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R&D Partnerships and Intellectual Property: Implications for U.S. Policy

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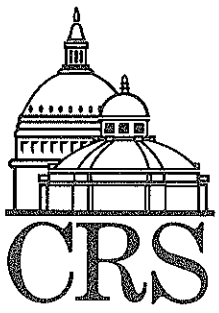

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R&D Partnerships and Intellectual Property: Implications for U.S. Policy

Summary

Congressional interest in the value of intellectual property has grown as technology becomes increasingly important to the United States. It is now widely accepted that technological progress accounts for up to one-half of the nation's economic growth. Concurrently, the role of patents has changed as the use of cooperative research and development (R&D) expands to facilitate this technological advancement and generate new products, processes, and services for the marketplace. Patents protect the inventor's investments in generating the knowledge that is the basis for innovation and are intended to promote "science and the useful arts" and serve as an incentive to the commercialization of new ideas. As R&D has become more expensive, ownership of title to inventions has been used by the federal government as a means to encourage cooperative work between the public and private sectors and among industry, universities, and non-profit organizations.

The relationship between patents and cooperative R&D is important to the discussion of policies surrounding intellectual property and congressional efforts to encourage collaborative ventures. Such joint efforts are an attempt to facilitate technological advancement within the industrial community. Academia, industry, and government can play complementary roles in technology development. Cooperative projects attempt to maximize the best work of the participants and to direct these efforts toward the goal of generating new goods, processes, and services for the marketplace. They allow for shared costs, shared risks, shared facilities, and shared expertise. While opponents argue that cooperative activities stifle competition, proponents contend that they are designed to accommodate the strengths and responsibilities of these sectors.

A major emphasis of legislative activity has been to augment research in the industrial community. This focus is reflected in executive branch and congressional efforts to encourage companies to undertake cooperative R&D arrangements and to expand the opportunities available for research. Various laws have created an environment conducive to joint ventures between government and industry, or between industry and universities, as well as among companies. To date, Congress has determined that providing title to inventions made under federal funding to contractors and/or collaborating parties should be used to support innovation. In return for patent ownership, Congress has accepted as satisfactory the anticipated payback to the country through goods and services to improve our health, welfare, and standard of living. These benefits have been considered more important than the initial cost of the technology to the government or any potential unfair advantage of one company over another in a cooperative venture. However, as such efforts become more widespread and as new issues emerge, additional decisions may need to be made on how to maintain a balance between the importance of bringing new products and processes to the marketplace and protecting the public investment in R&D.

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R&D Partnerships and Intellectual Property: Implications for U.S. Policy

Introduction

Congressional interest in the value of intellectual property has grown as technology becomes increasingly important to the United States. It is now widely accepted that technological progress accounts for up to one-half of the nation's economic growth.[1] Concurrently, the role of patents has changed as the use of cooperative research and development (R&D) expands to facilitate this technological advancement and generate new products, processes, and services for the marketplace. Patents protect the inventor's investments in generating the knowledge that is the basis for innovation and are intended to promote "science and the useful arts" and serve as an incentive to the commercialization of new ideas. As R&D has become more expensive, ownership of title to inventions has been used by the federal government as a means to encourage cooperative work between the public and private sectors and among industry, universities, and non-profit organizations.

This paper explores the relationship between patents and cooperative R&D within the context of attention to policies surrounding intellectual property and congressional efforts to encourage collaborative ventures. Such joint efforts are an attempt to facilitate technological advancement within the industrial community. Academia, industry, and government can play complementary roles in technology development. Cooperative projects attempt to maximize the best work of the participants and to direct these efforts toward the goal of generating new goods, processes, and services for the marketplace. They allow for shared costs, shared risks, shared facilities, and shared expertise. While opponents argue that joint ventures stifle competition, proponents contend that they are designed to accommodate the strengths and responsibilities of these sectors.

A major emphasis of legislative activity has been to augment research in the industrial community. This focus is reflected in executive branch and congressional efforts to encourage companies to undertake cooperative R&D arrangements and to expand the opportunities available for research. Various laws have created an environment conducive to joint ventures between government and industry, or between industry and universities, as well as among companies. Beginning in 1980, with the passage of legislation mandating the transfer of technology from government laboratories and permitting certain contractors to retain title to inventions made under federal funding, and continuing today in laws designed to make additional alterations

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[1]National Institute of Standards and Technology, *Technology and Economic Growth: Implications for Federal Policy*, by Gregory Tassey, October 1995, 6-12.

to policies regarding government-owned intellectual property, there has been congressional interest in facilitating innovation through collaborative R&D.

As cooperative efforts have expanded, various questions have been raised regarding the outcome of these ventures. Among the concerns are issues associated with the dispensation of certain intellectual property rights when federal funding is involved. What has been the effect of implementation of the legislative mandate? Are current government policies generating the intended results in facilitating joint activities or are there additional consequences that might need to be addressed? The information provided in this report is intended to offer background for congressional debates over incentives to collaborative research, patent reform legislation, and other bills associated with assignment of patents and licenses resulting from federally supported R&D.

Cooperative R&D

Collaboration in research and development permits work to be done which is too expensive for one company to fund or of marginal value for any given firm. As new technologies are generated and their impact more widespread, it has become ever more resource-intensive for industry to perform R&D. Concurrently, shortened product cycles have led to expanded demands for new technology and higher costs for technology development as reflected in the average 8.9% yearly increase (in real terms) in company support for such work between 1994 and 1998.[2] The rising expense of research and development has been juxtaposed with increasing international competition and shareholder demands for short-term returns.

Companies have developed alternative means of acquiring new technologies while controlling the requisite costs. Various firms have increased efforts to tap outside sources for the research underlying their products, particularly basic research. For example, over 90% of life science companies in the United States have had a cooperative relationship with universities.[3] Basic research is typically performed with little certainty that it will produce results in the future. Cooperative ventures permit businesses to develop a critical mass of human, technical, and financial resources. External alliances allow access to innovations without the expense and risks of generating them independently. Such arrangements also let large firms reduce losses if a collaboration does not work by terminating the joint activity, rather than altering in-house research with its attendant large fixed costs.[4]

Joint ventures allow for R&D that crosses traditional boundaries of expertise and experience. Such projects make use of existing, and support development of new

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[2]National Science Foundation, *Science and Engineering Indicators 2000*, available at [http://www.nsf.gov/sbe/srs/stats.htm] (Pdf format p. A-19).

[3]David Blumenthal, Nancyanne Causino, Eric Campbell, and Karen Seashore Louis, "Relationships Between Academic Institutions and Industry in the Life Sciences — An Industry Survey," *The New England Journal of Medicine*, 8 February, 1996, 369.

[4]Erica Whittaker and D. Jane Bower, "A Shift to External Alliances for Product Development in the Pharmaceutical Industry," *R&D Management*, July 1994, 257.

resources, facilities, knowledge, and skills. Collaboration is a means to stimulate innovation. Ideas, expertise, and know-how are combined, facilitating a mix that may lead to more creativity and invention. It appears that "merging technological knowledge and skills from different companies improves the innovation process."[5] In addition, it has been argued that, for certain industries, the more extensive a firm's emphasis on external sources of technical knowledge, the greater its total factor productivity growth.[6] It should be noted, however, that joint ventures are not always successful due, in part, to cultural differences between companies or organizations, as well as managerial and financial issues or conflicting goals and objectives.

In addition to joint projects among companies, industry-university cooperation in R&D provides another important means to facilitate technological innovation. Universities educate and train the scientists, engineers, and managers employed by companies. Traditionally, much of the basic research integral to certain technological advancements is performed in academia. Such institutions generally undertake fundamental research as part of the educational process without concerns associated with producing for the marketplace. The risks attached to work in this setting are fewer than those in industry where companies must earn profits.

Companies are increasingly looking to the academic community for research assistance. Prior to World War II, industry was the primary source of funding for basic research in academia. This financial support helped shape priorities and build relationships. After the war the federal government supplanted industry as the major financial contributor and became the principal determinant of the type and direction of the research performed in academic institutions. Thus, the connection between the university and industrial communities was broken. However, in the past 15 years, this break has been bridged for all the reasons discussed above. Industry funding for university R&D has expanded substantially. Between 1980 and 1998, there was an increase of 285% (in real terms); between 1990 and 1998, the growth was 35% (in real terms).[7] A study by Edwin Mansfield of the Wharton School of Business, demonstrated that "...over 10% of the new products and processes introduced in [the 8 industries explored] could not have been developed (without substantial delay) in the absence of recent academic research."[8]

The federal government represents another source of expertise, knowledge, technology, and advanced research facilities for industry. In certain cases, the government laboratories have scientists and engineers with experience and skills, as well as equipment, not available elsewhere. The government also has a vested interest in technology development. It does not have the mandate or resources to manufacture goods, but has a stake in the availability of products and processes to

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[5]Francis Bidault and Thomas Cummings, "Innovating Through Alliances: Expectations and Limitations," *R&D Management*, January 1994, 33.

[6]Alden S. Bean, "Why Some R&D Organizations Are More Productive Than Others," *Research/Technology Management*, January-February 1995, 26.

[7]*Science and Engineering Indicators 2000*. (Pdf version p. A-122).

[8]Edwin Mansfield, "Academic Research and Industrial Innovation: An Update of Empirical Findings," *Research Policy* 26 (1998): 775.

meet mission requirements. In addition, technological advancement contributes to the economic growth vital to the health and security of the nation. Collaboration between government laboratories and industry is not, however, just a one way street. In several technological areas, particularly electronics and computer software, the private sector is more advanced in technologies important to the national defense and welfare of this country. Interaction with industry offers federal scientists and engineers valuable information to be used within the government R&D enterprise.

Legislative Foundation for Cooperative R&D

Of major significance to the evolution of cooperative R&D was the enactment of P.L. 96-517, Amendments to the Patent and Trademark Act (commonly referred to as the "Bayh-Dole Act" after its two main sponsors).[9] This law was designed to utilize the ownership of inventions arising out of government-sponsored research and development to facilitate the commercialization of new technologies through collaboration among the research community, small business, and industry. It permits a contractor performing research for the federal government to retain title to any "subject invention" arising from that work if the contractor is a small business, university, or other non-profit institution, except under "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of [the law]."[10] The institution must commit to commercialization within a predetermined, agreed upon, time frame. As stated in the House report to accompany the bill, "the legislation establishes a presumption that ownership of all patent rights in government funded research will vest in any contractor who is a nonprofit research institution or a small business."[11]

Certain rights are reserved for the government to protect the public's interests. The government retains "... a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practices for or on behalf of the United States any subject invention throughout the world ..." March-in rights enable the federal agency to require the contractor to "... grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants ..." (with due compensation) or to grant a license itself under certain circumstances. The special situation necessary to trigger march-in rights involves a determination that the contractor has not made efforts to commercialize within an agreed upon time frame or that the "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor.... "[12]

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[9]For additional information see: Congressional Research Service, *Patent Ownership and Federal Research and Development (R&D): a Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, by Wendy H. Schacht, RL30320, 28 September, 1999.

[10]P.L. 96-517, sec. 200.

[11]House Committee on the Judiciary, *Report to Accompany H.R. 6933*, 96th Cong., 2nd sess., 1980, H.Rept. 96-1307, Part 1, 5.

[12]P.L. 96-517, sec. 203.

The government is "authorized" to withhold public disclosure of information for a "reasonable time" until a patent application can be made. This supplements existing patent law (35 U.S.C. 205) that prohibits the Patent and Trademark Office from releasing information associated with a patent until it is issued. Licensing by any contractor retaining title under this act is restricted to companies that will manufacture substantially within the United States. Initially, universities were limited in the time they could grant exclusive licenses to large companies for patents derived from government-sponsored R&D (5 of the *then* 17 years of the patent). This restriction, however, was lifted by P.L. 98-620, the Trademark Clarification Act of 1984. According to Senate Report 98-662, extending the time frame for licensing to large firms ". . . is particularly important with technologies such as pharmaceuticals, where long development times and major investments are usually required prior to commercialization."[13]

In a February 1983 memorandum concerning the vesting of title to inventions made under federal funding, President Reagan ordered all agencies to treat, as allowable by law, all contractors regardless of size as prescribed in P.L. 96-517. This, however, does not have a legislative basis. P.L. 98-620, noted above, further amended Bayh-Dole by loosening the time limitations for both disclosure of an invention to the government agency and for the amount of time provided within which to elect to take title. Non-profit institutions were subsequently permitted to assign title rights to another organization (e.g., one that markets technology) and government-owned, contractor-operated laboratories (primarily those of the Department of Energy) run by non-profits were permitted to retain title to inventions made in the facility with the exception of those dedicated to naval nuclear propulsion or weapons development. In addition, the Federal Technology Transfer Act (P.L. 99-502) allows firms regardless of size to be awarded patents generated under a cooperative research and development agreement (CRADA) with a federal laboratory.

Bayh-Dole also addressed licensing of government-owned inventions. Among the objectives of the legislation was the use of ". . .the patent system to promote the utilization of inventions arising from federally supported research or development; ... [and] 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 ...."[14] Title 35 USC section 209 circumscribes the licencing of these type of inventions. It permits federal agencies to offer non-exclusive, exclusive, or partially exclusive licenses under certain conditions and with specific rights retained by the government including the right to terminate the license if commercialization is not pursued as provided in the business plan or if the government needs the license for public use. Small businesses are given preference and licensees must agree that "... any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States."

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[13]Senate Committee on the Judiciary, *Report to Accompany S. 2171*, 98th Cong., 2nd sess., 1984, S.Rept. 98-662, 3.

[14]35 U.S.C. 200.

Other legislation facilitating collaborative R&D has been enacted. The Stevenson-Wydler Technology Innovation Act (P.L. 96-480), as amended, created institutional mechanisms by which federal agencies and their laboratories can move technology to the private sector as well as integrate industrial expertise into the federal R&D enterprise. Additional incentives are contained in the Federal Technology Transfer Act (P.L. 99-502) and the Defense Authorization Act of 1990 (P.L. 101-189) which allow government laboratories to enter into cooperative R&D agreements (CRADAs) with universities and industry. In pursuing joint efforts, the laboratory may accept funds, personnel, services, and property from the collaborating party and may provide personnel, services, and property (but **not** funds) to the other organization. The work performed must be consistent with the laboratory's mission. Preference for cooperative ventures is given to small businesses, companies which will manufacture in the United States, or foreign firms from countries that permit American companies to enter into similar arrangements. To date, over 5,000 CRADAs have been signed (including NASA Space Act Agreements).[15]

The Research and Experimentation Tax Credit originally mandated by the 1981 Economic Recovery Tax Act (P.L. 97-34), and extended several times (through June 30, 2004), allows a 20% credit for increases in a firm's qualified research costs above the average expenditures for the previous 3 tax years. Qualified costs include in-house expenditures such as wages for researchers, materials, and payments for use of equipment; 65% of corporate grants towards basic research at universities and other relevant institutions; and 65% of payments for contract research. It is applicable to 75% of a company's tax liability. Small, start-up firms also are eligible.

Investments in R&D are often costly, long term, and risky. To encourage increased private sector activity, various legislative initiatives have been enacted to facilitate joint ventures among government, business, and academia. It is argued that collaborative R&D reduces risks and costs, and permits work to be performed that crosses traditional boundaries of expertise and experience. This is the intent of the National Cooperative Research Act (P.L. 98-462) which clarifies the antitrust laws as they relate to joint research and eliminates treble damage awards for those ventures found in violation if prior disclosure to the government has been made. These changes came in response to industry's reluctance to enter into cooperative efforts because of the threat of antitrust prosecution. According to the Department of Justice, almost 750 joint research ventures have been filed since passage of this legislation.

The success of this law in stimulating collaborative work precipitated the enactment of the National Cooperative Production Amendments Act of 1993 (P.L. 103-42). The legislation extends the provisions of the National Cooperative Research Act to joint manufacturing ventures with certain reservations concerning location and ownership of the participating enterprises.

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[15]For more information see: CRS Issue Brief IB85031, *Technology Transfer: Use of Federally Funded Research and Development*, by Wendy H. Schacht.

The Role of Intellectual Property in Cooperative R&D

Legislative initiatives to foster collaborative work address the dispensation of patents arising from federal funding because of their role in providing an economic incentive for companies to pursue further development and commercialization of the results of R&D. Studies have shown that research funding only accounts for approximately 25% of the costs associated with bringing a new product or process to market. Patent ownership is seen as a means to encourage the additional, and often substantial investment necessary to create new goods and services for the marketplace. In an academic setting, the possession of title to inventions can provide motivation for the university to license the technology to the private sector for commercialization in anticipation of royalty payments.

The patent system was created by Article I, Section 8, Clause 8 of the U.S. Constitution to encourage new discoveries and their reduction to practice, commonly known as innovation. The grant of a patent provides the inventor with a means to capture returns to his invention through exclusive rights on its practice for 20 years from date of filing. This is intended to encourage those investments necessary to further develop an idea and generate a marketable technology. At the same time, the process of obtaining a patent places the concept on which it is based in the public domain. In return for a monopoly right to specific applications of the knowledge generated, the inventor must publish the ideas covered in the patent. As a disclosure system, the patent can, and often does, stimulate other firms or individuals to invent "around" existing patents to provide for parallel technical developments or meet similar and expanded demands in the marketplace.[16]

The utility of patents to companies varies among industrial sectors. An assessment of the aircraft and semiconductor industries found that patents were not the most successful mechanism for capturing the benefits of investments. Instead, lead time and the strength of the learning curve were determined to be more important.[17] In contrast, patents are perceived as critical in the drug and chemical industries. That may reflect the nature of R&D performed in those sectors, where the resulting patents are more detailed in their claims and therefore easier to defend.[18] The degree to which industry perceives patents as effective is "... positively correlated with the increase in duplication costs and time associated with patents."[19] In certain industries, patents significantly raise the costs incurred by nonpatent holders wishing

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[16]For more information see: CRS Report 97-599, *Patents and Innovation: Issues in Patent Reform*, by Wendy H. Schacht.

[17]Richard C. Levin and Alvin K Klevorick, Richard R. Nelson, and Sidney G. Winter. "Appropriating the Returns for Industrial Research and Development," *Brookings Papers on Economic Activity*, 1987, printed in *The Economics of Technical Change*, ed. Edwin Mansfield and Elizabeth Mansfield. (Vermont, Edward Elgar Publishing Co., 1993), 253.

[18]Ibid., 255 and 257. See also: Edwin Mansfield, "Intellectual Property Rights, Technological Change, and Economic Growth," in eds. Charls Walker and Mark A. Bloomfield, *Intellectual Property Rights and Capital Formation in the Next Decade*, (New York, University Press of America, 1988), 12 and 13.

[19]*Appropriating the Returns for Industrial Research and Development*, 269.

to use the idea or invent around the patent — an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods — and are thus viewed as important. However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g., in the 7%-15% range for electronics), and are considered less successful in protecting resource investments.[20]

Despite questions as to their efficacy, firms continue to patent their inventions. The number of domestic patents granted to U.S. inventors is growing.[21] This activity appears to be the result of additional perceived benefits including royalty payments, delays to imitators, and the ability to use patents as bargaining tools to meet alternative priorities of the firm.[22] The low expiration rate of high technology patents relative to patents on less sophisticated technologies may indicate the value that companies assign to such protection, even in industries where the life cycle of inventions is short.[23]

The Research Environment

The considerable growth in joint ventures in industry over the past 10 - 15 years has been influenced by various factors. The numerous mergers and acquisitions that took place in the business world during the latter 1980s led to restructuring that produced consolidations and laboratory closings and forced companies to look elsewhere for research.[24] The increased collaboration brought on by these factors has been accompanied by increased industry spending on R&D as noted previously. Such measures were accompanied by the congressional legislation described above. Partnerships also are a result of "... today's complex technologies, intense competition, and information overload [that] have required new approaches" beyond the funding of scientists to pursue their own interests.[25]

Many companies now only support in-house R&D designed to augment the core businesses of the firm. This is reflected in the shift in corporate strategies from basic to applied research and from corporate toward division-level, line-of-business research.[26] The emphasis is on technology to increase productivity and decrease time to market. However, technology outsourcing is not intended to end corporate R&D

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[20]Edwin Mansfield, Mark Schwartz, and Samuel Wagner. "Imitation Costs and Patents: An Empirical Study," *The Economic Journal*, December 1981, in *The Economics of Technical Change*, 270.

[21]*Science and Engineering Indicators 1998*, A-373.

[22]*Intellectual Property Rights, Technological Change, and Economic Growth*, 14.

[23]Donald J. Quigg, "Safeguarding Intellectual Property — Stimulus to Economic Expansion," in *Intellectual Property Rights and Capital Formation in the Next Decade*, 40.

[24]Emily Smith, "Glimpsing the Future in the Numbers," *Business Week*, 15June, 1990, 194.

[25]John Carey, "What Price Science?" *Business Week*, 26 May, 1997, 168.

[26]Irwin Feller and David Roessner, "What Does Industry Expect from University Partnerships?" *Issues in Science and Technology*, Fall 1995, 81.

but to increase the capability to do it.[27] Typically it is more costly and risky to develop new technologies than to improve upon existing ones. Thus, collaboration permits firms to acquire the basic research they need from other organizations. In 1996, companies funded $5 billion of external R&D. This was 4.7% of the total in-house work supported by firms, an increase from 3.6% in the early 1990s and under 2% in the early 1980s.[28] It appears that 20% of largest U.S. corporations outsource technology development.[29]

Recent studies by PricewaterhouseCoopers (formerly Coopers & Lybrand) identify numerous benefits that have resulted from partnering including increased sales of existing products; improved competitive position; development of more new products or business lines; and better operations or technology. Of the fastest growing U.S. firms, nearly two-thirds are involved in strategic partnerships.[30] have partnered in the past three years. Firms that partner:

- invest in more new product development;
- have less new products, although the ones that emerge are big winners;
- grow larger than others in terms of employee size and gross revenues;
- demonstrate a higher productivity rate; and
- experience "explosive growth."[31]

From the work undertaken by PricewaterhouseCoopers, it appears that "... collaborative growth firms are spending more on new product development while focusing more on bigger winners and on innovation ... [and] ... are not reluctant to go outside their organization to work with others in the development of their innovative new products."

Increasingly, industry is looking toward academia for the research necessary for product development. There has been significant growth in industrial support of university R&D. According to figures provided by the National Science Foundation, the private sector has funded an increasing percentage of the total amount of R&D performed in academia since the early 1960s. Throughout most of the later 1960s and 1970s, the business community was the source of 3% of total research and development performed in universities. By the mid 1980s, this had risen to 6% and in the 1990s to 7%. Industry payments to universities for R&D have been expanding.

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[27]John W. Verity, "Let's Order Out for Technology," *Business Week*, 13 May, 1996, 47.

[28]John E. Jankowski, "R&D: Foundation for Innovation," *Research/Technology Management*, March-April 1998, 17.

[29]*Let's Order Out for Technology*, 47.

[30]PricewaterhouseCoopers, "Strategic Alliances Give Big Revenue Boost to America's Fastest-Growing Companies," *Trendsetter Barometer*, November 30, 2000, available at [http://www.barometersurveys.com].

[31]PricewaterhouseCoopers, "Technology Businesses Making Big Commitments to Joint Ventures, But Important Planning is Being Overlooked," *Trendsetter Barometer*, September 11, 2000, available at [http://www.barometersurveys.com]. See also: Coopers and Lybrand, L.L.P., "Partnerships Pay off for Growth Companies," *Trendsetter Barometer*, 6 January, 1997.

In 1998, it is estimated that the private sector provided almost $1.9 billion to universities and colleges. Between 1985 and 1998, private sector funding of academic R&D experienced growth of over 100% as measured in constant dollars. [Note: comparisons of data prior to 1985 are unreliable since the National Science Foundation changed accounting procedures that year.] Preliminary figures show a 5% increase in financing between 1996-1997 and an increase of 6% between 1997-1998.[32]

The benefits to industry of R&D partnerships are apparent. PricewaterhouseCoopers found that "growth companies with university ties have productivity rates almost two-thirds higher than peers ...."[33] In the pharmaceutical industry, over one-quarter of new drugs depended on academic research for timely commercialization.[34] The research performed in institutions outside of industry has relevance to and is often incorporated into the work of the private sector. Of the papers cited in patents granted to U.S. companies during the years 1987-1988 and 1993-1994, 73% are "public science," authored at academic, governmental, and other public facilities.[35] Work prepared for the National Science Foundation by Francis Narin and his associates indicated that "... public science plays an essential role in supporting U.S. industry, across all the science-linked areas of industry, amongst companies large and small, and is a fundamental pillar of the advance of U.S. technology."[36]

Universities also are expanding their interaction with the private sector through licensing of inventions generated within academia. It is estimated that 19% of university research is done in conjunction with industry partnership efforts.[37] Between FY1991 and FY1995, university invention disclosures increased 29%, patent applications increased 53%, and licenses and options executed increased 66%.[38] In 1998 *alone*, universities granted 3,668 licenses, filed 4,808 patent applications, and received 3,224 patents. This compares with the ten years between 1975 and 1984,

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[32]*Science and Engineering Indicators, 2000.*

[33]Coopers and Lybrand L.L.P., "Growth Companies with University Ties Have Productivity Rates Almost Two-Thirds Higher Than Peers," *Trendsetter Barometer*, 26 January, 1995, 1.

[34]Nathan Rosenberg and Richard R. Nelson, "American Universities and Technical Advance in Industry," *Research Policy*, May 1994, 344.

[35]Francis Narin, Kimberly S. Hamilton, and Dominic Olivastro, "The Increasing Linkage Between U.S. Technology and Public Science, paper presented to the House Committee on Science, 17 March, 1997, 2.

[36]Ibid., 15.

[37]Wes Cohen, Richard Florida, and Richard Goe, "University-Industry Research Centers in the United States," Report to the Ford Foundation, 1993 referenced in Rosenberg and Nelson, *American Universities and Technical Advance in Industry*, 323.

[38]Information in this paragraph from: Association of University Technology Managers, "Licensing Survey FY1991-FY1995, Executive Summary," Association of University Technology Managers, Inc., Norwalk, 1997 and Association of University Technology Managers, "Academic Research Helps Drive U.S. Economy," December 2, 1999, available at [http://www.autm.net].

when universities applied for a *total* of 4,105 patents and were granted 2,944 patents. Analysis by the Association of University Technology Managers shows that the commercialization of academic research in 1998 generated $33.5 billion in economic activity and resulted in 280,000 jobs and the creation of 364 new companies. This is a "direct result" of the Bayh-Dole Act.

Issues and Opportunities

As cooperative research and development between the federal government and the private sector becomes increasingly ubiquitous, intellectual property issues continue to be explored. The interrelationships between patents and collaborative R&D are circular and complex. Laws addressing ownership of patents resulting from federally funded R&D have facilitated collaborative ventures at the same time that increased joint activities have augmented the importance of patent ownership. The expanding number and scope of cooperative efforts have given rise to new issues and opportunities. Since "proprietary technology advantage [is] a key business strategy,"[39] there are on-going concerns over the dissemination of patents arising from research and development supported by the federal government.

There are many benefits associated with the use of intellectual property to facilitate joint R&D. Federal agencies and major research universities have acknowledged that the patent provisions of the Bayh-Dole Act have had a positive impact on collaboration between academia and industry and on the commercialization of new technologies.[40] Perhaps, even more significantly, Dr. Bernadine Healy, former Director of the National Institutes of Health, argues that Bayh-Dole is responsible for the development and growth of the biotechnology sector.[41] An industry that was in its infancy 20 years ago, biotechnology now is in the forefront of national technological progress. This was achieved to a great extent by both the expansion of cooperative efforts among government, industry, and academia and by the intellectual property protection provided under the Bayh-Dole Act.

Congressional legislation has provided certain mandates and direction; however, implementation of these laws has led to new questions as to their impact and any unintended effects. For example, the recently enacted Technology Transfer Commercialization Act (P.L. 106-404), addresses on-going issues associated with the assignment of patents and licenses resulting from federally supported R&D as established under Stevenson-Wydler and Bayh-Dole. This law makes alterations in established practice to decrease the time delays associated with obtaining an exclusive or partially exclusive licence under P.L. 96-517. Previously, agencies were required to publicize the availability of technologies for three months using the *Federal*

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[39]Clarence M. Eidt, Jr. and Roger W. Cohen, "'Reinventing' Industrial Basic Research," *Research/Technology Management*, January-February 1997, 29.

[40]General Accounting Office, *Technology Transfer, Administration of the Bayh-Dole Act by Research Universities*, GAO/RCED 98-126, May 1998, 2.

[41]House Committee on the Judiciary, *Biotechnology Development and Patent Law*, Hearings, 102nd Cong., 1st sess., 20 November, 1991, 48.

Register and then provide an additional 60 day notice of intent to license by an interested party. The new legislation shortens the period to 15 days in recognition of the ability of the Internet to offer widespread notification and the necessity of time constraints faced by industry in commercialization activities. Certain rights are retained by the government. In addition, the bill allows licenses for existing government-owned inventions to be included in CRADAs.

The successful implementation of the legislative mandate to transfer technology has led to expanded use of CRADAs and to questions involving individual arrangements under this collaborative mechanism. In March 1997, a consortium of U.S. semiconductor companies (called the EUV LLC), led by Intel and including Motorola and Advanced Micro Devices, signed a cooperative research and development agreement with three Department of Energy laboratories to develop commercial applications for a semiconductor manufacturing technology known as extreme ultraviolet (EUV) lithography. However, concerns associated with this CRADA soon were voiced. Opposition arose over the participation of foreign equipment suppliers in applying the results of the collaborative work. Critics argued that the potential for providing foreign firms access to technology developments originating in federal laboratories would be detrimental to American companies and hurt national economic security interests. Proponents maintained that the law had been followed and the requirements for U.S. manufacture and existing export control regulations are sufficient to address concerns over foreign companies. In addition, they assert, since the consortium is funding the work in the federal laboratories, it should have the right to seek out and use the best manufacturing technology sources.[42]

Similarly, as successful collaborations have been established between the government and companies in the pharmaceutical and biotechnology sectors, questions are emerging as to the appropriateness of this relationship given the vast commercial potential of the results. The particular nature of health-related R&D and the substantial federal investment in this area have caused uncertainty over federal support of joint ventures in this arena. Many experts agree that closer cooperation can augment funding sources, increase technology transfer, stimulate additional innovation, lead to new products and processes, and expand markets. Yet others point out that collaboration may provide an increased opportunity for unfair advantages, excessive private sector profits at the expense of the public, conflicts of interest, redirection of research and less openness in sharing of scientific discovery.

Concerns also have been raised over whether or not industry-university collaboration alters the direction of academic research, affects the results of the work, and/or interferes with the dissemination of knowledge. The various laws facilitating cooperative R&D have the potential for generating conflicts of interest. Within the context of partnerships, companies and universities are anxious to secure a strong intellectual property position to protect their financial and resource investments. Adding to the possibility of competing claims, differing objectives may come into play

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[42]For a detailed discussion see: CRS Report 98-81, *Cooperative Research and Development Agreements and Semiconductor Technology: Issues Involving the "DOE-Intel CRADA,"* by Wendy H. Schacht and Glenn J. McLoughlin.

in industry-university collaborations. While academia promotes the free flow of information in a learning environment, firms typically prefer to delay publication of R&D results to provide the lead time sufficient to capitalize on an idea.

Research conducted by David Blumenthal and his colleagues at the Health Policy Research and Development Unit, Massachusetts General Hospital found that over 60% of companies that financed academic research had received patents, products, or sales as a result of cooperative work.[43] The majority of firms surveyed (82%) require that academic researchers keep information confidential to allow time to file a patent. Approximately one-half of the companies surveyed reported that agreements with universities included requirements to keep information confidential beyond the time necessary to file for a patent.

A question therefore arises whether or not intellectual property considerations adversely affect the conduct of research at universities. Additional work by Blumenthal, et. al. noted that 28% of university scientists engaged in life science research had received industry support. Comparing the activities of professors funded by companies with those who were not, the results demonstrated that:

> Faculty members with industrial research support are at least as productive academically as those without such support and are more productive commercially. However, faculty members who have research relationships with industry are more likely to restrict their communication with colleagues, and high levels of industrial support may be associated with less academic activity without evidence of proportional increases in commercial productivity.[44]

It appears that collaborative work augments "commercial productivity among some of the nation's most distinguished academic investigators" while not compromising their academic efforts.[45] Faculty members with research funding from industry had more peer-reviewed articles published and participated in more administrative activities at the university. However, there are risks that need to be considered. The data indicate "that investigators with industrial support are at least twice as likely to engage in trade secrecy or to withhold research results from colleagues as are investigators without such support." Those faculty members with primarily industry support (over two-thirds of their funding) were less academically productive and the articles they authored were considered less significant.

As discussed throughout this paper, collaborative research and development activities have had a significant positive effect on innovation. "Relationships between industry and academia are essential in order to meet a major goal of public policy: the translation of research findings into practical applications that improve the health and

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[43]David Blumenthal, et. al., *Relationships Between Academic Institutions and Industry in the Life Sciences —An Industry Survey*, 369-371.

[44]David Blumenthal, Eric G. Campbell, Nancyanne Causino, and Karen Seashore Louis, "Participation of Life-Science Faculty in Research Relationships with Industry," *The New England Journal of Medicine*, 5 December, 1996, 1734.

[45]Ibid, 1734-1738.

living standards of the American people."[46] However, as such efforts become more widespread and as new issues emerge, additional decisions may need to be made on how to maintain a balance between the importance of bringing products and processes to the marketplace and protecting the public investment in R&D.

To date, the Congress has determined that providing title to inventions made under federal funding to contractors and/or collaborating parties should be used to support innovation. The Bayh-Dole Act specifically states:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally-supported research or development; ... to promote collaboration between commercial concerns and nonprofit organizations, including universities; ... to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [and] 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....[47]

Companies that do not control the inventions arising from their investments tend to be less likely to engage in related R&D. This idea is reflected in the provisions of the Stevenson-Wydler Technology Innovation Act, the Bayh-Dole Act, and other legislation discussed above. In return for providing patent title to the collaborating party, the beneficiary is expected to commercialize the results of the research and development. Congress has accepted as satisfactory the anticipated payback to the country through new products and process to improve our health, welfare, and standard of living. In addition, commercialization brings increased revenues from taxes on profits, new jobs created, improved productivity, and economic growth. These benefits have been considered more important than the initial cost of the technology to the government or any potential unfair advantage of one company over another in a cooperative venture.

There are renewed questions as to whether or not the balance created remains proper. Concerns continue to be raised regarding the right of drug companies to set prices on drugs that were developed in part with federal funding or in conjunction with federal agencies. Conflicts have surfaced over federal laboratories patenting inventions which collaborating parties believe to be their own. In some agencies, delays continue in negotiating CRADAs because of disagreements over the dispensation of any intellectual property. Problems have been encountered at the National Institutes of Health in obtaining for use in government research new experimental compounds that have been developed and patented by drug companies because of concerns that the effectiveness of the intellectual property will be diminished if new applications are discovered. These and other issues may need to be explored as collaborative efforts among government, industry, and academia continue to expand.

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[46]Blumenthal, et. al., *Relationships Between Academic Institutions and Industry in the Life Sciences —An Industry Survey*, 373.

[47]P.L. 96-517, sec. 200.