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## THE RISE OF INTELLECTUAL PROPERTY PROTECTION IN THE AMERICAN UNIVERSITY

Intellectual property scarcely existed in the vocabularies of U.S. academic researchers and administrators even 15 years ago. Now it is an ever-present part of discussions on research policies and directions. This new importance of intellectual property in academia reflects a changing view of the relationships of research universities to the surrounding society. Until recently, research at universities has been relatively isolated from demands of economic utility, and education of graduate students has emphasized a career in academic research as the final goal. The university's contentment with this relative isolation was affected by two major events of the late 1980s and early 1990s: the fall of the Berlin wall, leading to an expected decrease in military funding of research, and the emphasis on balancing the federal budget—both producing a fear of a decline in federal funding of university research.

The reaction on the part of the university has been to emphasize the benefits of taxpayer funding of research and to seek increased research support from industry. Intellectual property plays an important part in both of these efforts.

*The impact of the Bayh-Dole amendment.* Economic development through exploitation of intellectual property is now widely touted as one of the major benefits of federally sponsored research. This effect was given a major boost by the passage of the Bayh-Dole Act (Public Law 96-517), implemented in 1980. The primary intent of this law was to foster the growth of technology-based small businesses by allowing them to own the patents that arose out of federally sponsored research.

Universities and other nonprofit recipients of federal funding were included in the definition of "small entities" benefiting from the Bayh-Dole Act, largely as an afterthought. Under the Bayh-Dole Act, the universities themselves would not develop the patented technologies, but would license the patents to industry. A provision of the law allowed the universities to retain royalties from such licensing and specified that a fraction of the royalties would be shared as personal income to the inventors. By law, the university's share of the royalties must be plowed back into its research and educational activities.

A key aspect of university licensing of their inventions under Bayh-Dole was the granting of exclusivity. How could the federal government justify allowing a single company to be given the advantage of intellectual property developed under taxpayer funding? The universities pointed out that exclusive licenses were imperative for the development of early-stage technology. The com-



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mercial licensee must devote substantial time and money to attempt to develop the technology, with no guarantee that it will be successful. Exclusive licenses are an inducement and reward for a company willing to step forward and take such a risk—knowing that if it succeeds in the development, the exclusive license will protect it from more risk-averse competitors.

Now almost all research universities in the United States have technology licensing operations. The number of U.S. patents granted to American universities in a year rose from about 300 in 1980 to almost 2000 in 1995. A survey of university licensing activities documents 5396 licenses granted by universities between 1991 and 1995.\* More than 250 new companies were formed directly through university licenses in 1996—and a total of more than 1900 companies since the inception of the Bayh-Dole Act in 1980. Hundreds of products are already on the

market that were developed under licenses—ranging from new vaccines to computer security systems, electronic music chips, chemotherapeutic agents, and low-pollution industrial burners.

The direct economic impact of technology licensing on the universities themselves has been relatively small (a surprise to many who believed that royalties could compensate for declining federal support of research). Although a very few, and highly visible, "blockbuster" inventions such as the Cohen-Boyer gene-splicing patent from Stanford University and the University of California, the fax patent owned by Iowa State, and the cisplatin patents of Michigan State University have made tens of millions for universities, most university licensing offices barely break even. In contrast, the impact of university technology transfer on the local and national economies has been substantial, and leads to the conclusion that the Bayh-Dole Act is one of the most successful pieces of economic development and job-creation legislation in recent history. It has been estimated<sup>†</sup> that more than 200,000 jobs have been created in the United States in product development and manufacturing of products from university licenses, with the number increasing fairly rapidly as the licenses mature.

These results of university licensing have been noted with great interest by local communities, state legislatures, the U.S. Congress, and many policy-makers abroad. Locally, some universities have noted a lessening (and even "sweetening") of the "town/gown" conflict, as cities such as Cambridge see new companies and jobs springing up out of the universities in their communities. State governments are setting aside moneys specifically to fund technology transfer offices and new-company incubators in their universities. The phrase "Bayh-Dole" is heard frequently in Japan and Germany as their educational ministries seek to emulate the U.S. university technology transfer system.

*Industrial support of university research.* Parallel with the development of the university infrastructure for protection and licensing of intellectual property has come an increased interest in re-

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\*D. E. Massing, Ed., *AUTM Licensing Survey, FY1991-1995. Five-Year Survey Summary* (Association of University Technology Managers, Norwalk, CT, 1996), p. 58. <sup>†</sup>L. Pressman, S. K. Guterman, I. Abrams, D. E. Geist, L. Nelsen, *J. Assoc. Technol. Managers* 7, 49 (1995).

search partnerships between industry and universities—from both partners. Universities see industrial support as potential replacement for funds cut by the federal government. Industry has many reasons for increased interest: Technology is developing too rapidly for in-house development to be sufficient; central research laboratories with cutting-edge scientists were closed down in the draconian down-sizing of the late 1980s and early 1990s, and companies are reluctant to rebuild them; universities have specialized facilities and staff that cannot readily be obtained elsewhere; and companies can experiment with new technologies and approaches at universities without committing to hiring permanently the expertise that will be needed to develop these technologies.

Intellectual property terms have become vitally important. The company wants to be assured that it can use the results of the research—and that these results will not be available to their competitors. But most universities insist that dissemination of research results is key to their identity and mission and will not agree to keep the project results secret. The key to resolving this dilemma is to grant patents: The university will publish the results, but will first agree to file patents that will protect the company's exclusivity in the commercial marketplace.

The critical factor in making this accommodation work is an efficient, knowledgeable technology transfer process at the university. The negotiators must be savvy about both technology and business, able to understand the industrial partner's needs and to craft reasonable intellectual property terms that meet those needs while preserving the rights, policies, and freedom of action of the university. These university technology transfer professionals are part of a new and surprisingly creative profession.

*Impact on students.* An unpredicted effect of the increasing interest in exploitation of university intellectual property has been that on students and the educational process. Contrary to expectations that patenting and technology transfer might somehow shut out students from full participation in the research process, the effect has instead been to motivate students and to increase their awareness of the potential commercial utility of their research findings.

Many engineering, design, and business development courses now include at least one session on patenting and technology transfer. Product development courses, previously unknown, are now popular in even the most science-based engineering schools. The biggest impact of university technology transfer on students comes from the success of start-up companies based on university licenses. The process tends to be very visible on campus, providing role models for many students. At the Massachusetts Institute of Technology, for example, the annual student business plan contest elicits 75 to 100 entries, a large fraction of which are based on plans that the students fully intend to turn into businesses. Of the six semifinalists each year, more than half achieve venture capital financing, and many who do not make the semifinals nevertheless go on to form successful companies.

Entrepreneurship courses and entrepreneurship tracks in MBA programs are now among the most popular offerings in business schools, and an increasingly large number of graduates are seeking employment in venture capital or in start-up companies. A relatively new trend is that of joint programs

between engineering and business schools, many of which stress moving technology "from the laboratory to the production floor."

*The future: trends and problems.* University management of intellectual property is still young, and both policy-makers and technology transfer officers are learning by doing. Most policies have been formed ad hoc, with modifications made as problems arise. Yet the field is beginning to mature. Certain norms have arisen and some issues, such as taking of equity in start-up companies as a form of royalties, were initially highly controversial, but have become accepted as experience is gained and the predicted disasters have been largely averted through thoughtful formation and enforcement of policies. With maturity, however, are coming new problems and challenges, as there is an inherent conflict between free dissemination of knowledge (widely accepted as the university's primary mission), industry needs for confidentiality and control of intellectual property, and the university's obligation to protect and foster the development of its intellectual property in the cause of public economic development.

Although the past 10 years have shown that effective compromises can be wrought between these competing objectives, new situations show that these compromises may not be sufficient. Examples include:

- Restricted availability or delays in exchange of "research tools" (such as vectors or transgenic mice) in biological research.
- "Inappropriate" granting of exclusive licenses (such as the licensing of receptor "targets" for high-throughput drug screening) where wide availability might better foster development.
- New forms of collaboration with industry that do not lend themselves to the "sponsored research" model. For example, should the university insist on owning the intellectual property when a company sponsors a design competition in an undergraduate design class for ideas to improve the company's camera? Or how

should the university treat collaborative projects where the student spends half of his or her time as an intern in the company's laboratory, and half in the university lab?

- Trading-off of benefits to the university may conflict with the expectations of the researchers. A recent suit against the University of California (*Singer v. The Regents of the University of California*), for example, alleged that the university gave overly favorable licensing terms to a company in return for sponsored research funds, depriving the inventors of substantial potential royalties.

- Tenure evaluations. Junior faculty members worry about whether participation in technology transfer is good or bad for their tenure prospects. Some are concerned that any such activities will lead to the assumption that their academic pursuits are not primary in their minds. Others assume that licenses are critical to the tenure committee deciding that the researcher's technology is "important."

Policy fiat, changes in the law, or even attempts to categorize types of intellectual property and the "appropriate" handling of them are very likely doomed to have overly broad effects with harmful, unintended consequences. The answer at the present time seems to be to handle situations on a case-by-case basis, but under a process of continual dedication within the university to "do the right thing"—and a continuing search to discover what the "right thing" is.

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