

Hearing Testimony

Oversight hearing on “Gene Patents and Other Genomic Inventions,”
House Committee on the Judiciary, Subcommittee on Courts and
Intellectual Property, July 13, 2000.

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SUMMARY

Technology transfer, the transfer of research results to the commercial marketplace for public benefit, is an important way for universities, teaching hospitals, and research institutions to demonstrate the relevance of their research programs, introduce innovation to the commercial sector, and enrich the lives of citizens. It has been estimated that in fiscal year 1998, the patent and licensing activities of academic institutions resulted in \$33.5 billion in economic activity, supported 280,000 jobs in the economy, and resulted in \$3 billion in federal and state tax revenues.

Patents to genetic discoveries made during university research can be pursued without disrupting the core values of publication and sharing of information, research results, materials, and know-how. Universities pursue patents to gene discoveries in the context of the Bayh-Dole Act, the pioneering, enabling legislation that permitted universities to take title to inventions made with the use of federal research support. Within the concepts embodied in the Bayh-Dole Act, universities carefully consider and balance the needs for

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publication of research results, the sharing of materials with other researchers, and the desire for commercial development of discoveries in the public interest. Often, the technology transfer manager and the researcher work collaboratively to protect an invention within the deadlines that the researcher has for publication. Universities can, and do, protect inventions to genetic information for commercial development, and effectively disseminate research results and materials. This activity supports economic growth; allows universities to attract, retain, and reward talented faculty; and promotes closer ties with industry that often result in additional research support.

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Mr. Chairman, my name is James Severson. I am pleased to speak before this subcommittee in two capacities. The first is that I am the President of the Cornell Research Foundation, a not-for-profit subsidiary of Cornell University, which has as its main mission the identification, protection, and licensing for commercial development of inventions made at Cornell University. In my second capacity, I am the current President of the Association of University Technology Managers (“AUTM[®]”). AUTM is a nonprofit association with membership of more than 2,300 technology managers and business executives who manage intellectual property—one of the most active growth sectors of the U.S. economy. AUTM’s members come from more than 300 universities, research institutions, teaching hospitals, and a similar number of companies and government organizations.

In the context of my remarks to you, technology transfer refers to the transfer of research results from universities to the commercial marketplace for public benefit.

The growth of the pursuit of patents resulting from research on campus can be traced to the passage in 1980 of the Patents and Trademark Amendments Act (P.L. 96-517, also known as the Bayh-Dole Act, and later amended by P.L. 98-620). The Bayh-Dole Act was intended to promote investment by the private sector in the commercialization for the public good of discoveries made

using research funds provided by the federal government. This pioneering legislation created a uniform policy among federal agencies that fund research to enable not-for-profit research institutions to elect to retain title to inventions made with funds provided by the federal government. Prior to the Bayh-Dole Act, the government retained title to these inventions, but it was cumbersome for a company to obtain a license. Consequently, few inventions were licensed for development and commercialization.

The Bayh-Dole Act requires institutions that retain title to inventions and patent them to show a preference in their licensing activities for small companies and to require that products to be sold in the United States be manufactured in the United States. The government retains the right to practice the invention on a royalty-free basis and retains march-in rights to ensure that important inventions are commercially developed. Also, the Bayh-Dole Act specifies that any income derived from the licensing of inventions be used to support further research and education, support patent protection for other discoveries with commercial application, and provide an incentive to researchers to participate in these activities.

By all accounts, this relatively simple change in the rules for the management of innovations has had a profound impact on the development and commercialization of inventions made at universities, and on the economy. Starting in fiscal year 1991, AUTM has conducted an annual survey of the patenting and licensing activity of U.S. universities, teaching hospitals, and research institutions as well as some Canadian institutions. During the period surveyed, annual invention disclosures by U.S. universities doubled to nearly 10,000; the number of licenses that U.S. universities have entered into grew threefold to over 3,000; and in fiscal year 1998, 279 new companies were formed with university technology. For fiscal year 1998, AUTM estimated that technology transfer activity from these academic institutions resulted in \$33.5 billion in economic activity, supported 280,000 jobs in the economy, and resulted in \$3 billion in federal and state tax revenues. These measures reflect the delivery of commercial products to the public, products that in many instances would not

have reached the public without the protection afforded to institutions of higher education by the Bayh-Dole Act.

The concept embodied in Bayh-Dole, development of inventions made with federal funds for the public good, is an excellent fit with the mission of universities. Most universities see their mission as teaching, research, and outreach. Technology transfer is an important part of the broad goal of outreach and represents one way that university research programs connect to the local community. Many local and state leaders in business and government look to research universities as a source of new ideas and business opportunities to enhance the vitality of the local economy and to attract and develop jobs in their community. Universities are often described as “an engine for economic growth.” Today, the protection and commercialization of academic research is one way for universities to attract, retain, and reward talented faculty who wish to see the results of their research programs benefit society. A commitment to the protection of research results is important for universities to develop closer ties to companies, and to attract additional funds to support research programs.

I understand that this subcommittee is interested in learning how patents for genes affect openness and sharing of information among academic institutions. This issue is complex and impinges upon the publication and dissemination of research results and the sharing of research tools.

Most universities are not engaged in gene sequencing to the same extent as companies, and universities have not engaged in the broad scale patenting of genetic information. For the most part, invention disclosures made for gene sequences are considered for patenting on a case-by-case basis and in the context of the requirements of Bayh-Dole. Specifically, the question that universities ask is, What is the best means to protect and disseminate this information for the public good? Many inventions made at universities are at a very early stage of development and require extensive follow-on research, including proof of principal, before any company will invest in its commercial development. In

many cases, innovations never reach the threshold for commercial development.

Should patenting go forward, one issue that is considered is the effect on the publication of the results of the research. Publication of research results is a core value for universities, and in my experience, the ability of university researchers to publish is carefully protected by university administration, grant and contract officers, and technology transfer managers. In practice, the pursuit of a patent rarely delays the publication of results. Technology transfer practitioners at universities work to protect an invention within the deadlines that researchers have to publish a manuscript or present data at scientific conferences. Often the parties must balance collaboratively the need to publish against the desire to protect valuable intellectual property. Accordingly, much of the gene sequence information that is developed at universities is placed into the public domain by publication in the scientific literature or by listing the gene sequence in publicly available databases for broad access by the scientific community.

If a university pursues a patent, licensing on a nonexclusive basis (that is, making the gene available to a number of companies) is often the best means for technology transfer to benefit the public, especially if the gene is useful as a tool, or if the gene is a potential target for drugs. This practice makes the invention widely available and derives the broadest benefit from the invention. I would like to give you an example from our program at Cornell. In 1989, Professor Ray Wu of the Department of Molecular Biology and Genetics disclosed to the Cornell Research Foundation a gene that he isolated and sequenced from rice for a protein called actin and its associated promoter. The discovery was striking because of the strength with which the promoter affected the transcription of the gene. Feeling that the strong promoter might have value, the case manager at the Cornell Research Foundation initiated a patent application on the discovery. In addition to pursuing a patent for the discovery, Dr. Wu and Cornell made the invention widely available to other researchers through biological materials transfer agreements, a common mechanism for researchers to exchange research materials. As a result of this wide distribution, the

promoter was available to numerous research programs, and, subsequently, it was discovered that this promoter is the best available in helping make plants tolerant to certain herbicides. At this point, Cornell Research Foundation has nonexclusive licenses with twelve companies that are developing crop plants with herbicide tolerance.

I make this example to illustrate two points. The first is that even if a patent has been pursued, there is still the opportunity for the university to share the gene itself, and associated information and biological materials, with other researchers for further discovery and potential development. The second point is that discoveries made at universities are early-stage technologies and may take a significant time to make their way into products. Professor Wu made his discovery in 1989, but products that make use of his discovery are still in development.

In other instances, exclusive licensing may be preferred and may offer the only practical way to induce a company to assume the risks of time and investment in early-stage inventions. To illustrate with another example from Cornell, in 1994 William Holloman of the Department of Microbiology of the Cornell Medical College, working with a colleague, discovered a class of enzymes that is extremely efficient for the repair of breaks in chains of nucleic acids—the building blocks of genes. This basic repair mechanism is termed recombination and is important from the standpoint of understanding the biology of how cells repair themselves. However, it was also recognized that these enzymes might be useful to develop novel methods to repair genetic defects in cells. A start-up company approached Cornell Research Foundation to obtain a license to the discovery. Because of the long period required to develop products and the cost involved in development, the only means to attract venture capital backing was through an exclusive license to the patents for this discovery. Even though an exclusive license was granted for the invention, Professor Holloman published the results of his research after the submission of the patent application, and he continues to conduct basic research in the same area.

In summary, technology transfer, the transfer of research results to the commercial marketplace for public benefit, is an important way for universities, hospitals, and research institutes to demonstrate the relevance of their research programs, introduce innovation into the commercial sector, and enrich the lives of citizens. These discoveries can be pursued without disrupting the core values of publication and sharing of information, research results, materials, and know-how.

I appreciate the invitation to speak before you today and I look forward to your questions and comments.

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Industry Perspectives on Licensing University Technologies: Sources and Problems

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ABSTRACT

We report results of a survey of industry licensing executives who identified personal contacts between their R&D staff and university personnel as the most important source of university technologies. Journal publications and presentations at professional meetings were also important. While the least important sources were marketing efforts by universities and canvassing of universities, a number of executives did indicate that they were important. For those who do not license-in from universities, the most important reasons for not licensing-in (other than limited overall license-in activities) were reasons related to the nature of university research. A number cited university policies regarding delay of publication and ownership.

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1. Introduction

In a recent article in this *Journal*, Jansen and Dillon (1999) report the results of a survey of five universities' and one national lab's technology transfer offices regarding the source of over 1,100 leads for licenses adoptions. Perhaps their most important result is a confirmation of technology transfer "office lore" that inventors are the primary source of license leads. In particular, they find that 56% of the licenses covered by their survey resulted from leads originating with the inventor/researcher. The next largest source of leads, marketing by the technology transfer staff at 19%, pales in comparison.

Recently we conducted a survey of businesses who license-in technologies to assess how they identify university technologies of interest to them, as well as factors that influence the extent to which they license-in from universities.² Our results therefore complement those of Jansen and Dillon by providing an *industry* perspective on the license process. However, unlike Jansen and Dillon who asked respondents for the primary leads by license, we asked for the *importance* of various sources in identifying university technologies to license-in. Our results, like those of Jansen and Dillon, show the extreme importance of the inventor in matching university inventions with industry needs.

In addition, we examine the importance of journal publications, patent searches, presentations at professional meetings, and a routine canvass of university technologies. Because our data include information on the number of licenses executed by each business unit, we are able to relate the means of identifying technologies to scale effects in licensing. We find that large licensing-in business units are more likely to routinely canvass universities for technologies; journal publications are also relatively more important for those businesses.

Finally, because our survey included industry licensing executives who license-in from some sources but who do not license-in from universities, we could examine reasons those business units have not licensed from universities. Not surprisingly, we find that the

nature of university technologies is an important factor, as is also university refusal to transfer ownership to the company.

In the next section, we discuss the details of the survey. Section 3 discusses the question and responses regarding sources of university technologies for those who license-in such technologies. Section 4 turns to questions relevant to those who do not license-in from universities. Finally, Section 5 concludes.

2. Survey Design

The sample was drawn from the mailing list of the Licensing Executive Society, Inc., U.S.A. and Canada (LES). This list includes all current and past LES members, as well as individuals who have contacted LES for information on licensing or the operations of LES. This list also identifies individuals by title, thus we could eliminate many individuals who are not actively engaged in licensing (e.g. patent attorneys, university faculty and students, consultants). We called companies with multiple entries to ensure a single response from each suitable business unit and to identify the most appropriate respondent. We asked surveys to be completed by each business unit within a firm that has autonomous license-in responsibilities. Hence, for some firms, there are several survey respondents. Further, telephone calls allowed us to eliminate businesses that do not license-in technology from any source or who do not sponsor university research, as well as firms no longer in business. This left us with 1,385 business units in the sample. The survey was conducted in the fall and winter of 1998-99. We had 300 respondents (a response rate of 21.7%); of these, 112 indicated they had licensed-in university technologies from U.S. universities over the period 1993-97, and 188 indicated that all of their licenses were from other sources, though 55 of the latter had sponsored research at U.S. universities during that period.

Many of the companies on the LES list are not publicly traded so it is impossible to conduct the usual tests for selectivity bias. We can, however, compare the total of all licenses and industry sponsored research reported in the *AUTM Licensing Survey, FY 1997* (AUTM 1998) to the number of licenses and amount of sponsored research

of our respondents.³ Of the 112 firms who licensed-in university technologies, 104 gave information on the number of their license agreements with universities. These 104 respondents executed 417 licenses in 1997, which represents approximately 15% of the total reported by AUTM for U.S. universities. Our survey is explicit in differentiating between licenses and options whereas AUTM lumps both together; thus, our estimate and the AUTM figure are not strictly comparable. However, according to our survey, the bulk of university contracts (aside from research agreements) are licenses; in our survey, licenses outnumbered options by about 4 to 1. Seventy-one respondents reported \$307 million of support to U.S. universities, which is approximately 17% of the comparable AUTM figure of \$1,786 million reported for research expenditures supported by industry. If the firms with missing sponsored research expenditures had the same average research expenditure as the 71 usable responses, then our respondents account for about 28% of all industry research support at U.S. universities.

Seventy-nine firms listed the primary universities with whom they licensed during the preceding five years, and 64 listed the primary universities with whom they sponsored research. Many who did not answer this question indicated confidentiality concerns. They were reluctant—in spite of assurances of confidentiality—because knowledge of the universities with whom they deal can give competitors information as to the strategic direction the firm might take in the future. Eighty-five universities are mentioned (many are mentioned by a number of firms) and they cover most of the major U.S. research universities; based on the FY 1997 AUTM survey, they represent 35 of the top 50 industry-supported universities and 40 of the top 50 universities according to licenses executed. It is reasonable to conclude that our sample represents a substantial portion of all industry/university contractual agreements of the recent past.

Of the 188 who responded to the survey that they license-in technologies but not from universities, 172 reported that they had 1,038 license-in agreements in 1997; 55 reported that they had sponsored research at U.S. universities. Fifty-two of these reported nearly \$390 million of sponsored research in 1997. It is interesting

that the average level of sponsored research support for respondents who did not license-in from universities is around 75% higher than it is for those who do license-in from universities.

3. Sources of University Technologies

We asked each respondent the question, “When you license-in university technology, how important are each of the following in identifying the technology?” We provided six potential sources, which are noted below:

1. Journal publications
2. Patent searches
3. Presentations at professional meetings
4. Marketing efforts by the university’s technology transfer office
5. Personal contacts between our R&D staff and university personnel
6. Our licensing staff routinely canvass universities for new technologies

A category “other” was included, but we do not report those results here as only nine respondents noted other sources. For each source, respondents were asked to rate the importance of the source on a scale from 1 (extremely important) to 5 (not important). Respondents were permitted a response of “Don’t know.” These six source questions are reported in Table 1 along with the percentage of respondents indicating the 5 degrees of importance. We do not report the percentage of “Don’t know” responses. Table 1 also provides the number of respondents (# Resp.) answering for each potential source.

In Table 2 the mean (average) response to the sources question as well as the weighted average response with weights equal to the number of university licenses executed by the respondent’s

business unit over the period 1993-97 are provided. The weighted mean is given by

$$Wgt. Mean = \sum_{i=1}^n w_i X_i / \sum_{i=1}^n w_i$$

where n = number of respondents, w_i = number of university licenses executed by the i th business unit, and X_i = response of the i th business unit. The weighted mean gives a higher (lower) weight to those business units that executed large (small) numbers of university licenses over the period 1993-97 relative to other respondents. For example, the average response to source 1, "Journal publications," is 2.51 while the weighted average is 2.20. This indicates that journal publications are relatively more important to those business units who executed relatively large numbers of university licenses. The situation is reversed for source 2, "Patent searches," which is relatively more important for those with fewer numbers of licenses. Not all respondents provided the number of university licenses executed over this period so the number of respondents used to calculate the weighted means is smaller than the total number of respondents answering the question in regard to sources.

Table 1. Responses to Sources Question

Sources	# Resp.	Percentage of Respondents				
		Extremely Important	2	3	4	Not Important
1. Journal publications	102	19.6	31.4	31.4	13.7	3.9
2. Patent searches	101	24.0	33.0	24.0	10.0	9.0
3. Presentations at professional meetings	99	13.1	37.4	31.3	16.2	2.0
4. Marketing efforts by the university's technology transfer office	100	12.0	15.0	23.0	26.0	24.0
5. Personal contacts between our R&D staff and university personnel	106	45.7	31.4	14.3	2.9	5.7
6. Our licensing staff routinely canvass universities for new technologies	98	9.3	19.6	16.5	24.7	29.9

Table 2. Mean and Weighted Mean Responses to Sources Question

Sources	Average Responses		Weighted Average Responses	
	# Resp.	Mean	# Resp.	Wgt. Mean
1. Journal publications	102	2.51	81	2.20
2. Patent searches	101	2.49	80	2.74
3. Presentations at professional meetings	99	2.57	78	2.25
4. Marketing efforts by the university's technology transfer office	100	3.35	77	3.25
5. Personal contacts between our R&D staff and university personnel	106	1.91	82	1.96
6. Our licensing staff routinely canvass universities for new technologies	98	3.44	76	2.72

What immediately stands out in Tables 1 and 2 is the extreme importance of personal contacts between industry R&D staff and university personnel. While our question did not differentiate university inventors/researchers from TTO staff,⁴ it is almost surely the case that the personal contacts of industry R&D staff with university researchers are very important. This result, as we noted above, is in agreement with the results of Jansen and Dillon. What also stands out is the relative unimportance of TTO marketing efforts. More than 77% of respondents gave a score of 1 (extremely important) or 2 to personal contacts while only 27% gave such scores to marketing efforts. Note that while marketing efforts are substantially less important than personal contacts, which is in agreement with Jansen and Dillon, there are still a fairly large proportion of industry licensing executives who view marketing efforts as important.

There is a similarity in responses across the sources concerning publications, patent searches, and presentations at professional meetings. We tested for equivalence of the responses across these three sources using pairwise tests for equivalence of the 5-category multinomial distributions and we found that the responses to source 1 are not significantly different (at any conventional level of significance) from responses to sources 2 and 3. Responses to

sources 2 and 3 responses, however, are significantly different at a 5% significance level.

Note also that the raw scores show a similarity across source 4 (marketing efforts) and source 5 (canvassing universities). Our test for differences in the responses for these two sources also indicates no significant difference in the raw scores. However, when we weight by the number of licenses executed over 1993-97 matters change somewhat. The weighting scheme does not affect the marketing result: the mean score is 3.35 and the weighted mean score is a very similar 3.25, but the canvassing source mean score of 3.44 falls to 2.72 when weights are used. The suggestion is that large licensing-in business units are more likely to canvass for university technologies. This makes sense as it suggests an economy of scale effect for business licensing staff in such activities.

Responses to source 5, personal contacts, are significantly different from responses to all other sources.

Finally, for the sources question, we examined whether the responses by respondent for each of the sources are correlated. This is, we look at whether, for example, an individual respondent's answers to source 1 are correlated with his/her answers to source 2. The simple correlations are found in Table 3. If responses are not significantly correlated at least at the 10% level, we do not include the correlation and so indicate with an "ns" to indicate not significant.

It is important to note the difference in the tests for correlations and the tests for differences in the distributions of aggregate responses. In the latter we are testing whether the proportion of respondents who indicate scores of 1 (extremely important), 2, 3, 4 and 5 (not important), for, say, journal publications is different from the proportion of respondents who indicate those scores for, say, patent searches. The correlations that we turn to now consider whether an individual respondent's answers to, for example, journal publications are correlated with their answers to, say, patent searches.

Table 3. Correlations of Responses to Sources Question

Sources	<u>Source Number</u>				
	2	3	4	5	6
1. Journal publications	ns	0.43	ns	ns	ns
2. Patent searches		ns	ns	-0.17	ns
3. Presentations at professional meetings			ns	0.17	ns
4. Marketing efforts by the university's technology transfer office				0.21	0.39
5. Personal contacts between our R&D staff and university personnel					0.27

ns = not significantly different from zero at a 10% level.

Journal publications and presentations at professional meetings are fairly highly correlated with a value of 0.43. It is not surprising that these two sources are closely related, as one would strongly suspect that it is the R&D staff of a firm who are examining journal publications and attending professional meetings. This point is supported by a positive, significant correlation (albeit small) between personal contacts and presentations at professional meetings. Personal contacts are often made and maintained at professional meetings so the latter correlation is not surprising.

It is somewhat surprising that neither journal publications or presentations is correlated with patent searches, which suggests that patent searches may, to some extent, be undertaken by the licensing staff independent of the R&D staff. Note the negative, significant correlation (albeit small) between personal contacts of the R&D staff and patent searches suggesting, perhaps, that patent searches are used in lieu of active participation of R&D staffs in the licensing process (or, possibly, small R&D staffs). Marketing efforts, personal contacts, and canvassing are all positively and significantly correlated.

4. Reasons for Not Licensing-In from Universities

Above we considered the importance of various sources for industry in identifying university technologies to license-in. Here

we take a different look at the licensing process and ask why some firms choose not to license-in from universities. We restrict attention to firms that engage in license-in activities, but which either never license-in from universities or who had not done so since 1993. We asked each respondent in this group, “Which of the following are reasons why you have not licensed-in U.S. university technologies since 1993?” Seven reasons were provided and a yes/no response was permitted for each reason. The reasons are listed in Table 4. One hundred and eighty-two responded to this question. Because multiple reasons were permitted, we had 431 “yes” responses. Answers are displayed in Table 4 in two ways. The second column of the table (% Yes - Respondents) gives the percent of the 182 respondents who indicated “yes” to each reason while the third column (% Yes - Responses) gives the percentage of the 431 “yes” responses that fell into each category. Note that the latter column sums to 100% while the former does not.

Respondents were then asked, “Which of the explanations [in the above question] is the *most important* reason for your not licensing-in from universities?” One hundred and seventy-five responded and the percent indicating each of the seven reasons is listed in the next-to-the-last column (% Most Imp’t.) of Table 4.

Because many of the respondents indicated that they rarely license-in from any source a meaningful analysis should make some accommodation for those firms that rarely license-in from any source. To that end, we exclude anyone who noted that the *most important* reason was that they rarely license-in. These results are reported in the final column (% Excluding “a”) of Table 4. For instance, excluding those who rarely license-in and who list this as the most important reason, 32.8% of respondents list the early stage nature of university technologies as the most important reason for not licensing-in from universities.

Setting aside the responses to the “rarely license-in” reason, the most important reasons for not licensing-in university technology relate, not surprisingly, to the nature of university research; the research is either at too early a stage or the research is not relevant to the firm’s line of business. Two reasons relate to university

policies. The first concerns delay of publication and the second deals with ownership of the technology. Large fractions of the respondents list these reasons (about 1 in 5 for the first and 1 in 3 for the second). However, few list them as the most important reasons for not licensing-in university technologies. Of the reasons listed, concerns about faculty cooperation for further development is the least cited.

We found somewhat surprising the number of respondents who both noted the “other” category and who noted it as the most important reason for not licensing-in from universities. Any respondent who noted “other” was asked to specify the other reason and fifty-one provided that information. The reasons were quite varied and few respondents indicated similar reasons. Some respondents listed reasons that appear to be close to the reasons we provide and some listed reasons that are unclear. However, nine respondents listed reasons having to do with difficulties in dealing with universities. Examples are “general attitude ... is poor ... do not view industry as a ‘Customer’”; “arrogance ... do not like working with small firms”; “complexity of deal and ... weird expectations”; and “too cumbersome.” Five respondents noted that licensing fees for university technology are too high.

Table 4. Reasons for Not Licensing-In from Universities

Reasons	% Yes – Respondents	% Yes - Responses	% Most Imp’t.	% Excluding “a”
a. We rarely license-in research from any source	57.7	24.1	27.4	
b. University research is generally at too early a stage of development	48.9	20.4	22.9	32.8
c. Universities rarely engage in research in our line of business	37.4	15.6	16.0	21.9
d. University policies regarding delay of publication are too strict	20.3	8.5	1.1	1.6
e. University refusals to transfer ownership to our company	31.3	13.1	10.9	14.8
f. We are concerned about obtaining faculty cooperation for further development of the technology	15.9	6.7	0.6	0.8
g. Other	28.0	11.7	20.6	28.1

5. Conclusion

Recently, we conducted a survey of industry licensing executives concerning their relations with universities. Respondents included not only those who actively license-in from universities, but also those who license-in but who do not license-in from universities. The former set was asked, among other things, the importance of various sources in identifying university technologies to license-in. The latter set was asked about the reasons that they do not license-in from universities.

Jansen and Dillon (1999) found that personal contacts of inventors are the most important source of licenses. In agreement with their result, industry licensing executives overwhelmingly identified personal contacts between their R&D staff and university personnel as the most important source of university technologies. Further, and related to activities of their R&D staff, journal publications and presentations at professional meetings were also of importance. The least important sources were marketing efforts by universities and canvassing of universities. However, while these are the least important sources, a number of licensing executives did indicate that they were important.

For those who do not license-in from universities, the most cited and important reasons for not licensing-in from universities (other than limited overall license-in activities) were reasons related to the nature of university research. A number did cite university policies regarding delay of publication and ownership, but they are less important than the nature of university research.

NOTES

- ¹ This research has been supported by the Alan and Mildred Peterson Foundation, Purdue University, and the Sloan Foundation and the National Bureau of Economic Research under the NBER Project on Industrial Technology and Productivity. We would like to express our appreciation to the Licensing Executive Society, Inc. (U.S.A. and Canada) and particularly Mark Peterson and Tom Small for their support in conducting the industry survey. We are indebted to James Adams, Wesley Cohen, Barbara Newman, Jennifer Parsons, and John Walsh for their suggestions.
- ² While there is an extensive economics literature on the ways that businesses learn and apply academic research, existing studies have not focused on licensing per se. For notable examples, see Mansfield (1995), Cohen et al. (1998), and Adams (1998).
- ³ Data are derived from the AUTM Licensing Survey: FY 1997 report. The comparison of research funding to the AUTM data is not strictly correct as the AUTM data records research expenditures.
- ⁴ We asked the question in this way as our primary interest here was in the role of industry researchers.

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Technology Transfer and Economic Growth

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ABSTRACT

This paper presents the economic framework supporting the conclusion that federal programs—such as the Bayh-Dole Act of 1980—that increase the pay-off from research and development funding (R&D), can be effective agents of economic growth. A review of the literature in this field provides evidence that links investment in research to economic growth. By modifying the traditional Cobb-Douglas production function to include a research and development input, in addition to the capital and labor input, this study defines how multi-factor productivity (MFP) growth is controlled by the interaction of R&D and its commercialization. The combined contribution to MFP growth is defined as the product of the elasticity of output for R&D and the rate of growth of the R&D input. Evidence supporting the importance of the elasticity component for multi-factor productivity growth is presented, and the study then concludes that programs to increase the elasticity of output for R&D—what is referred to as increasing the pay-off from R&D—may be an effective means to realize a larger return on the investment in R&D.

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A. Introduction

In this paper the authors present the role of innovation in stimulating economic growth. Part B presents evidence from the literature, which demonstrates that spending on R&D has traditionally resulted in innovations that have been shown to increase productivity and economic growth. Armed with this evidence, Part C redefines the Cobb-Douglas production function to include an R&D input and calculates the contribution of this input to multi-factor productivity. The Cobb-Douglas production function represents the relationship between factors of production, such as capital and labor, and the output of these factors.¹ This economic model will demonstrate that one effective method to increase multi-factor productivity is to expand programs that increase the elasticity of output for R&D. Evidence supporting this conclusion is presented in Part D. Finally, in Part E, this paper presents evidence that the Bayh-Dole Act² has increased the payoff from R&D. According to the model, the authors conclude that the Bayh-Dole Act will be an effective tool for increasing economic growth into the future.

B. Charting the Path from Research Funding to Economic Growth

Traditional economic models stress that productivity growth is integral in sustaining economic growth because of population growth and resource scarcity. Productivity is the mechanism by which economic resources expand. Multi-factor productivity growth is the preferential indicator of overall economic performance; it measures the efficiency with which capital, labor, and R&D are used together in production.

Technological change is one of the most important components involved in productivity growth. There is a consensus that improvements in knowledge are probably the single most important source of growth in per capita national income. Societies with high wages continue to experience high rates of growth only if they remain on the edge of the technical frontier.

Robert Solow and Edward Denison have estimated the contribution of traditional inputs to total output over time, and both have calculated a “residual,” which is the growth in output not attributable to increases in the traditional inputs. Solow’s work concluded that there is an unexplained residual accounting for 80% of the growth in output per worker between 1909 and 1949.³ Denison used a slightly different method to calculate the residual, studying the years from 1929-1969, but he still accounted for 69% of the growth by the residual.⁴ These two studies conclude that at least a quarter or more of the productivity residual can be explained by R&D activity. Frederic Scherer found that in the post-war period, research and development efforts have added to the rate of growth by about one percentage point per year; in his study, R&D would explain approximately half the rate of growth in productivity per year.⁵ More recently, Boskin and Lau performed a study demonstrating that 30-50% of economic growth in society comes from the introduction of new technologies.⁶ We can thus conclude that technological progress is a vital source of economic growth and that R&D is a vital source of technological progress.

The literature tying research expenditures to economic growth is extensive. Many studies have estimated the rate of return on investment in R&D and verified that the profitability of R&D exceeds that of other investments.⁷ Economists have long linked the pace of technological change to the magnitude of the resources devoted to research and development as well as to the payoff from R&D.⁸ Edwin Mansfield estimated the private rate of return on investment in R&D to be 25%;⁹ he calculated the social rate of return on R&D at 56%. More recently, Stiglitz has reported the social rate of return on R&D investment to be approximately 50%, with the private rate of return around 20-30%.¹⁰ Coe and Helpman demonstrated that substantial benefits accrue preferentially to the business and country performing the research, although they admit there are large spillovers.¹¹

C. Accounting for Research and Development within the Traditional Cobb-Douglas Production Function

There is little doubt about the role of government-sponsored research in maintaining and improving the quality of life in this country. Yet, as the United States begins to observe its declining importance in the world economy, concern has again been focused on American innovation, the return extracted from research investments, and the general decline in the rate of growth of American productivity.

In 1988, Martin Baily and Alok Chakrabarti published *Innovation and the Productivity Crisis*. They aimed to discover the explanation for the slowdown in productivity that occurred in the 1980s.¹² Their research, as well as research by Denison,¹³ has suggested the slow pace of innovation was a major reason for falling productivity growth.

Slow innovation would occur because of a decline in the pace of technological change. Although there is extensive literature in economics (spearheaded by Joseph Schumpeter) relating to economic development in terms of “spurts or waves” of innovation, for this study’s purposes, the discussion will be limited to three broad possibilities for such a collapse in technological change. First, there was a decrease in technological opportunities. Second, opportunities were present, but they were not exploited by industry managers. Last, innovations were made, but they did not result in productivity increases.

Baily and Chakrabarti use the first possibility as a stepping-stone to design a framework within which they can test whether decreasing growth in R&D expenditures could have caused a decrease in technological opportunities, a decrease in innovation, and therefore, a corresponding decrease in productivity growth. Below we lay out their framework, based on Robert Solow’s studies.

First we need to assume that output (Q), is a simple Cobb-Douglas function of the capital input (K), the labor input (L), and the R&D input (R). This function can be written

$$(1) \quad Q = f(K,L,R) \text{ or } Q = AK^{\alpha}L^{\beta}R^{\Omega}$$

In this equation, the functional relation between inputs and outputs represents the technology of production. For any production unit, output is assumed to be functionally related to the use of inputs. One can then view technological progress as a continuing change in the form of the production function that leads to more output for given amounts of inputs. In this specification, α , β , and Ω are fixed parameters. They are the elasticities of output with respect to the input they represent: capital, labor, and R&D. The intercept term is A, and it may increase over time as a result of technological change or organizational innovations unrelated to R&D.

An increase in the R&D input increases multi-factor productivity (MFP), according to equation (1), by increasing the amount of output produced with a given quantity of capital and labor. The magnitude of the contribution of the R&D increase to multi-factor productivity is computed as follows:

$$\begin{aligned}(2) \quad & \text{Contribution of R\&D to MFP growth} \\ &= \Omega * \text{rate of growth of the R\&D input} \\ &= \Omega (d \ln R / dt)\end{aligned}$$

which states that the contribution of R&D to multi-factor productivity growth is the elasticity of output for R&D—what we call the pay-off from R&D—multiplied by the rate of growth of the R&D input.

Following Solow's and Baily and Chakrabarti's lead, it is appropriate to define the concept of the R&D input, (R), as a stock, computed in the same manner as the stock of capital. The stock of R&D consists of a weighted average of R&D spending over a

number of years, with two important features. First, there is usually a lag from 2-15 years before a given R&D expenditure shows up in production. Secondly, superimposed upon this lag is a depreciation effect.

Baily and Chakrabarti compute the contribution of R&D to growth and to the slowdown of the 1980s. They conclude that at the most only a 0.15 percent decline in multi-factor productivity growth can be attributed to a weakness in R&D spending.¹⁴ Their look at R&D spending, therefore, fails to deliver clear evidence that the quantity of R&D spending fell enough to explain the decline in growth for this period of time. They also present case studies of different industries demonstrating that although there were exceptions, managers did take advantage of opportunities available to them. Thus, they conclude the decline in productivity growth was not a result of a decrease in technological opportunities.

Unfortunately, the results for the time period studied (1970-1985) still seem to run counter to the view that supports increasing R&D spending as a method to increase productivity and economic growth. According to Baily and Chakrabarti, technological opportunities may not progress to innovations that would result in productivity increases. Baily and Chakrabarti present three possibilities for the slowdown in productivity growth. First, the slowdown in the growth in productivity could have been caused by something that is unrelated to R&D or innovation. Second, technological opportunities could have declined, but econometric and modeling problems obscured the decline. The model this paper developed will not address these explanations. Instead, the model will be used to demonstrate that Baily and Chakrabarti's third explanation for the slowdown in productivity, specifically that it wasn't a collapse in technological change that decreased productivity, but a decrease in the pay-off from R&D, truly explains the slowdown in the growth of productivity. Technology performed acceptably during this time period, but the application of the technology to productivity was not successful. Therefore, productivity did not increase because the technology was not transferred, refined, or diffused to the industries where it could have been used to increase productivity.

This explanation, confirmed theoretically from the model, supports Baily and Chakrabarti's earlier data relating to the collapse of technological change by demonstrating not that innovation collapsed, but that the lack of diffusion caused the pay-off to decrease. It remains consistent with the view linking the pace of technological change to the magnitude of the resources devoted to R&D multiplied by the payoff to R&D, because it includes the payoff from R&D as a factor affecting productivity growth. Increasing resources devoted to R&D while simultaneously experiencing a decrease in the payoff from R&D of a similar magnitude would create a net zero gain in technological change's contribution to productivity.

The focus now returns to the original Cobb-Douglas function and the need to estimate the elasticity of output with respect to R&D, (Ω). The payoff from R&D can be measured by the value of this parameter and is directly related to R&D's contribution to multi-factor productivity growth. Based on the data from the past few decades, it also becomes the enabling variable in tying R&D expenditures to productivity and ultimately to economic growth. Without a system to realize the full benefit of R&D to commercial application, R&D spending does not generate significant increases in productivity. Baily and Chakrabarti conclude the same when they say, "the biggest problem lies in the failure to take advantage of opportunities... it is precisely in the area of commercialization of technology that the U.S. has had problems."¹⁵ Research and development expenditures must be supplemented with more effective means to increase the elasticity of output for the R&D input.

D. Realizing the Pay-off from R&D: Support for the Cobb-Douglas Production Function from Henry Ergas's Work

There are many observations in the literature that support the above conclusion. Most of these observations are framed within the debate of supporting the development process from basic research through commercial application. Many experts call for reforms in the current structure that include changes in policy,

relations with industrial firms, and attitudes both within the university and within industry.

Henry Ergas presents one of the best studies highlighting the effect of technology on economic growth, based on the experience of the major economies of the Organization for Economic Cooperation and Development. Ergas distinguishes two strategies for economic growth. The first pushes out the technological frontier by developing leading-edge technologies. The other strategy concentrates on diffusing technology that has already been developed. Ergas notes that while America has been very successful, recently, in pushing out the frontier, as noted by the increase in Nobel Prize winning scientists, countries such as Germany and Japan have been more effective at refining and diffusing these technologies into existing industry. Therefore, these countries demonstrated greater growth in productivity during the 1980s.¹⁶ Richard Nelson's cross-country analysis suggests similar conclusions.¹⁷

The most important element in Ergas's work is that taking advantage of available technology is more important to growth than creating new technology. Stated differently, productivity increases rely on diffusing and refining technology. Therefore, Japan and some European nations that have been effective in refining technology have enjoyed high productivity growth.¹⁸

Ergas's conclusions support Baily and Chakrabarti's studies demonstrating that the American slowdown occurred because the U.S. economy failed to incorporate new technologies efficiently into production rather than because the scientific frontier ceased to expand. Combining these findings into our previous conclusion, productivity growth and economic output are highly dependent not just on the funds appropriated to R&D spending, but on the elasticity of output with respect to R&D. Therefore, as evidenced by Germany and Japan during the 1980s, programs geared to increase this elasticity should result in greater economic growth from a given level of R&D spending.

Of course, it may not be appropriate for every country to follow a strategy of diffusion and catch-up as a method for increasing productivity growth. Someone has to be the leader. If everyone is diffusing technologies, then the question arises as to who is creating the technologies that will be used to generate the innovation and productivity growth of future generations? Bailly and Chakrabarti comment that “The entire game is dangerous because the very success of the countries that are catching up erodes the return to the pioneer.”¹⁹ The United States has been the recent leader, and this experience has created a disadvantage for American industries. Foreign countries borrowed what they needed and have put their efforts into refining products and improving processes. The United States has developed a comparative advantage in creating opportunities, and a comparative disadvantage in exploiting them. Unfortunately, Ergas’s work demonstrates that productivity gains result from the exploitation of creative ideas.

E. The Need for Government Programs and the Failure of the Market

Armed with this economic model, the study can now address the reason why the United States’ market system does not permit efficient economic growth, even though it invests extensively in R&D. This section will begin with a discussion of the failure of our current market system, illustrating why it is important for the government to take steps to ensure a pay-off from R&D. It will then present recent data attributable to the Bayh-Dole Act to demonstrate an example of a government program that can increase the pay-off from R&D. Based on the model this paper developed, government officials can now explain why the Bayh-Dole Act is one effective method to realize a larger return on the government’s investment in R&D.

The market system does not permit the natural diffusion of innovation to the market because the private sector under-invests in commercializing the results of basic research. This occurs for two reasons. First, capital markets may not be able to evaluate accurately the risks in pursuing commercial R&D. In order to

calculate the premium one would receive for assuming the risk of investing in R&D, there must be a means to establish the magnitude of that risk. This is difficult, and research shows that large organizations and capital markets cannot accurately evaluate this discount rate.²⁰

The second reason for under-investment is a result of the appropriability problem. This is defined as the gap between the private and the social rates of return to R&D, which creates an externality imposing an implicit tax on technology development. In simpler terms, the return to the innovating company may not match the returns to society. Private returns may not be enough to justify the innovation, even though the impact of the innovation on productivity growth would be tremendous.

The returns to private companies accrue from two sources. Either the cost of production is decreased, or a new or better product is created that can be sold at a greater profit. To recoup the costs of innovating, the innovator must sell at a price level above the average production cost. However, if it is possible to imitate the product, competing products or processes could drive the price down, pushing the profit margin below the cost of innovation. It becomes clear immediately that competition, the hallmark of our market system, may reduce innovation by reducing the return to the original innovator below a profitable point. As a result, it has been proposed that monopolists may have a greater incentive to innovate.²¹

Edwin Mansfield and Frederic Scherer have estimated the effect of one industry's R&D on the productivity growth rate in other industries using the same product. Mansfield found that the initial company's R&D is about one-third to one-half as important as the secondary company's R&D in influencing productivity growth.²² Using a more complicated approach, Scherer found that the first company's R&D was three times as important as the downstream firm's R&D in influencing productivity growth.²³ The important point is that both researchers conclude that much of the benefit of technical advance is passed on to consumers. Because this would not enter into the profitability calculations, the profitability to the

company may be too small to justify investment. One can thus conclude that the market economy provides insufficient incentives for efficient rates of expenditures on developing R&D.

The appropriability problem may also mean there is little or no private sector funding for basic research or for research in the “middle-ground.” Middle-ground projects can be defined as applied research projects that have commercial applications, but where the results are too general to make them attractive to private companies. Research and development will only be conducted where there is an adequate private rate of return. As we mentioned in Part B, however, the social rate of return is often much greater than the private rate of return, and the contribution to productivity growth should justify expenditures on developing some of these technologies.

In the United States there has been a noticeable absence of clear mechanisms to support middle-ground research. This is known as the “technological gap theory,” and it suggests that a large gap exists between scientific advances made in academic research and technologies exploited in the market.²⁴ This technology gap also creates a “funding gap.” Focused applied research requires an expenditure of resources universities do not have and industry is unwilling to fund.

One explanation for the lack of support for middle-ground research develops from our linear conception of the development process. To an important extent the following linear model of technology development has been perceived by the scientific community: innovations result from advances in basic scientific knowledge that are then applied by industry to products and processes. Industry often draws on scientific advances accomplished in universities and in research labs and performs applied research and development, turning these advances into marketable products or new processes.

This model is an oversimplification. It enshrines basic science as an isolated source of new knowledge needing nothing from the practical problems of the day. This simplification can be dangerous

for middle-ground research if important feedbacks that occur at each level are ignored. In the United States this misunderstanding of the technology linkage has resulted in no clear support for middle-ground research, and therefore, no means to realize a pay-off from R&D expenditures.

There are two avenues for increasing middle-ground research. The first is to provide more government funding in targeted development programs administered by the government. Linda Cohen and Roger Noll's, *The Technology Pork Barrel*, reviews the success of this strategy by examining six government projects.²⁵ They explain that targeted R&D programs are justified when there are exceptionally large economic spillovers that firms cannot capture. However, the numerous failures they review leads to the conclusion that the government-funded, targeted approach to increasing middle-ground research is not effective. The federal decision-making process, management pitfalls, and technological optimism on the part of the government technologist, who advocated the program, are all cited as major reasons for the failure.

The other avenue to increase middle-ground research would be to alter market conditions so that firms themselves will generate more of this type of research. Market conditions can be altered in a variety of ways such as by enacting tax breaks or creating incentive systems for investing in "middle-ground research." The Bayh-Dole Act is another example of a method to stimulate middle-ground research along this path, as this Act created incentives for the government, universities, industry and small businesses to engage in collaborative relationships involving the transfer of technology.

The Bayh-Dole Act (P.L. 96-517, later amended by P.L. 98-620) was the first in a series of federally mandated changes. Such changes also resulted in the Stevenson-Wydler Technology Innovation Act [(P.L. 96-480; later amended by the Federal Technology Transfer Act (FTTA) of 1986 (15 U.S.C. 3710))] and the Small Business Innovation Development Act (P.L. 97-219, as amended by P.L. 99-443, and P.L. 102-564). One of the important

provisions of the Bayh-Dole Act was that this Act created a uniform federal patent policy that clearly stated the universities may elect to retain title to inventions developed through government funding. The new assumption was that a synergy would exist when all the players (universities, government, and industry) were linked together, the grand total being far greater than the arithmetic sum of parts. The government was dramatically changing its approach to research commercialization as a result of stagnant productivity growth. The Bayh-Dole Act became a “Magna Carta” to the universities, offering the incentives needed to support investment in developing offices that could facilitate commercialization of university research and ideally attract more research funding to the university.

As Mowery and Ziedonis note,²⁶ prior to 1980 it was possible to retain title to university inventions discovered using federal funds. However, it was done on a case-by-case basis, and universities had to petition the federal government. Schools such as the University of California system had been engaged in this activity prior to 1980, and Mowery and Ziedonis even conclude that the growth in disclosures occurred prior to 1980.

The University of California system is the exception though. First, the study by Mowery and Ziedonis mentions only disclosures, and not other measurements such as licenses and investment streams. In addition, for the majority of universities, growth in university technology transfer really exploded only after 1980. Prior to 1980, fewer than 250 patents were issued to universities each year and only about 25 institutions engaged in technology transfer. The AUTM Survey data show that U.S. universities have averaged more than 1,800 U.S. patents issued annually since FY 1993, with more than 2,600 issued patents reported by 132 U.S. universities in 1998 alone.²⁷

Harvey Brooks presents a thorough picture of the development of science policy after World War II.²⁸ He states that before the late 1970s, patents issued for federally supported university research were usually assigned to the government, which had no particular mechanism or policy for fostering further development. Each

sponsoring agency had its own guidelines regarding patent policy, and exclusive licenses were rare. By 1978 the federal government had licensed only 4% of the 28,000 patents it owned. By the end of the 1980s, the situation had changed dramatically. Most universities with significant research programs had established policy guidelines and special offices to deal with intellectual property. The offices were becoming more aggressive in both patenting and licensing university inventions that were now assigned to the universities. The linear model, critiqued earlier, was losing its support, at least within the university-industry setting, and the gains were dramatic. This is illustrated below in accounts reviewing the performance since the Bayh-Dole Act.

First, the General Accounting Office's 1998 review concentrated on a review of the administration of the Act. It concluded the Act was working as Congress intended, with officials within the agencies and universities reporting a positive impact. The GAO concluded that the transfer of technology was occurring better than when the government retained title to inventions.²⁹

Second, according to the Association of University Technology Managers (AUTM), between 1991 and 1998, a review of data from a subset of the U.S. universities who provided data every year since 1991 shows that invention disclosures by U.S. universities increased by 59% since 1991. New patent applications for these universities increased by 164% for this same period, reflecting an average annual rate of increase of 15%. Licenses climbed by 120% at an average annual rate of increase of 12%. In 1999, AUTM reported that \$33.5 billion and 280,000 jobs were supported by the commercialization of university inventions during FY 1998. These jobs are high-paying, high-quality employment. AUTM estimated the sale of products developed from inventions made in the course of academic research amounted to \$29 billion in FY 1998.³⁰ In addition, Lori Pressman at M.I.T. reported that licensee companies invested an estimated \$4.5 billion prior to sales to bring the inventions to market.³¹

In addition, there are now more than 200 universities engaged in technology transfer, eight times more than in 1980. More than

1,900 companies have been formed through licensing activity since the inception of the Bayh-Dole Act.³² A recent study of patent applications shows that 73% of prior art cited in patents comes from publicly funded research.³³ Also, in a recent study by Pharmaceutical Research and Manufacturers of America, it was estimated that about 20% of a company's discovery budget will go into external funding, up from 4% in 1994. Collaborations, alliances, joint ventures within universities, labs, and industry will permit this growth.³⁴

These data clearly demonstrate that the Bayh-Dole Act, by allowing universities to elect to retain title to inventions developed under federally funded research programs and by encouraging the universities to collaborate with industry to promote the utilization of these inventions, has been an effective means to increase middle-ground research, and thereby, to increase the pay-off from R&D. As demonstrated earlier, this increase will ultimately affect productivity and economic growth.

The Bayh-Dole Act has narrowed the "technological gap" between research and product development, by permitting industry to become involved in the development of federally funded basic research. The result, according to our economic model, should be a growth in multi-factor productivity occurring with an appropriate lag period, which will translate into economic growth.

F. Conclusion

This paper began by presenting a model that demonstrates how government expenditures are translated into economic growth. After presenting the model, evidence was provided to justify the appropriateness of this model. Based on this model, the paper demonstrated that the "productivity crisis" of the 1980s resulted from no effective method for realizing a pay-off from R&D. The paper then presented a method to increase this pay-off, which lay in altering market conditions so that firms themselves will generate more of this type of research to increase "middle-ground" research and in offering the incentives needed to encourage the successful commercialization of research results. The Bayh-Dole Act was

presented as one example that increased output. Based on the success of the Bayh-Dole Act in stimulating the pay-off from R&D, we should expect to witness stronger economic growth in the years to come as a result of the nation's R&D investments.

NOTES

- ¹ For an excellent explanation of the Cobb-Douglas production function, see <http://cobweb.creighton.edu/knudsen/longrun1/sld001.htm>.
- ² P.L. 96-517, Patent and Trademark Amendments Act of 1980.
- ³ Robert M. Solow, "Technological Change and the Aggregate Production Function," *The Review of Economics and Statistics*, 39 (August 1957): 312-320.
- ⁴ Linda R. Cohen and Roger G. Noll, *The Technology Pork Barrel*, Washington D.C.: The Brookings Institution, 1991: 8.
- ⁵ Frederic M. Scherer, "Inter-Industry Technology Flows and Productivity Growth," *The Review of Economics and Statistics*, 64 (November 1982): 627-634.
- ⁶ Michael J. Boskin and Lawrence J. Lau, "Contributions of R&D to Economic Growth," edited by Smith and Barfield, *Technology, R&D, and the Economy*, Washington D.C.: The Brookings Institution, 1996: 75-113.
- ⁷ Cohen and Noll, 17.
- ⁸ M. Baily and A. K. Chakrabarti, *Innovation and the Productivity Crisis*, Washington D.C.: The Brookings Institution, 1988: 35.
- ⁹ Edwin Mansfield, "Microeconomics of Technological Innovation," edited by Ralph Landau and Nathan Rosenberg, *The Positive Sum Strategy: Harnessing Technology for Economic Growth*, Washington D.C.: National Academy Press, 1986: 307-325.
- ¹⁰ J. Stiglitz et al., *Supporting R&D to Promote Economic Growth: The Federal Government's Role*, Washington, D.C.: Council of Economic Advisors, October 1995.
- ¹¹ D. Coe and E. Helpman, *European Economic Review*, 39(859), 1995.
- ¹² Martin Baily and Alok Chakrabarti, *Innovation and the Productivity Crisis*, Washington, D.C.: The Brookings Institution, 1988: 1-5.
- ¹³ Edward F. Denison, *Trends in American Economic Growth, 1929-1982*, Washington, D.C.: The Brookings Institution, 1985.
- ¹⁴ Baily and Chakrabarti, 36-40.

- ¹⁵ Bailly and Chakrabarti, 119.
- ¹⁶ Henry Ergas, "Does Technology Policy Matter?" edited by Bruce R. Guile and Harvey Brooks, *Technology and Global Industry*, Washington D.C.: National Academy Press, 1987: 191-245.
- ¹⁷ Richard R. Nelson, *High Technology Policies: A Five Nation Comparison*, Washington D.C.: American Enterprise Institute, 1984.
- ¹⁸ Bailly and Chakrabarti, 103.
- ¹⁹ Bailly and Chakrabarti, 106.
- ²⁰ Cohen and Noll, 18.
- ²¹ Cohen and Noll, 25.
- ²² Edwin Mansfield, "Basic Research and Productivity Increase in Manufacturing," *American Economic Review*, 70 (December 1980): 863-873.
- ²³ Frederic M. Scherer, "Inter-Industry Technology Flows and Productivity Growth," *The Review of Economics and Statistics*, 64 (November 1982): 627-634.
- ²⁴ "The Government Role in Civilian Technology: Building a New Alliance," *National Academy of Sciences*, Washington D.C.: National Academy Press, 1992.
- ²⁵ Cohen and Noll, 50.
- ²⁶ David Mowery and Arvidis Ziedonis, "Biotechnology and the Law," Conference at U.C. Berkeley, 1997.
- ²⁷ AUTM Web site (www.autm.net), see Survey. Also, *AUTM Licensing Survey: FY1998*, edited by Daniel E. Massing, The Association of University Technology Managers, Inc. (AUTM), 1999.
- ²⁸ Harvey Brooks, "Evolution of U.S. Science Policy," edited by Smith and Barfield's, *Technology, R&D, and the Economy*, Washington D.C.: The Brookings Institution, 1996: 15-48.
- ²⁹ "Technology Transfer: Administration of the Bayh-Dole Act by Research Universities," *GAO Report* (RCED-98-126), May 7, 1998: 4.
- ³⁰ *AUTM Licensing Survey, FY 1998*, The Association of University Technology Managers, Inc. (AUTM), 1999.

- ³¹ Lori Pressman et al., "Pre-Production Investment and Jobs Induced by M.I.T. Exclusive Patent Licenses: A Preliminary Model to Measure the Economic Impact of University Licensing," *Journal of the Association of University Technology Managers*, Vol. 7. The Association of University Technology Managers, Inc., 1995. Updated by the "Summary Estimated Sales on Licensed Technologies, Pre-Production Investment, and Jobs Projection (FY98 and FY97)," Association of University Technology Managers, 1999.
- ³² Kenneth D. Campbell, *M.I.T. Tech Talk*, April 15, 1998.
- ³³ F. Narin et al., "The Increasing linkage Between U.S. Technology and Public Science," (unpublished), 1998.
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Assessing the Effectiveness of Technology Transfer Offices at U.S. Research Universities

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ABSTRACT

Since passage of the 1980 Bayl-Dole Act, almost all U.S. research universities have established an office of technology licensing intended to facilitate technology transfer to private companies. We developed a six-item scale to measure *technology transfer effectiveness*—defined as the degree to which research-based information is moved successfully from one individual or organization to another—for 131 U.S. research universities. Universities that are relatively more effective in technology transfer are characterized by (1) higher average faculty salaries, (2) a larger number of staff for technology licensing, (3) a higher value of private gifts, grants and contracts, and (4) more R&D funding from industry and federal sources.

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During recent decades American research universities have become increasingly involved in various technology transfer activities by establishing technology business incubators (Miar 1997; Tornatzky, Batts, McCrea, Lewis & Quittman 1996), technology parks, venture capital funds for start-up companies, university research foundations, and technology licensing offices (AUTM, 1998). This trend toward what Slaughter and Leslie (1997) called “academic capitalism” is also illustrated by an increase in the number of university-based research centers (Cohen, Florida, & Goe 1994), and by the tendency for some universities to retain partial ownership in the start-up companies spinning out of university research. Through this variety of boundary-spanning activities, research universities seek to facilitate the transfer of technological innovations to private companies in order (1) to create jobs and to contribute to local economic development, and (2) to earn additional funding for university research. Technology transfer from research universities has been increasingly recognized as an engine for economic growth in the United States (DeVol 1999; Slaughter & Leslie 1997). This relatively new role for research universities has been greeted with considerable discussion and debate (Campbell 1997; Lowen 1997).

The purpose of the research presented here is to investigate the role of the office of technology licensing at American research universities in transferring research results to private companies in the form of licensed technologies. Despite the growing importance of technology transfer from university research to private companies, relatively little investigation has been conducted on this topic to date.

The present study addresses three main research questions:

- #1. How did the innovation of establishing an office of technology transfer diffuse among research universities in the United States?*
- #2. Can a measure of technology transfer effectiveness be developed for U.S. research universities?*

#3. What are the characteristics of research universities that are relatively higher and relatively lower in technology transfer effectiveness?

A *research university* is a university whose primary missions emphasize (1) the conduct of research, and (2) the training of graduate students in how to conduct research. The first research universities developed in Germany; examples were the University of Göttingen (founded in 1737) and the University of Berlin (established in 1810). The idea of the research university spread to the United States: First to Johns Hopkins University (which began in 1876) and Clark University (in 1890), and then to Stanford University (in 1891) and the University of Chicago (in 1892). Today, several hundred U.S. universities consider themselves research universities, and the number is increasing. Our present study is based on data from 131 research universities that responded to an annual survey about technology transfer during FY 1996 from AUTM (the Association of University Technology Managers).²

The Diffusion of University Offices of Technology Transfer

Here we answer Research Question #1: *How did the innovation of establishing an office of technology transfer diffuse among research universities in the United States?* While some U.S. research universities established an office of technology licensing as early as 1925 (the University of Wisconsin at Madison), 1935 (Iowa State University), and 1940 (MIT), most research universities did not adopt this idea until after 1970. Wisconsin and, later, Stanford University, served as the model for many other research universities as they became increasingly involved in technology transfer through a marketing approach. The Bayh-Dole Patent and Trademark Amendments Act of 1980, amended by Public Law 98-620 in 1984, facilitated patenting and licensing on a broad scale by research universities (Sandelin 1994). This legislation shifted the responsibility for the transfer of technologies

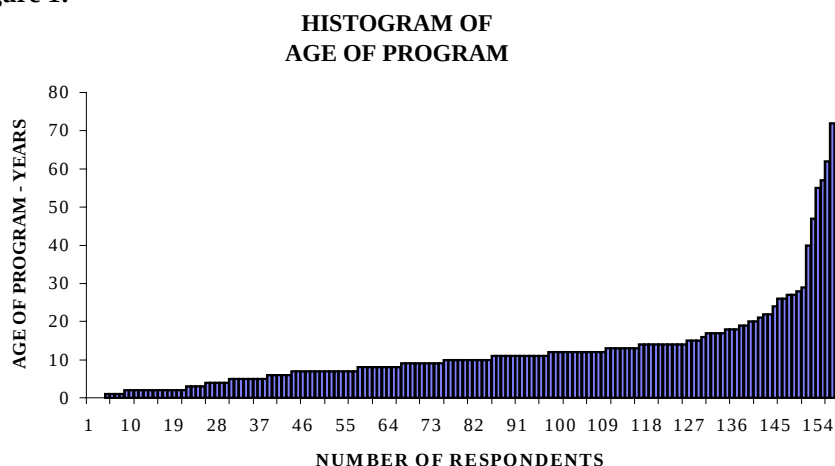
stemming from federally funded research, from the federal government to the research universities that conducted the research. The Bayh-Dole Act has been called “the ‘Magna Carta’ for university technology transfer” (Jamison, 1999). According to Sandelin (1994), at least 60 percent of all invention disclosures at universities arise from federally funded research, and so university offices of technology transfer have defined their role on the basis of the Bayh-Dole Act. Sandelin concluded from his analysis: “By almost any measure, the passage of Public Law 96-517 [the Bayh-Dole Act] achieved the intended results: To encourage the disclosure and protection of innovation from publicly supported research; and to see the commercial development of products from such innovation for public benefit.”

The rise of biotechnology R&D and, more generally, of research in the life sciences, since the early 1980s also boosted the number of research universities with offices of technology licensing, and increased the incomes earned by these offices (Mowery, Nelson, Sampat & Ziedonis 1999). Today, at least 70 percent of all license income earned by universities comes from the life sciences, with the remainder mainly from the physical sciences, including engineering (AUTM 1998). Mowery et al. (1999) found that most invention disclosures, patents, and licensing at Columbia University were concentrated in a very small number of departments: The medical school, electrical engineering, and computer science. Our visits to a dozen research universities in 1999 suggest a similar degree of concentration of technology transfer activity in a relatively few departments at each university. The exact departments vary somewhat from university to university, but medicine, veterinary medicine, microbiology and biology, computer science, electrical engineering, chemistry, and agriculture (especially crop science) are frequently sources of patents, licenses, and start-ups.

Membership in the Association of University Technology Managers has grown to over 2,000 individuals (about half are affiliate members, meaning they are not employees of a university or academic research or medical center), with virtually all U.S.

research universities now having an office of technology licensing (Figure 1). All of the dozen universities that we visited in 1999 were becoming more proactive in seeking innovation disclosures from faculty members, in patenting technologies, and in marketing the intellectual property rights to these technologies to private companies. All of the universities that we visited were expanding the staff of their office of technology transfer, with several doubling the number of staff.

Figure 1:



The spread of university offices of technology licensing followed this curve (published in the FY 1996 AUTM Licensing Survey) that is characteristic of the cumulative rate of adoption of an innovation (Rogers 1995), with larger, more research-oriented universities tending to adopt first, followed over ensuing years by universities with a smaller amount of external research funding and that devote fewer resources to R&D and to technology transfer (Table 1). Selected characteristics of research universities are shown by deciles (categories each containing ten percent of the survey participants) in their date of establishing an office of technology transfer in Table 2. The date of adoption is indicated by the first year in which a university reported in the AUTM Survey

that it devoted at least 0.5 FTE to technology transfer.

Table 1. Characteristics of 131 U.S. Research Universities Using NSF 1996 Data Related to Their Date of Establishing an Office of Technology Transfer Using 1996 AUTM Data Ranked by the Zero-Order Correlation (r).

Characteristics of Research Universities	Number of Research Universities Reporting Program Start Date	Relationships with the Date of Establishing an Office of Technology Transfer ^a	
		Zero-Order Correlation (r)	Coefficient of Multiple Correlation (R^2)
1. Number of Professional Staff for Technology Transfer	113	.264**	.217*
2. Non-Faculty Research Staff	66	.258*	-.027
3. Private Gifts, Grants, and Contracts	98	.251*	.070
4. Federally Funded R&D Expenditures	111	.243*	.009
5. Total R&D Expenditures	112	.240*	.016
6. Number of Support Staff for Technology Transfer	106	.234*	-.048
7. Industry R&D Expenditures	110	.234*	.002
8. Average Faculty Salary	111	.227*	.079
9. State and Local Govt. R&D Expenditures	111	.217*	.116
10. Total Graduate S&E Students	112	.216*	.176
11. Other R&D Expenditures	97	.207*	.012
12. Total S&E Postdoctorates	111	.197*	-.133
13. Equipment (book value)	96	.176	-.214*
14. Library Expenditures	98	.158	.040
15. Endowment Income	88	.136	.162
16. Endowment (market value)	95	.131	-.098
17. Buildings (book value)	96	.119	-.269**
18. Institutional R&D Expenditures	109	.119	-.049
19. Number of Faculty	111	.055	-.259**
20. Opening Fall Enrollment of Students	97	.035	.081
21. Land (book value)	96	.015	-.012

* Correlations significantly different from zero at the 5 percent level.

** Correlations significantly different from zero at the 1 percent level.

a The date of adoption is the year in which a university reported assigning at least 0.5 FTE to technology transfer (AUTM 1997).

For the 113 universities that reported a start-date for their office of technology transfer, Table 1 shows that the number of professional staff in this office is correlated .264 with the date of establishing the office. Thus, the number of staff are an important correlate of the start-date. This relationship is also shown in Table 2 by the decreasing average number of professional staff in the office of technology transfer by deciles in the date of establishing this office. For example, the first decile of 11 universities to have an office averaged five professional staff while the last decile of 14 universities averaged one professional staff member.

Table 1 also shows that when the effect of the other 20 university characteristics was removed (by multiple correlation) from the correlation between the number of professional staff and the date at which a university started its office of technology transfer, the zero-order correlation of .264 dropped to a multiple correlation of .217. Thus, when other variables are removed staff continue to be highly related to the program start-date.

R&D expenditures of a university in Table 1 are correlated .240 with the date of establishing an office of technology transfer. When the other 20 variables were controlled by multiple correlation, however, this correlation of .240 dropped to .016, which is not significantly different from zero. In other words, when one removes the affect of all other variables Research Expenditures becomes less of an indicator as to when the office started than when all selected characteristics are considered.

Table 2 is presented on the following page and, as stated above, shows the correlation of staff with program start-date. It can also be observed from Table 2 that the programs with the earlier average Year of Adoption of 0.5 FTE Assigned to Technology Transfer, reflect universities with higher total R&D expenditures, enrollments, and number of faculty.

Table 2. Averages on Selected Characteristics of 131 U.S. Research Universities Using FY 1996 Data Ranked as to Their Year of Adoption of 0.5 FTE in Technology Transfer.

	Selected Characteristics of 131 U.S. Research Universities							
	Year of Adoption (0.5 FTE Assigned to Tech. Transfer)	N	Tech. Transfer Effectiveness Scores ^a	No. of Prof. Staff for Tech. Transfer	Total R&D Expend. (\$000)	Enrollment	No. of Faculty	Annual License Income
(Highest in Start Date)								
1 st	1956	11	38 th	5	\$206,901	19,668	1,881	\$7.3 Mil
2 nd	1978	11	28 th	9	\$386,561	43,442	1,569	\$7.9 Mil
3 rd	1982	11	50 th	4	\$175,477	19,340	1,094	\$6.8 Mil
4 th	1984	11	63 rd	2	\$131,443	14,081	1,258	\$1.5 Mil
5 th	1986	11	59 th	2	\$108,482	18,198	1,238	\$2.3 Mil
6 th	1987	11	61 st	2	\$136,213	26,930	772	\$1.0 Mil
7 th	1989	11	62 nd	3	\$135,499	14,677	638	\$1.0 Mil
8 th	1990	11	87 th	2	\$90,764	17,781	595	\$0.5 Mil
9 th	1993	11	60 th	2	\$148,893	23,636	768	\$3.1 Mil
10 th	1995	14	96 th	1	\$56,275	22,277	470	\$0.7 Mil
(Lowest in Start Date)								

^a Details on calculations of the technology transfer effectiveness scores are discussed on page 62.

The diffusion of technology transfer offices may have been influenced by the so-called “big winner” technologies that have occurred at some universities. Examples are the \$160 million that Michigan State University has earned over the life of two cancer-related patents (Blumenstyk 1999), the \$37 million that the University of Florida has earned from the sports drink Gatorade, the \$27 million that Iowa State University has been paid for the fax algorithm, and the \$143 million earned by Stanford University for the recombinant DNA gene-splicing patent (Odza 1996). A “big winner” can dominate the total license income at a research university; for example, \$18 million of Michigan State University’s \$18.3 license income in FY 1997 came from the two cancer-related drugs (Erbisch 1999).

The AUTM Licensing Survey—administered by AUTM on an annual basis—of United States and Canadian research universities includes 89 percent of the top 100 U.S. research universities (as determined by the National Science Foundation). Various indicators of technology transfer from university offices of technology licensing are shown in Table 3 on the following page. The AUTM surveys indicate that all measures of technology transfer from U.S. research universities increased from FY 1996 to FY 1997. This upward trend in indicators of technology transfer activity has been reported by the AUTM annual surveys since the first year for which the survey reported data, FY 1991 (see Table 3).

Much of the university share of technology licensing income noted in Table 3 at \$483 million in FY 1997, was used by research universities to support further research, providing a return on investment for the public funding of research universities. Of the sponsored research expenditures of \$21.4 billion by the research universities responding to the 1996 AUTM Survey, \$13.9 billion (65 percent) came from the federal government and \$1.9 billion (9 percent) came from private industry (AUTM 1997). The balance of \$5.6 billion (26 percent) came from a variety of sources including foundations and state and local governments.

Table 3. Indicators of Technology Transfer from University Offices of Technology Licensing.

Indicators of Technology Transfer	FY 1996 (N=131)	FY 1997 (N=132)	% Increase 1996-1997
1. Number of invention disclosures	8,119	9,051	+12%
2. Number of new U.S. patent applications	2,734	3,644	+33%
3. Number of U.S. patents issued	1,776	2,239	+26%
4. Number of new technology licenses	2,209	2,707	+23%
5. Number of start-up companies	184	258	+40%
6. License income	\$365 Mil	\$483 Mil	+32%
7. U.S. economic activity attributed to technology transfer from academic institutions ^(a)	\$24.8 Bil	\$28.7 Bil	+16%
8. Number of jobs, supported by technology transfer from academic institutions ^(b)	212,500	245,930	+16%
9. Number of technology licenses to small companies	1,099	1,135	+3%

Note (a) and (b): These data are based on total participants in the survey in each year, respectively; specifically, 159 U.S. universities, teaching hospitals, research institutes, patent management firms and 14 Canadian institutions in FY 1996 and a similar number of participants (175) in FY 1997.

Detractors of university patenting and licensing point to such potential problems as possible conflicts of interest that may be created for faculty members, delays in publication of research results to accommodate patent filing or to benefit university-licensed companies, and the possible shift from basic research to more applied research, which has a higher potential for yielding patents and licenses (Sandelin 1994; Campbell 1997). However, Mowery et al. (1999) found that little shift to more applied research had occurred due to the Bayh-Dole Act at Columbia University, Stanford University, or in the University of California System.

In general, “Doing technology transfer is an integral part of being a first-rate research university” (Tornatzky & Bauman 1997). We summarize our answer to Research Question #1 regarding the diffusion of university offices of technology transfer as due (1) to the 1980 Bayh-Dole Act; (2) to the growth of the biotechnology and other life sciences industries and their reliance on academic research and its resulting patents; and, perhaps, (3) to the attraction of scoring a “big winner” (a technology that can be marketed by a university for several million dollars).

Technology Transfer Effectiveness

Why are some research universities much more active in technology transfer activities than are others? The Stanford University Office of Technology Licensing (OTL) earned an income of \$52 million from license income in FY 1997, which is the equivalent of 13 percent of the University’s total sponsored research expenditures. The OTL staff of 19 handled 248 invention disclosures, filed 128 new patents, licensed 15 start-up companies, managed 272 licensed technologies that yielded income in 1997, and reported over 1,044 active technology licenses (AUTM 1998). The mission of the Stanford University OTL “is to promote the transfer of Stanford technology for society’s use and benefit while generating unrestricted income to support research and education” (Sandelin 1994).

During 1997, MIT’s office of technology licensing, with a staff of 27, had 360 invention disclosures, filed 200 new patents, licensed 17 start-up companies, managed 255 licenses that yielded income, and earned \$21.2 million in technology license income (AUTM 1998). MIT’s 205 active patent licenses as of 1993 (reported at 463 by FY 1997) were associated with almost one billion dollars of investment and created 2,000 jobs (Pressman et al. 1995). Spin-off companies from MIT accounted for only 35 percent of the technology licenses, yet created 77 percent of the induced investment and 70 percent of the jobs.

In comparison to Stanford and MIT, the office of technology licensing at a smaller research university in FY 1997 handled three invention disclosures and applied for six patents. Two of this university's technologies were licensed, and the annual license income was about \$25,000. The staff of this university's office of technology licensing consisted of one person, part-time. So while most research universities have offices of technology transfer, the accomplishments of these offices vary considerably. How can these university-to-university differences in the performance of offices of technology transfer be measured?

Technology is information that is put into use in order to accomplish some task (Rogers 1995). *Technology transfer* is the application of information into use (Rogers 1995). *Technology transfer effectiveness* is the degree to which research-based information is moved successfully from one individual or organization to another.⁴ O'Keefe (1982) and Bozeman (1994) argued that a lack of agreement on the conceptualization of technology transfer effectiveness is one obstacle to its study. Past scholarly writing indicates a variety of definitions and measurements of technology transfer effectiveness.

Bozeman (1994) utilized the number of technology licenses, a federal R&D laboratory's ability to get other organizations to use the technology they created, the commercial impacts on the organizations receiving these technologies, and the level of monetary benefits to both the federal R&D laboratory and to individual researchers, as measures of technology transfer effectiveness from federal R&D laboratories. With the exception of the number of technology licenses, the other variables in Bozeman's measure are laboratory directors' perceptions. For example, the ability of federal laboratories to convince other organizations to use their technologies, and the commercial impacts on the organizations receiving these technologies were rated by the directors of the federal R&D laboratories. The validity of such measures, based on the perceptions of individuals who might have a vested interest in presenting a favorable picture of their organizations' accomplishments, might be questionable.

Geisler and Clements (1995) measured the success of technology transfer activities by federal R&D laboratories to commercial companies as (1) the number of cooperative research and development agreements (CRADAs) with private companies, (2) the number of technology licenses, and (3) the perceived impacts of the technologies transferred on commercial applications as estimated by respondents both in federal R&D laboratories and in private companies. This measure reflects the perspectives of the receivers of the technologies developed by federal R&D laboratories, as well as the federal laboratories' perspectives. However, such measures of technology transfer effectiveness again depend on perceptions rather than on more objective data, such as the number of technology licenses, patents, and so forth actually achieved.

Sandelin (1994) argued that patenting and licensing are useful and obvious measures of technologies transferred from universities. Muir (1993) utilized such indicators of the performance of university technology transfer offices as invention disclosures, evaluations of inventions by prospective receivers in industry, income-generating and industrial R&D support agreements, patents, and institutional support for a technology transfer office. However, Muir's measure of the effectiveness of a technology transfer office did not include the income yielded by technology licensing and other types of technology transfer. In his effort to develop comparative measures of university licensing activities, Trune (1996) suggested using the number of invention disclosures, the number of licenses/options executed, the amount of license income received, the number of research dollars, the number of licenses generating income, and the number of licenses active, as individual measures of the performance of research universities in technology transfer. However, Trune did not construct a composite measure of the overall technology transfer effectiveness of research universities.

Developing a Measure of Technology Transfer Effectiveness

The present study (1) proposes a composite measure of technology transfer effectiveness, and (2) then investigates factors that influence the relative effectiveness of technology transfer from U.S. research universities to other organizations, mainly private companies. Research Question #2 is: *Can a measure of technology transfer effectiveness be developed for U.S. research universities?* We previously defined technology transfer effectiveness as the degree to which research-based information is successfully moved from one individual or organization to another. The present study seeks to develop a composite measure of technology transfer effectiveness for each research university of study.

Technology transfer from a research university is a process consisting of several steps (Figure 2). The first step in the process is an invention disclosure, recognition of the information about a new technology developed by a faculty member, a graduate student, or a staff member in a university that is conveyed to the university's office of technology licensing.⁵ A second step in the technology transfer process is patenting. Once a new technology is patented by a research university, the university owns the intellectual property rights and can license the patented technology to another organization. The next step in the process occurs when an individual or organization, usually a commercial company, secures a license from the research university for the patented technology. After this licensing agreement is executed, and, given commercial uses of the licensee, the research university may begin earning income from the transferred technology.

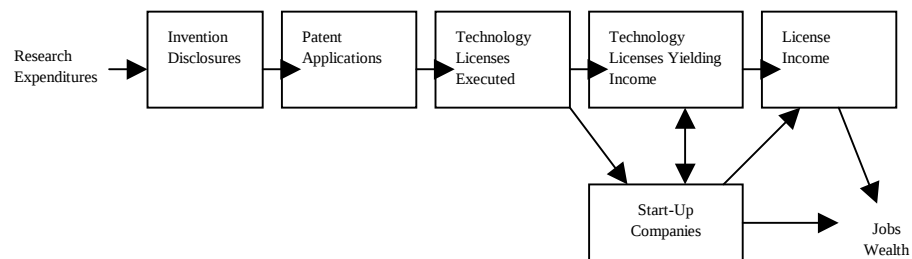


Figure 2: The Process of Technology Transfer from a Research University.

This technology transfer process often requires several years after a technology is patented before the university earns royalties (income from product sales) from the licensed technology. Since technology transfer from research universities is a process, it is valuable to take all of the main steps in this process into consideration in measuring technology transfer effectiveness, rather than using just a single variable indicating one step in the process.

The number of start-up companies from a university should be included in a comprehensive measure of the technology transfer effectiveness for a research university. In a commercial context, a *spin-off company* is a new company that is formed (1) by former employee(s) of a parent organization, (2) around a core technology that originated in, and then was transferred to, the new company (Carayannis, Rogers, Kurihara & Allbritton 1998; Steffensen, Rogers & Speakman 1998). A university-related start-up company (essentially similar to a spin-off) obtains a new technology by licensing it from a university's office of technology transfer. In FY 1997, 11 percent of the licenses were to start-up companies (AUTM 1998). Thus technology transfer from research universities contributes to creating new commercial companies, and thus jobs and economic growth.

The present study utilizes six variables to measure technology transfer effectiveness from a research university: (1) the number of invention disclosures received, (2) the number of U.S. patents filed, (3) the number of licenses/options executed, (4) the number of licenses/options yielding income, (5) the number of start-up companies, and (6) the gross licensing income received. Our six-item scale reflects certain of the four dimensions of technology transfer strategies utilized by federal R&D laboratories, as suggested by Shama (1992):

1. Passive technology transfer, such as publishing research results in scientific journal articles or making invention disclosures (our scale item #1).

2. Active technology transfer, such as filing patent applications (scale item #2), executing technology licenses and options (scale item #3), obtaining income from licenses/options (scale item #4), and earning income from technology licenses (scale item #6).
3. Entrepreneurial technology transfer, as indicated by the number of start-up companies (scale item #5).
4. Technology transfer for local economic development (none of our six scale items index this variable, although we could calculate a measure of it if data were available in the AUTM surveys).

In response to Research Question #2, *Can a measure of technology transfer effectiveness be developed for U.S. research universities?*, we developed a measure of technology transfer effectiveness for U.S. research universities; this scale appears to be internally reliable, and is generally consistent from one year to the next. Data for 131 U.S. universities on the six variables of study were obtained from the AUTM Licensing Survey for FY 1996 (AUTM 1997).⁶ The six variables are expressed in different measurement units, from the number of patents, to millions of dollars of licensing income. In order to make these variables comparable, we converted each of the six variables to standard scores (z-scores).⁷ Thus we treat each of the six variables as equally important contributions to the technology transfer effectiveness of a U.S. research university. The composite measure of technology transfer effectiveness for each university is obtained by averaging each university's z-scores for the six variables, rank-ordering the 131 universities on the basis of their average z-scores for the technology transfer effectiveness measure, and assigning rank scores from 1 (highest technology transfer effectiveness) to 131 (lowest technology transfer effectiveness).⁸

The reliability of this six-item measure is indicated by Cronbach's alpha, a coefficient of the internal consistency of the scale items (Cronbach 1951; Carmines & Zeller 1979), of .95. The internal

consistency of a scale is the proportion of common variance in an index with multiple scale items (Bowers & Courtright 1984). The six variables are highly intercorrelated with each other and all are significantly associated with the composite six-item measure of technology transfer effectiveness (see Table 4). These correlations are all still significantly different from zero at the 1 percent level of significance when the effect of including each scale variable in the composite six-item measure is removed.

Table 4 shows that the number of invention disclosures at each of the 131 universities is correlated .884 with total technology transfer effectiveness scores, which means that they share 78 percent of common variance (computed by squaring the correlation of .884). Similar interpretations may be made for the other variables as well. In comparison, Table 4 shows that the number of start-ups from each university is correlated .718 with total technology transfer scores, explaining 51.6 percent common variance. Again, other similar interpretations could be made for the other variables.

Each of the six indicators of technology transfer effectiveness in Table 4 are highly related to the total (six-item) scores, with each of the six variables explaining a unique part of the variance in the total scores. This result was expected; each of the six indicators contribute a unique part of the variance in total technology transfer scores (as was suggested by Figure 2). Of importance is that the variables are more highly correlated with the six-item composite measure (see last column in Table 4), than when compared to a single variable. This finding supports the theory that all variables combined are more critical to technology transfer effectiveness than are one single variable. For example, total U.S. patent applications filed are correlated .928 with the six-item scale considered, compared to a range from .693 to .893 when patent applications are correlated with each of the other scale items.

Table 4. Correlations of Six Technology Transfer Effectiveness Scale Items for 131 U.S. Universities in Fiscal Year 1996.

Effectiveness Scale Items	Intercorrelations of Effectiveness Scale Items						
	1	2	3	4	5	6	7 ^a
1. Invention disclosures received	--	.943* *	.777* *	.850* *	.686* *	.692* *	.884* *
2. Total U.S. patent applications filed		--	.828* *	.893* *	.693* *	.755* *	.928* *
3. Licenses and options executed			--	.873* *	.730* *	.696* *	.872* *
4. Licenses/options yielding income				--	.650* *	.810* *	.919* *
5. Number of start-ups					--	.551* *	.718* *
6. Gross license income received						--	.768* *
7. Technology transfer effectiveness scores							--

** These correlations are significantly different from zero at the 1 percent level of significance.

^a These item-total score correlations are adjusted by removing the effect of including each scale item in the total scores.

Several U.S. universities did not respond to all of the questions asked in the FY 1996 AUTM Licensing Survey questionnaire. The mean of a variable for all of the universities responding on that variable was used to estimate the missing data needed to complete the data set for Table 4.⁹

Table 5, shown on the following page, expresses the six-item composite measure of technology transfer effectiveness as the rank-order of the 131 U.S. research universities responding to the FY 1996 AUTM Survey (Table 5) and groups these universities in accordance with that ranked order by deciles.¹⁰ It may be observed in Table 5 that the research universities that have a higher computed technology transfer effectiveness score report more technology transfer activity, demonstrated by a higher average number of invention disclosures, patent applications filed, licenses executed, and start-ups formed per decile.

Table 5. Deciles of the 131 U.S. Research Universities' Scores on Technology Transfer Effectiveness Using FY 1996 Data Ranked by Technology Transfer Effectiveness and Grouped by Deciles.

	Average Technology Transfer Measures							
	N	Technology Transfer Effectiveness Scores	No. of Invention Disclosures	No. of U.S. Patents Filed	No. of Licenses Executed	No. of Licenses Yielding Income	No. of Start-Up Companies	License Income Received
(Highest technology transfer effectiveness scores)								
1 st	13	7 th	227	115	71	163	5.8	\$15.5 Mil
2 nd	13	20 th	109	57	38	77	2.4	\$4.9 Mil
3 rd	13	33 rd	90	39	19	53	1.6	\$2.5 Mil
4 th	13	46 th	55	20	13	27	1.8	\$1.5 Mil
5 th	13	59 th	43	20	9	19	1.2	\$1.4 Mil
6 th	13	72 nd	38	15	7	14	.6	\$0.7 Mil
7 th	13	85 th	23	12	4	11	.4	\$1.2 Mil
8 th	13	98 th	19	9	4	7	.2	\$0.2 Mil
9 th	13	111 th	16	7	2	7	0	\$0.2 Mil
10 th	13	124 th	4	3	1	2	0	\$0.03 Mil
(Lowest technology transfer effectiveness scores)								

Characteristics of Universities Related to Technology Transfer Effectiveness

Research Question #3 is: *What are the characteristics of research universities that are relatively higher and relatively lower in technology transfer effectiveness?*

In order to determine the factors related to the technology transfer effectiveness scores of the research universities of study, we used data provided mainly by the National Science Foundation. Twenty-one characteristics of research universities in 1996 are examined: (1) professional FTEs for technology licensing, (2) support staff for technology transfer, (3) endowment assets at the end of the year, expressed at market value, (4) endowment income, (5) total R&D expenditures, (6) Federally funded R&D expenditures, (7) R&D expenditures provided by state and local government, (8) R&D expenditures provided by industry, (9) institutional R&D expenditures, (10) other R&D expenditures, (11) land value (book value at the end of the year), (12) buildings value (book value at the end of the year), (13) equipment value (book value at the end of the year), (14) private gifts, grants, and contracts, (15) number of students at fall enrollment, (16) number of faculty, (17) average faculty salary, (18) number of non-research staff, (19) total graduate science and engineering (S&E) students, (20) total S&E postdoctoral fellows, and (21) library expenditures.¹¹

The Carnegie Foundation's (1987) categories of research universities also serve as one independent variable in the present study. Trune (1995) noted that due to differences in resources, infrastructure, size, local industry, and teaching and research priorities, it is difficult to compare universities in their technology transfer effectiveness. We prefer to utilize such independent variables (as these characteristics of universities) to explain the technology transfer effectiveness scores of the 131 research universities. An alternative research strategy, discussed later in the Conclusions section, would be to calculate ratio measures of technology transfer effectiveness, e.g., by dividing this score by the millions of dollars of total R&D expenditures of a university. Such

ratio measures help remove the influence of university size from indicators of technology transfer effectiveness.

We used the Carnegie Foundation (1987) categories to examine differences in the technology transfer effectiveness of our 131 research universities of study in FY 1996. The Carnegie Foundation categories¹² are (1) Research Universities I, (2) Research Universities II, (3) Doctorate-Granting Universities I, (4) Doctorate-Granting Universities II, (5) Comprehensive Universities and Colleges I, and (6) Medical Schools and Medical Centers. The Carnegie Foundation categories of research universities differ in technology transfer effectiveness, with the 72 Research Universities I having higher effectiveness (Table 6).

Table 6. Technology Transfer Activities by Research Universities by Carnegie Category.

Carnegie Categories	No. of Research Universities	No. of Start-up Companies	License Income	Mean Technology Transfer Effectiveness Scores ^a
1. Research Universities I	72	2.2817 ^b	4,733,625 ^c	41 st
2. Research Universities II	20	.3500	576,712	93 rd
3. Comprehensive Universities I	4	.5000	104,404	96 th
4. Doctorate-Granting Universities I	6	.0000	116,060	117 th
5. Doctorate-Granting Universities II	14	.5714	132,166	103 rd
6. Medical Schools and Medical Centers	11	.4545	871,885	79 th
Totals	127 ²	1.4603	2,873,309	--

^a Expressed in rank-ordered scores from 1st to 131st.

^b These means are significantly different at the 1 percent level of significance (for the other 55 research universities).

^c The Carnegie Category for four research universities was not available.

Start-up companies are an important means of moving technology from a research university to private companies (Rogers et al. 1999). The Carnegie categories of research universities had different numbers of start-up companies in 1996, and they differed considerably in average license income (see Table 6), depending on what Carnegie Category is observed. These findings are consistent with our results as they confirm that universities committed to research, i.e., Research Universities I, have a higher technology transfer effectiveness score.

Table 7 shows selected characteristics of the 131 research universities studied ranked by the average technology transfer effectiveness score per decile. Table 8 lists the 21 characteristics of research universities selected from NSF data ranked by their zero-order correlation. All 21 independent variables are significantly related to technology transfer effectiveness scores on the basis of zero-order correlations (r); that is, without controlling on the other 20 independent variables.

A multiple regression analysis identified the relationships of each of the 21 independent variables in Table 8 with the dependent variable of technology transfer effectiveness scores, while controlling on the other independent variables. The 21 independent variables were entered in a linear regression model in a stepwise manner. Table 8 shows that, for example, total R&D expenditures by each university correlated .855 with technology transfer effectiveness scores. But when the effect of the other 20 variables describing the 131 universities were removed (by multiple correlation) from the relationship of total R&D expenditures with technology transfer effectiveness, this correlation dropped to .024 (R^2). In other words, total R&D expenditures is so highly interrelated with certain of the other 20 characteristics (such as indicators of university size) that this variable's correlation with technology transfer effectiveness shrank to almost no relationship when studied alone.

Table 7. Selected Characteristics of 131 U.S. Research Universities
Ranked as to Technology Transfer Effectiveness.

	Enroll- ment	No. of Faculty	Averag e Faculty Salary (\$)	University Resources ^a (\$000)	% with a Medical School	Total R&D Expend. (\$000)	Federally Financed R&D Expend. (\$000)	No. of Staff in Tech. Transfer ^b
(Highest in technology transfer effective- ness scores)								
1 st	38,304	1,881	73,080	4,086,265	77%	453,901	306,137	21.3
2 nd	19,035	1,569	63,866	2,020,969	77%	236,772	132,874	7.7
3 rd	18,171	1,094	62,092	1,765,048	62%	182,757	109,188	4.8
4 th	18,678	1,258	58,375	1,424,632	69%	148,646	87,998	5.2
5 th	18,684	1,238	59,999	1,442,230	77%	112,430	64,476	3.5
6 th	14,773	772	61,100	661,232	69%	100,805	56,512	2.8
7 th	15,054	638	53,823	499,836	46%	71,559	35,775	2.2
8 th	9,710	595	48,351	277,514	38%	39,568	20,040	1.9
9 th	16,022	768	55,187	572,146	31%	45,463	23,250	1.5
10 th	12,182	470	45,032	279,196	21%	19,163	11,146	.6
(Lowest in technology transfer effective- ness scores)								

^a University resources include land, buildings and equipment (book values), endowment (book value, market value) and endowment income.

^b The number of staff in technology transfer includes the number of professional staff and the number of support staff in technology transfer.

Table 8. Selected Characteristics of Research Universities Related to Technology Transfer Effectiveness Scores.

Characteristics of Research Universities	Relationships with Technology Transfer Effectiveness Scores	
	Zero-Order Correlation (r)	Coefficient of Multiple Correlation (R^2)
1. Number of Professional Staff for Technology Transfer	.834**	.128
2. Number of Support Staff for Technology Transfer	.857**	.285**
3. Endowment (market value)	.318**	-.168
4. Endowment Income	.302**	.214*
5. Total R&D Expenditures	.855**	.024
6. Federally Financed R&D Expenditures	.876**	.070
7. State & Local Government R&D Expenditures	.410**	.047
8. Industry R&D Expenditures	.711**	.075
9. Institutional R&D Expenditures	.655**	-.072
10. Other R&D Expenditures	.740**	-.080
11. Land (book value)	.165*	-.228*
12. Buildings (book value)	.761**	-.135
13. Equipment (book value)	.677**	-.013
14. Private Gifts, Grants, and Contrasts	.754**	.155
15. Opening Fall Enrollment of Students	.527**	.052
16. Number of Faculty	.626**	-.006
17. Average Faculty Salary	.488**	.370**
18. Non-Faculty Research Staff	.762**	.022
19. Total Graduate S&E Students	.764**	.079
20. Total S&E Postdoctorates	.809**	-.170
21. Library Expenditures	.796**	.105

* Correlations significantly different from zero at the 5 percent level of significance.

** Correlations significantly different from zero at the 1 percent level of significance.

Each independent variable in Table 8 needed to produce an R^2 (that is, to explain a percent of the variance in the dependent variable of technology transfer effectiveness) that was significantly different from zero at the 5 percent level in order to be included in the final regression equation. The five variables of average faculty salary; support staff (in FTEs) for technology licensing; private gifts, grants and contracts; industry R&D expenditures; and federally financed R&D expenditures were included in the equation. These variables were used to produce the results in Table 9. Some 85 percent of the variance in technology transfer effectiveness was explained by these five independent variables together (Table 9).

Table 9. Zero-Order Correlations of Five Independent Variables with Technology Transfer Effectiveness for 131 U.S. Research Universities.

Characteristics of Research Universities	Zero-Order Correlations with Technology Transfer Effectiveness Scores						Multiple Correlation Coefficient (R^2)
	#1	#2	#3	#4	#5	#6	
#1. Average Faculty Salary	--	.275*	.397*	.247*	.358*	.491*	.443*
#2. Support Staff for Technology Transfer		--	.707*	.738*	.945*	.878*	.364*
#3. Private Gifts, Grants, Contracts			--	.583*	.756*	.769*	.321*
#4. Industry R&D Expenditures				--	.781*	.717*	.191*
#5. Federally Funded R&D Expenditures					--	.881*	.130*
#6. Technology Transfer Effectiveness Scores						--	--

* Correlations significantly different from zero at the 5 percent level of significance.

** Correlations significantly different from zero at the 1 percent level of significance.

All the regression coefficients in Table 9 are positive, which means that technology transfer effectiveness scores vary directly with changes in the five independent variables. One interpretation from Table 9 is that average faculty salaries explain 44.3 percent of the variance in the technology transfer effectiveness scores.

The number of support staff for technology transfer is an important predictor of a university's technology transfer effectiveness, accounting for 36.4 percent of the variance in technology transfer effectiveness scores. The FY 1996 AUTM Licensing Survey measured the number of support staff (in FTEs) in a technology transfer office at a research university who provide staff support for technology transfer activities. This support staff does not include people who provide professional support, such as an industrial liaison or an intellectual property legal counsel, but who are not involved in technology transfer activities. Our results suggest that the number of staff support is more important in technology transfer effectiveness than the number of FTEs in professional services for technology licensing. However, this may be an anomaly in the data, due to the manner the question was asked in that year. In review of the current definition and more recent data, a reasonable hypothesis would be that the Licensing FTE, i.e., professional and support staff devoted to licensing activity, would be highly correlated with effectiveness.

Finally, we found that technology transfer effectiveness scores are related ($r = .395$) with the year in which a research university established its office of technology licensing. Thus being relatively earlier in adopting the idea of technology transfer is positively associated with technology transfer effectiveness. Note, however, that when squared this correlation is only 16%, and hence there are other variables that are important as well, many of which are described throughout this paper, that contribute to overall technology transfer effectiveness.

Conclusions

Our data showed that universities that have more research resources were the first to adopt the idea of having an office of technology licensing. University offices of technology licensing spread more quickly after passage of the 1980 Bayl-Dole Act.

We proposed here that technology transfer from a research university is a process consisting of a sequence of six steps or stages. A composite six-item measure of technology transfer effectiveness was developed for each research university of study using the following variables:

- (1) number of invention disclosures received by a university per year;
- (2) number of total U.S. patent applications filed;
- (3) number of licenses/options executed;
- (4) number of licenses/options yielding income;
- (5) number of start-up companies formed; and
- (6) gross license income received by a university from its licensed technologies.

Twenty-one selected characteristics were reviewed to determine their correlation to a high technology transfer effectiveness score. Further analysis brought out that universities that are relatively more effective in technology transfer are characterized by (1) higher average faculty salaries, (2) a larger number of staff for technology licensing, (3) a higher value of private gifts, grants and contracts, and (4) larger R&D expenditures from industry and federal sources.

The leading U.S. research universities in technology transfer effectiveness have more research resources, higher faculty pay, and are more committed to technology transfer. They also tended to be relatively earlier in establishing an office of technology licensing. Carnegie Research Universities I, a classification indicating a strong commitment to research and to doctoral teaching, have

higher technology transfer effectiveness scores than other types of research universities.

Research universities that are larger in size, regardless of how size is measured, have more research resources and faculty, and have developed more research-based technologies. Smaller universities tend to have fewer research resources and develop fewer technologies from their research.

Ratio measures of technology transfer effectiveness (such as technology transfer effectiveness indicators per million dollars of total R&D expenditures or per faculty member) will be developed as next steps in our research. We also expect to construct a measure of local/regional technology transfer effectiveness, by calculating the number of start-ups and technology licensing royalties earned by a university from in-state companies. The present investigation was limited to the analysis of variables available (1) from AUTM's annual licensing surveys, and (2) from the National Science Foundation's database of university characteristics. Future research might pursue alternative data sources so as to obtain measures of other variables related to technology transfer effectiveness. For example, our visits to a dozen research universities in 1999 suggested the importance of top university administrators' support and commitment to technology transfer as important to the performance of offices of technology licensing. Also, as mentioned previously, the amount of venture capital investment in a state or region probably is related to the number of start-up companies spinning-off of a research university, and perhaps to other indicators of technology transfer effectiveness.

NOTES

- ¹ During 1999-2000 Rogers was on sabbatical leave at the Center for Communication Programs, Johns Hopkins University; Yin is a doctoral student at Penn State University. The authors acknowledge support for the present research from the Mitsubishi International Corporation, San Francisco. They also thank the following individuals for their suggestions regarding the present paper: Jon Sandelin, Office of Technology Licensing, Stanford University; Fred Rogers, President, Select University Technologies, Inc. (SUTI); and Charles Wellborn, President, University of New Mexico Science and Technology Corporation.
- ² The *AUTM Licensing Survey* is administered annually by the Association of University Technology Managers, Inc. Strictly speaking, not all of the 131 institutions participating in the FY 1996 Survey are research universities. Some 11 of the 131 institutions are stand-alone medical schools (for example, the Oregon Health Sciences University), and 20 are categorized by the Carnegie Foundation for the Advancement of Teaching (1987) as "Doctorate-Granting Universities," in that they award doctoral degrees but do not give such a high priority to research as do the "Research Universities." Finally, 4 of the 131 institutions are classified as "Comprehensive Universities and Colleges," defined as institutions that award bachelors and masters degrees, and conduct some research. For purposes of simplicity in the present paper, we refer to all 131 institutions as "research universities," as is the usual convention.
- ³ While many such offices at research universities are called "Technology Licensing" or "Technology Transfer," a variety of other names are also used, such as "Intellectual Property," "Technology Transfer and Industry Relations," and "Patent and Copyright Administration." In the present paper, we use "technology licensing" and "technology transfer" interchangeably.
- ⁴ Our definition of technology transfer effectiveness is a more specific dimension of organizational effectiveness. Organizational scholars generally define *organizational effectiveness* as the degree to which an organization fulfills its objectives (Goldhaber, 1993).
- ⁵ Exactly what constitutes an invention disclosure varies somewhat from university to university.
- ⁶ We utilized data from the FY1996 AUTM Survey because these were the

latest data available at the time that we conducted the present data-analysis, and because they thus matched with the 1996 National Science Foundation data on the characteristics of research universities, which we utilize in Tables 1, 2, 7, 8, and 9. We also computed this measure of technology transfer effectiveness for the 132 research universities responding to the FY 1997 AUTM Survey; the 1996 and the 1997 scores are highly correlated ($r = .916$), with 84 percent common variance. Most universities only changed slightly in the rank order of the technology transfer effectiveness scores, usually remaining within the same decile of universities from one year to the next. Thus, because there was no significant change to the results, the analysis was not modified to use FY 1997 data. The FY 1996 AUTM data were also retained in the present analysis, as the comparison with the selected characteristics from NSF also used 1996 data.

- ⁷ A z-score is calculated as the difference between an observation on some variable (for example, the average number of invention disclosures by a university) and the mean for that variable (the average number of invention disclosures for all 131 universities), divided by the standard deviation for the number of invention disclosures for the 131 universities. In essence, a z-score (also called a standard score) expresses each observation in terms of standard deviation units from the mean.
- ⁸ For more discussion of the methods of calculation used to determine the composite measure of technology transfer effectiveness, the first author may be contacted at the University of New Mexico, (505) 277-7569.
- ⁹ Some 2.3 percent of the 131 research universities did not answer the question about their number of licenses/options executed, 0.8 percent did not respond to the question about their number of licenses/options yielding income, 1.5 percent provided missing data to the question about their number of start-up companies, and 0.8 percent did not respond to the question about their gross licensing income.
- ¹⁰ The University of California System reports its technology transfer data in the AUTM surveys for the entire System, as the Office of Technology Transfer for the System handles more than half of the total technology transfer activities, and several of the nine University of California universities do not have their own office of technology transfer.
- ¹¹ We were unable to obtain data on the amount of venture capital investment available in a given state or region, although we expect this variable to be highly related to technology transfer effectiveness, especially the number of start-up companies spinning-off of a university.
- ¹² *Research Universities I* are institutions that offer a full range of

baccalaureate programs, are committed to graduate education through the doctorate degree, and give high priority to research (Carnegie Foundation, 1987). These institutions annually receive \$33.5 million in Federal support, and award at least 50 Ph.D. degrees each year. *Research Universities II* are institutions that offer a full range of baccalaureate programs, are committed to graduate education through the doctoral degree, and give a high priority to research (Carnegie Foundation, 1987). They receive annually between \$12.5 and \$33.5 million in Federal support for research and development, and award at least 50 Ph.D. degrees each year. *Doctorate-Granting Universities I* are institutions that offer a full range of baccalaureate programs, are committed to graduate education through the doctorate degree, and award at least 40 doctorate degrees annually in five or more academic disciplines (Carnegie Foundation, 1987). *Doctorate-Granting Universities II* are institutions offering a full range of baccalaureate programs, whose mission includes a commitment to graduate education through the doctorate degree, and award annually 20 or more Ph.D. degrees in at least one discipline or 10 or more Ph.D. degrees in three or more disciplines (Carnegie Foundation, 1987). *Comprehensive Universities and Colleges I* are institutions enrolling at least 2,500 students that offer baccalaureate programs and graduate education through the masters degree, with more than half of their baccalaureate degrees awarded in two or more occupational or professional disciplines such as engineering or business administration (Carnegie Foundation, 1987). *Medical Schools and Medical Centers* are institutions that award most of their professional degrees in medicine; in some instances, their programs include other health professional schools such as dentistry, pharmacy, or nursing (Carnegie Foundation, 1987).

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Licensing Transgenic Mice: A Short Tutorial

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I. INTRODUCTION

Transgenic mice are phenomenal research tools, which are of interest to both industry and academic researchers. Many technology transfer offices will be faced with the challenge of licensing transgenic mice. In this paper we hope to illustrate some of the unique issues that arise in licensing transgenic mice and to provide some strategies for successful commercialization. We will discuss patent and licensing options and provide some examples from our own experience in transgenic mouse licensing at the Massachusetts Institute of Technology.

II. TRANSGENIC MOUSE MODELS—WHAT ARE THEY AND WHAT ARE THEY GOOD FOR?

Genetically altered mice are valuable research tools for the biotechnology and pharmaceutical industries, and for academic scientists, primarily because they serve as mammalian models of human disease. Mice that are missing a known gene can provide important insights into the gene's function in a living animal, thereby confirming theories about the role of the gene. Transgenic mice can be used commercially to validate drug targets by helping researchers

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determine whether a specific gene is involved in a disease. The researchers can then determine whether the gene (or its protein) is a good target for their drug-screening efforts. Transgenic mice can be used as a means of obtaining critical pre-clinical information about the efficacy and toxicity of candidate pharmaceutical compounds. The expense of caring for and maintaining large colonies of animals make transgenic mice impractical for high-throughput drug screening.

What are transgenic or knock-out mice and how are they made? The term transgenic mouse is the colloquial term for any genetically engineered mouse. In scientific terms, a transgenic mouse is a mouse that has a foreign gene added to all of its cells. A knock-out mouse is a mouse that has had a specific gene deleted (or made inactive) in all of its cells. The making of a transgenic mouse is a long and laborious process that can take up to a year. First, the genetic change is engineered in a single mouse embryonic stem cell—an undifferentiated cell that has the potential to turn into any cell in the body. The altered stem cell is then added to an early-stage mouse embryo that is implanted into a surrogate mother. The researchers will then breed the progeny of these mice for several generations to obtain mice that have the genetic alteration in all of their cells.

III. LICENSING

A. Important Issues in Licensing Mice

1. Is it necessary to file a patent application?

In addition to the usual factors that need to be weighed in deciding whether or not to file a patent application (e.g., whether or not the investigator has published, market size, etc.), there are factors specific to transgenic mice that should influence the patenting decision.

Ever since the landmark decision in 1988 granting a patent to Harvard University for the transgenic mouse now known as “Oncomouse,”¹ it is possible to obtain patent protection for a genetically engineered mammal. However, the patent office no longer grants patents that are as broad as the Oncomouse patent, which claims any non-human mammal containing any activated oncogene sequence. The prosecution of transgenic mouse patent applications is complex and, therefore, very expensive. Thus, while it is possible to get a patent issued, it will be costly and claims will be limited to a mouse in which a particular gene has been inactivated or added.

What is the value of a patent on a transgenic mouse? If the mouse will be used mainly as a research tool, either in academic or industrial labs, it is not necessary to patent it in order to gain value, even after publication. Because of the difficulty involved in developing a transgenic mouse, most companies are willing to pay for a license to an existing mouse rather than use their resources to duplicate work a university researcher has already done. Because the university (with the cooperation of the investigator) controls access to the materials (i.e., the mice), it is possible to receive significant licensing revenue without a patent.

The usual reason under the Bayh-Dole Act² for filing for a patent on a university invention is to induce investment in product development. Because the mice are most often used in research and do not need further development, this reason is generally not applicable. In addition, the royalties gained from licensing mice are not usually enough to justify the expense of a patent.

However, there are always exceptions. If the mouse model could serve as a standard toxicology test for

the pharmaceutical industry, the model is likely to have significant sales, and a patent might be worthwhile. For example, researchers at the National Institute of Environmental Health Sciences have proposed that using two transgenic mouse strains that are prone to tumors can reduce the test time for pharmaceutical toxicology testing from two years to six months.³ The FDA is considering accepting these data in lieu of the standard two-year rodent assay. The time savings will be of significant value to the pharmaceutical industry.

2. Whose mouse is it? Determining ownership.

It is necessary to determine whether a single academic institution wholly owns the mouse model. Did the investigator use materials from another institution? Were there any restrictions on the use of the materials? Is this mouse the result of a cross of two mice where the same institution did not fully own both parents? It is important to check any existing Material Transfer Agreements before deciding on a licensing strategy.

3. Bailment.

Bailment is a concept used in licensing unpatented biological materials. The owner of the material uses bailment to protect the owner's rights to the progeny and derivatives of the material, distinguishing it from a sale, which would grant the buyer unlimited rights to use of the material. Bailment is covered in detail in the *AUTM Journal* paper by P. Martin Simpson, Jr.⁴

The following wording is included as a section in the termination clause of the M.I.T. Tangible Property License Agreement to protect the institution's ownership rights.

"Upon termination, LICENSEE will return or destroy the

TANGIBLE PROPERTY and such destruction shall be confirmed in writing.”

(See Appendix A for the full text of this agreement.)

4. Cre-lox and Oncomouse.

There are some potentially blocking patents of which a licensing professional should be aware. We discuss some patents below that are being enforced that affect the licensing of transgenic mice. Our discussion is not meant to be a comprehensive list of all potential roadblocks; remaining alert to all issues that might arise is critical.

- a. *Cre-lox*. Cre-lox is a very powerful and widely used technology that allows site-specific recombination of DNA. A researcher can flank a known gene with lox DNA and contact the lox site with Cre to mutate the flanked DNA and inactivate that known gene. This tool gives researchers the ability to knock-out specific genes thereby creating knock-out mice. The Cre-lox patent (USPN 4,959,317)⁵ is owned by E.I. DuPont de Nemours and Company (DuPont).

For many years, DuPont asked that universities sign a license agreement in order to use the Cre-lox technology and to transfer Cre-lox mice to other academic labs. Many universities found the terms of the license agreement unacceptable and did not sign. Consequently, transfer of important Cre-lox materials between academic labs was limited and research was impeded. Then on July 1, 1998, DuPont signed a landmark agreement⁶ relating to the Cre-lox technology with the National Institutes of Health (through the Public Health Service) and Jackson Laboratories (referred to as Jackson Labs hereafter).⁷ The

agreement stated that any researcher affiliated with or receiving support from NIH may use the Cre-lox technology for noncommercial purposes without a license from DuPont. Further, the mice may be distributed to other academic labs and investigators for academic research under a Material Transfer Agreement (MTA) (the terms of which are included in the agreement). The recipient institution may not further distribute the mice without a license from DuPont. If the researcher wishes to distribute the Cre-lox mice to a for-profit company, the commercial entity must first obtain a commercial research license from DuPont for a fee. Further restrictions on academic researchers include: (1) they may not use the Cre-lox technology to create a library of mouse embryonic stem cells, (2) they may not use the Cre-lox technology in higher plants or for agricultural applications, and (3) they may not use the Cre-lox technology on any industrially sponsored research projects.

Importantly, this agreement allows universities to freely license novel discoveries made through the use of the Cre-lox technology (such as functions of novel genes, drugs discovered through the novel genes, etc.) without accounting to DuPont. In addition, DuPont will not take any part of the fees the universities receive for licensing the Cre-lox mice (provided the for-profit licensees have taken a license with DuPont).

Jackson Labs has agreed to serve as a repository for Cre-lox mice and to abide by the DuPont restrictions. As such, Jackson Labs will send out Cre-lox mice to academic institutions under an appropriate MTA, and will only send Cre-lox mice to companies that have signed a license with DuPont.

- b. *Oncomouse*. In 1984, Harvard University received the first patent on a transgenic animal, which has come to be known as Oncomouse. Harvard obtained very broad claims, the broadest of which is “any transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.”⁸ Later patents cover the cells derived from these animals.⁹ The patents are exclusively licensed to DuPont as a consequence of having sponsored the research at Harvard that led to the Oncomouse.

For years DuPont asked that academic labs take a license to the Oncomouse patent. The DuPont agreement restricted noncommercial use of all tumor-prone transgenic mice and restricted the transfer of these mice between academic labs. As in the case of the Cre-lox patents, many universities found these terms unacceptable. On January 18, 2000, DuPont signed an agreement¹⁰ with NIH similar to the Cre-lox agreement. Academic researchers can now use the Oncomouse technology without license from DuPont for noncommercial research and can transfer the mice to other academic labs under an MTA. If universities wish to license transgenic mice (or cell lines) that fall under the Oncomouse patents, they must notify the commercial entities of the Oncomouse patents, notify DuPont of the request, and the commercial entity must obtain a license from DuPont. In addition, at DuPont's request, the university must provide a reasonable number of mice to DuPont at no cost. Further limitations are that non-profit institutions may not use the Oncomouse to test compounds for any commercial purpose, to produce products for any

commercial purpose, or in any industrially sponsored research.

As in the Cre-lox agreement, universities are not required to share licensing fees with DuPont (as long as the commercial entity has signed a license with DuPont), and DuPont is not asking for a share of licensing revenue received for discoveries made using the mice.

B. Structures for License Agreements

There are a variety of ways to structure license agreements depending on the value of the mouse, the potential uses of the mouse, and how broad the distribution will be. Here we present some of the more common ways M.I.T. chooses to structure its licenses.

1. Two-tiered licensing.

“Two-tiered licensing” means distributing the mice to any academic institution under an MTA, but restricting a company’s access to the mice through a fee-based license agreement. This structure serves the purpose of making the mice widely available to academic institutions, while still generating some licensing income for the university and investigator. The mice can be sent directly from the researcher’s lab or can be deposited with a distributor. (We will discuss the advantages of using a distributor below.) The majority of the license agreements at M.I.T. fall into this category.

Academic Institutions

Mice are sent to academic institutions under an MTA, which prohibits the recipient from further distributing the mice but does not restrict breeding or cross-breeding. At M.I.T., we prefer to use the Uniform

Biological Material Transfer Agreement (UBMTA)¹¹ when possible. The UBMTA is a pre-negotiated MTA for transfer of materials between non-profit organizations and it is endorsed by the NIH. If both institutions (recipient and provider) have signed the UBMTA (see AUTM Web site for signatory institutions¹²), investigators may send materials under the Implementing Letter,¹³ allowing for ease of transfer without the need to negotiate the MTA terms. If the recipient institution has not signed the UBMTA, M.I.T. will use the related New Simple Letter Agreement,¹⁴ which is also endorsed by the NIH.

In the event that the UBMTA is not available for use, i.e., both parties have not signed the Master Agreement, the following definition of Material is used by M.I.T. in M.I.T.'s MTA agreement:

“Material” shall mean the _____ mice, and any additional progeny or unmodified derivatives thereof.”

The provider's retention of part ownership of cross-bred mice is accomplished with the following language in the grant of rights section of the MTA:

“Provider retains ownership of any Material included or incorporated within modifications.”

Companies

The mice are sent to companies under the M.I.T. “Tangible Property License Agreement,” which is broader than an MTA but not as comprehensive as a normal patent license agreement (see Appendix A). The most common fee structure used at M.I.T. is a one-time fee, the magnitude of which varies depending on the value of the mouse model. The general range is from \$10,000 to \$100,000. Fees in

the higher end of this range are possible when the model is very valuable or when the company is using the model for validation of therapeutic compounds. When a company is at the point of validating a therapeutic compound, for example, the company has already invested significant amounts of money in developing this family of compounds, thus the additional information that the mouse model can provide to the company is worth a lot. To assess an appropriate fee based on desired use, we always first ask companies what they plan to do with the mice before setting a fee. Because the mouse model at M.I.T. has not enabled the identification of the drug candidate, but rather the validation of its therapeutic value, it has been difficult for companies to agree to reach-through royalties.⁺ We therefore often seek to gain value by structuring the fees on a milestone basis, or over a few years. Most of the time, the fees are on the low end of the \$10,000 to \$100,000 range. This License Agreement prohibits transfer of the mice to third parties, but allows breeding and cross-breeding; however, M.I.T. retains joint ownership of cross-bred mice. This is accomplished by inserting the following language in the GRANT section of the License Agreement:

“Provider retains ownership of any Material included or incorporated within modifications.”

The field of use may be restricted to certain types of research.

⁺ Reach-through royalties refer to royalties on sales of a drug that is discovered or validated using a research tool but that is NOT covered by the claims of a patent held by the research tool owner.

What follows are two examples of M.I.T. licenses that follow the two-tiered model.

Example One. The K-ras mouse was developed by Tyler Jacks and Leisa Johnson at the M.I.T. Center for Cancer Research. It is an important cancer model. This mouse has been licensed to three companies. Because of the mouse's value as a unique therapeutic model, companies have been willing to pay significant fees for access to the mouse. In one license agreement, the license fee is payable over a few years. In another license agreement, part of the fee is payable when the company determines—using the mouse model—that their drug has a significant anti-tumor effect. The investigator distributes this mouse directly from his lab.

Example Two. In 1992, Robert Weinberg and Tyler Jacks developed a transgenic mouse at the Whitehead Institute in which they had knocked-out the p53 gene, which is a tumor suppressor. When the p53 gene is functioning normally, it will cause a damaged cell to die. When the p53 gene is missing, damaged cells do not die, which can lead to tumor formation (hence the healthy p53 is called a tumor suppressor). M.I.T. did not file a patent on this mouse. The p53 mouse is licensed on a two-tiered system, using Jackson Labs as M.I.T.'s exclusive distributor. Companies that request the mice from Jackson Labs are informed of M.I.T.'s ownership and the requirement for an additional license from M.I.T. We then follow up with commercial licensees. Six license agreements have been signed with companies for this mouse. The fee charged for the p53 mouse is on the low end of the range because a different p53 knock-out mouse is available from another supplier. In 1998, Jackson Labs sent M.I.T.'s p53 mouse to over 1,000 academic researchers.

2. Single-tiered licensing.

“Single-tiered licensing” refers to sending the mice to anyone who asks for them (commercial or nonprofit) with minimal fees and minimal restrictions (i.e., they can breed, but not distribute, the mice beyond their own lab). As in two-tiered licensing, the mice can be maintained and distributed either from the investigator’s lab or through a distributor.

3. Exclusive licensing.

In exclusive licensing, the mice are sent to a single company. We rarely license transgenic mice on an exclusive basis at M.I.T. However, this may be an appropriate scheme if the mouse is being licensed as a part of a larger patent portfolio or if the mouse would be used to produce antibodies and not as a research tool. Keep in mind that distribution to researchers at academic institutions would still be necessary if the work was done under NIH sponsorship or published in a peer-reviewed journal; however, this distribution could be accomplished with an MTA with strong restrictions on further distribution, cross-breeding, etc. At M.I.T. it is our policy to make research materials available to academic institutions for noncommercial research, even if the research materials are exclusively licensed to a company.

C. Using a Distributor

A mouse distributor is a company that will breed and maintain transgenic mouse strains and send them to researchers and companies upon request. Several companies do this work, a few of which we will discuss below.

There are benefits to using a distributor. Distributors breed and maintain the stocks so that the investigator

does not have to keep the strain going in his or her lab, taking up space and resources. Distributors will handle the shipping and paperwork involved in distributing the mice, which again takes pressure off the researcher. Also, the distributor takes care of marketing the mice.

However, there are also disadvantages to using a distributor. The licensing office loses much of the control it would otherwise have if the mice were held locally. Most distributors will send the mice to any company that requests them and is willing to pay for the mice. If the mouse is very valuable and distribution to companies should be governed by individually negotiated license agreements, or if the investigator wants to maintain strict control over distribution, using a distributor may not be advantageous.

License agreements with distributors may be exclusive or nonexclusive. In an exclusive arrangement, it is important for the university licensing office to retain certain rights—namely, to retain the right for the university to use the mouse for its own internal use; the right to distribute the mouse to other academic institutions from the university lab, or the agreement should ensure that the distributor will maintain an adequate supply of the mice so that they will be available to academics; and, under certain circumstances, the right for academic recipients to breed and cross-breed the mice.

1. Not-for-profit distributors.

Jackson Labs is a non-profit entity in Bar Harbor, Maine, and is the leading repository for transgenic mice, with thousands of mice in their inventory. Jackson Labs will accept and keep stocks of many mouse strains, including those that have limited market value. Jackson Labs, however, does not accept all mice. It will evaluate each strain. Jackson Labs charges relatively low prices for the mice and

generally imposes few restrictions on the use of the mice.

2. For-profit distributors.

There are many for-profit companies that will breed and distribute mice. Some examples are Taconic Farms and Charles River Laboratories. Because these companies are for-profit organizations, we usually enter into a basic license agreement with them with a royalty on all sales. The distributors sometimes use a differential pricing strategy, charging a modest fee for each mouse while restricting breeding, but granting breeding and/or cross-breeding rights for a significantly higher fee.

IV. CONCLUSIONS

Transgenic mice have revolutionized research and drug discovery and have proven to be of great value to both academic and industrial researchers. In spite of their great potential, however, transgenic mice have not generated large amounts of income for universities. Nonetheless, with a thoughtful licensing strategy, it is possible to bring in a reasonable amount of income for the investigator and the institution, and to provide a valuable service to the research community through dissemination of research materials.

The methods we have discussed for licensing transgenic mice have evolved over years of trying different licensing strategies. We expect that the scientific tools and business models will continue to evolve and that licensing models will continue to change to meet these needs.

Appendix A

Tangible Property License Agreement for For-Profit Companies

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
and
<<COMPANY>>
TANGIBLE PROPERTY LICENSE AGREEMENT

This Agreement is made and entered into this ____ day of _____, 200__, (the "EFFECTIVE DATE") by and between the MASSACHUSETTS INSTITUTE OF TECHNOLOGY, a corporation duly organized and existing under the laws of the Commonwealth of Massachusetts and having its principal office at 77 Massachusetts Avenue, Cambridge, Massachusetts 02139, U.S.A. (hereinafter referred to as "M.I.T."), and _____ a corporation duly organized under the laws of _____ and having its principal office at _____ (hereinafter referred to as "LICENSEE").

WITNESSETH

WHEREAS, M.I.T. is the owner of certain TANGIBLE PROPERTY (as later defined herein) relating to M.I.T. Case No. _____, "_____" by _____, and has the right to grant licenses under said TANGIBLE PROPERTY;

WHEREAS, LICENSEE desires to obtain a license under the TANGIBLE PROPERTY upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, the parties hereto agree as follows:

1 - DEFINITIONS

For the purposes of this Agreement, the following words and phrases shall have the following meanings:

1.1 "TANGIBLE PROPERTY" shall mean the [mouse strain name] mice and any additional progeny or unmodified derivatives thereof.

1.2 "FIELD OF USE" shall mean for research purposes only. [Expand as necessary]

2 - GRANT

2.1 M.I.T. hereby grants to LICENSEE the nonexclusive right and license for the FIELD OF USE to use the TANGIBLE PROPERTY, for ten (10) years, unless this Agreement shall be sooner terminated according to the terms hereof.

2.2 M.I.T. retains ownership of any TANGIBLE PROPERTY included or incorporated within modifications.

2.3 LICENSEE shall not have the right to enter into sublicensing agreements.

2.4 LICENSEE agrees not to transfer the TANGIBLE PROPERTY to third parties.

2.5 Nothing in this Agreement shall be construed to confer any rights upon LICENSEE by implication, estoppel or otherwise as to any technology or patent rights of M.I.T. or any other entity other than the TANGIBLE PROPERTY.

3 - ROYALTIES

3.1 For the rights, privileges and license granted hereunder, LICENSEE shall pay M.I.T. a License Fee of _____ Dollars (\$_____), due immediately upon the EFFECTIVE DATE.

3.2 All payments due hereunder shall be paid in full, without deduction of taxes or other fees that may be imposed by any government.

4 - PRODUCT LIABILITY

4.1 LICENSEE shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold M.I.T., its trustees, directors, officers, employees and affiliates, harmless against all claims, proceedings, demands and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys' fees, arising out of the death of or injury to any person or persons or out of any damage to property, resulting from the production, manufacture or consumption of the TANGIBLE PROPERTY or arising from any obligation of LICENSEE hereunder.

4.2 M.I.T., ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND AFFILIATES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY M.I.T. THAT THE PRACTICE BY LICENSEE OF THE LICENSE GRANTED HEREUNDER SHALL NOT INFRINGE THE PATENT RIGHTS OF ANY THIRD PARTY.

IN NO EVENT SHALL M.I.T., ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER M.I.T. SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

5 - EXPORT CONTROLS

LICENSEE shall comply with all United States laws and regulations controlling the export of certain commodities and technical data, including without limitation all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries. LICENSEE hereby gives written assurance that it will comply with all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself, and that it will indemnify, defend, and hold M.I.T. harmless (in accordance with Section 4.1) for the consequences of any such violation.

6 - NON-USE OF NAMES

LICENSEE shall not use the names or trademarks of the Massachusetts Institute of Technology, nor any adaptation thereof, nor the names of any of its employees, in any advertising, promotional or sales literature without prior written consent obtained from M.I.T., or said employee, in each case, except that LICENSEE may state that the TANGIBLE PROPERTY is licensed from M.I.T.

7 - ASSIGNMENT

This Agreement is not assignable and any attempt to do so shall be void.

8 - TERMINATION

8.1 If LICENSEE shall cease to carry on its business, this Agreement shall terminate upon notice by M.I.T.

8.2 Upon any material breach or default of this Agreement by LICENSEE, M.I.T. shall have the right to terminate this Agreement and the rights, privileges and license granted hereunder effective on sixty (60) days' prior written notice to LICENSEE. Such termination shall become automatically effective unless LICENSEE shall have cured any such material breach or default prior to the expiration of the sixty (60) day period.

8.3 LICENSEE shall have the right to terminate this Agreement at any time on six (6) months' prior written notice to M.I.T., and upon payment of all amounts due M.I.T. through the effective date of the termination.

8.4 Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination; and Articles 1, 4, 5, 6, 8.4, 8.5, and 10 shall survive any such termination.

8.5 Upon termination, LICENSEE shall return or destroy the TANGIBLE PROPERTY, and such destruction shall be confirmed in writing.

9- PAYMENTS, NOTICES AND OTHER COMMUNICATIONS

Any notices required or permitted under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be sent by hand, recognized national overnight courier, confirmed facsimile transmission,

confirmed electronic mail, or registered or certified mail, postage prepaid, return receipt requested, to the following addresses or facsimile numbers of the parties:

If to M.I.T.: Technology Licensing Office, Room NE25-230
 Massachusetts Institute of Technology
 77 Massachusetts Avenue
 Cambridge, MA 02139-4307
 Attention: Director
 Tel: 617-253-6966
 Fax: 617-258-6790

If to LICENSEE: _____

 Attention: _____
 Tel: _____
 Fax: _____

All notices under this Agreement shall be deemed effective upon receipt. A party may change its contact information immediately upon written notice to the other party in the manner provided in this Section.

10 - MISCELLANEOUS PROVISIONS

10.1 All disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the laws of the Commonwealth of Massachusetts, U.S.A.

10.2 The parties hereto acknowledge that this Agreement sets forth the entire Agreement and understanding of the parties hereto as to the subject matter hereof, and shall not be subject to any change or modification except by the execution of a written instrument signed by the parties.

10.3 The provisions of this Agreement are severable, and in the event that any provisions of this Agreement shall be determined to be invalid or unenforceable under any controlling body of the law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

10.5 The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

IN WITNESS WHEREOF, the parties have duly executed this Agreement the day and year set forth below.

MASSACHUSETTS INSTITUTE
OF TECHNOLOGY

By _____

Name _____

Title _____

Date _____

<<COMPANY>>

By _____

Name _____

Title _____

Date _____

NOTES

- ¹ USPN 4,736,866, "Transgenic non-human mammals," by Philip Leder and Timothy Stewart, issued April 12, 1988.
- ² 35 U.S.C. § 200.
- ³ Tennant, R.W., J.E. French, and J.W. Spalding, "Identifying chemical carcinogens and assessing potential risk in short-term bioassays using transgenic mouse models," *Environmental Health Perspective*, 103(10), October 1995: 942-950.
- ⁴ P. Martin Simpson, Jr., "Use of Bailment in Transferring Technology from a University," *Journal of the Association of University Technology Managers*, Vol. 10 (1998): 85-100.
- ⁵ USPN 4,959,317, "Site-specific recombination of DNA in eukaryotic cells," by Brian Sauer, issued September 25, 1990.
- ⁶ <http://www.nih.gov/od/ott/cre-lox.htm>.
- ⁷ Jackson Laboratories is a non-profit entity located in Bar Harbor, Maine. It is the leading repository for transgenic mice.
- ⁸ USPN 4,736,866, "Transgenic non-human mammals," by Philip Leder and Timothy Stewart, issued April 12, 1988.
- ⁹ USPN 5,087,571, "Method for providing a cell culture from a transgenic non-human mammal," by Philip Leder and Timothy Stewart, issued February 11, 1992. USPN 5,925,803, "Testing method using transgenic mice expressing an oncogene," by Philip Leder and Timothy Stewart, issued July 20, 1999.
- ¹⁰ <http://www.nih.gov/od/ott/oncomous.htm>.
- ¹¹ AUTM Web site (<http://www.autm.net>). See Agreements/UBMTA/Federal Register for UBMTA as published in Federal Register, March 8, 1995. See also NIH Biomedical Research Resources at AUTM Web site for related discussions in regard to sharing biomedical research resources.
- ¹² <http://www.autm.net>; Agreements; UBMTA; Signatories.
- ¹³ <http://www.autm.net>; Agreements; UBMTA; Implementing Letter.
- ¹⁴ <http://www.autm.net>; Agreements; UBMTA; New Simple Agreement.