed out to be particularly helpful (NIH 1999). OECD has identified a number of access issues that might slow down the pace of innovation, including blocking patents or overly broad patents, increased secrecy and high costs for licensing key inventions (OECD 2002b).

10.2 Funding Early-Stage Technology Development

It is widely recognized that there is a funding gap for early-stage technology development and that markets for allocating risk capital to such activities are not efficient. Congressman Vern Ehlers among others have used the term "Valley of Death" to dramatize the particular challenges facing entrepreneurs engaged in the transition from invention to innovation (NIST 2002). Early stage companies often experience a situation where they are making profits but have a negative cash flow because of the need to invest in equipment and personnel. It has been particularly difficult to raise the 250,000 dollars to 1–2 million dollars necessary to address this challenge. There is a funding gap between the lower start-up capital requirements and below the venture capital minimum investment (typically 3 million dollars). There are a few potential sources: reinvesting profits from the firm, an individual wealthy investor ("business angel") buying company stock or SBICs (Small Business Investment Companies) and other government-subsidized community development venture funds.

The Business Retained Income During Growth and Expansion (BRIDGE) Act of 2002 (S 1903) was introduced by Senate members to address this problem. The Act would allow growth companies to use deferred corporate tax payments as collateral against which they could borrow bank funds to meet their growth needs. According to supporters, the BRIDGE Act would help fill the early-stage capital gap and establish banking relationships for future needs for these companies.

Until 1993, there was no particular incentive for individual investors to specifically consider supporting early-stage growth companies. Section 1202 in the Internal Revenue Code enacted in 1993 was designed to address this problem for small businesses. However, it has been argued that further legislation is necessary to improve the situation. The Affordable Small Business Stimulus Act of 2002 (S 1676) has been proposed to revive 1202 by extending benefits to investments in companies with less than 100 million dollars in paid-in capital. The capital gains exclusion would be increased from 50 percent to 75 percent and, in the case of critical technology companies to 100 percent.

Regarding the third source of financing, the provision of S 1676 together with other bills would allow tax-exempt entities such as pension funds and university endowment funds to invest in SBICs without incurring unrelated business taxable income liability. This would increase the sources of available funding and could encourage more investments in early-stage growth companies, according to supporters of this policy (von Bargen 2002).

10.3 Bayh-Dole Challenges

Even if most people seem to support the current intellectual property protection regime, some challenges are discussed. First, the principles of Bayh-Dole have been questioned recently by linking its practices to the high prices consumers must pay for new drugs. The main argument is that taxpayers must pay again for goods based on research they have already paid for. In a debate in the Washington Post, Birch Bayh and Bob Dole defended their Act against claims that it inflated the costs for pharmaceuticals, requiring consumer to pay twice for the same drugs (Washington Post 2002). They argued that for every dollar spent on research; at least 10 dollars must be spent by industry to bring a product to market, often with lead times of five to seven years from the time industry gets involved. The Act has enticed firms to seek public-private research collaboration thus helping patients get new drugs sooner, said Bayh, Dole. Others have argued that the government should use its march-in rights to force pharmaceutical companies to lower prices for certain drugs (Economist 2002, personal communication with Javed Afzal).

A second issue concerns the legal complications over intellectual property rights in cases of joint appointments. It is becoming increasingly common that researchers belong to more than one institution. For example, a federally funded researcher at a university may also belong to the research staff of a federally funded laboratory. In such cases, the right to research results could be claimed by both institutions causing legal complications (RAND 2003).

Third, it has been discussed whether the commercialization of university research and the introduction of Bayh-Dole have affected academic research agendas. So far, there is little evidence of impact on the content of research. The portfolio of university research has shifted somewhat in recent years but this is largely independent of Bayh-Dole, according to analysts (Mowery et al. 2001, Bok 2003).

Finally, the increasing costs for patents and the time it takes to get them approved are causes for concern. In fact, many biotechnology executives have lobbied in favor of higher fees in an attempt to speed patent examinations and reduce the huge backlog of applications. Faster approval is necessary to speed drugs to market and would help start-ups to use their patents as important fund-raising tools. One problem is that Congress and the Administration is diverting money from patent fees for other uses, according to biotechnology officials. This has made it difficult for the U.S. Patent and Trademark Office to get the necessary resources to keep up with the applications flow. Biotechnology patent applications have more than doubled since 1996, reaching more than 47,000. However, over the same period, the number of biotechnology patent examiners has increased only 12 percent, to 368. The time lag has now reached 19 months, which exceeds the guideline of 14 months, established by the American Inventor's Protection Act in 1999. A plan is discussed to reform the current procedures in order to save the entire patent system from collapsing (Krasner 2003).

10.4 Improving Technology Transfer Practices

In their report to the President, the President's Council of Advisors on Science and Technology (PCAST), concluded that the existing technology transfer legislation works and should not be altered. The successful commercialization of research results in the life science and biotechnology sector is the most important evidence for this. Technology transfer practices in other sectors (such as the semiconductor industry) are more fragmented. However, it is believed that improving the practice of technology transfer rather than altering the legislation best addresses these differences.

First, government departments, agencies and labs need to formalize their oversight of and accountability for technology transfer. Successful technology transfer requires leadership from the highest government level. It is suggested that each agency specifically commit to technology transfer in its mission statement and that each agency provide an annual report to account for their progress. It is important that different agency practices and attitudes be aligned.

Second, it is important to recognize the differences between industries while establishing consistent practices within industries. A technology licensing practice has been developed within the life science sector during the last decade. This template for technology transfer is well suited for long product development time frames and has contributed to the commercial success of the field. However, conditions are different for other industries, i.e. software, communications and information technology where the value of intellectual property is highly variable. In these cases, time to market is usually shorter and other drivers than intellectual property may be much more important for commercial success. Government guidelines should allow for these differences and at the same time seek consistency within each industry sector.

Third, "best practices" for technology transfer should be documented and metrics defined to measure effectiveness. The purpose is to facilitate rapid learning for new institutions and to set expectations for first time licensees. Measurements must be able to accommodate different missions of licensing institutions. For example, universities may seek to contribute to the local and regional economy as well as to the growth of the national economy. Finally, "education" should be a part of government's technology transfer mission. A more active approach is needed to support the internal education process as well as the external marketing (PCAST 2003). AUTM offers short courses at its annual meetings, but no university has yet set up a serious program to provide such training, according to Henry Etzkowitz.

11 Concluding Remarks

This report has provided an overview of the commercialization of research results in the U.S. This is a crucial aspect of the world-leading U.S. system of innovation. Its success can be demonstrated by the number of companies created, by the economic growth generated, and by the public support and acceptance of the R&D effort and technology transfer activities. The system has developed during the last 40 years and spurred, what has been called an "entrepreneurial revolution" that has changed the fundamental dynamics of the American economy. A mixture of public policies set the rules and created the environment for this development. Policies for the formation of financial markets, the provision of R&D, the protection of intellectual property, the investment in talented people, the facilitation of mobility between sectors, the deregulation of industry sectors, the commitment to open international trade and the support for a dependable infrastructure have all played an important part in creating a functioning and successful system (see for example NCE 2002).

Together with the U.S., Sweden has been rated very high in several recent comparative innovation studies. This includes top rankings by the European Innovation Scoreboard (EIS 2002) and the OECD Science, Technology and Industry Scoreboard (OECD 2003). Some innovation metrics are shown in Table 11-1. Sweden has a tradition of large export-oriented and, in many cases, R&D intensive companies. This structure is now transforming and clusters of innovative firms are emerging, often around universities and the large firms, creating dynamic economic regions specialized, for example, in the areas of biotechnology and wireless communications. A commitment to R&D by the government and larger firms, dynamic academic environments, a well developed IT infrastructure, an educated workforce and early adopters ("curious customers") of new technologies are all factors that have contributed to this success in innovation.

TABLE 11-1
Selected innovation indicators relevant for technology transfer. Ranking within European Union in paranthesis

Indicator	USA	EU	Sweden	Finland	UK
Public R&D expenditures (percent of GDP), latest data from 1999–2001	0.66	0.67	0.94 (2)	**0.98 (1)**	0.66 (7)
Number of patent applications at the USPTO in high-technology patent classes, per million population, 2000	**92**	12	47 (1)	42 (2)	15 (6)
EPO high-tech patent applications per million population, 2000	50	28	95 (2)	**138 (1)**	28 (7)
Share of EPO patent applications by inventor's country (percent), 1999	28	**48**	2.0 (6)	1.5 (7)	5.5 (3)
EPO patent applications (average annual growth rate 1991–1999, percent)	6.2	7.3	11 (4)	**16 (3)**	6 (12)
Biotechnology venture capital per million units of GDP, 2001	**340**	-	135 (4)	50 (7)	50 (5)

Sources: EIS 2002, OECD 2003

Although Sweden and the U.S. have leading systems of innovation, both countries are facing future challenges. Both countries are looking for policy reforms to optimize their respective systems in a knowledge-intensive economy. The final section of this report will focus on some Swedish challenges where the U.S. system has a strong position. It is important to point out that comparing the U.S. with other countries is difficult because of a number of factors, including size, political system and social culture. Policies need to be adapted to the local environment before they are introduced. Despite the national differences and the policy transfer challenges, the U.S. has been and will be a source of policy lessons and inspiration for many countries, including Sweden. It is generally agreed that the U.S. system works well, both among foreign observers and among analysts and technology transfer workers in the U.S. It has become a model for many other countries.

11.1 U.S. Strengths and Swedish Challenges

The Swedish innovation system faces a number of challenges related to the commercialization of research results. One important line of argument is that there is a Swedish "growth paradox". In short, it means that despite the high input, for example in the form of the world's highest R&D spending per capita, several output measures, such as economic growth and GDP per capita, have remained unsatisfactorily low. A related observation reveals that Sweden has few growth-oriented entrepreneurial firms. In fact, more firms are starting than are currently growing. It is thus an important political goal to make sure that more firms are growing in order to create employment and economic growth. Most analysts agree that the explanation for this situation includes the lack of venture capital, particularly from private sources (business angels), and the lack of management competences to start and grow businesses. The underlying factors that are pointed out are usually a less developed entrepreneurial culture and the lack of efficient incentives for investors and innovators. The primary setting for entrepreneurial activities in Sweden has traditionally been inside the large companies (see for example VINNOVA 2003).

This report has outlined five factors or enablers that have been crucial for the successful commercialization of research results in the U.S.: (1) availability of private capital, (2) ownership of research results, (3) entrepreneurial skills, (4) small business involvement and (5) government programs. Together, these basic components have provided the framework for commercialization at universities. Other factors may also be important, but the selected factors are believed to be particularly relevant for technology transfer. The following is a summary of U.S. strengths and Swedish challenges for each of these factors and for commercialization at universities.

Availability of private capital

Private industrial and individual investors have played an important role for U.S. technology transfer. The regulatory environment has promoted the growth of investments in high-tech companies by "business angels" and venture capitalist to an extent unmatched by any other county. A combination of tax reforms, banking and bankruptcy laws and pension fund regulations have facilitated private capital accumulation and increased the willingness to invest in high-risk enterprises.

Sweden on the other hand has had very few business angels and venture capital is primarily provided by large institutions. A variety of government support systems has been established to compensate for the lack of private capital in Sweden. For example, the Technology Link Foundations established in the mid-90s provided early-stage funding that supplemented private investments. These foundations have been evaluated and are regarded as filling an important funding gap. In the U.S., the Small Business Investment Company program has been pointed out as an interesting example of leveraging private investments with government funding.

Like in some other countries, the Swedish venture capital industry grew rapidly in the late 1990s before the "dot.com" collapse. It is widely agreed that there is a need for reforms that enable the creation of private venture capital. In particular, there is a need for "smart money" – the combination of funding and entrepreneurial competences. Both Sweden and the U.S. (and many other countries) have experienced an increasing lack of early-stage financing. There has been a general shift towards later-stage investments. In both countries, policy-makers are focusing their attention on the critical provision of early-stage investments.

Ownership of research results

It is widely recognized in the U.S. that the Bayh-Dole Act has been instrumental in creating a favorable environment for technology transfer. Its key component, assigning the rights to research results from federal funding agencies to the performing institutions, has inspired policy-making in many other countries, including Japan, Germany and Denmark.

Several arguments have been presented in support of the Act. First, because of the law, universities and other performing institutions had to assume the overall responsibility for the commercialization effort. This has created an infrastructure of technology transfer offices with skilled personnel and a professional process operating under a uniform legal framework. Second, the mandatory disclosure rule has contributed to driving more inventions out of the research laboratories, increasing the volume of possible inventions to commercialize. It has also been easier to measure and evaluate the system since it becomes more transparent. Finally, Bayh-Dole established clear rules and roles as well as a uniform interface for industry to deal with academic inventions.

In Sweden, the individual researchers have full ownership of the results from their research – the so-called "university teacher privilege" – since the 1940s. One leading argument in keeping the privilege is that it creates incentives for researchers to engage in commercialization. Universities have developed a supporting infrastructure of patent and licensing offices that make agreements with researchers to assist in technology transfer. The income distribution from these operations is typically one third each to the researcher(s), the research lab and the university respectively. This is similar to the situation in the U.S.

Entrepreneurial skills

The U.S. has a strong entrepreneurial culture. Studies show that the U.S. ranks high when it comes to start-up experience and the number of people working in newly formed companies. It is often pointed out that Americans are more willing to take risks compared to people in other countries and that it is easier to start over again after a business failure. However, it is important to note that this culture has developed in the context of, among other things, facilitating tax and bankruptcy reforms and of a system of well-developed entrepreneurial education at universities and colleges.

The same studies have shown that Sweden is relatively weak at entrepreneurship compared to for example the U.S. and the U.K., and as a result has limited entrepreneurial activities at universities. Swedes may be more risk averse and think that it is safer to be employed than to start a new company. The traditional industry structure of large companies, labor market policies and weak individual incentives have contributed to this situation, according to many analysts. Swedish policy-making is currently focusing on reforms in several areas to improve incentives for starting and growing small businesses.

Small business involvement

The U.S. has had a broad small business program since the 1950s. The Small Business Innovation Research (SBIR) program and the related Small Business Technology Transfer (STTR) program have been pointed out as particularly interesting in terms of commercializing R&D. These programs assign a specific percentage of the federal R&D budget for small businesses and both programs have grown rapidly during the last decade. Evaluations of these "R&D procurement" programs have been positive and they are considered to play an important role in the overall technology transfer effort. Another program is the Small Business Investment Companies (SBIC) that have been a significant source of venture capital in the U.S.

Even if Sweden has had a number of national small business programs, administered mainly by the Swedish Business Development Agency (NUTEK), there is no comprehensive small business and entrepreneurship policy. There has been a program similar to SBIR in the past and policy-makers are now investigating the possibility of re-introducing this program. A challenge for Sweden is how to best interact with policy-making at the European Union level and to work towards the goal to create the world's most competitive market for small businesses and entrepreneurs by 2010. It is, for example, important to increase the participation of Swedish firms in international programs.

Government programs

Apart from the initiatives discussed above, the U.S. government is supporting several programs to facilitate the commercialization of research results. The Department of Defense has played a leading role in the area of R&D funding, "dual-use" S&T programs and technology procurement that has promoted cooperation between government, academia and industry. Other important programs that have contributed to this interaction include the Industry-University Cooperative Research Centers by the National Science Foundation and the Advanced Technology Program by the Department of Commerce. Project BioShield is an interesting example were the government guarantees a market for novel counter-terrorism technologies.

Sweden has a history of successful public technology procurement, for example in the telecommunications and aircraft industries. Competent public buyers stimulated R&D and created competitive products in the marketplace. This demand-side instrument has little significance today because of, for example, the deregulation of many industry sectors and certain provisions in the European Union public procurement regulations. However, NUTEK has acted as a catalyst for technology development in several areas, including energy efficient devices, during the 1990s. Similar to the U.S., Sweden has created a number of competence centers with the purpose to promote multidisciplinary research and knowledge exchange between academia and industry. The program started in the mid-90s and is managed by several government agencies, including the Agency for Innovation Systems (VINNOVA).

Commercialization at universities

Programs for technology transfer have been implemented at most U.S. universities, in particular because of the Bayh-Dole legislation in the early 1980s. In general, licensing revenues have been small compared to the overall university R&D effort. Patent and licensing offices have been supplemented by offices for sponsored research and industry liaison offices to cover a wide range of university-industry interactions. Activities are typically governed by a set of policies, including guidelines for patenting, licensing, equity ownership, copyright, consulting and contracts with industry. Policies have been developed to protect the rights of researchers and to preserve core academic values as well as to protect the university from conflicts of commitment and conflicts of interest. Some universities are very successful and serve as role models for others, such as the University of California (UC) system and Stanford University.

The major drivers for the researcher to be involved in technology transfer are the possibility of getting a share of licensing revenues and becoming engaged in well-paid consulting work. Inventors are typically involved in the process of preparing patent applications and marketing but licensing officials are responsible for certain parts of invention evaluation and decision-making. Private universities seem to pursue commercialization more aggressively than public institutions. They are also more flexible when it comes to, for example, financial compensation to inventors and rules for owning equity in start-up firms. Both UC and Stanford encourage industry involvement and it is becoming more and more recognized that such contacts actually benefit academic research activities.

Similarly to the situation in the U.S., Swedish universities have a significant role in performing publicly funded R&D. Besides the private sector, academia is therefore an important source of inventions to be commercialized. A difference is that universities in Sweden are public authorities and receive the majority of their funding from the government budget. The public and private universities in the U.S. both have a diversity of funding sources. In addition, while the so-called institute sector in Sweden is rather limited, the U.S. allocates substantial R&D resources to a large number of federal laboratories and federally funded R&D centers.

To bridge the gap between academia and industry/society, Swedish universities have been assigned a "third mission", a policy that has developed since the 1970s and was codified by law in the 1990s. Apart from education and research, universities have three additional responsibilities: technology transfer, regional economic development and "public relations". Universities have made different interpretations of the third mission and diverse forms of measures and actions have been implemented. Of particular interest are the university holding companies that were formed in the mid-90s. Their mission is to manage R&D firms with the purpose to commercialize research results. The Technology Link Foundations described above, together with the holding companies established patent and licensing offices to support the process of technology transfer. Sometimes these various efforts are competitive, rather than collaborative, at the regional level and thus too small to have much effect, according to some analysts.

A specific characteristic of Swedish universities is that they are public authorities. This has implications for openness and secrecy regulations. University departments typically decide whether to take on contract research or to participate in publicly funded R&D. Swedish researchers may carry out sideline activities (such as contract research and consulting work) within certain limits. "Third mission" activities are formally regarded as an advantage when employing/promoting researchers, but it is argued that it has low priority. The traditional academic incentive system based on peer review and publication is still stronger and does not encourage working with industry or technology transfer activities. A revised incentive system is needed that put more weight on the third mission, according to many analysts.

Many universities both in Sweden and in the U.S. have created various programs and initiatives to support commercialization and interaction with industry around their campuses. These might include educational and networking programs, incubators located in science parks and “green houses” for student start-ups as well as legal, management and financial support.

As economic growth is moving to the top of the political agenda in Sweden, policy-makers are looking for ways to address these technology transfer challenges. At the same time, the R&D landscape is shifting when large firms are outsourcing R&D and cutting down on more basic research internally. This trend towards “open innovation” is seen in many OECD countries. When corporate R&D becomes more narrow, applied and short-term, it means additional challenges for the public R&D system to support basic research and the development and commercialization of disruptive technologies. This means new roles, and may require new supporting conditions, for academic technology transfer, public research institutes and private R&D firms.

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Appendix A: Technology Transfer Legislation

A summary of legislation related to technology transfer and cooperative R&D, listed in chronological order (RAND 2003, appendix B).

The Morrill Land-Grant Act of 1862

- Promoted education and innovation in science and technology by forming a system of publicly supported research universities.

National Aeronautics and Space Act of 1958 (PL 85–568)

- Granted NASA broad discretion in the performance of its functions.
- Authorized the NASA Administrator to enter into and perform such contracts, leases, cooperative agreements, or other transactions as may be necessary in the conduct of its work and on such terms as it may deem appropriate, with any agency or instrumentality of the United States, or with any State, Territory, or possession, or with any political subdivision thereof, or with any person, firm, association, corporation, or educational institution.
- Permitted the Administrator to engage in international cooperative programs pursuant to NASA's mission.

The Freedom of Information Act (1966) (PL 104–231) [5 USC 552]

- Provided a vehicle to inform the public about federal government activities.
- Gave citizens the right to request agency records and have them available promptly.

Stevenson-Wydler Technology Innovation Act of 1980 (PL 96–480) [15 USC 3701–3714]

- Focused on dissemination of information.
- Required Federal Laboratories to take an active role in technical cooperation.
- Established Offices of Research and Technology Application at major federal laboratories.
- Established the Center for the Utilization of Federal Technology (in the National Technical Information Service).

Bayh-Dole Act of 1980 (PL 96–517)

- Permitted universities, not-for-profits, and small businesses to obtain title to inventions developed with governmental support.
- Provided early on intellectual property rights protection of invention descriptions from public dissemination and Freedom of Information Act (FOIA).
- Allowed government-owned, government-operated (GOGO) laboratories to grant exclusive licenses to patents.

Small Business Innovation Development Act of 1982 (PL 97–219)

- Required agencies to provide special funds for small-business R&D connected to the agencies' missions.
- Established the Small Business Innovation Research Program (SBIR).

Cooperative Research Act of 1984 (PL 98–462)

- Eliminated the treble-damage aspect of antitrust concerns of companies wishing to pool research resources and engage in joint pre-competitive R&D.
- Resulted in consortia, e.g., the Semiconductor Research Corporation (SRC) and Microelectronics and Computer Technology Corporation (MCC), among others.

Trademark Clarification Act of 1984 (PL 98–620)

- Permitted decisions to be made at the laboratory level in government-owned, contractor operated (GOCO) laboratories as to awarding licenses for patents.
- Permitted contractors to receive patent royalties for use in R&D or awards, or for education.
- Permitted private companies, regardless of size, to obtain exclusive licenses.
- Permitted laboratories run by universities and nonprofit institutions to retain title to inventions, within limitations.

Japanese Technical Literature Act of 1986 (PL 99–382)

- Improved the availability of Japanese science and engineering literature in the United States.

Federal Technology Transfer Act of 1986 (PL 99–502)

- Made technology transfer a responsibility of all federal laboratory scientists and engineers.
- Mandated that technology transfer responsibility be considered in employee performance evaluations.
- Established a principle of royalty sharing for federal inventors (15 percent minimum) and set up a reward system for other innovators.
- Legislated a charter for the Federal Laboratory Consortium for Technology Transfer and provided a funding mechanism for that organization to carry out its work.
- Provided specific requirements, incentives and authorities for the Federal Laboratories.
- Empowered each agency to give the director of GOCO laboratories authority to enter into cooperative R&D agreements and negotiate licensing agreements with streamlined headquarters review.
- Allowed laboratories to make advance agreements with large and small companies on title and license to inventions resulting from Cooperative R&D Agreements (CRADAs) with government laboratories.
- Allowed directors of GOGO laboratories to negotiate licensing agreements for inventions made at their laboratories.
- Provided for exchanging GOGO laboratory personnel, services, and equipment with their research partners.
- Made it possible to grant and waive rights to GOGO laboratory inventions and intellectual property.
- Allowed current and former federal employees to participate in commercial development, to the extent that there is no conflict of interest.

Malcolm Baldrige National Quality Improvement Act of 1987 (PL 100–107)

- Established categories and criteria for the Malcolm Baldrige National Industry Award.

Executive Orders 12591 and 12618 (1987): Facilitating Access to Science and Technology

- Promoted the commercialization of science and technology.

Omnibus Trade and Competitiveness Act of 1988 (PL 100–148)

- Placed emphasis on the need for public-private cooperation in assuring full use of results and resources.
- Established centers for transferring manufacturing technology.
- Established Industrial Extension Services within states and an information clearinghouse on successful state and local technology programs.
- Changed the name of the National Bureau of Standards to the National Institute of Standards and Technology and broadened its technology transfer role.
- Extended royalty payment requirements to non-government employees of federal laboratories.
- Authorized Training Technology Transfer centers administered by the Department of Education.

National Institute of Standards and Technology Authorization Act for FY 1989 (PL 100–519)

- Established a Technology Administration within the Department of Commerce.
- Permitted contractual consideration for rights to intellectual property, other than patents, in cooperative research and development agreements.
- Included software development contributors eligible for awards.
- Clarified the rights of guest worker inventors regarding royalties.

Water Resources Development Act of 1988 (PL 100–676)

- Authorized Army Corps of Engineers laboratories and research centers to enter into cooperative research and development agreements.
- Allowed the Corps to fund up to 50 percent of the cost of the cooperative project.

National Competitiveness Technology Transfer Act of 1989 (PL 101–189)

- Granted GOCO federal laboratories the opportunity to enter into CRADAs and other activities with universities and private industry, under essentially the same terms as stated under the Federal Technology Transfer Act of 1986.
- Allowed information and innovations, brought into and created through cooperative agreements, to be protected from disclosure.
- Provided a technology transfer mission for the nuclear weapons laboratories.

Defense Authorization Act for FY 1991 (PL 101–510)

- Established model programs for national defense laboratories to demonstrate successful relationships among federal government, state and local governments, and small businesses.
- Provided for a federal laboratory to enter into a contract or memorandum of understanding with a partnership intermediary to perform services related to cooperative or joint activities with small businesses.
- Provided for the development and implementation of a National Defense Manufacturing Technology Plan.

Intermodal Surface Transportation Efficiency Act of 1991 (PL 102–240)

- Authorized the Department of Transportation to provide not more than 50 percent of the cost of CRADAs for highway research and development.
- Encouraged innovative solutions to highway problems and stimulated the marketing of new technologies on a cost-shared basis of more than 50 percent if there is substantial public interest or benefit.

American Technology Preeminence Act of 1991 (PL 102–245)

- Extended Federal Laboratory Consortium (FLC) mandate, removed FLC responsibility for conducting a grant program, and required the inclusion of the results of an independent annual audit in the FLC Annual Report to Congress and the President.
- Included intellectual property as potential contributions under CRADAs.
- Required the Secretary of Commerce to report on the advisability of authoring a new form of CRADA that permits federal contributions of funds.
- Allowed laboratory directors to give excess equipment to educational institutions and nonprofit organizations as a gift.

Small Business Technology Transfer (STTR) Act of 1992 (PL 102–564)

- Established a three-year pilot program – Small Business Technology Transfer (STTR) – at the Department of Defense (DoD), Department of Energy (DOE), Department of Health and Human Services (HHS), the National Aeronautics and Space Administration (NASA), and the National Science Foundation (NSF).
- Directed the Small Business Administration (SBA) to oversee and coordinate the implementation of the STTR Program.
- Designed the STTR to be similar to the Small Business Innovation Research (SBIR) program.

- Required each of the five agencies listed above to fund cooperative R&D projects involving a small company and a researcher at a university, federally funded research and development center, or nonprofit research center.

National Department of Defense Authorization Act for 1993 (PL 102–25)

- Facilitated and encouraged technology transfer to small businesses.

National Defense Authorization Act for Fiscal Year 1993 (PL 102–484)

- Established the DoD Office of Technology Transition.
- Extended the streamlining of small-business technology transfer procedures for nonfederal laboratory contractors.
- Directed the DOE to issue guidelines to facilitate technology transfer to small businesses.
- Extended the potential for CRADAs to some DoD-funded Federally Funded Research and Development Centers (FFRDCs) not owned by the government.

National Defense Authorization Act for Fiscal Year 1994 (PL 103–160)

- Broadened the definition of a laboratory to include the weapons production facilities of the DOE.

National Technology Transfer and Advancement Act of 1995 (PL 104–113)

- Gave CRADA partners sufficient intellectual property rights to justify prompt commercialization of inventions resulting from a CRADA.
- Authorized CRADA partners the right to an exclusive or nonexclusive license resulting from a CRADA.

Technology Transfer Commercialization Act of 2000 (PL 106–404)

- Improved the ability of federal agencies to license federally owned inventions by reforming technology-training authorities under the Bayh-Dole Act.
- Permitted laboratories to bring already existing government inventions into a CRADA.

Sammanfattning

USA har under många år med framgång lyckats omvandla forskningsresultat och nya teknologier till kommersiellt gångbara produkter och tjänster. Kommersialisering av nya teknologier har bidragit till ekonomisk utveckling och tillväxt. Teknologiöverföring började institutionaliseras inom den akademiska världen och den federala regeringen efter andra världskriget och har ökat avsevärt under de två senaste årtiondena, i stor utsträckning initierat av politiska reformer.

Denna rapport ger en översikt av omfattningen och olika former av teknologiöverföring samt bakomliggande reformer och aktörer i USA. Syftet är att identifiera styrkefaktorer i USA som är relevanta för Sverige och de utmaningar som är relaterade till kommersialisering av forskningsresultat. Särskild uppmärksamhet ägnas kommersialiseringen vid universiteten i USA. Fem viktiga områden som stödjer teknologiöverföring tas upp och diskuteras. Fokus vad gäller exempel och siffror ligger på medicinsk och bioteknologisk forskning och utveckling (FoU).

Federal och akademisk teknologiöverföring

- Under 2002 investerade den federala regeringen i USA 89 miljarder dollar i FoU. Universitet och högskolor utförde FoU för 37 miljarder dollar (av totalt 292 miljarder dollar). Industrin är den ojämförligt största investeraren och aktören i fråga om FoU och svarade för cirka 70 procent av den totala FoU-verksamheten. Denna andel är ungefär densamma i Sverige.
- Federalt finansierad tillämpad FoU (ej inräknat grundforskning och försvarsspecifik FoU) uppgick till 32 miljarder dollar och kan anses vara ”kandidater för teknologiöverföring”. Department of Health and Human Services (HHS) dominerar detta område och forskning inom livsvetenskaperna är utan jämförelse den ledande disciplinen.
- Federala myndigheter redovisade 4 200 uppfinningar, gjorde mer än 2 100 patentansökningar och mer än 1400 patent utfärdades under år 2000. HHS svarade för cirka tio procent av dessa siffror. HHS är den ledande myndigheten när det gäller antalet licenser och licensintäkter.
- National Institutes of Health (NIH) svarar för den största delen av HHS FoU. Cirka 85 procent av NIH-finansierad FoU genomförs av externa organisationer, som till exempel universitet och sjukhus. NIH:s teknologiöverföringsprogram är det mest framgångsrika av den amerikanska regeringens program i termer av genererade royaltyintäkter (52 miljoner dollar från mer än 1 700 licenser under år 2000). Det anses allmänt att federalt stöd (i synnerhet genom NIH) kraftigt bidragit till skapandet av den framgångsrika bioteknikindustrin i USA.

- Federal lagstiftning har varit viktig som stöd för teknologiöverföringen, genom att till exempel tillåta att federala myndigheter ingår samarbetsavtal inom forskning och utveckling (Cooperative Research and Development Agreements, CRADA) med den privata industrin (det finns för närvarande cirka 3 000 aktiva avtal), genom att det utförande företaget får behålla äganderätten till FoU-resultaten och genom att kräva att alla federala laboratorier skapar en organisation för teknologiöverföring.
- Av universitetens och högskolornas totala FoU-kostnader (33 miljarder dollar under 2001) svarade den medicinska forskningen för den största andelen (30 procent). Den största medicinska institutionen vad beträffar FoU-utgifter är University of California.
- Direkt industristöd är den vanligaste formen av samarbete mellan universitet och industri. Det har funnits en stadig trend mot ökande industristöd under senare år men dess andel av total akademisk FoU har legat kvar mellan sex och åtta procent. Procenttalet är ungefär detsamma i Sverige. Industrifinansieringen uppgick till 2,2 miljarder dollar under 2001. Duke University och MIT fick det största industristödet.
- Universitet och högskolor hade inkomster på cirka 830 miljoner dollar i royalities och annan ersättning från licenser för uppfinningar under 2001. Detta utgjorde inte mer än två till tre procent av den totala akademiska FoU-verksamheten. Columbia University låg högst med en inkomst på 130 miljoner dollar. De största inkomsterna kom från ett fåtal mycket framgångsrika licenser. Av cirka 23 000 aktiva licenser som rapporterats under 2001 genererade endast 131 mer än en miljoner dollar i årlig inkomst. De flesta av universitetens licensbyråer täcker knappt sina egna kostnader.
- Universiteten rapporterade totalt 11 259 uppfinningar under 2001. De lämnade in 9400 patentansökningar i USA, undertecknade mer än 3 300 licenser och skapade 402 nya företag. Mer än 3800 nya företag har grundats baserat på en licens från en akademisk institution sedan 1980. Av dem bedrev 2 100 företag fortfarande verksamhet år 2001. Trenden är att universiteten satsar eget kapital (aktier) i de nya företagen (i cirka 70 procent av företagen under 2001).
- Regionala innovationskluster är viktiga för kommersialiseringen av forskningsresultat. Högteknologiska kluster utgör cirka 2,5 procent av det totala antalet anställda i USA. I New York-området finns det utan jämförelse största bio/farmaceutiska klustret. Nio större bioteknikcenter (inklusive de dominerande Boston- och San Franciscoområdena) fick mer än 4,4 miljarder dollar i NIH:s FoU-finansiering under år 2000. Venture capital-investeringar om cirka 9 miljarder dollar och avtal med större läkemedelsföretag till ett värde av 10 miljarder dollar gjordes mellan 1995 och 2001.

- Det finns ett ökande antal affärsinkubatorer i Nordamerika. Under 2001 fanns det 950 inkubatorer som bistod mer än 35.000 nya företag, erbjöd heltidsanställning för nästan 82.000 anställda och genererade årliga intäkter om mer än 7 miljarder dollar.
- Inkubatorer med en bioteknisk/biomedicinsk inriktning skaffade mer kapital, fick mer forskningsstöd, innehade fler patent och licensierade fler teknologier än andra typer av inkubatorer. Däremot hade de en långsammare intäktstakt och anställningstillväxt.

Kommersialisering vid universiteten

- Huvudsakligen som ett resultat av Bayh-Dole Act har akademiska institutioner i hela USA skapat en stark nationell infrastruktur för teknologilicensiering (mer än 200 teknologiöverföringsorganisationer (technology transfer offices eller TTOs)). Några av de mest framgångsrika institutionerna är Stanford University, MIT, Columbia University och University of California System.
- Patent- och licensieringsbyråer har kompletterats med kontor för sponsrad forskning och industrisamarbete för hantering av en mängd interaktioner mellan universiteten och industrin. Aktiviteterna styrs normalt av handlingsprogram (policies), inklusive riktlinjer för patent, licensiering, aktieägande, copyright, konsultverksamhet och avtal med industrin. Handlingsprogram har utvecklats för att skydda forskarnas rättigheter och för att bevara de akademiska kärnvärdena samt för att skydda universitetet från intresse- och åtagandekonflikter.
- Obligatorisk redovisning av uppfinningar är en viktig policy på universiteten. Anställda på University of California ombeds till exempel att underteckna ett patentavtal i vilket de samtycker till att redovisa alla potentiellt patenterbara uppfinningar och att ge universitetet alla rättigheter till uppfinningarna.
- Statliga universitet, inklusive University of California, har ett ”public service”-uppdrag att säkerställa att forskningsresultat görs tillgängliga till nytta för allmänheten. Industriengagemang uppmuntras och det tillstås alltmer att sådana kontakter faktiskt är till fördel för den akademiska forskningen.
- Privata universitet tycks driva kommersialiseringen på ett mer aggressivt sätt än de statliga institutionerna. De är också flexiblare när det gäller till exempel ekonomisk kompensation till uppfinnarna samt regler för aktieägande i nya företag.
- Det som främst driver forskarens engagemang i teknologiöverföringen är möjligheten av att få ta del av licensintäkterna och att få ägna sig åt välbetalt konsultarbete.

- Forskare vid Stanford University får en tredjedel av nettointäkterna från licensieringen av sina uppfinningar. På University of California får uppfinnarna 35 procent av nettoinkomsten.
- En viktig fråga är hur man får forskarna att redovisa sina uppfinningar. Det beräknas att mindre än hälften av de utvecklade teknologierna redovisas. Enligt vissa studier är de ”främsta” forskarna minst benägna att göra sig besväret att kommersialisera sin forskning. En förklaring är att de flesta uppfinningar kräver ytterligare FoU av mer tillämpat slag än den ursprungliga forskaren önskar ägna sig åt.
- En utmaning för TTO-systemet är att hitta kompetent personal. Affärsuppgörelser blir alltmer komplexa och personalen måste behärska många kompetensområden. Förutom kunskapen om det vetenskapliga arbetet bakom uppfinningen måste de ha marknadsförings- och förhandlingskompetens samt juridisk kompetens.

Viktiga faktorer som möjliggör teknologiöverföring

1. Teknologiöverföringens finansiering

- Industrin och enskilda privata investerare (”affärsänglar”) är de viktigaste finansieringskällorna för teknologiutveckling i ett tidigt skede (ej venture capital). Affärsänglarnas investeringar har ökat snabbt under senare år – det finns minst 170 affärsängelsgrupper i USA. Flera skattereformer har kraftigt bidragit till att skapa incitament för privata investeringar.
- Riskkapitalister har spelat en viktig roll vid bildandet av nya högteknologiska företag. Handlingsprogram för småföretag på 1950-talet, pensionsfondsbestämmelser och policies som underlättade förvärv var viktiga federala initiativ som hjälpte till att skapa denna marknad. Investeringarna har minskat radikalt från 94 miljarder dollar toppåret 2000 till 19 miljarder dollar under 2002. Fokus ligger nu på mindre riskfyllda investeringar i ett senare skede.
- Dessutom gynnar värdepappers-, bank- och konkurslagar den enskilda fordringsägaren på ett sådant sätt att entreprenören inte riskerar att förlora hus och hem om affärerna misslyckas. Dessa bestämmelser banar väg för den allmänt spridda uppfattningen att affärsmisslyckanden kan accepteras.

2. Policy för immateriell egendom

- Den amerikanska patentlagen ligger till grund för skyddet av immateriell egendom. Sedan 1950-talet har en serie tillägg och domstolsbeslut stärkt patentskyddet, till exempel genom rätten att ta patent på modifierade levande organismer år 1980.

- Den federala regeringens huvudmetod för att främja teknologiöverföring är att bevilja immateriella rättigheter till den utförande institutionen vars FoU finansieras med federala medel, som till exempel universitet, federala laboratorier och privata företag (Bayh-Dole och Stevenson-Wydler Acts). Institutionerna är fria att kommersialisera resultaten men måste dela vinsten med uppfinnarna.
- Det anses allmänt att Bayh-Dole Act varit framgångsrik och att den hjälpt till att etablera nya verksamheter, skapa nya industrier samt öppna nya marknader. Sedan 1980 beräknas licensiering av innovationer ha bidragit till att etablera 2 200 företag, mellan 250 000 och 300 000 jobb samt ha bidragit med 30–40 miljarder dollar till den amerikanska ekonomin varje år.

3. Entreprenörskap och utbildning

- Entreprenörskap är mycket vanligt i USA. Cirka sex procent av alla vuxna startar nya företag.
- Utbildning i entreprenörskap har bidragit till att skapa den nödvändiga kompetensen och inställningen. Mer än 1500 universitet och högskolor erbjuder någon typ av utbildning. Nästan 500 miljoner dollar har investerats i mer än 250 professurer och andra tjänster i entreprenörskap. Babson College driver det största och högst rankade programmet.

4. Policy och program för småföretag

- Sedan 1950-talet har den amerikanska Small Business Administration (SBA) tillhandahållit ekonomisk, teknisk och verksamhetsrelaterad hjälp till små företag. SBA är den största enskilda ekonomiska bidragsgivaren till småföretag med en portfölj av affärslån, lånegarantier och katastroflån, värda mer än 45 miljarder dollar och en portfölj av venture capital om 13 miljarder dollar (2002).
- Small Business Investment Company-programmet (SBIC) tillhandahåller kapital, långsiktiga lån och verksamhetsrelaterad hjälp till småföretag, särskilt under tillväxtstadiet. Under 2002 hjälpte SBIC 2853 företag med 2,3 miljarder dollar (ned 50 procent från 4,7 miljarder dollar under toppåret 1999). SBIC:s finansiering av venture capital-typ utgjorde cirka 11 procent av all venture capital-finansiering under 2002.
- Small Business Innovation Research-programmet (SBIR) ger stöd åt småföretag för att konkurrera om federala FoU-anslag. Small Business Technology Transfer-programmet (STTR) stödjer småföretag som samarbetar med ideella forskningsinstitutioner för att konkurrera om sådana projekt. Genom dessa program reserveras en viss procent av federala FoU-medel för småföretag. SBIR-programmet har haft en snabb tillväxt sedan 1983.

5. Övriga regeringsinitiativ och program

- Industry-University Cooperative Research Centers (IUCRC:s) och Engineering Research Centers (ERC:s) administreras genom National Science Foundation (NSF). Det finns för närvarande cirka 50 IUCRC och 20 ERC. NSF-investeringen ska stödja samarbeten mellan universitet och industri inom forskningsområden som antingen är nya eller under utveckling. Det är framförallt företagen som står för finansieringen. Avsikten är att dessa center så småningom skall bli självförsörjande (vanligtvis inom en tioårsperiod).
- Advanced Technology Program (ATP) skapades 1990 av Department of Commerce. Detta offentlig-privata partnerskapsprogram finansierar högriskforskning för utveckling av teknologier som utlovar betydande kommersiella vinster. Programmet kan komma att avvecklas successivt av Bush-administrationen.
- Projektet BioShield är ett exempel på ett initiativ från regeringens sida att använda FoU-upphandling för att stimulera innovation. Enligt administrationens förslag kommer 6 miljarder dollar att investeras under tio år för att utveckla och tillgängliggöra moderna, effektiva läkemedel och vacciner som skydd mot biologiska och kemiska terroristattacker. Tanken är att regeringen skall garantera en marknad för innovativa teknologier mot terrorism.

Problem och utmaningar

Problem och utmaningar omfattar de eventuella negativa effekterna av forskningens kommersialisering på universitet och högskolor (som till exempel sekretess, eventuella intressekonflikter och svårigheter att få tillgång till forskningsmaterial), hur man skall hantera finansieringen av teknologiutveckling i ett tidigt skede, problem med Bayh-Dole och det nuvarande systemet för att skydda immateriell egendom samt sätt att förbättra metoderna för teknologiöverföring inom nuvarande juridiska ramverk.

Styrkefaktorer i USA och utmaningar i Sverige

Slutligen har fem avgörande faktorer (inom ovannämnda områden) för en framgångsrik teknologiöverföring i USA valts ut och diskuterats i förhållande till de utmaningar som Sverige står inför vad gäller kommersialiseringen av forskningsresultat. Dessa faktorer är (1) tillgång på privat kapital, (2) äganderätt till forskningsresultaten, (3) entreprenöriell kompetens, (4) deltagande av småföretag samt (5) statliga program.

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