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The Bayh-Dole Act and High-Technology Entrepreneurship in U.S. Universities: Chicken, Egg, or Something Else?

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I. Introduction

During the 1990s, the era of the "New Economy," numerous observers (including some who less than 10 years earlier had written off the U.S. economy as doomed to economic decline in the fact of competition from such economic powerhouses as Japan) hailed the resurgent economy in the United States as an illustration of the power of high-technology entrepreneurship. The new firms that a decade earlier had been criticized by such authorities as the MIT Commission on Industrial Productivity[1] for their failure to sustain competition against large non-U.S. firms were seen as important sources of economic dynamism and employment growth. Indeed, the transformation in U.S. economic performance between the 1980s and 1990s is only slightly less remarkable than the failure of most experts in academia, government, and industry to predict it.

A central "cause" of U.S. economic resurgence in the 1990s, according to the experts who arguably had misdiagnosed the causes of U.S. economic decline during the 1980s, was university-industry research collaboration and technology transfer, especially the licensing by U.S. universities of patented inventions. Moreover, many of these accounts attributed the dramatic growth in U.S. university patenting and licensing after 1980, as well as the broader growth in high-technology entrepreneurship within the U.S. economy during the 1990s, to changes in U.S. public policy during the 1980s, particularly the Bayh-Dole Act of 1980.[2] Implicit in many of these characterizations was the argument that university patenting and licensing were essential to this asserted growth in the economic contributions of U.S. university research.[3] Similar characterizations of the effects of the Bayh-Dole Act have been

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[1] See Dertouzos et al. (1989); for an earlier critique of the Commission's critique, see Mowery (1999).
[2] "Regulatory reform in the United States in the early 1980s, such as the Bayh-Dole Act, have [sic] significantly increased the contribution of scientific institutions to innovation. There is evidence that this is one of the factors contributing to the pick-up of US growth performance…" (OECD, A New Economy?, 2000, p. 77).
[3] "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance. Before Bayh-Dole, the fruits of research supported by government agencies had gone strictly to the federal government. Nobody could exploit such research without tedious negotiations with a federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government owned patent.

articulated by the President of the Association of American Universities,[4] the Commissioner of the U.S. Patent and Trademark Office,[5] and the Technology Review.[6]

Although it seems clear that the criticism of high-technology startups that was widespread during the period of pessimism over U.S. competitiveness was overstated, the recent focus on patenting and licensing as the essential ingredient in university-industry collaboration and knowledge transfer may be no less exaggerated. The emphasis on the Bayh-Dole Act as a catalyst to these interactions also seems somewhat misplaced, ignoring as it does the long history, extending to at least the earliest decades of the 20th century, of collaboration and knowledge flows between universities and industry in the United States. This paper reviews the evidence on university-industry interactions and technology transfer, focusing in particular on the role of the Bayh-Dole Act in (allegedly) transforming this relationship. I also examine recent research that considers the Act's effects on the formation of new, knowledge-based firms that seek to exploit university inventions. This research is in its infancy, and much remains to be done if we are to better understand the relationships among high-technology entrepreneurship, the foundation of new firms, and the patenting and licensing activities of U.S. universities before and after 1980.

II. How does academic research influence industrial innovation? A review of recent studies

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And without that, few firms were willing to invest millions more of their own money to turn a basic research idea into a marketable product." (Economist, 12/14/02).

[4] "In 1980, the enactment of the Bayh-Dole Act (Public Law 98-620) culminated years of work to develop incentives for laboratory discoveries to make their way to the marketplace promptly, with all the attendant benefits for public welfare and economic growth that result from those innovations. Before Bayh-Dole, the federal government had accumulated 30,000 patents, of which only 5% had been licensed and even fewer had found their way into commercial products. Today under Bayh-Dole more than 200 universities are engaged in technology transfer, adding more than $21 billion each year to the economy."

[5] "In the 1970s, the government discovered the inventions that resulted from public funding were not reaching the marketplace because no one would make the additional investment to turn basic research into marketable products. That finding resulted in the Bayh-Dole Act, passed in 1980. It enabled universities, small companies, and nonprofit organizations to commercialize the results of federally funded research. The results of Bayh-Dole have been significant. Before 1981, fewer than 250 patents were issued to universities each year. A decade later universities were averaging approximately 1,000 patents a year."

[6] "The Bayh-Dole Act turned out to be the Viagra for campus innovation. Universities that would previously have let their intellectual property lie fallow began filing for – and getting patents at unprecedented rates. Coupled with other legal economic and political developments that also spurred patenting and licensing, the results seems nothing less than a major boom to national economic growth."

A number of recent studies based on interviews and surveys of senior industrial managers in industries ranging from pharmaceuticals to electrical equipment have examined the influence of university research on industrial innovation. All of these studies (GUIRR, 1991; Mansfield, 1991; Levin et al., 1987; Cohen, Nelson, & Walsh, 2002) emphasize the significance of interindustry differences in the relationship between university and industrial innovation. The biomedical sector, especially biotechnology and pharmaceuticals, is unusual in that university research advances affect industrial innovation more significantly and directly in this field than is true of other sectors.

In these other technological and industrial fields, universities occasionally contributed relevant "inventions," but most commercially significant inventions came from nonacademic research. The incremental advances that were the primary focus of firms' R&D activities in these sectors were largely the domain of industrial research, problem-solving, and development. University research contributed to technological advances by enhancing knowledge of the fundamental physics and chemistry underlying manufacturing processes and product innovation, and experimental techniques (including instrumentation).

The studies by Levin et al. (1987) and Cohen et al. (2002) summarize industrial R&D managers' views on the relevance to industrial innovation of various fields of university research (Table 1 summarizes the results discussed in Levin et al., 1987). Virtually all of the fields of university research that were rated as "important" or "very important" for their innovative activities by survey respondents in both studies were related to engineering or applied sciences. These fields of U.S. university research frequently developed in close collaboration with industry. Interestingly, with the exception of chemistry, few basic sciences appear on the list of university research fields deemed by industry respondents to be relevant to their innovative activities.

TABLE 1 HERE

The absence of fields such as physics and mathematics in Table 1, however, should not be interpreted as indicating that academic research in these fields does not contribute to technical advance in industry. Instead, these results reflect the fact that the effects on industrial innovation of basic research findings in such areas as physics, mathematics, and the physical sciences are realized only after a considerable lag. Moreover, application of academic research results may require that these advances be incorporated into the applied sciences, such as chemical engineering, electrical engineering and material sciences. The survey results summarized in Cohen et al. (2002) indicate that in most industries, university research results play a minor role in triggering new industrial R&D projects; instead, the stimuli originate with customers or from manufacturing operations. Pharmaceuticals is an exception, since university research in this field often triggers industrial R&D projects.

Cohen et al. (2002) further report that the results of "public research" performed in government laboratories and universities were used more frequently by U.S. industrial firms (on average, in 29.3% of industrial R&D projects) than prototypes emerging from these external sources of research (used in an average of 8.3% of industrial R&D projects). A similar portrait of the relative importance of different outputs of university and public-laboratory research emerges from the responses to questions about the importance to industrial R and D of various information channels (Table 2). Although pharmaceuticals is unusual in its assignment of considerable importance to patents and license agreements involving universities and public laboratories, respondents from this industry still rated research publications and conferences as a more important source of information. For most industries, patents and licenses involving inventions from university or public laboratories were reported to be of little importance, compared with publications, conferences, informal interaction with university researchers, and consulting.

TABLE 2 HERE

The consistency in the findings of the Levin et al. study and the more recent survey conducted by Cohen and colleagues is striking—the "New Economy" notwithstanding, the late 1990s do not present a sharp contrast with the late 1970s. At the same time, it is important to highlight the fact that these surveys focus primarily on established firms and the Levin study in particular is concerned almost exclusively with manufacturing—such important "service sector" industries as software (which scarcely existed at the time of the Levin survey) are excluded. Additional research on the relationship between the innovative activities of smaller firms, especially those in knowledge-intensive industries, and better coverage of innovation in the nonmanufacturing sector are needed in future research. We also lack comparably detailed information on the relationship between academic research and firms' innovative activities in other industrial economies.

Nonetheless, these studies highlight a difference in the relationship between academic research and industrial innovation in the biomedical field and those of other knowledge-intensive sectors. This work also suggests that academic research rarely produces "prototypes" of inventions for development and commercialization by industry—instead, academic research informs the methods and disciplines employed by firms in their R&D facilities. Finally, the channels rated by industrial R&D managers as most important in this complex interaction between academic and industrial innovation rarely include patents and licenses. Perhaps the most striking aspect of these survey and interview results is their limited influence on the design of recent policy initiatives to enhance the contributions of university research to industrial innovation.

III. The Bayh-Dole Act and Academic Patenting in the United States

A. The "pre-Bayh-Dole" era

The pre-1980 patenting activities of U.S. universities built on research collaborations between university and industrial researchers that spanned many channels of technology and knowledge exchange, including publishing, training of industrial researchers, faculty consulting, and other activities. University-industry collaboration in turn was facilitated by the unusual structure of the U.S. higher education system (especially by comparison with those of other industrial economies) during the 20th century. The U.S. higher education system was significantly larger, included a very heterogeneous collection of institutions (religious and secular, public and private, large and small, etc.), lacked any centralized national administrative control, and encouraged considerable interinstitutional competition for students, faculty, resources, and prestige (See Geiger, 1986, 1993; Trow, 1979, 1991, among other discussions). In addition, the reliance by many public institutions of higher education on "local" (state-level) sources for political and financial support further enhanced their incentives to develop collaborative relationships with regional industrial and agricultural establishments. The structure of the U.S. higher education system thus strengthened incentives for faculty and academic administrators to collaborate in research and other activities with industry (and to do so through channels that included much more than patenting and licensing) long before the Bayh-Dole Act's passage.

The collaboration between university and industrial researchers, combined with the focus of many U.S. university researchers on scientific problems with important industrial, agricultural, or other public applications, meant that a number of U.S. universities patented faculty inventions throughout the 20th century. Nevertheless, despite the adoption by a growing number of universities of formal patent policies by the 1950s, many of these policies, especially those at medical schools, prohibited patenting of inventions, and university patenting was far less widespread than was true of the post-1980 period. Moreover, many universities chose not to manage patenting and licensing themselves. Collaboration between university and industrial researchers, combined with the focus of many U.S. university researchers on problems with important industrial or agricultural applications, meant that a number of U.S. universities patented faculty inventions throughout the 20th century. Although U.S. universities were patenting patent faculty inventions as early as the 1920s, few institutions had developed formal patent policies prior to the late 1940s, and a number of these policies embodied considerable ambivalence toward patenting. Many of the universities active in patenting chose not to manage patenting and licensing themselves, in many cases because of concern over the political consequences of a visible role in profiting from faculty inventions, and in other cases because of fears that their nonprofit tax status could be jeopardized.[7]

The Research Corporation, founded in 1912 by Frederick Cottrell, a University of California faculty inventor who wished to use the licensing revenues from his patents to support scientific research,

[7] Etzkowitz's discussion of the debate within MIT over institutional patent policies during the 1930s (1994, p. 404) notes that "In 1936, the committee on patents of the institute put forward the view that: 'There is recognized to be danger in deriving any income whatever from inventions, first because of possible influence upon our tax exempt status, and second because of possible criticism of our methods leading to ill will among those upon whom we must depend for support. The first difficulty seems to be avoided if the actual handling of our affairs is delegated to some other organization.'"

assumed a prominent role as a manager of university patents and licensing. Even in these early decades of patenting and licensing, biomedical technologies accounted for a disproportionate share of licensing revenues for the Research Corporation and other early university licensors, such as the Wisconsin Alumni Research Foundation. Public universities were more heavily represented in patenting than private universities during the 1925-45 period.

World War II and the Cold War that followed transformed the structure of the U.S. national innovation system (Mowery and Rosenberg, 1998). Nowhere was this transformation more dramatic than in U.S. universities. Formerly funded largely by state governments, the U.S. Agriculture Department, and industry, academic research experienced a surge of federal funding. As the growth in university-industry research links had done during the 1920s and 1930s, increased federal funding of university research strengthened two motives for university involvement in patenting. First, the expanded scale of the academic research enterprise increased the probability that universities would produce patentable inventions. Second, many federal research sponsors required the development of a formal patent policy.

As in the prewar period, many universities during the 1950s and 1960s “outsourced” patent management (McKusick 1948). Data on Research Corporation Invention Administration Agreements (IAAs) reveal the dimensions of this trend: As of 1940, only three of the nation's 89 "Research Universities" (as classified by the Carnegie Commission's 1973 taxonomy) had signed IAAs with the Research Corporation. By 1950 this number had increased to 20 and by the mid-1960s nearly two-thirds of the Carnegie Research Universities were Research Corporation clients.

Well into the 1960s, many U.S. universities continued to avoid direct involvement in patent administration, and others maintained a "hands off" attitude towards patents altogether. Columbia's policy left patenting to the inventor and patent administration to the Research Corporation, stating that "it is not deemed within the sphere of the University's scholarly objectives" to hold patents, and Harvard, Chicago, Yale, and Johns Hopkins adopted similar positions. All of these universities, as well as Ohio State and Pennsylvania, discouraged or prohibited medical patents. Other universities allowed patents on biomedical inventions only if it was clear that patenting would be in the public interest.[8] This institutional ambivalence toward patenting began to change during the 1960s, although the prohibitions on medical patenting at Columbia, Harvard, Johns Hopkins, and Chicago were not dropped until the 1970s. The pace of change accelerated during the 1970s, in response to federal initiatives in R&D funding and patent policy.

The decade of the 1970s represented a watershed in U.S. university patenting and licensing. Universities expanded their patenting, especially in biomedical fields, and assumed a more prominent role in managing their patenting and licensing activities, supplanting the Research Corporation. Agreements between individual government research funding agencies and universities contributed to the growth of patenting during the 1970s. Private universities also expanded their patenting and licensing during this decade. The number of universities establishing technology transfer offices and/or hiring technology transfer officers began to grow in the 1970s. Although the Act was followed by a wave of entry by universities into management of patenting and licensing, growth in these activities was well-established by the late 1970s. Indeed, as we note below, lobbying by U.S. research universities was one of several factors behind the passage of the Bayh-Dole Act in 1980.

1. Sources of growth in university patenting during the 1970s

The growth of university patenting during the 1970s reflected changes in the sources of academic research funding and advances in biomedical research that were basic research results with considerable promise for profitable application in industry, a very unusual combination. In addition, of course, reductions in the rate of growth in federal funding of university research during the early 1970s heightened the interest of university faculty and administrators in the potential revenues associated with licensing these research advances. Increased academic interest in licensing revenues combined with growing dissatisfaction with the performance of the leading institutional “agent” charged with

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[8] Columbia's policy stated that "It is recognized, however, that there may be exceptional circumstances where the taking out of a patent will be advisable in order to protect the public. These cases must be brought to [the University administration] for is consideration and approval” (Cited in Palmer 1962, p. 175).

responsibility for handling many universities' patenting and licensing transactions, the Research Corporation, to produce entry by a number of universities (particularly private universities) into direct management of their patenting and licensing.

Just as would be true of the Bayh-Dole bill at the end of the 1970s, increased university interest in managing patents and licenses during the late 1960s was associated as both cause and effect with changes in federal policy toward patenting of federally funded research. The development of new agency-specific waivers for patent rights was both a response to greater demands for such rights from universities and a contributing factor in the growth of university patenting during the 1970s.

In response to criticism of its management of intellectual property rights associated with publicly funded pharmaceutical research (Harbridge House, 1968a, p. II-21; GAO, 1968, p. 11), the federal Department of Health, Education and Welfare (HEW), which housed the National Institutes of Health, in 1968 established Institutional Patent Agreements (IPAs) that gave universities with "approved technology transfer capability" the right to retain title to agency-funded patents.[9] Although exclusive licensing was allowed under the terms of the IPAs, academic institutions, academic institutions were required to make good faith efforts to license inventions non-exclusively.

In addition, HEW began to act more quickly on requests from universities and other research performers for title to the intellectual property resulting from federally funded research. Between 1969 and 1974 the agency approved 90% of petitions for title, and between 1969 and 1977 the agency granted IPAs to 72 universities and non-profit institutions (Weissman 1989). The National Science Foundation (NSF) instituted a similar IPA program in 1973, and the Department of Defense began in the mid-1960s to allow universities with approved patent policies to retain title to inventions resulting from federally funded research.

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[9] HEW had instituted an IPA program in 1953 and 18 universities had negotiated IPAs with the agency by 1958. But after 1958, no additional requests for IPAs were approved by HEW because "opinions of responsible agency officials differed concerning the value of such agreements" (GAO 1968, p. 24). Pharmaceutical companies also complained that these IPAs were ambiguous about the scope of exclusive rights that licensees could retain.

Approximately one-quarter (49/212) of the Carnegie Research and Doctoral Universities had IPAs with either HEW or NSF during the 1970s. These institutions accounted for 73% of university patenting over the 1970s, and would continue to account for 55% of university patenting over the 1980s. Another 27 of these universities petitioned the government for title during the 1974-80 period (as indicated by acknowledgements in "government interest" section of their patents). Together, institutions that either petitioned for rights or had IPAs accounted for 92% of patents during the 1970s, and 85% of university patents during the 1980s. As we note below, many of the most active patenters in the post-Bayh-Dole era were among the leaders in patenting government-funded research during the 1970s.

The decade of the 1970s represented a watershed in the growth of U.S. university patenting and licensing. U.S. universities expanded their patenting, especially in biomedical fields, and assumed a more prominent role in managing their patenting and licensing activities, supplanting the Research Corporation. The institutional ambivalence that had characterized the pre-1940 debates within MIT and other leading universities over direct involvement in management of patenting subsided, for reasons that are not well understood, and a number of universities entered into or significantly expanded their direct management of patenting and licensing. Private universities in particular expanded their patenting and licensing rapidly during this decade—their share of university-assigned patents grew from 14% in 1960 to 45% in 1980. The number of universities establishing technology transfer offices and/or hiring technology transfer officers began to grow in the late 1960s, well before the passage of the Bayh-Dole Act. Although the Act was followed by a wave of entry by universities into management of patenting and licensing, growth in these activities was apparent by the late 1970s. Indeed, lobbying by U.S. research universities was one of several factors behind the passage of the Bayh-Dole Act in 1980. The Act therefore is as much an effect as a cause of expanded patenting and licensing by U.S. universities during the post-1960 period.

B. Origins of the Bayh-Dole Act

By the 1970s, many U.S. universities were able to patent the results of federally funded research via agency-specific IPAs or similar programs at the Defense Department, as well as through case-by-case petitions. But HEW policy discussions in the late 1970s triggered concern among many U.S. research universities that their ability to patent and license government funded inventions might be curtailed. These concerns, along with growing dissatisfaction within Congress and the industrial community over the lack of uniformity in patent rights to inventions resulting from federally funded research, provided the immediate impetus for the introduction in 1978 of the bill that eventually became the Bayh-Dole Act.

In August 1977, HEW's Office of the General Counsel expressed concern that university patents and licenses, particularly exclusive licenses, could contribute to higher healthcare costs (Eskridge, 1978). The Department ordered a review of its patent policy, including a reconsideration of whether universities' rights to negotiate exclusive licenses should be curtailed.[10] During the ensuing 12-month review by HEW of its patent policies, the agency deferred decisions on 30 petitions for patent rights and 3 requests for IPAs.

In response to HEW's review of its patent policies, according to Broad (1979a), "[u]niversities got upset and complained to Congress" (476). Windham (2000) notes that a patent attorney from Purdue University and a congressional staffer who previously had worked at the University of Arizona, both of which sought more liberal policies towards patenting publicly funded research, respectively asked Senators Bayh and Dole to introduce a bill liberalizing and rationalizing federal policy. In September 1978, Senator Robert Dole (R-KS) held a press conference where he criticized HEW for "stonewalling" university patenting (commenting, "rarely have we witnessed a more hideous example of overmanagement by the bureaucracy") and announced his intention to introduce a bill to remedy the situation (Eskridge, 1978, p. 605). On September 13, 1978, Senators Birch Bayh (D-IN) and Dole introduced S. 414, the University and Small Business Patent Act.

[10] The purpose of the HEW review was "to make sure that assignment of patent rights to universities and research institutes did not stifle competition in the private sector in those cases where competition could bring the fruits of research to the public faster and more economically", according to the testimony of Comptroller General Elmer Staats during the Bayh-Dole hearings (United States Senate Committee on the Judiciary 1979, p.37).

The Act proposed a uniform federal patent policy that gave universities and small businesses rights to any patents resulting from government-funded research.[11] The bill lacked provisions that had been included in most IPAs, including the requirement that a participating university must have an "approved technology transfer" capability. In contrast to the language of many IPAs between universities and HEW, the bill imposed no restrictions on the negotiation by universities and other research institutions of exclusive licensing agreements.[12]

Many members of Congress had long opposed any federal grant of ownership of patents to research performers or contractors (Broad, 1979b). The Bayh-Dole bill nevertheless attracted little opposition. The bill's focus on securing patent rights for only universities and small business weakened the argument that such patent-ownership policies would favor big business.[13] The bill's introduction in the midst of debates over U.S. economic competitiveness also proved crucial to its passage. An article in *Science* discussing the debate on the Bayh-Dole bill observed that:

> The critics of such legislation, who in the past have railed about the "giveaway of public funds" have grown unusually quiet. The reason seems clear. Industrial innovation has become a buzzword in bureaucratic circles … the patent transfer people have latched onto this issue. It's about time, they say, to cut the red tape that saps the incentive to be inventive (Broad 1979b, p. 479.)

A number of universities, including Harvard University, Stanford University, the University of

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[11] Identical legislation (H.R. 2414) was introduced in the House of Representatives by Rep. Peter Rodino (D-NJ) in 1979.

[12] "Another IPA restriction dropped in the Dole-Bayh bill is the requirement that grantees and contractors try first to offer non-exclusive licenses. 'It's too hard and inefficient a process,' [a Bayh aide said]. 'Universities don't have the financial capability to beat the bushes and try to find someone who is willing to accept a license on a nonexclusive basis' (Henig, 1979, p. 281).

[13] A contemporary account noted that limiting the bill to universities and small businesses was "a tactical exclusion taken to ensure liberal support" (Henig 1979, p. 282). A Senate aide commented, "We'd like to extend [the policy] to everybody … but if we did the bill would never have a chance of passing" (Broad, 1979b, p. 474). The original bill also included several provisions designed to defuse criticism that it would lead to "profiteering" at the expense of the public interest, including a recoupment provision requiring that institutions pay back a share of licensing income or sales to funding agencies. The final version of the Bayh-Dole Act eliminated this provision, "because there was no agreement on whether the funds would be returned to the agencies or to general revenue, or how the collection and auditing functions would be conducted" and "fears that the costs of the infrastructure required to administer such a program would exceed the amounts collected." See http://www.nih.gov/news/070101wyden.htm.

California,[14] and the Massachusetts Institute of Technology, lobbied for passage of the bill, and throughout the debates representatives of these and other research universities were active in "commenting and helping to develop the final language" of the House and Senate versions of the bill (Barrett, 1980). Not surprisingly, witnesses from active institutional patenters (including Stanford, Purdue, and Wisconsin) testified in support of the bill, as did representatives from various university associations (including the American Council on Education, the Society for University Patent Administrators, and the National Association of College and University Business Officers) and the Research Corporation. The support of these groups was supplemented by positive statements from witnesses representing various small businesses and small business trade groups, like the National Small Business Association, the Small Business Legislative Council, and the American Society of Inventors. But the prominent role of research universities in lobbying for the Act highlights the extent to which the Bayh-Dole Act was a response to increased university patenting during the 1970s, rather than an exogenous "cause" of the post-1980 growth in patenting and licensing.

The Bayh-Dole Patent and Trademark Amendments Act of 1980 provided blanket permission for performers of federally funded research to file for patents on the results of such research and to grant licenses for these patents, including exclusive licenses, to other parties. The Act facilitated university patenting and licensing in at least two ways. First, it replaced a web of Institutional Patent Agreements (IPAs) that had been negotiated between individual universities and federal agencies with a uniform policy. Second, the Act's provisions expressed Congressional support for the negotiation of exclusive licenses between universities and industrial firms for the results of federally funded research.

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[14] As Kevles (1994) points out, the University of California also filed an *amicus curiae* brief in the *Diamond v. Chakrabarty* case, in which the U.S. Supreme Court ruled that patents on life forms were valid. Had the Chakrabarty patent not been upheld as valid, the Reimers patenting and licensing strategy for the Cohen-Boyer invention would have been utterly useless. Indeed, much of the post-1980 growth in university licensing rests on an array of other policy initiatives and judicial decisions during the 1980s that strengthened patentholder rights overall and in such new areas as computer software and biotechnology (see below and Mowery et al., 2004 for further discussion).

The passage of the Bayh-Dole Act was one part of a broader shift in U.S. policy toward stronger intellectual property rights.[15] Among the most important of these policy initiatives was the establishment of the Court of Appeals for the Federal Circuit (CAFC) in 1982. Established to serve as the court of final appeal for patent cases throughout the federal judiciary, the CAFC soon emerged as a strong champion of patentholder rights.[16] But even before the establishment of the CAFC, the 1980 U.S. Supreme Court decision in *Diamond v. Chakrabarty* upheld the validity of a broad patent in the new industry of biotechnology, facilitating the patenting and licensing of inventions in this sector. The origins of Bayh-Dole thus must be viewed in the context of this larger shift in U.S. policy toward intellectual property rights.

C. The Effects of Bayh-Dole

How did the Bayh-Dole Act affect patenting by U.S. universities? Since overall patenting in the United States grew during this period, indicators of university patenting need to be normalized by overall trends in patenting or R&D spending. Figures 1-2 present two such indicators that span the period before and after the Bayh-Dole Act. Figure 1 depicts U.S. research university patenting as a share of domestically assigned U.S. patents during 1963-99, in order to remove the effects of increased patenting in the United States by foreign firms and inventors during the late 20th century. Universities increased their share of patenting from less than 0.3% in 1963 to nearly 4% by 1999, but the rate of growth in this share begins to accelerate before rather than after 1980. Figure 2 plots the ratio of aggregate university patenting at time *t* to aggregate academic R&D expenditures at time *t-1*, for application years 1963-1993.[17] The Figure reveals an increase in aggregate university "patent propensity" after 1981 (as pointed

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[15] According to Katz and Ordover (1990), at least 14 Congressional bills passed during the 1980s focused on strengthening domestic and international protection for intellectual property rights, and the Court of Appeals for the Federal Circuit created in 1982 has upheld patent rights in roughly 80% of the cases argued before it, a considerable increase from the pre-1982 rate of 30% for the Federal bench.

[16] See Hall and Ham (1999) for an analysis of the effects of the CAFC and related policy shifts on patenting in the U.S. semiconductor industry.

[17] Data on total academic R&D were obtained from National Science Board (2000), Appendix Table 4-4.

out by Henderson et al. 1998), but this is the continuation of a trend that dates at least as far back as the early 1970s; there is no evidence of a "structural break" in trends in patent propensity after Bayh-Dole.[18]

FIGURES 1-2 HERE

Another issue of interest in academic patenting is the distribution among technology fields of university patents during the pre- and post-Bayh-Dole periods. Figure 3 displays this information for U.S. research university patents during 1960-1999, and highlights the growing importance of biomedical patents in the patenting activities of the leading U.S. universities during the period. Non-biomedical university patents increased by 90% from the 1968-70 period to the

FIGURE 3 HERE

1978-80 period, but biomedical university patents increased by 295%. This rapid growth in biomedical patents also reflected growth of the IPA program of the major biomedical funding agency (HEW) during the 1970s. The increased share of biomedical disciplines within overall federal academic R&D funding, the dramatic advances in biomedical science that occurred during the 1960s and 1970s, and the strong industrial interest in the results of this biomedical research, all affected the growth of university patenting during this period.

Moreover, the trends in Figure 3 if anything understate the extent to which biomedical inventions dominate universities' licensing income. Licensing data from the University of California 9-campus system, Stanford University, and Columbia University cited in Mowery et al. (2004) show that biomedical patents accounted for more than 66 - 85% of the gross licensing revenues of these academic institutions by the mid-1990s. Another important point about these institutions' licensing revenues is the small size of overall academic budgets that they represent. To cite only example, the annual net licensing

[18] As we have pointed out elsewhere (Mowery et al., 2001) The Bayh-Dole Act did not dramatically affect the patenting and licensing activities of universities that had long been active in this area, such as Stanford University and the University of California. Indeed, the biomedical patents and licenses that dominated these institutions' licensing revenues during the 1980s and 1990s had begun to grow before the passage of the Bayh-Dole Act. Columbia University, an institution with little experience in patenting and licensing before 1980 (and an institution that prohibited the patenting of inventions by medical faculty until 1975), also had filed for its first "blockbuster" patent before the effective date of the Act. Nevertheless, the Act did increase patenting of faculty inventions at both Stanford and the University of California, although many of these patents covered inventions of marginal industrial value and did not yield significant licensing royalties.

revenues of the University of California system after payments to inventors averaged roughly $16 million during fiscal 1999-2003, less than .5% of the system's annual research expenditures of nearly $3 billion. Keeping in mind that the UC system is among the U.S. academic institutions with the highest gross licensing revenues, it is obvious that the financial contributions to university operating budgets from patent licensing are trivial in most cases, and negative for a great many institutions.

Another aspect of universities' licensing activities that is directly relevant to discussions of "academic entrepreneurship" concerns the characteristics of the firms licensing university patents. Although many of the positive evaluations of the economic effects of the Bayh-Dole Act highlight the role of small-firm startups as beneficiaries of these licensing transactions, the data compiled by the Association of University Technology Managers (AUTM, 2001, 2002) suggest that firms founded specifically to commercialize the licensed technology account for a minority of licensees. The AUTM annual reports for 2001 and 2002 indicate that 14 – 16% of university patent licensees in these years were startup firms founded to exploit the licensed inventions. More than one-half (50 - 54%) of academic licensees during this period were small (fewer than 500 employees) firms already in existence, while roughly one-third (32 – 33%) of licensees were large firms. The emphasis in recent academic research (DeGregorio and Shane, XXX) on the role of university "spinoffs" in the licensing activities of U.S. universities thus needs to be qualified by a recognition that such startups are much less significant in absolute numbers as licensees than large firms.

After Bayh-Dole, universities increased their involvement in management of patenting and licensing, setting up internal technology transfer offices to manage licensure of university patents. Figure 4 shows the distribution of years of "entry" by universities into patenting and licensing, defined as the year in which the universities first devoted .5 FTE employees to "technology transfer activities" (AUTM, 1998). Although "entry" accelerated after Bayh-Dole, growth in this measure of university commitment to "technology transfer" predates Bayh-Dole. Longitudinal data on university licensing activities are less complete, but the available data indicate that in FY2000, U.S. universities signed more than 4000 license agreements, representing more than a doubling since FY1991 (AUTM, 2000).

FIGURE 4 HERE

Figure 5 plots the patenting activity (number of patents, listed by year of application) by university for U.S. universities in the 1970s and 1980s. The leading institutional patenters in the 1970s were also the leaders in the 1980s, further underscoring the influence of the 1970s on patenting during the first decade of the "Bayh-Dole era." A log-log regression of volume of patenting in the 1980s on volume of patenting in the 1970s (for each of the 212 Carnegie research and doctoral universities) yields an estimated elasticity of .98.

FIGURE 5

The observations in the Figure are weighted by patents per institution, a datum characterized by a very skewed distribution, and the visual correlation therefore is sensitive to outliers. A simple test that is less sensitive to outliers yields similar results, however—38 of the 54 institutions (72%) in the top quartile of the distribution of institutional patenters for the 1970s are represented among the 53 institutions in the top quartile for the 1980s.

The characterizations of the catalytic effects of the Bayh-Dole Act that were mentioned in the Introduction to this paper cite little evidence in support of their claims beyond simple counts of university patents and licenses. But growth in both of these activities predates Bayh-Dole and is rooted in internationally unique characteristics of the U.S. higher education system. Nor does evidence of increased patenting and licensing by universities by itself indicate that university research discoveries are being transferred to industry more efficiently or commercialized more rapidly, as Colyvas et al. (2001) and Mowery et al. (2001) point out. Current research thus provides mixed support at best for a central assumption of the Bayh-Dole Act, i.e., the argument that patenting and licensing are necessary for the transfer and commercial development of university inventions.

IV. Case studies

In order to shed greater light on the actual processes involved in university-industry technology transfer, we compiled a set of case studies of such transfer, all of which involve patented inventions that were subsequently licensed to firms. These case studies thus do not reveal as much as we would like about the other channels of technology transfer, but in almost all cases, other channels for interaction and knowledge exchange emerge as important complements to the licensing transactions. The case studies also highlight the field-specific and invention-specific differences in the technology transfer process and the role of patents and licenses in this process. There is substantial variation across the cases in the importance of patents and licenses, the role of the university, the importance and involvement of the academic inventor, and even the directionality and characteristics of the knowledge flows between university and industry.

The five case studies are the following:

1. Cotransformation: a process to transfer genes into mammalian cells (Columbia University).
2. Gallium Nitride: a semiconductor with both military and commercial applications (University of California).
3. Xalatan: a glaucoma treatment (Columbia University).
4. Ames II Tests: a bacteria assay for testing potential carcinogenic properties of pharmaceuticals and cosmetics (University of California).
5. Soluble CD4: a prototype for a drug to fight AIDS (Columbia University).[19]

Columbia University's patenting and licensing activities were important to the development and commercialization of Xalatan, a glaucoma treatment. University patents and licenses were less important to transfer and commercialization, however, for two other inventions discussed in this paper (the Axel cotransformation process and Soluble CD4): firms learned about the inventions through informal scientific and technological communities and invested in commercialization without clearly established or exclusive property rights to the inventions.

Two other inventions (Gallium Nitride and the Ames II Tests) were licensed by inventor-founded start-ups after established firms elected not to license the inventions. These inventor-founders argued that protection for their intellectual property was important to the foundation of their firms, but it remains unclear whether patent protection was necessary for the commercial development of their inventions.

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[19] See Chapter 7 of Mowery et al. (2004) for a fuller description and discussion of these five cases. Professor Robert Lowe of Carnegie-Mellon University co-authored the chapter, along with David C. Mowery and Bhaven Sampat.

Previous work on university-industry technology transfer has highlighted the importance of inventor cooperation in developing embryonic technologies (Jensen and Thursby, 2001) and inventions associated with considerable know-how or tacit knowledge (Lowe, 2002; Shane, 2002). These five cases, however, reveal considerable contrast in the role of the university inventor in technology commercialization. In three of the five cases, inventor-founded start-up firms played a central role in commercialization, and inventors necessarily were heavily involved. In the fourth case, the efforts of established firms to exploit the university invention were aided by the inventor. In the fifth case, by contrast, the licensees required no assistance from the inventor. Moreover, much current research on the role of the academic inventor overlooks the influence on the process of technology transfer and "absorption" by licensees or other firms of R&D activity already underway within the relevant industry. The gallium nitride, cotransformation, and soluble CD4 inventions were exploited by industrial nonlicensees of the relevant patents, largely because the university research advances represented important "proofs of concept" that directed well-informed industrial researchers to pursue related research. The amount and extent of prior industrial R&D activity, therefore, is an important influence on the technology transfer process and can affect the role of patents and licensing.

As the gallium nitride case illustrates vividly, industrial R&D activity also can directly influence the academic research agenda in a fashion not unlike that described immediately above. Much of the early research activity in gallium nitride applications was undertaken within industry in the United States, Europe, and Japan. Sustained university patenting activity began only in the 1990s, nearly two decades after the first industrial patents. Just as university patenting of key inventions served to direct industrial attention to important areas of research, industrial R&D influenced the direction of the academic research agenda. The flow of knowledge and technology between university and industrial research is a two-way flow, despite frequent caricatures of this flow as exclusively moving from academia to industry.

In the cotransformation case, firms had the capabilities and incentives to use the process for their own research and drug production in the absence of exclusive rights to the invention. Indeed, it appears that technology transfer occurred in spite rather than because of the patents, licenses, and involvement of the university technology transfer office. The university patent produced significant income for Columbia, but no evidence suggests that the patent and associated nonexclusive licenses facilitated commercialization. Columbia's nonexclusive licensing agreements for the Axel cotransformation patent, like the equally renowned (and lucrative) Cohen-Boyer patent jointly licensed by the University of California and Stanford University, do not appear to have accelerated or otherwise made feasible the commercial development of this invention. Instead, these licensing agreements were used by Columbia to levy a tax on the commercialization of an invention that was published in the scientific literature and whose commercial development in the absence of licensing almost certainly would have occurred on the basis of the technical information and demonstration of feasibility provided by the publication.[20] The cotransformation case also suggests that involvement by the university inventor in the commercialization process is less crucial when potential users possess sufficient "absorptive capacity" to exploit the invention.

The GaN case, like that of cotransformation, is one in which patents *per se* were not essential for university-industry technology transfer. Unlike the Axel cotransformation patents, however, the GaN patents generated little licensing income for the University of California's Santa Barbara campus (UCSB). These differences in the licensing history of the GaN and cotransformation patents reflect differences in the level of demand for the technologies they respectively supported, as well as underlying differences in the legal strength and economic value of patents in the biomedical and electronic fields. Another important contrast with the Axel case was the role of the inventors in such technology transfer as did occur with the GaN patents--faced with limited interest from established industrial firms as potential licensees for their patents, the UCSB engineering faculty who had developed these technologies started their own firm.

[20] Neils Reimers, the first head of Stanford's Office of Technology Transfer and manager of the licensure of Cohen-Boyer, subsequently noted, "whether we licensed it or not, commercialization of recombinant DNA was going forward. As I mentioned, a nonexclusive licensing program, at its heart, is really a tax ... [b]ut it's always nice to say "technology transfer. (Reimers, 1998)

The Xalatan case differs from the cotransformation and GaN cases in that patents appear to have been important to the transfer and commercialization of this technology. In part, the importance of patents reflected the fact that this invention resembled the "prototypes" discussed by Jensen and Thursby (2001)--a lengthy and costly period of development was necessary to bring this invention to market. And the inventor's know-how and involvement were indispensable to this development process, in contrast to the cotransformation patents. But the Xalatan case illustrates another issue in exclusive licensing agreements for university patents that appears as well in the soluble CD4 case. Although a firm may be willing to sign an exclusive licensing agreement with the university (and although most such agreements include "due diligence" or "best efforts" clauses that commit a licensee to invest in the development of an invention), it is difficult for any licensor, let alone an academic licensor, to ensure that their licensee will undertake the costly process of technology development in a timely fashion. Indeed, the difficulties faced by academic licensors in ensuring “due diligence” by licensees has been cited by XXXXX is reflected in the frequent use in such contracts of “march-in” provisions.

The commercialization of the Ames II Tests presents some interesting similarities and contrasts with the GaN and Xalatan cases. Like GaN and Xalatan, inventor involvement was important and reflected the importance of tacit know-how for the inventions' applications. It seems likely that without the participation of the inventor, a license alone would not have sufficed to commercialize the Ames II Tests. But in contrast to GaN, patent protection for this invention and the exclusive licensing contract negotiated by its industrial commercializer proved to be important, just as was the case for Xalatan. Indeed, its license for the Ames II Test patents significantly enhanced the availability of venture finance for the startup firm that undertook the commercial development of the Ames II tests.

The CD4 case illustrates the commercial and technical uncertainties involved in bringing an embryonic invention, even one that appears to have great commercial potential, from laboratory to marketplace. This case also provides some evidence that exclusive licenses may not be necessary, even for embryonic inventions, if their potential profitability is sufficiently large and downstream innovations can themselves be patented. Moreover, the case highlights the risks associated with exclusive licensing agreements for such innovations, since it is often difficult for licensing professionals to determine which of several potential licensees (in the rare cases in which several firms are interested in pursuing licenses) is most likely to bring the invention to market successfully. Finally, this case (like the cotransformation case) suggests that in contexts where firms have strong links with the relevant scientific and technological communities, inventor involvement may be less critical for commercialization.

A central premise underpinning the Bayh-Dole Act is the belief that patenting and licensing are necessary to facilitate the development and commercialization of publicly funded university inventions. Although the Act does not mandate that universities follow any single specific policy in patenting and licensing faculty inventions, university administrators and technology licensing officers frequently assume that the technology transfer process is essentially similar in different technologies and industries. But these case studies reveal great heterogeneity within even a small sample of technologies. There are significant differences among these cases in the role of intellectual property rights in inducing firms to develop and commercialize university inventions, in the role of the inventor in postlicense development and commercialization, and in the relationship between academic and industrial research activities in different technical fields.

The heterogeneity within this small sample of cases underscores the need for caution in generalizations about the nature of the technology transfer process and the role of formal intellectual property rights in that process. This heterogeneity also highlights the importance of flexibility in the technology management policies and practices of universities. Patents and an exclusive license were important to successful commercialization in one of these five cases (Xalatan), but in at least two cases (cotransformation and GaN) it seems likely that development and commercialization would have gone forward without a patent on the university invention. In these cases, other means of appropriability, such as specialized knowledge or the prospect of a patent on downstream inventions, were sufficient to induce firms to invest in development and commercialization. The case of soluble CD4 also illustrates the difficulties that university licensing officers face in selecting among prospective licensees when the ultimate commercial prospects and commercialization capabilities of both the invention and the licensees are highly uncertain.[21]

The cases also reveal considerable differences in the extent of inventor involvement and the role of the inventor in development and commercialization. In at least two cases (soluble CD4 and cotransformation) one or more of the licensee firms had little or no interaction with the inventor, since firms had sufficient experience and internal expertise in the field of the invention or had strong relationships with external scientists with such experience. In these cases, the knowledge and know-how gap between the university inventor and a would-be industrial commercializer was relatively small, reflecting previous investments by the industrial firm in internal capabilities and external monitoring of scientific developments.[22] But two other inventions discussed in this paper (GaN and Ames II) were developed and commercialized by startup firms in which inventors played a central role. Interestingly, however, only one of these two startups (Widegap Technologies, founded to develop the GaN invention) was founded by the inventors, and it was not a licensee. The startup that sought to commercialize the Ames II tests (Xenometrix) was not founded by the inventor, although the tests' inventor did join the firm after its foundation and Xenometrix did agree to a license for the invention.

The nature of feedback between industrial and academic research differs among these cases. Bayh-Dole was implicitly based on an assumption of a "linear model" of innovation, in which universities perform basic research with little concern for application and private firms invest in applied research and commercialization. In this view, patent-based incentives are essential to link universities, inventors, and industry in the commercialization process. But this assumption does not accurately describe university-industry interactions, before or after Bayh-Dole, in many technical fields. Indeed, in most of the cases discussed in this paper, there was considerable overlap between the scientific and industrial communities in the nature of research activities (including publication). Consistent with the work of Zucker, Darby,

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[21] Nonetheless, interviews with licensing officers suggest that very few university inventions face such strong demand from prospective licensees that the officer can select among several "applicants" for a license in a given field of use.

[22] The substantial flow of scientific papers from industrial scientists in AIDS research that was noted earlier also supports this characterization of the firms engaged in commercial development of the soluble CD4 invention.

and colleagues on biotechnology (Zucker et al., 1998, 2001), in these cases technology transfer from universities to firms took place via a range of channels, including labor mobility and research collaboration. There is also little evidence of significant delays in the disclosure or publication by academic researchers of their research advances. All of these inventions were the subject of published papers, and in a majority of the cases the publications appeared before patent applications were filed.

There are significant differences among industries in the influence of academic research on industrial innovation as well as in the channels through which these influences operate. This research also suggests significant interindustry differences in the importance of patents as vehicles for knowledge transfer among firms or between universities and industry and further reveals significant differences among industries in the importance of patents and licenses as channels for the transfer of knowledge and technology between universities and industry. These case studies do suggest, however, that patents may be important for start-up firms in their search for financing. Consistent with previous studies, the evidence from this very small sample of cases suggests that university patenting and licensing were more important for the biomedical inventions than for the electronics invention included in these cases. But these cases also reveal considerable heterogeneity in the technology transfer process among biomedical technologies.

V. Conclusion

Academic entrepreneurship (defined in this case as the involvement of university faculty and researchers in commercial development of their inventions) has been a unique characteristic of the U.S. higher education system for most of the past 100 years. As noted earlier in this paper, the unusual engagement of academic personnel in quasi-commercial pursuits reflected a longstanding history of collaborative research between university faculty and industry, as well as the unusual structural characteristics of the U.S. “system” of higher education that created strong incentives for faculty and administrators both to seek financial support and links with industry. Moreover, much of this entrepreneurial activity involved patenting of university inventions and in some cases, their licensure to industrial firms. This long history of interaction, as well as academic patenting and licensing, contributed to the formation of the political coalitions that led to the passage of the Bayh-Dole Act in 1980.

Nevertheless, it is a fallacy to associate the entrepreneurial activities of university faculty exclusively with patenting and licensing. Moreover, the occasional tendency to elevate patenting and licensing to a central position in the processes that mediate the 2-way flows of knowledge and technology between universities and industry is a serious (indeed, dangerous) distortion of the reality of these relationships. A substantial body of research suggests that industry and academic researchers interact and exchange knowledge through a diverse array of channels, among which patenting and licensing is but one and in most sectors far from the most important one. As the data discussed earlier in this paper on academic patenting, licensing, and licensing revenues suggest, however, the biomedical sector is different, and patents appear to be especially important channels for technology transfer. Nevertheless, the case studies summarized in this paper highlight considerable variation in the importance of patents and licenses even within the biomedical sector.

In spite of the dramatic growth in the literature on this topic, research on "academic entrepreneurship" and technology transfer between universities and industry still lacks an integrated analysis of the various channels through which these processes operate. We know very little, for example, about the interactions among academic patenting, licensing agreements, and flows of personnel between universities and industry. We lack empirical data or analyses on the links between industry-funded research within universities and the operation of different channels of technology transfer between industry and academia. Little or no work has been done on the rate of licensing of university inventions by faculty-founded startups (recall that the AUTM data address the role of startups as licensees, not the reverse). Current research (including much of that in Mowery et al., 2004) is dominated by the countable rather than the most economically important forms of interaction.

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Table 1: The relevance of university science to industrial technology

Science	# of Industries with "relevance" scores		Selected industries for which the reported "relevance" of university research was large (≥ 6).
	≥ 5	≥ 6	
Biology	12	3	Animal feed, drugs, processed fruits/vegetables
Chemistry	19	3	Animal feed, meat products, drugs
Geology	0	0	None
Mathematics	5	1	Optical instruments
Physics	4	2	Optical instruments, electronics?
Agricultural science	17	7	Pesticides, animal feed, fertilizers, food products
Applied math/operations research	16	2	Meat products, logging/sawmills
Computer science	34	10	Optical instruments, logging/sawmills, paper machinery
Materials science	29	8	Synthetic rubber, nonferrous metals
Medical science	7	3	Surgical/medical instruments, drugs, coffee
Metallurgy	21	6	Nonferrous metals, fabricated metal products
Chemical engineering	19	6	Canned foods, fertilizers, malt beverages
Electrical engineering	22	2	Semiconductors, scientific instruments
Mechanical engineering	28	9	Hand tools, specialized industrial machinery

Source: Previously unpublished data from the Yale Survey on Appropriability and Technological Opportunity in Industry. For a description of the survey, see Levin et al. (1987).

Table 2: Importance to Industrial R&D of Sources of Information on Public R&D (including university research)

Information source	**% rating it as "very important" for industrial R&D**
Publications & reports	41.2%
Informal Interaction	35.6
Meetings & conferences	35.1
Consulting	31.8
Contract research	20.9
Recent hires	19.6
Cooperative R&D projects	17.9
Patents	17.5
Licenses	9.5
Personnel exchange	5.8

Source: Cohen et al. (2002).

Figure 1: University Patents as a Share of All Patents w/ Domestic Assignees, 1948-1996

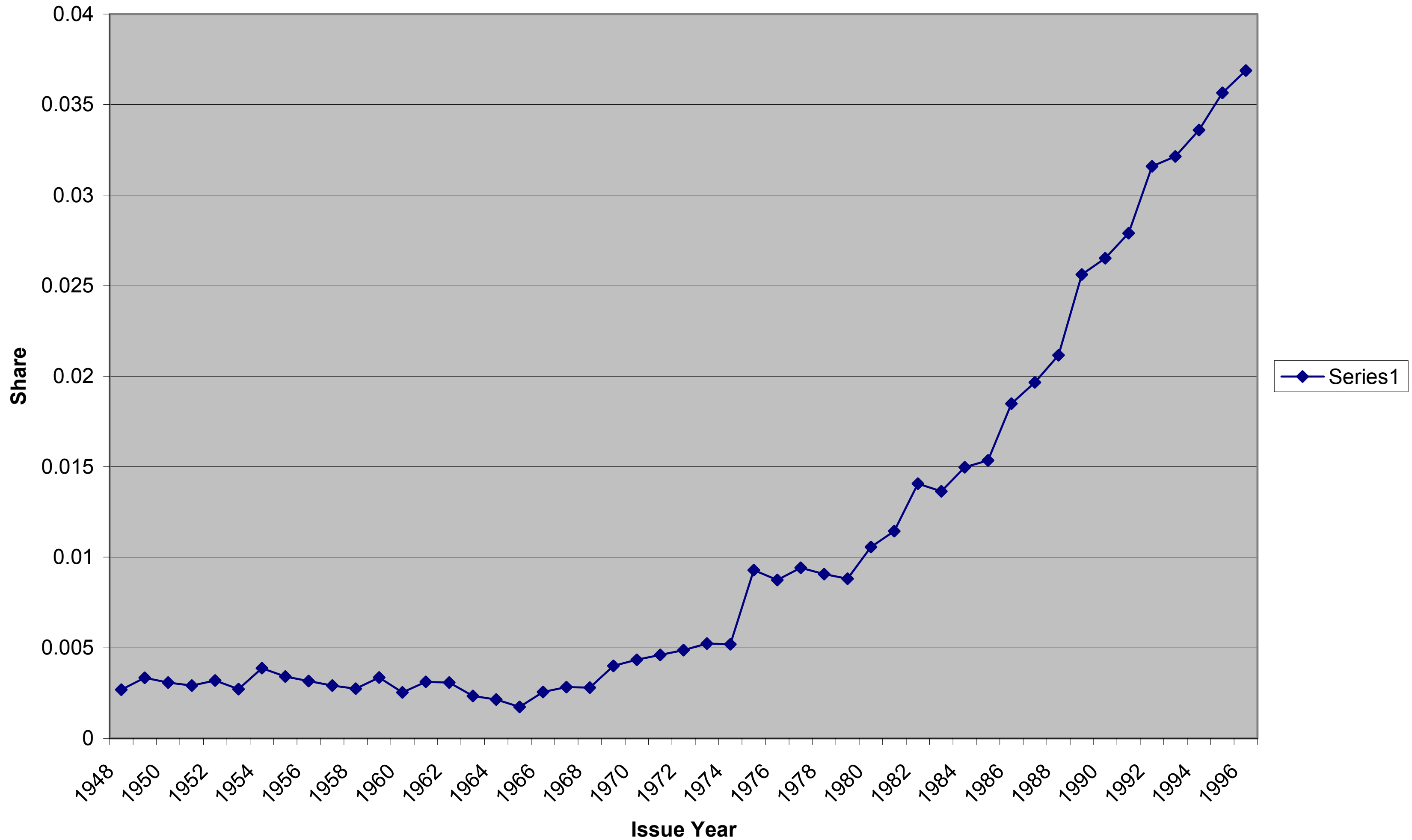

Figure 2: University Patents Per R&D Dollar, 1963-1993

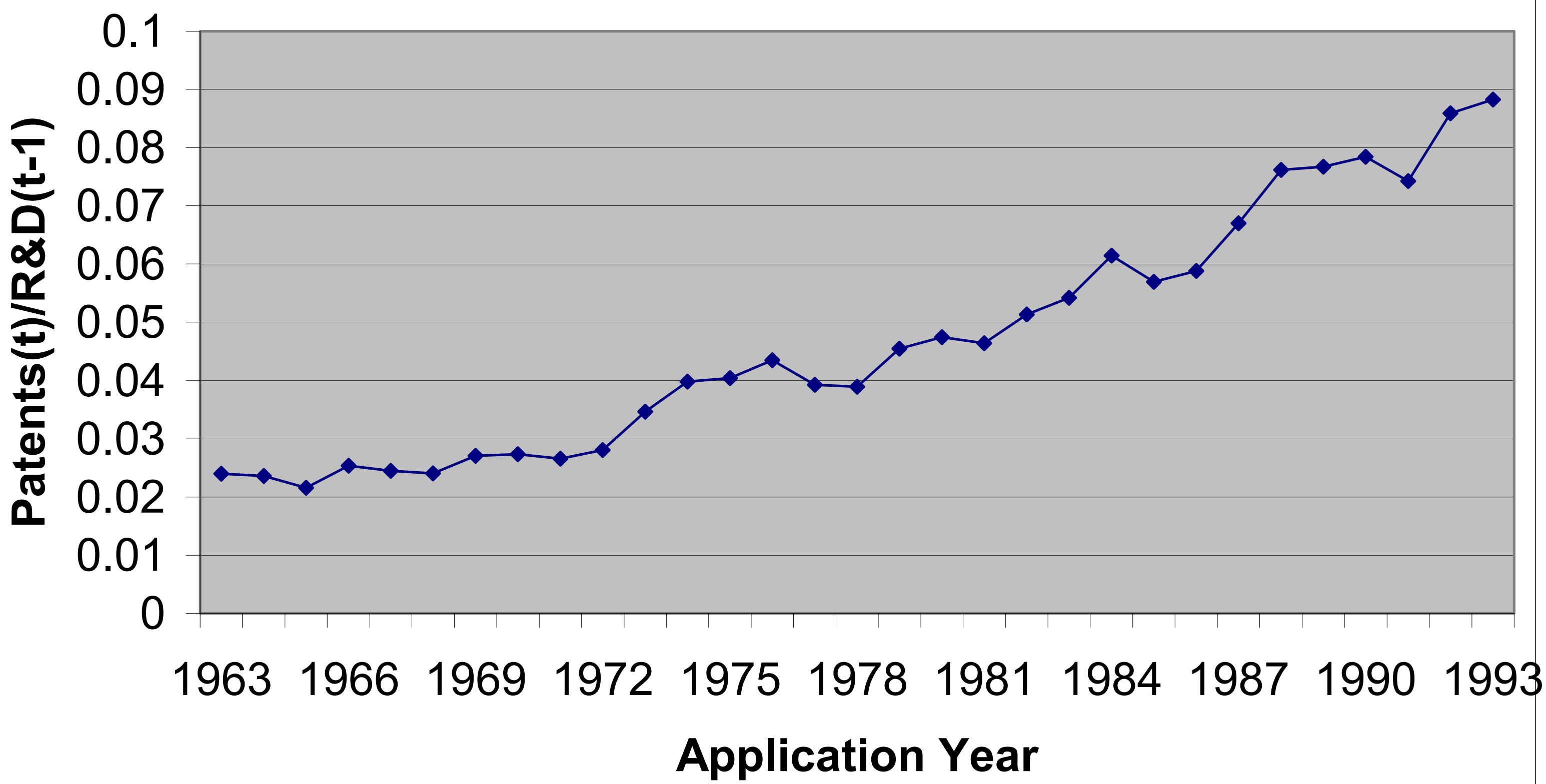

Figure 3: Technology Field of Carnegie University Patents, 1960-1999

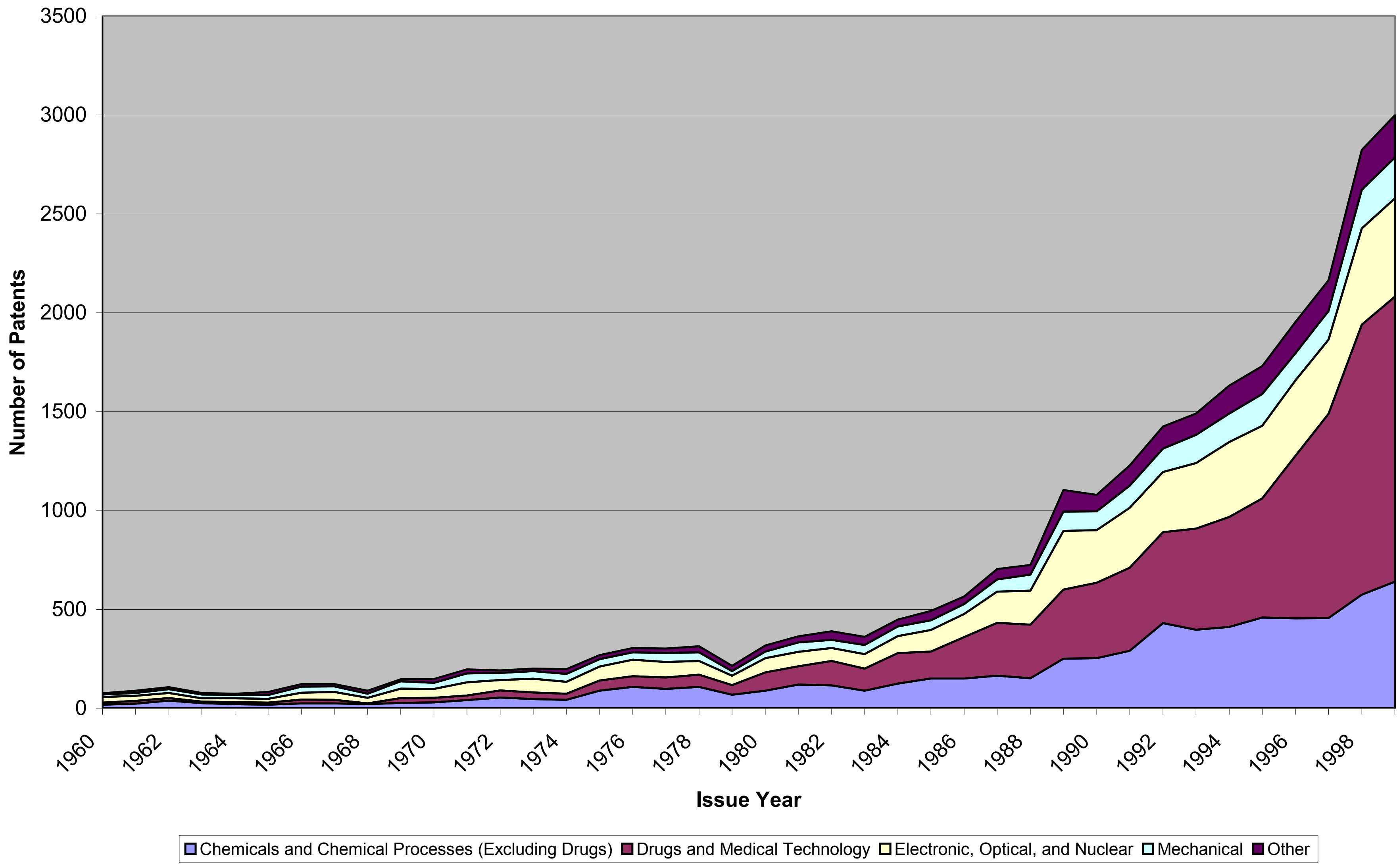

Figure 4: Year of "Entry" into Technology Transfer Activities

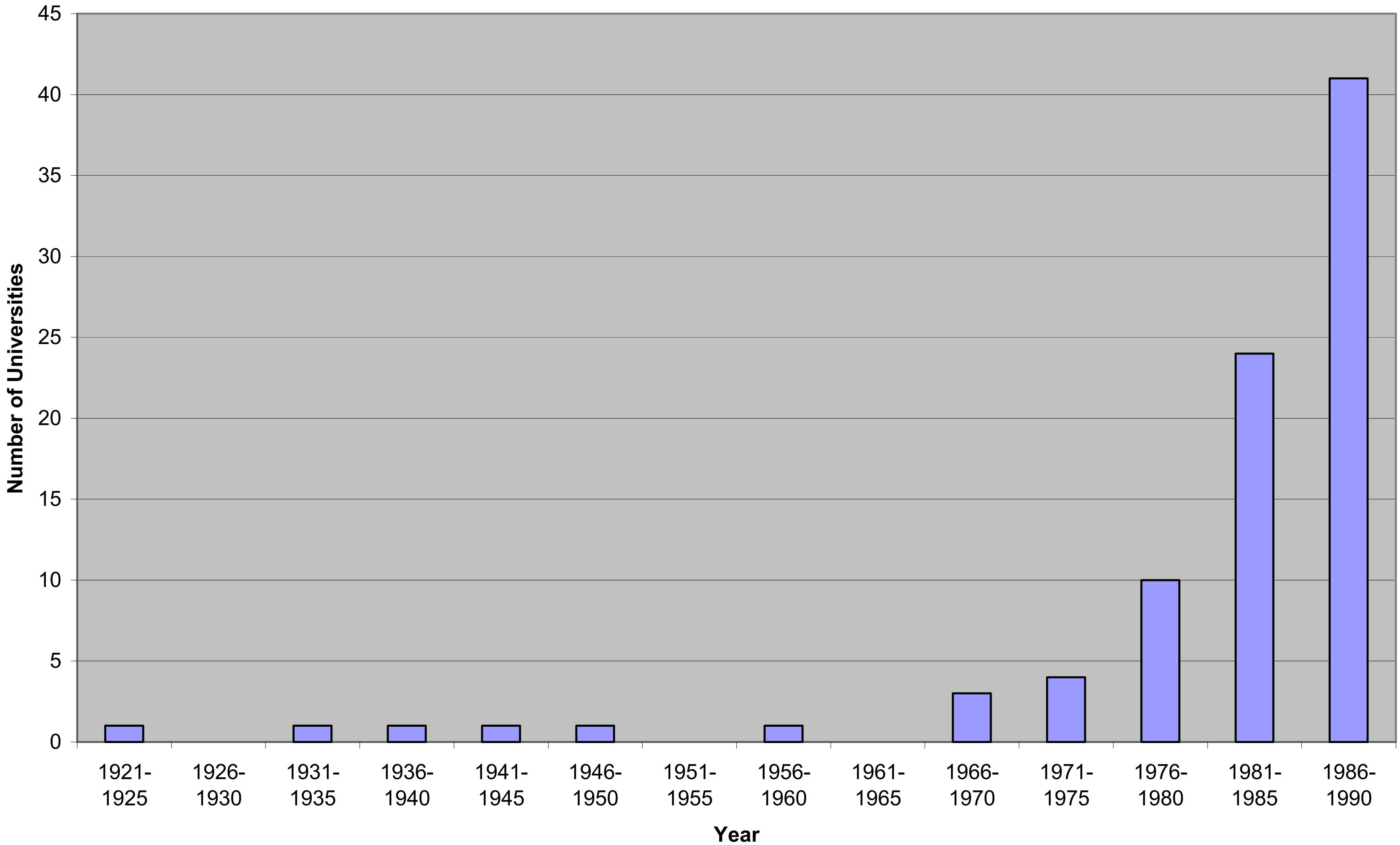

Figure 5: U.S. research university patenting in the 1970s and 1980s