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Response of John A. Fraser, President
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RETURN ON INVESTMENT IN RESEARCH

<u>Introduction:</u>

Is it not funny that over three centuries, leaders in the know in the USA understood what this is all about?

… "I can not forbear intimating to you the expediency of giving effectual encouragement as well to the introduction of **new and useful inventions** from abroad as to the exertions of skill and genius in producing them at home"….

George Washington, State of the Union Address, January 8, 1790[1]

[The U.S. patent system] "adds the fuel of interest to the fire of genius in the discovery and production of new and useful things."

*Abraham Lincoln**[2]

"One of our hopes is that after the war there will be full employment".

To reach that goal the full creative and productive energies of the American people must be released. To create more jobs, we must make new and better and cheaper products. We want plenty of new, vigorous enterprises. But new products and processes are not born full-grown. They are founded on new principles and new conceptions which in turn result from basic scientific research. Basic scientific research is scientific capital. Moreover, we cannot any longer depend upon Europe as a major source of this scientific capital. Clearly, more

[1] Quoted in W. Copan NIST Presentation
[2] Quoted in W. Copan NIST Presentation

and better scientific re Vannevar Bush search is one essential to the achievement of our goal of full employment. " *Vannevar Bush*[3]

The above quote contains a promise: Fund science and jobs will be created through new, better and cheaper products.

Science helped win WWII – more and better food, efficient logistics to move men and materials and better weapons (radar and the bomb). Science, according to Bush, will help prevent a recession after the war and build the economy and create jobs. Fund science at universities and federal labs and this will happen.

Response:

First, I will address the specific examples of challenges presented by Under Secretary Copan in his background PowerPoint deck.

- **Difficulty negotiating IP terms and indemnification provisions.**

These are real, difficult issues.

1. Some situations have terms that are hard to negotiate because they are difficult, or they have no precedent. The university experience may be helpful. Universities tend to delegate signature of the Institution down to the Director of the TT Office. In many cases, the Directors have obtained approval for generic Licensing terms and generic business terms. In other cases, the Director makes a recommendation for action and seeks input from local legal counsel and the Director's supervisor, usually a VP Research. In some cases, the VPR may decide to NOT sign having made a judgement call on behalf of the University. In all cases, the key to this challenge is having a clear path for approval and priority attention from the various university officials when advice is needed.

2. Some situations have hard to negotiate terms when the Company or its counsel for this matter is unfamiliar with the Licensing terms usual for not-for-profit Institutions. Occasionally, I have resolved this challenge by having the Company or its counsel talk directly to the Director of a TTO at a larger, experienced University which has deep experience. Such independent, 'no

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[3] Science the Endless Frontier 1945 Vannevar Bush – Author - – Summary of the Report, pg6.

dog in the fight' advice clears log jams, occasionally.

3. Some universities have adopted standard EXPRESS language agreements, particularly for start-up companies based on university technology. This approach is relatively new (since the last 10 years) but is slowly gaining in frequency. The first Express License was offered by the University of Edinburgh in Scotland, Office of Collaborations and were royalty free but applied only to preselected IPs that the Office had trouble licensing and were being given away to get them in the hands of the private sector.

   More recently Express licenses in the US are for start-up companies, or slow-moving IPs that the OTT has trouble licensing.

4. Indemnification. Universities are highly risk adverse organizations, much like Federal Agencies. I have found it useful to tell potential Licensees upfront that certain 'boilerplate' terms (indemnification, legal venue, etc.) are non-negotiable because of the culture of the organization as extremely risk averse. As in the case of trade secrets below, some companies refuse to deal with the organization because of this 'inflexibility'. This is an issue which may be a deal breaker but breaking the 'standard indemnification' language is not worth the deal. But in all cases, it is worth reviewing the language and discussing the impact and expectations around such language to ensure both Parties share a common understanding of the issues and the resulting language.

- **<u>Inconsistent practices and interpretation of authorities across US Gov.</u>**

In 2000, The University of Washington and Stanford University created the Summer Institute. It was a 2-day activity on the UW campus for 2 years, then at Stanford for its final year. The audience was Vice Presidents Research or Presidents of Universities. <u>The purpose was a primer on Academic Technology Transfer.</u> <u>Not the Nuts and Bolts of Licensing, etc., but the purpose and Strategy of enhancing the University reputation, though TT, the University level Policy Issues that needed to be addressed and realistic setting of expectations for TT results over time.</u> Such a mechanism was a hands-on engagement of senior Laboratory personnel in a relaxed setting, where participants can 'let their hair down' in both the formal and informal settings. Formal presentations were interspersed with a lot of informal interactions. In spite of its success according to participants, it was terminated when the organizer champions (all time was given as volunteers) took on additional university responsibilities.

This type of activity might be part of a response to this challenge.

- **<u>Inability to copyright software and digital products developed by USG-operated labs</u>**

It is unclear to me why this Policy was initiated originally, but I suggest that it is outdated. It would seem reasonable as a minimum to review this situation in a modern context. Universities are beginning to address IP commercialization in the form of copyright software and digital products and have found ways to ensure retention of rights for use of the IP by the University for University education, research and other non-commercial uses such as patient care.

- **<u>Challenges in protecting trade secrets when collaborating with Federal laboratories</u>**

Universities face the same challenge and particularly given the educational nature of the institution. Corporate collaborators recognize this issue, but eventually either decide to accept the University mechanisms to protect trade secrets or they do not. Universities have adopted specific, acceptable mechanisms to handle the IP of Others.

- **<u>Concern about March-in Rights</u>**

This is a real concern as the clauses have been prostituted for drug pricing control campaigns, in spite of the legislative champions stating that such purposes were not rational.

It is believed that the original purpose of such rights was to give the relatively inexperienced TT university community a bargaining position with Licensees who were not using their best reasonable efforts in commercialization.

Dr. Ashley Stevens stated at the NIST public event that such rights were no longer needed and could be voided. I agree.

- **<u>Requiring Feds to leave government service to be entrepreneurs.</u>**

It is unclear to me why this Policy was initiated originally, but I can easily understand the rational for it at the time. This is a complex issue with major perception concerns. I suggest that it is now outdated and can accommodate some flexibility while balancing concerns prudently. Universities (which on this topic are very different organizations) allow carefully crafted "Leave of Absence" or "Sabbaticals" as part of their culture. Some of these have fully paid salaries, some totally unpaid, some partially paid.

An 'Entrepreneurial Leave of Absence' for 2 years (difficult to accomplish a lot in 12 months), could be offered within federal labs. At the end, the person can return to the same position without any impact on fringe benefits, Pensions, etc., if they wished. This is a non-issue for Agencies with Guest researchers on soft money but could work well for full government employees.

- **<u>Conflict of interest provisions that make it difficult for Feds to access resources needed to commercialize technology.</u>**

Let's distinguish a situation where there is a "potential" for a conflict of interest and a situation which is an "actual" conflict of interest. Most university people involved in in technology transfer realize that if there is no 'potential' for conflicts, there is no 'interest'. The key is to identify potential conflicts and manage them in an open and transparent manner to prevent them from becoming an actual conflict of interest (CoI). One can identify conflicts as being either Personal, Institutional or Financial.

Many universities have a Policy where the researchers have the responsibility to identify potential conflicts and to seek advice from the Office of Technology Transfer. Many potential conflicts arise during the licensing of a researcher's research results into a start-up company where the researcher will have a financial benefit. In Florida, University Policy has a defined Form to be used in such circumstances to "declare" the facts of the situation. A second Form is used to show how the potential conflict is to be 'Managed', so that it does not become an actual conflict. The Policy outlines who needs to be involved is the review of the Forms and decision making and in oversight of the situation. The situation is reviewed yearly or more often if there is a major change in circumstances. By use of such a Policy, the potential conflict, which cannot be avoided, are managed. The attached is a copy of a useful innovation – a short explanation at Rutgers University where potential conflicts are allowed, if managed, examples where the conflict is unacceptable and other circumstances where detailed discussion is needed before a decision can be made. Such conflicts are managed on site at the university, not at a state or national level.

Second, I will address other key issues:

1. Setting Priorities. We are where we are because the technology transfer mandate in federal labs is an unfunded mandate. The key is to address this issue from the viewpoint of the Agency/Lab Director who has resources which are limited and a mandate which is not. Stretching resource across various responsibilities which are specifically funded is hard enough these days. Stretching resources across unfunded mandates in addition, leads to calculations of what can be ignored without fatal consequences to the Laboratory, to the personal career trajectory of the Director and senior leadership and to Congressional Funding.

For me, addressing this issue in a clear, positive manner is key to actually changing things in the Federal Laboratories.

2. Comparing University Licensing Volume and Federal Laboratory Volume. It is very difficult to compare Metrics and reach useful conclusions. Reading through the Highlights of AUTM's US Licensing Survey FY 2015 (see https://www.autm.net/fy2015-survey/) and the Federal Laboratory Technology Transfer, Fiscal Year 2015 Summary Report to the President and the Congress (see https://www.nist.gov/tpo/federal-laboratory-interagency-technology-transfer-summary-reports), shows that there are definitional differences (the fiscal year being an obvious one, etc.). The research expenditures are listed as: Fed ($46 billion), University ($66 billion). Again, it is not clear how comparable these numbers are – federal lab expenditures are not focused on curiosity driven research as at Universities, it is much more focused on specific mandates – all of which may lead to differences in the volume of funded research which could lead to patentable invention disclosures. The federal Labs list New Licenses and Invention Licenses. The Universities list Licenses (usually of patented inventions) and Options to Licenses – again definitional problems for comparisons. To be able to make useful comparisons, one would have to convene a group of experts and spend a couple of days sorting out definitions and then might reach the conclusion that the numbers that are comparable are not provided as such by the reporting organizations!

3. Metrics for Success. I include a paper of mine which addresses Lessons Learned in this area as of 2008. In essence, success measures will depend on the age of the licensing office to a degree. Licensing Transaction Inputs, Outputs and Outcomes can be gathered and reported by the reporting organizations. These can be measured and compared. Impacts, both Economic and Societal require separate, specific studies after the transactions.

One example I am very familiar with is the Impact of the license from Florida State University (FSU) to Bristol Myers Squibb (BMS) for a process BMS used for a limited number of years to manufacture its Taxol anti-cancer drug.

In 2009-2010, while I was Director of the TTO at FSU, Senior Legal counsel at BMS who was involved in the license negotiations provided me with the following information upon my request:

Q. What was the impact of the drug? Ans. In the first 5 years of using the FSU manufacturing process for Taxol, 2 million women used Taxol to battle ovarian and breast cancer. That is 2 million families impacted.

Q. What was the cost to the cancer patient of the FSU Royalty on Taxol sales in the US (4.25%). Ans. BMS manufactured, labelled and received FDA approval for Taxol. BMS would sell the drug to wholesalers like McKesson and include the

FSU royalty in that price. McKesson would add a markup and sell on to hospital buying groups. These groups would add a markup and sell on to individual hospitals and they would sell on to the patient (or their insurer). BMS estimated that a one-time infusion of the drug into a patient would be priced at $600 in 2008.

Multiple infusions were necessary over time. BMS knew what the mark-ups were along this distribution channel and estimated that for each $600 charge, the FSU royalty would be about **one half of one cent** within the $600 ($0.005).

These are the types of anecdotal facts that can be gathered from successful commercialization's impact years after the initial License.

Metrics for Success (continued): Other pieces of information:

4. MIT published a Study in 1996 (attached) entitled Pre-Production Investment and Jobs Induced by MIT Exclusive Licenses: A preliminary Model to Measure the Economic Impact of University Licensing (Lori Pressman lead author. Lori is the lead author on the recent 'BIO Report of the Impact of University Licensing'). By gathering numbers from all Exclusive licensees, MIT discovered that they invested roughly $1 million per year for product development between the time of License signing and product market entry (at which point royalties would be paid). The economic benefit accrued to the local communities where the Licensees were located. What made this result especially significant was that two other large universities (University of Pennsylvania and Ohio State University) did the same study using the same methodology and obtained the same results.

5. Time to Market. Oren Herskowitz, Head of the TTO at Columbia University lead a study that determined the length of time between filing a Patent and signing a License at Columbia. The study is at https://vimeo.com/techventures – 'Patents, Licensing, etc.', about 14-16 minutes into the video, I believe.

6. Social Rate of Return: I presented the following at the NIST Public meeting in June:

Some work has already been done in this area of the Return on Investment of Research and largely forgotten. Remember it and build on it. Ensure that such current academic research in this area is properly funded and build on it.

Edwin Mansfield, Professor at the University of Pennsylvania published in early 1970's to 2000s[4].

- Mansfield's most highly cited paper, which is entitled "Academic research and industrial innovation" (1991). For products, he finds that on average for the seven industries studied, 11% of the new products could not have been developed without recent academic research. The variation between industries is substantial, ranging from a low of 1% in the oil industry to a high of 27% in the drug industry. The average time lag between the academic research and the industrial innovation is about 7 years.

- In the seventh most cited paper (1977) of Mansfield, entitled "Social and private rates of return from industrial innovations", the authors estimated that the median private rate of return was about 25% and the median social rate of return was about 56%. **The paper remained a foundation for government technology policy to encourage firm R&D in the 1980's and early 2000's.**

The credibility of the general finding was strengthened after being twice replicated by NSF-sponsored research and published in 1978.

For the 20 innovations studied in the replication by Robert R. Nathan Associates, the median social rate of return was 70%, while the median private rate of return was 36% (Robert, 1978, p. 5, p. 7). For a different set of 20 innovations studied in the replication by Foster Associates, the median social rate of return was 99%, while the median private rate of return was 24% (Foster, 1978, p. iii).

7. Communication: Last but very important. Licensing done in the federal laboratories needs to be communicated via compelling stories, often and widely. In 2007 or so, BIO published a CD about Biotechnology and its Impact, as a legislative communication tool. It may still be on their web site. The 20-minute video explained the 'magic' of biotechnology by showing families whose lives had been affected by disease where a biotechnology derived drug had helped alleviate or cured the disease. Of the 20 minutes, 2 were spent on the science, the rest was all about impact on individual lives.

   I had often wondered what would happen if AUTM or the FLC went to 'Madison Avenue' and found the 'right people' and let them loose on 'our' stories to see how they could communicate. Being slick is not the answer, Madison Avenue knows how to communicate emotions and Impact. Somewhere an AUTM or FLC member has a cousin who works on Madison

[4]ftp://ftp.ige.unicamp.br/pub/CT001%20SocCiencia/Agosto%2030/Diamond%20on%20Mansfield.pdf

Avenue and could identify the right people without getting caught up in federal procurement issues.

I trust this information will prove of use.

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Communicating the Full Value of Academic Technology Transfer: Some Lessons Learned

John Fraser

John Fraser is the Assistant Vice President for Research & Economic Development and Executive Director for the Office of IP Development & Commercialization at Florida State University. Mr. Fraser has over 20 years of experience in the field of academic technology transfer and recently occupied the position of President, for the Association of University Technology Managers, during the 2006–2007 term.

Since the 1980 passage of the US Bayh-Dole act, academic technology transfer has gained profile, globally, as a key component of knowledge driven economic development. The following article provides information on this phenomenon in the United States and conveys lessons learned by a practitioner.

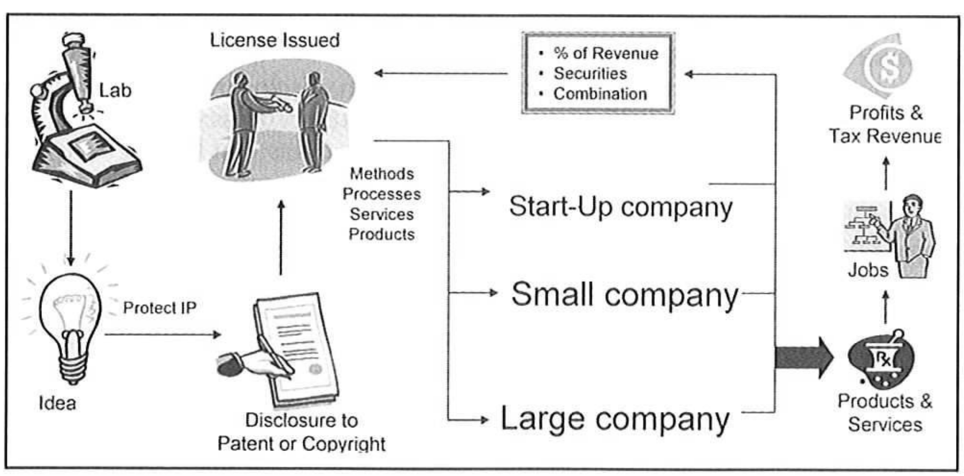
AUTM

The Association of University Technology Managers (AUTM) is a global professional association engaged in licensing and technology transfer of discoveries, from academic centers to corporations.[1] There are approximately 3,500 individual members of the organization around the world. Two thirds are employed in an academic setting; 80 percent in the United States, 9 percent in Canada, and 11 percent in as many as 40 other countries. Through facilitating technology transfer (protected by patent, copyright or trademark), between academic institutions and the corporate sector, AUTM members play a significant role in developing products that save lives, improve life, and increase productivity and competition. The primary purpose of the association is to advance, encourage and advocate the importance of this activity.

What Is Academic Technology Transfer?

There are over 200 offices of technology licensing or technology transfer, based in an academic setting in the United States. Representatives from these

Exhibit 1: Lab To Market — A Chain of Value



Source: The Florida Research Consortium offices collaborate with faculty members to explore potential applications for the research in progress. In addition, they conduct seminars to attract faculty interest and work with external patent attorneys to obtain rights protection for intellectual property. An equal amount of time is spent communicating with corporations that are active in the identified area of application for the specific technology. If there is a level of interest, a license or option deal is constructed (see Exhibit 1) providing the company with rights to develop and then sell a product based on the research. In some cases, the university receives a contract, accompanying the license deal, which pays for further research to outline the commercial potential in further detail.

Lesson 1: Clearly Written Policies Accelerate the Activity—Purpose of the Bayh- Dole Act

Academic technology transfer received a major boost in 1980, with the passage of the Bayh-Dole Act by Congress.[2] Essentially, by being pre-assigned the option to acquire ownership of IP created using federal grants, universities and small businesses would have certainty of ownership. Senators Bayh and Dole believed that such certainty would increase the commercialization of academic and small business discoveries into products that would improve the economy and US competitiveness. At the time of passage of the act in 1980, the US auto and steel industries were reeling under foreign competition. As Senator Bayh said; "We had lost our number one competitive position in steel and auto production. In a number of industries we weren't even no. 2."

A number of universities enthusiastically supported this law and in 1980 took up the challenge of technology transfer. Interest expanded, until in 2005 AUTM's Annual Licensing Survey identified technology transfer activities in 228 universities, hospitals and research institutes.

With the passage of Bayh-Dole, many universities adopted written policies to clarify the conduct of commercialization activities on their campuses. Specifically, these addressed disclosure mechanisms, IP protection, commercialization responsibilities and, in the case of success, profit distribution from successful technology transfer. Such policies established technology transfer as an acceptable academic pursuit and a creative vehicle for the benefit of society, in line with the Bayh-Dole Act.

Lesson 2: Academic Technology Transfer Works!

Yes, technology transfer works. In fact, it is quite amazing to consider the far reaching advances developed through this process and their profound impact, both on the economy as well as society. Some of the older, better known products include:

- *Taxol*—an anti-cancer drug made by a process invented at Florida State University
- *Gatorade*—a sports drink, developed at the University of Florida
- *Pablum*—a baby food from the University of Toronto
- *Vitamin Enriched Milk*—created from research at the University of Wisconsin
- *Stannous Fluoride (in Crest Toothpaste)*—first combined at Indiana University
- *Bufferin*—the buffers in buffered aspirin, from the University of Iowa
- *Eudora*—the email program
- *Mosaic*—processing software for the Netscape browser, both from the University of Illinois

More recent products include:

- *Farecast*—a Web site that helps travelers save money by forecasting the best time to buy airline ticket, designed at the University of Washington
- *ALEKS*—intelligent student tutoring software from the University of California
- ADEPT—a diagnostic system to detect early stage Alzheimer's, credited to the University of Glasgow, Scotland
- DUSA—a light based therapy for types of cancers, invented at Queens University, Canada.[3]

Invention disclosures, patents, licenses, etc. are all parts of the process, but the ultimate goal is to help create products that benefit society.

The aforementioned innovations are only a few examples. AUTM reports in its FY 2005 Annual Licensing Survey that 527 new products were introduced into the market in 2005 for a total of 3,641 introduced from FY98 through FY05.[4] These well-known products of daily life all have at least one thing in common: Each and every one of them originated from discovery and invention at a university. Some of them were patented; some of them are protected by copyright. All were licensed to a company as an idea, which the company then commercialized and brought into the marketplace.

The impact of the thousands of such products on society and the economy illustrates without question that academic technology transfer really works.

Lesson 3: The Impact of Technology (How You Measure Success Matters)

For a number of years, observers of the field generally assumed that the best way to measure the impact of technology transfer was through the licensing income received each year. This approach bred an assumption that the most successful technology transfer offices were those that pushed for the highest payment and made the most money on deals. This may make sense in a commercial setting, but overlooks key issues in an academic setting, where the core mission of the institution is education, research, and community service. As Kevin Cullen elegantly points out in his article in the December 2006 *Milken Review*, universities will continue with an activity even if it generates a financial loss, as long as it has positive impacts in the local and larger community.[5]

Current thinking is that the impact of technology transfer should be measured more comprehensively, by taking into account a number of different factors. These include: increased financial support of the research activity, the number of licensing deals concluded, the number of products and services introduced to the marketplace, the number of companies and jobs created by the private sector as a result of a license (spinout companies), as well as induced financial investment for product development, etc. Other measures include the impact of testing facilities, research parks and incubators in the community around the academic center.

From the academic perspective, licensing income represents an isolated indicator of overall success; important, to be sure, but not the sole end of a licensing program. Frankly, the amount of licensing income generated is not under the control of the university at all. Rather, it is entirely dictated by market pressures, the usefulness of the actual product and how adeptly the company brings the two together. Because the inherent risks and monetary costs of developing basic research into a marketable product are so high, a university's technology transfer office generally considers the commitment and capabilities exhibited by a commercial company, first and foremost, not how much they are willing to pay.

Lesson 4: Inputs, Outputs, Outcomes, and Impacts All Count at Various Points in Commercialization

Increasingly in North America, the success of academic technology transfer is not registered through *Inputs*, the number of disclosures, or patents realized. Nor is it measured by *Outputs*, the number of licensing agreements signed. Instead, considered more significant are the *Outcomes*, reflected in the products brought to the marketplace, and the *Impacts* that these products have on our society, in terms of increased productivity and competition, lives saved, and improved quality of life. This recognition is occurring despite the fact that universities exercise no influence over the Outcomes and Impact, but only the Inputs and Outputs.

Personal experience also has shown that the metrics one should use for an academic technology transfer program depend on the age of that program. For example, an office that is less than five years old should measure progress by the number of disclosures, patents filed, confidentiality agreements signed, and licensing or research contracts signed. An office between five and ten years old should place less emphasis on these variables (Inputs) and begin to look at the Outputs, such as deals signed, increased funding to the research base of the university, and licensing income. After 10 years, more emphasis should be placed on measuring the Outcomes of the activity, such as the number of products in the marketplace. The previous Inputs and Outputs are still relevant measures, but of importance to managing the office, less so for measuring success. After 10 years, the Impact of the activity can be meaningfully measured through the number of lives saved, improvements to the lives of patients and also increased competitiveness and productivity as a result of the products introduced to the marketplace.

In summary, early in the life of an Office, measuring Inputs provides a valid testament to the relative success of that program. Later, Outputs receive more consideration (assuming the university has dedicated enough resources to allow this to happen). As the Office and its relationships with faculty and corporate partners mature, Outcomes produced by the licensed companies become increasingly important. Ultimately, once a number of products have been in the market for some time, Impact represents the truest barometer of success.

Lesson 5: Return on Investment (ROI)

I am often asked: What is the ROI in tech transfer? First you need to stop and realize that the person is really asking: What is the *financial* Return on Investment? I usually start my answer by pointing out that my ROI calculation always begins by recognizing that the financial aspect is only one element (and usually not the most revealing) of a determination of return on investment. Other elements include: the enhanced reputation of the university in the local economy; student enrichment through association with the activity in research labs and the Licensing Offices; and, not least of all, the national and international credibility enhancement for the institution.

The financial return depends on the financial investment. Many observers look at the major investment of public funds in research and look to the academic technology transfer for a return, as its purpose is to move research discoveries into products. Fair, but very incomplete. The financial ROI depends as well on the financial investment in the office of technology transfer and whether or not there are sufficient resources to affect the outcome of commercialization. Calculations using recent AUTM Annual Licensing Surveys show that, for all the reporting university programs, the average licensing income amounts to 3 to 3.5 percent of the yearly reported research expenditures—a modest financial return. And for any year it is based on licensing deals done years before. The full impact and return is only truly realized once all other, non-financial elements are taken into account.

Lesson 6: How Academic Discoveries Develop into Products that Benefit People

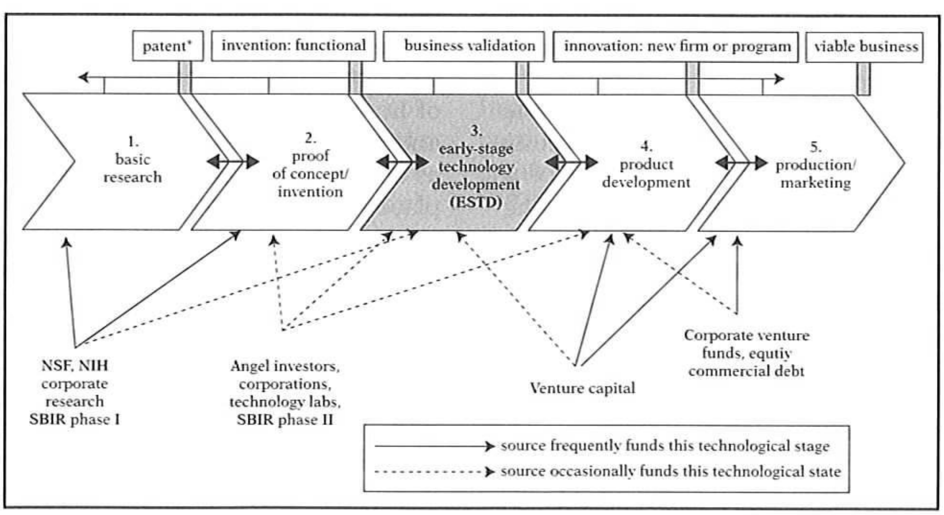
Universities do not undertake product development or product sales. Commercialization, therefore, occurs through licensing commercial rights to a company for development, or, in 15 percent of all yearly licenses, by creating a new company (a spinoff company) and basing its product development on a license from the university.

The process of developing a product in a corporation is complicated and extensive. Over the last several decades, the basic research and proof of concept activities (Steps 1 and 2 in Exhibit 2) often occur in a university setting and are licensed into a company for further evaluation, then development and distribution of a product. AUTM members act as conduits between the companies and the universities.

Lesson 7: Academic Technology Transfer Is an Enormous Activity in the United States

Academic technology transfer is an enormous activity, fuelled by annual US university research expenditures in the billions of dollars.[6] US based AUTM members signed 4,932 new licenses, transferring commercialization rights to companies in FY'05. At any one time, AUTM members report there are over

Exhibit 2: Sequential Model of Development and Funding



Source: AAAS Article on Innovation

28,000 current active US licenses in place, each representing a one-on-one relationship between a university and a company.[7] Such arrangements exist in every state and every part of the country.

Of the 4,932 licenses, 628 were used to create a newly incorporated spinout company. AUTM members reported 5,171 new spinouts since 1980. In 2005, 527 new products were introduced into the market, bringing the total entering the market to 3,641 from FY98 through FY05.[8]

Lesson 8: Start-Up Companies—One Aspect of Economic Impact

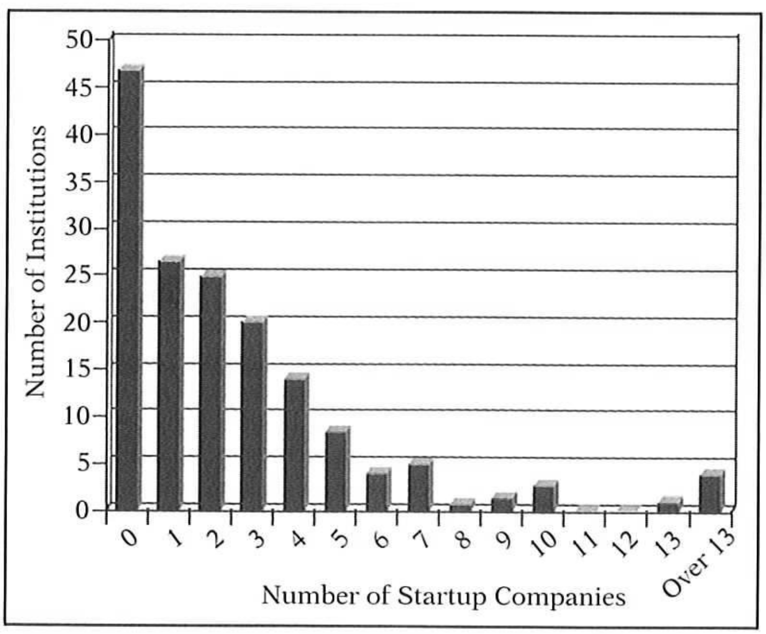
Exhibit 3 shows that many institutions are assisting their faculty in this activity and the number of start-ups, per institution, is very diverse. For fiscal year 2005, 20 universities created three start-up companies each and four universities each created over 13 start-ups. Naturally, the universities with the largest research expenditures are clustered on the right side of the chart. This tells you that not every university functions at the same level of technology transfer activity. There were 47 universities that reported no start-ups that year.

Exhibit 4 shows another fascinating aspect of academic start-ups: Individuals represent almost half of the initial investors. Professional, institutional investors whether venture capital groups, government or corporate investors do not dominate the initial investor groups. The largest fraction of reported funding came from neighbors, friends, and family.

Lesson 9: New Metrics

Academic technology transfer has gained profile through the publishing of the AUTM Annual Licensing Survey. This gold standard report has provided consistent definitions and reports on the US and Canadian activity for the past 15 years. The number of disclosures, the number of patents, the number of licenses and the gross licensing income is presented. The easiest measure to track in the Survey, and the one given prominence in the accompanying Press Release, was the Gross Licensing Income total. Over time, readership expanded while the notion of universities as local engines of economic development gained momentum. Academic technology transfer was one interface of the university and the local economy. Given the data presented and the emphasis, readers assumed that the purpose of technology transfer was simply lucrative licenses—the income. Overlooked and underemphasized were the economic benefits attributable to start-up companies, research parks, bolstering the research base and new products entering the marketplace—the impact.

Exhibit 3: Figure US-29: Startup Companies Formed by US Universities, 2004



Source: AUTM Annual Licensing Survey Summary, FY 2005

Exhibit 4: Table US-18: Sources of Funding for New Startups Formed by US Respondents in 2004

Individuals	**Number**	**%**
Friends and Family	94	20.5%
No External Funding	57	12.4%
Individual Angel(s)	49	10.7%
Angel Network	26	5.7%
Institutional Sources		
Venture Capital	85	18.6%
State Funding	36	7.9%
SBIR/STTR	32	7.0%
Corporate Partner	25	5.5%
Institutional Funding	26	5.7%
Other	28	6.1%
Total	**458**	**100.1%***
Number of U.S. Respondents	155	

*Because of rounding, total does not equal 100%

Source: AUTM Annual Licensing Survey Summary, FY 2004

AUTM is moving beyond its traditional metrics to create additional measures of success and provide a broader understanding of the process, as well as the impact. AUTM has undertaken a pilot experiment with counterpart organizations in the United Kingdom (UNICO) and in Canada (ACCT). In all three countries there is coordinated consultation with senior academic leadership, policy makers, politicians and grant providers to help identify new metrics, collect the data and publish it. Initial results are expected in 2008.

The traditional approach to quantifying this activity no longer provides as complete a picture as the public requires. Following are some of the additional metrics that AUTM, UNICO, and ACCT may implement to measure the impact of technology transfer. Although incomplete, it provides some sense of the direction.
Internal to the Institution

- Research partnerships
- measured by Numbers and $$ size
- Products in market
- measured by Case studies

External to the Institution/Impact in the Community

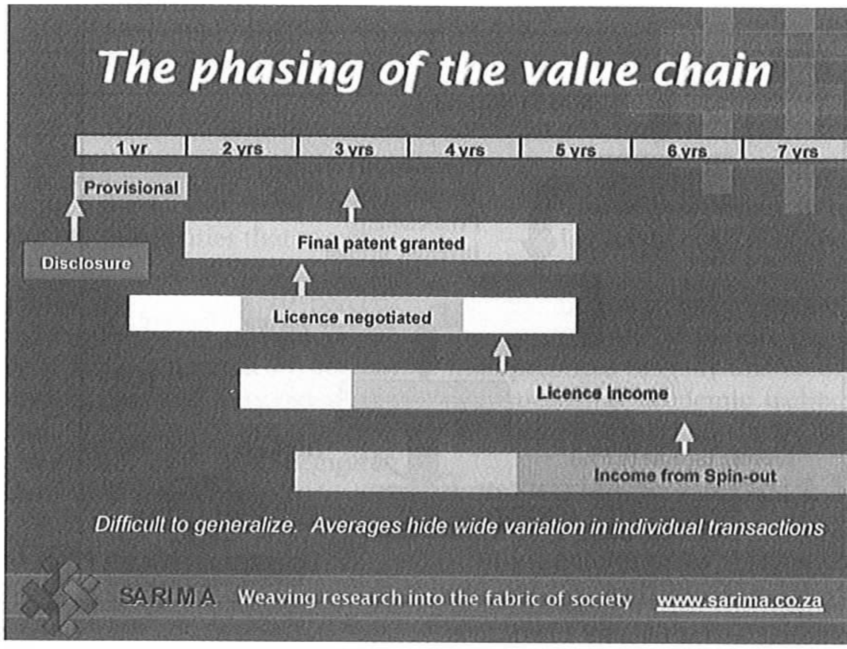
- Research Park, Incubators
  — measured by Local licenses, interactions with university
- Local start-up companies
  — with technology licenses
  — without technology licenses
  — measured by (i) jobs created and sustained, (ii) Investments in product development, and (iii) stories and case studies

Lesson 10: Time Is a Major Factor in the Technology Transfer Process

Exhibit 5, created by SARIMA in South Africa, in 2005 represents a study of data from many countries including South Africa, the United Kingdom, the United States and Canada. As illustrated, the interval separating disclosure by the university and introduction of the eventual product into the marketplace by the corporation, is measured in many years. The color bars indicate the spread of the data for any measurement. The SARIMA study found that, from the point of disclosure, granting a company a license took well over three years on average in these countries. Notice the difference between licensing income from licenses granted to existing companies, versus successful product introduction (licensing income) by spin-out companies; a significant number of years after founding of the spin-out. Caroline Bruce, of UBC in Canada, pointed out that a pharmaceutical product takes much, much longer than indicated in Exhibit 5. (As an aside, a necessary characteristic of people active in academic technology transfer is patience and wanting to create a portfolio of licenses).

A fascinating study is underway, lead by Dr. Ashley Stevens at Boston University and Dr. Mark Rohrbach at the NIH, which emphasizes impact and time. Preliminary results were displayed as a poster at the 2007 Annual AUTM meeting in San Francisco. Of the new molecular entity drugs approved by the US Food and Drug Administration (FDA), during the past several decades, over 115 are based on a key patented invention from a university or within the NIH intramural laboratories. According to Dr. Stevens, (verbal communication) preliminary data showed that, on average, a period of 5.6 years elapsed between receipt of an external grant to perform research, the disclosure of the invention and filing the key patent. On average, a further 12 years passed until the patented invention was developed into a drug and received approval from the FDA.

Exhibit 5



Source: SARIMA, South Africa, provided by Tony Heijer.

Lesson 11: Failure Is a Key Characteristic of Academic Technology Transfer

Failure is much too drastic a term, but I use it to make a point. Not everything we handle turns into gold. The flow diagram (Exhibit 6) was created by Lou Berneman, while at the University of Pennsylvania, from all AUTM Surveys conducted during the 1990s. He found that, of the reported disclosures that resulted from the $200 billion in funded R&D, 50 percent of them lead to patents and 50 percent did not. Only 50 percent of the filed patents were licensed. The other 50 percent stayed in the filing cabinet! Of the signed licenses, 10 percent went to start-up companies (14 percent in 2005). Of the 25,000 licenses current in FY'99, only 125 had royalties of over $1 million that year. Small numbers! Hence, this trend reflects a great deal of work and expenditure allocated to patents, which for the most part generate only modest financial returns (if that is all you measure).

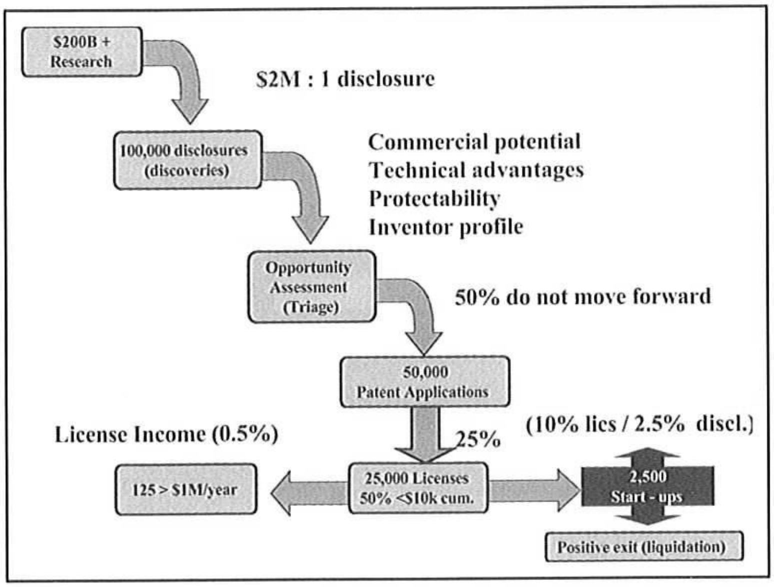
Over 99 percent of the licenses in place generated a yearly income of less than $1 million each. It was reported recently that in the enormous University of California system, only slightly more than 4 percent of all licenses earned more than $100,000 per year.[9] Therefore, universities engaging in technology transfer for the sole purpose of making money, or to replace declining state or federal financing, are in for a major disappointment, in my opinion.

Lesson 12: The External Environment Is Changing

Recently, a significant number of recent US Supreme Court cases have changed the landscape of academic technology transfer. In the August 2007 edition of Newsletter *Technology Transfer Tactics*, R. Polk Wagner, of the University of Pennsylvania during an audio conference commented on the following cases and legislation:

- *MedImmune v. Genentech*: Companies can now obtain a license and later sue to have the patent invalidated or declared non-infringing. This ruling represents "a big shift of power to licensees and away from patentees."
- *e-Bay v. MercExchange*: "This is a big loss for patentees because injunctions are no longer almost automatic, so patents are naturally weaker and enforcement is much more costly."
- *KSR v. Teleflex*: "The fact that KSR is out there gives challengers another crack at the patent". People will "need to think through very carefully in terms of patenting strategy whether [a potential patented technology] is indeed something that no one had thought of before, and that nobody could have thought of before even though all elements of it were preexisting. That's the key argument you're going to have to make—the same argument as before KSR, but I think it will be a little

Exhibit 6: From Disclosure to Patent Royalties



Source: AUTM Data FY 19991–2000

bit harder to win those cases today, particularly with simplistic technologies". His advice is to keep documents from people, who at the time of the invention, did not think what was being proposed as an invention would work.

- Patent Reform Act 2007: Wagner noted many elements, but pointed to the "establishment of post-grant opposition procedures, which will create a system of 'mini-trials' at the USPTO that would attempt to resolve patent disputes before going to the expense of full scale litigation". Major players in the professional venture capital community have written Congress and pointed out that the open-endedness of this element will greatly add to the risk of an early stage start-up based on recently patented technology, in that a challenger has a relatively inexpensive way to call the validity of the patent into question. (In the opinion of the author of this paper this element, if passed as is, will have a devastating effect on the willingness of seed stage investors to invest in university start-up companies).
- USPTO Rule changes: While an injunction has delayed implementation, Wagner states that the changes will "radically alter the way people do patent prosecution, change the nature of examination and make [patenting] harder, more costly, and more risky."

Overall, the presumption of patent validity that strengthened significantly, starting during the term of President Reagan, seems to be significantly weakening during the term of President Bush, 25 years later.

Lesson 13: After 25 Years, Big Players Are Not the Only Players

As indicated below,[10] the distribution of deals with different sized companies has remained relatively steady in the last half decade. Note particularly the drop in licenses with large companies (over 500 employees) and the significant number of licenses to start-up companies (defined as companies founded on the license). But the real action remains with small companies (under 500 employees).

FY	Total Licenses/ Options	To: Start-Ups	To: Small Co's	To: Large Co's
'99	3,792	12%	50%	38%
'04	4,624	14%	54%	32%

Lesson 14: Having a Large Institutional Research Base Matters

The following figures include the top US research universities, reporting to AUTM by yearly research

U's FY2005	%	FTEs	%	3 yr Royalty Totals (B $$)	%	Median Age
Top 20	14	234	35	2,357	77	1983
Top 30	21	322	48	2,597	85	1983
All 141	100	667	100	3,064	100	1989

expenditure, and separates the largest (top) 20, the largest 30, then all of the 141 universities that reported in FY 2005.[11]

The top 20 universities (representing 10 percent of the 191 institutions) employed 35 percent of the licensing professionals (FTEs), generated 77 percent of the three-year royalty averages and were older than the median of the other 80 percent of the reporting universities. Relative to royalty cash flow, being big matters, as does length of time active in the industry.

Lesson 15: Know Your Commercial Partner

Jack Sams has worked with me at FSU for the past decade. While an IBM employee, he licensed the DOS operating system from Bill Gates at Microsoft for IBM to power the early IBM PC. He has pointed out that, while there are different approaches to licensing in the IT community compared with the pharma/biotechnology sector, the more important cultural differences exist between the academic sector and the private sector:

Industry Perspective

- Everyone is an employee
  - — Works on assigned portions of a problem
  - — Results belong outright to employer
  - — Royalty payments to employees are rare to non-existent
  - — Results are secret
  - — Work is largely anonymous
  - — Management controls use of work
  - — Above items are the assumed starting point for external collaboration.

University Perspective

- Employees are primarily teachers/professors
  - — Research is self-directed
  - — Research funds are personally solicited
  - — Results are the property of the researcher
    - Academic publication and attribution is the primary goal
    - Sometimes required to assign rights to University
    - Entitled to share in revenue thus obtained
  - — May retain control of use/revision of works.[12]

The key point is that corporate attitudes in negotiating an academic license are based on the above common practices (usually unstated) inside the company. The successful academic technology transfer officer will recognize this and clarify the differences for all.

Lesson 16: Expect Problems

In an enterprise as vast as US academic technology transfer, with 28,000 active relationships between one university and one company (all involving cultural differences, egos, time zones, and generational differences), expect problems. Recently, Congressional hearings and articles have purported to show that not all is well with regards to Bayh-Dole. There have been articles stating that the system does not work, that a major overhaul of academic technology transfer is required and the Bayh-Dole Act needs to be changed and "improved." These authors point to a number of anecdotal stories and presume to project a few instances into a general condemnation of the entire system. Mark Crowell, a recent AUTM President, pointed out in a 2006 COGR Workshop that "the plural of such anecdotes is not data" on which to make decisions.

It would be a real surprise if there were not problems in a system this large and complex with so many different players. This is a human interaction activity, with many people involved. Change is constantly occurring; sometimes internally driven, other times in response to external pressures. Problems are an unavoidable part of this landscape. "Don't throw the baby out with the bath water"!

Lesson 17: Communicating the Value of Public Sector Technology Transfer

AUTM's "Better World Report" [13] (BWR) is a new tool for communicating the value of academic technology transfer. Each annual edition contains 125 stories of products in the marketplace, all based on academic inventions. Behind it is a database of almost 500 stories from the United States, the United Kingdom, Canada and, increasingly, other countries. Collectively, these stories supplement the data in the Annual Licensing Survey.[14]

Lesson 18: The Nine Points to Consider—Neglected Diseases

In the summer of 2006, representatives from 12 of the leading US universities wrote a paper entitled: "Nine Points to Consider," [15] which identified certain shared perspectives emerging within the academic community. In it, they stated:

> Recognizing that each license is subject to unique influences that render "cookie-cutter" solutions insufficient, it is our aim in releasing this paper to encourage our colleagues in the academic technology transfer profession to analyze each licensing opportunity individually in a manner that reflects the business needs and values of their institution, but at the same time, to the extent appropriate, also to bear in mind the concepts articulated herein when crafting agreements with industry. We recognize that many of these points are already being practiced. In the end, we hope to foster thoughtful approaches and encourage creative solutions to complex problems that may arise when universities license technologies in the public interest and for society's benefit.

The Ninth Point, in particular, illustrates new currents shaping activities in the community:

> *Point 9:* Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world.

Summarized from the text: Universities share a social compact with society. As educational and research institutions, they share a vested responsibility to generate and transmit knowledge, both to students and society at large. Centers of higher learning assume a specific and central role in helping to advance knowledge in many fields and to manage the deployment of resulting innovations for the public benefit. In no field is the importance of doing so clearer than it is in medicine.

Around the world millions of people suffer and die from preventable or curable diseases. The failure to address this serious problem has many causes. However, there is an increased awareness that responsible licensing demands consideration of human needs in developing countries and underserved populations. This includes a responsibility, on behalf of both academia and industry, for finding a way to share the fruits of what we learn globally at sustainable and affordable prices, for the benefit of the world's poor.

The details involved in any agreement attempting to address this issue are complex, requiring expert planning and careful negotiation. The application will vary in different contexts. The principle, however, is simple. Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of essential medical innovations.

Conclusion

Today, academic technology transfer licensing is recognized as a key component of knowledge-driven economic development. It is having a substantial economic and social impact, as measured by products which save lives, improve the quality of life and increase the competitiveness and productivity of the licensed corporations.

1. *http://www.autm.net.*
2. Senator Bayh reminisced about the purpose of the bill and the cut and thrust around its passage in the December 2006 *LES Nouvelles Journal*, pages 215ff.
3. AUTM has created a publication (The Better World Report—*http://www.betterworldproject.net/*) which is a compilation of modern products based on discoveries at academic centers and commercialized by companies around the world. Like many universities, my employer Florida State University (FSU) has a Product Showcase page of discoveries which lead to products (*http://www.techtransfer.fsu.edu/*).
4. *http://www.autm.net/about/dsp.Detail.cfm?pid=207.*
5. *http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=477&cat=MIR.*
6. $42 billion in US R&D expenditures (FY'05); *http://www.autm.net/about/dsp.Detail.cfm?pid=207.*
7. *http://www.autm.net/about/dsp.Detail.cfm?pid=207.*
8. *http://www.autm.net/about/dsp.Detail.cfm?pid=207.*
9. Chronicle of Higher Education, November 23, 2007, p. A21.
10. These figures are from the AUTM Annual Licensing Survey Summary 199, 2005.
11. These figures are from the AUTM Annual Licensing Survey 2005 data, from an idea of Dr. Ashley Stevens.
12. Attributed: Jack Sams from FSU CREATE Presentation 2007.
13. *http://www.betterworldproject.net/.*
14. A favorite story of mine involves an anti-stuttering device, invented at East Carolina University, brought to market by a start-up company.
15. *http://www.autm.net/* (bottom of AUTM home page).

<u>*New approach saves time, helps faculty stay in compliance*</u>

Streamlined COI policy guides faculty involved in Rutgers spin-offs

Spin-off companies create unique challenges for university TTOs because faculty inventors are often torn between the responsibilities involved with launching a new business and their university work. Further, trying to stay on the safe side of an institution's conflict-of-interest policy is challenging, in large part due to the typical length and complexity of the rules governing COI.

Recognizing that these issues can rob both faculty and TTO staff of valuable hours that could be better spent on other matters, New Brunswick, NJ-based Rutgers University has taken steps to streamline its process so everyone involved understands what the big conflict-of-interest issues are before they run afoul of university policy.

Complexity creates barriers

The problem with the way many universities handle COI is that various aspects of the issue are often covered in five or more different policies, according to **Michael Pazzani**, PhD, VP for research and graduate and professional education, and chair of the COI committee at Rutgers. For example, one policy may deal with how much time a faculty member can devote to the new business outside of the university, another policy may cover issues related to the university actually doing business with a company owned by an employee, and yet another policy may spell out the conflict-of-interest rules related to National Institutes of Health grants.

Such complexity can present huge barriers to spin-off companies because faculty inventors have a hard time fully grasping what they can and cannot do under university policy. "What happened [here at Rutgers] was that a [COI] committee would review things, and it would find problems with just about anything a faculty member wanted to do because [he or she] didn't navigate the several dif-

continued on page 179

Conflict of Interest with Faculty Owned Companies

General Principle
- Keep your company activities separate and distinct from your Rutgers professor activities.
- Expect your company to be treated exactly like any other company. The fact that it is partially owned by a Rutgers faculty member does not give it any special privileges.

Easy
- Hire FORMER students, postdocs, employees as company employees
- License IP from Rutgers in exchange for cash or equity
- Consult with company up to 5 eight hour days a month.
- Work for company more than 5 days a month while on leave of absence.
- Use Rutgers equipment for a fee that is the same as that already used by others.
- Serve as chair of scientific advisory board of company
- Assign IP created wholly by company employees other than Rutgers employees to company

Hard
- Involve students taking a leave of absence from Rutgers University.
- Use Rutgers equipment for a fee if not already available to others.

Impossible
- Involve your current students in your company
- Consult for more than 5 eight hour days a month while a full-time faculty member.
- Use Rutgers facilities, equipment, supplies, etc. unless covered by a formal written contract.
- Have future IP not funded by company be automatically licensed or controlled by the company.
- Subcontract to the company from Rutgers.
- Negotiate with Rutgers on behalf of a company.

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COI policy continued from p. 178

ferent policies correctly," says Pazzani.

Recognizing that the process needed to be simplified, about 18 months ago Pazzani and fellow COI committee members devised a brief, one-page summary of the main issues that typically arise with faculty-owned businesses, along with information regarding whether various practices are acceptable or not acceptable according to university rules. **(See box on p. 178)** "We separated out in plain language what is easy to do, what is hard but not impossible, and what is impossible to do [under university policy]," explains Pazzani.

For example, while it is fine to hire former students to work in a faculty-owned enterprise, the university frowns upon the practice of employing current Rutgers students.

The document also makes it clear that the new company can only use Rutgers equipment under the same rates and conditions as other outside entities, and it spells out how much time the faculty member can reasonably devote to the new business while maintaining his or her full-time university job. "The biggest problem I think most universities encounter is that faculty intermix their private and university lives," says Pazzani. "They may answer university e-mail at four in the morning or shop at Amazon.com at work, and that is all fine until one has a company with a fiduciary responsibility. Then they need to make sure that it is separate and distinct from their Rutgers duties."

While the chief goal of the plain language summary was to provide faculty members with an easy-to-grasp guide to structuring their enterprises within the COI rules, Pazzani points out that it has also significantly trimmed the time spent in conflict-of-interest committee meetings. "The meetings now typically take an hour or two as opposed to a series of three-hour sessions, and they are also less focused on what the policy should be and more focused on implementing the policy," he says. "It is better to give advice in advance and then be constructive in how you are managing a conflict than ... having a faculty member propose something we all know the committee will say no to."

Contact Pazzani at pazzani@rutgers.edu or 732-932-1500. ▶

TTO enlists alumni attorneys to provide discounted services

The Office of Technology Transfer at Lehigh University in Pennsylvania is only four years old, and it is not yet a large operation. But in those four years Lehigh inventors have disclosed more than 70 new inventions and the office has filed patent applications on more than half that number. Eight patents have been issued to university researchers, and five start-up companies have been formed based on Lehigh inventions. Though total revenues remain modest at $300,000 in fiscal year 2008, the OTT's growth rate is solid, up from just $12,000 in 2005.

The accelerating activity requires the services of patent attorneys, and with a modest budget the tech transfer team at Lehigh has found a creative way to afford those services: They use alumni patent attorneys who are willing to work at discounted rates for their alma mater. "I'd say our overall savings range from 20% to 30%," offers **Yatin S. Karpe,** PhD, senior manager of the OTT.

Starting from scratch

When Karpe joined the office more than two years ago, "we definitely did not have relationships with outside organizations; we had to start from scratch," he recalls. "That was especially true on the patenting side." Karpe quickly recognized the importance of obtaining patent services as reasonably priced as possible given the office's modest budget.

The move to solicit discounted legal work from alums was actually prompted by one attorney who approached the OTT, recalls **Thomas Meischeid,** the office's interim director. "He was very interested in giving back to the university," Meisheid says. "He offered us discount rates, and now he's with a firm that is trying to expand its IP portfolio."

The fact that the attorney approached the university provided a clue that it wasn't just the OTT that viewed a discount arrangement as favorable. Though the attorneys and firms involved do offer a cut rate, they achieve a new line of steady business as well as the PR value of working with the university, Karpe notes. As for the specifics of negotiating the discount, he continues, "it's just like negotiating a license; it's a mutually beneficial relationship. I assume they see establishing a relationship with the

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Pre-Production Investment and Jobs Induced by MIT Exclusive Patent Licenses: A Preliminary Model to Measure the Economic Impact of University Licensing

Lori Pressman, Sonia K. Guterman, Irene Abrams,
David E. Geist, and Lita L. Nelsen

ABSTRACT

This paper examines the effectiveness of invention licensing at the Massachusetts Institute of Technology (MIT) Technology Licensing Office (TLO) in achieving one of the major objectives in the Bayh-Dole act: to induce investment by the commercial sector in the development of inventions arising from government-funded research at universities, and by doing so, to enhance economic development. Data on investment and jobs created were obtained directly from the licensees. Conservatively, we estimate that just under a billion dollars have been invested by the commercial sector toward the development and early commercialization of licensed inventions from MIT alone, and that over two thousand jobs have been created and/or sustained as a direct result of these licenses. The term *pre-production investment* is used here to refer to money spent developing new products and efficient ways to produce and market these products. It excludes the costs of producing (or investment required to produce) mature products. This sum does not include investment and jobs generated by non-exclusive patent license agreements, or by no longer active exclusive patent license agreements, or by any type of copyright license agreement. Approximately 77% of the investment in MIT technology and 70% of the jobs in this study are associated with start-up companies, which account for only 35% of the total number of licensees (see Table 4). A preliminary extrapolation to all university licenses, based on the MIT data and on the results of the Association of University Technology Managers (AUTM) surveys (1,2), suggests that total pre-product introduction development investment nationwide in university-based technology is in the range of at least \$2 to \$5 billion per year.

BACKGROUND

Previous studies of the economic impact of university licensing have focused on the economic impact after product introduction (1,2). For example, the AUTM's Economic Impact Committee is in the process of refining its estimates of job creation from licenses that have matured into product sales. Based on 1993 royalty income of \$350 million (U.S. institutions reporting), the current estimate of the committee is \$17 billion of product sales and 137,000 jobs (3). This measure of commercial success, while important, underestimates the total economic impact of university licensing because it omits the economic impact of university licensing *before* first sales of licensed products. University technology is typically very forward-looking, and requires very large investments to bring products to market. Investment levels in development remain high even after the first sales of licensed products. An economic impact analysis based on product sales alone reveals only a fraction of the total effect of university licensing on the U.S. economy. This paper offers a complementary approach to studying the early impact of a technology program by focusing on pre-production investment.

Lori Pressman, Sonia K. Guterman, Ph.D., Irene Abrams, and David E. Geist, are professional staff members of the Technology Licensing Office at the Massachusetts Institute of Technology. Lita L. Nelsen is Director of this program.

Most university licenses are only recently consummated. The average university license is probably no more than three years old. An earlier paper has shown that the university licenses that do succeed in bringing a product to market take an average of eight years to do so (4). Since the passage of the Bayh-Dole Act, the pace of patenting and licensing in universities has grown at an exponential rate (4). Thus, one can expect a considerable increase in the next ten years in both product sales (and concomitant manufacturing job creation) and in investment in development arising from new licenses.

INTRODUCTION

The primary goal of this paper is to create a model to examine licensing activity at the Massachusetts Institute of Technology (MIT) in the context of certain objectives outlined in the Bayh-Dole Act, with the emphasis on quantifying licensee investment in product development and, therefore, jobs created in product development. A case study of university licensing is presented in this paper by MIT, describing certain activities and impacts derived therefrom. From there we make a preliminary extrapolation to the economic impact of product development investment resulting from university licensing nationwide.

The Bayh-Dole Act, named after its senate co-sponsors, (PL 96-517, enacted in 1980) allowed universities to elect to retain title to inventions arising from their federally funded research and to grant licenses to patents deriving from these inventions. The preamble, reproduced below, describes the objectives of the new law.

35 U.S.C. § 200. Policy and objective

> *"It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against the nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area."*

Measuring how well an organization has met some of the objectives in the preamble to Bayh-Dole is fairly straightforward; measuring performance against other objectives is not so straightforward. What is the measure to indicate whether a university has "promote(d) the commercialization and public availability of its inventions"?

University inventions are "embryonic." At the time a university is ready to hand its inventions off to industry, most have not even reached the prototype state, much less demonstrated manufacturability and practicality in the market. These inventions will require substantial investment in product and market development, and many may never succeed. Thus the task of the university in licensing these inventions is to find industrial licensees willing to make the high-risk investment.

The Bayh-Dole Act, allowing the university to grant exclusive licenses, enables the university to make that high-risk investment more attractive to industry: if the company makes the investment and succeeds in developing the product, *exclusive patent protection* will reduce its market risk. Thus one important measure of a university's success in carrying out the objectives of Bayh-Dole is the level of product development investment the university has "induced" through its licensing efforts.

DEFINITIONS

The definitions used during this study are defined throughout this paper and provided here as an easy reference for the reader.

Biotechnology Licenses: Licenses for human therapeutics and diagnostics, and for chemicals produced by living organisms.

"Classic" Start-up: A company where the MIT licensed technology is the enabling technology in the formation of the company and either (i) the company has raised at least half a million dollars in investment capital or (ii) it is selling product and is paying earned royalties.

Induced Investment: Pre-Production Investment outside the licensor that is directly traceable to license agreements.

Induced Investment Rate: Induced Investment per License per Year.

Induced Investment Ratio: Induced Investment/Revenue to MIT.

Investment Outlier: A license inducing more investment than most of the other licenses.

Large Entity: A company employing more than 500 people.

Pre-Production Investment: Money spent developing new products and efficient ways to produce and market these products. It excludes the costs of producing (or investment required to produce) mature products.

Physical-Science Licenses: Licenses for lasers, semiconductor components, novel materials, novel manufacturing processes, computer architectures, control systems, and medical devices.

Revenue Outlier: A license generating more revenue than most of the other licenses.

Revenue to MIT: License issue fees, reimbursed patent costs, license maintenance fees, and earned royalties.

Small Entity: A company employing fewer than 500 people.

METHOD

At the time the data were assembled (early 1995), the MIT TLO had 205 *active, exclusive, patent* license agreements: 104 licenses to 89 separate companies for biotechnology products, and 101 licenses to 99 separate companies outside the biotech area. These licenses cover over 700 issued patents and patent applications, the majority of which were federally funded, and thus attributable to Bayh-Dole objectives.

Biotechnology licenses include licenses for human therapeutics and diagnostics, and for chemicals produced by living organisms. Licenses outside the biotech area include licenses for lasers, semiconductor components, novel materials, novel manufacturing processes, computer architectures, control systems, and medical devices and will be referred to as physical-science licenses.

The 104 exclusive, active biotechnology licenses cover 388 issued patents and patent applications, 246 of which (63%) were funded by the U.S. Government. The biotechnology licenses represent a total of 524 active license years, or an average duration of 5.04 years per license. The 101 active, exclusive physical-science licenses cover 314 issued patents and patent applications, 241 of which (77%) were funded by the U.S. Government . The 101 active, exclusive physical-science licenses represent a total of 426 active license years, or an average duration of 4.22 years per license.

Seventy-one of the licenses were granted to "classic" start-up companies (see Definitions for "classic" start-up). Ninety-seven of the licenses are to other small entities (using the Federal Government definition of a small entity as a company employing fewer than 500 people). Thirty-seven of the licenses are to large entities. Eighty-nine, or 44%, of the licenses are to companies located in Massachusetts, reflecting the impact on the local economy.

Several complementary methods were used to gather the induced investment data, but in all cases the licensee itself provided the figures on investment and employment. Sources of the self-reported data include:

1. Letters from CEO's or project managers to the MIT TLO stating the total dollars invested toward the commercialization of licensed products, and stating the number and type of employees working on the project. Such letters were written at the request of a TLO staff member. The licensees were assured that the data would be presented only in aggregate form and the confidentiality of the individual respondents would be strictly maintained.

2. Business plans showing the amount of money, the number and kind of personnel, and the time budgeted for each phase of development of the licensed products. Submission of such business plans and business plan updates are required in the diligence section of MIT exclusive license agreements. Follow-up phone conversations were made to the companies to confirm that the allocated money had been spent according to the schedule in the business plan. If the company's plans had changed since submission of the written plan, the updated numbers were used.

3. Balance statements from start-up companies. These audited statements, required by the MIT TLO in the reports and records section of its license agreements, show the total sum raised by start-up companies. If the technology that started the company included other non-MIT technology, the company was contacted to help pro rate the investment appropriately.

4. Questionnaires filled out by licensees that asked for the amount of investment brought into their company as a result of the license, and how that investment had been allocated between research and development and production and marketing efforts. The questionnaire also asked how many full-time equivalent employees were working on the licensed products, how many of those were in research and development, and how many were in production and marketing.

5. Follow-up phone conversations. This was an important part of the data clarification and verification process.

It would not have been possible to gather this privileged data without the ongoing business relationship that exists between the MIT TLO and its licensees. We doubt that a request for such information from an entity other than the licensor would have elicited such a helpful response, and we suggest that other offices interested in gathering similar information do so in the context of their ongoing relationship with their licensees.

Detailed data were gathered by the above method for a sample of biotechnology licenses and for a sample of physical-science licenses. The physical-science sample is comprised of all the exclusive, active, patent licenses of one of the authors (Pressman), and the average license is 3.79 years old, somewhat younger than the 4.22 year average for all MIT licenses in the physical sciences. The main methods for gathering the data on the eighteen licenses in the physical-science sample were: requesting a personal letter from the CEO or project manager; verifying the numbers on business plans already in the licensing office files; and reviewing balance statements from the start-up companies. A questionnaire was used to supplement this information and to gather additional information on employment associated with the license. One company in the physical-science sample had a mature product line and had made significant investment in setting up production facilities. This company had also made very significant investment in research and development. For the purpose of this study, which is focusing on pre-product introduction high risk investment, the R&D number only was used.

The data for the biotechnology sample was generated by sending the questionnaire described in point 4 above to every third licensee in an alphabetized list of the exclusive, active, biotechnology patent licensees. In the biotechnology sample, the average license is 4.3 years old, younger than the 5.04 year average for all biotech licenses. Unfortunately, our experience with the biotech samples pointed out a weakness of the questionnaire method versus the personal interview method. Investment data from large entity biotech licensees was frequently not available. This produced significant distortion, particularly for one pharmaceutical product now on the market where investment was undoubtedly of the order of magnitude of $50 to $150 million, but no self-reported data on investment were given.

RESULTS

Tables 1P and 1B below, representing the physical-science sample ("1P") and the biotech sample ("1B"), respectively, illustrate the primary role played by start-up companies in investment and employment generation:

Table 1P:

	THE PHYSICAL-SCIENCE SAMPLE			
	Total	**Start-ups**	**Other Small Entities**	**Large Entities**
Number of Licenses	18	9	5	4
Avg. Age of License in Years	3.8	4.9	2.7	2.6
Induced Investment in $M	$ 66	$ 58	$ 2	$ 6
Full-Time Equivalent ("FTE") Employees	215	173	20	22

Table 1B:

	THE BIOTECH SAMPLE			
	Total	**Start-ups**	**Other Small Entities**	**Large Entities**
Number of Licenses	19	7	9	3
Avg. Age of License in Years	4.3	5.4	3.6	3.8
Induced Investment in $M	$ 139	$ 119	$ 19	$ >>.4[b]
Full-Time Equivalent ("FTE") Employees	255	186	59	, 10[b]

b See Method section for a discussion of the difficulty of obtaining informative data from the biotech large entities licensees. The actual number is much higher, but difficult to quantify.

The total self-reported investment for both samples is $205 million, and the total self-reported number of full-time equivalent employees is 470. In both samples, a large fraction of the investment is made by start-up companies, accounting for a large fraction of the jobs. In the physical-science sample, over eighty-five percent of the investment is associated with start-up companies, and over eighty percent of the jobs are associated with start-up companies. In the biotech sample, over eighty-five percent of the reported investment is associated with start-up companies, and seventy percent of the jobs are associated with start-up companies. This result is biased by the differential response of the start-ups and by the difficulty of the large-entity, biotech licensees in accurately identifying investment directly attributable to efforts to commercialize licensed products. (Two-thirds of the start-ups and small entities answered the questionnaire while only half of the large entities did so.)

It is interesting to point out the internal consistency of the self-reported investment and jobs data. A well-accepted estimate of money needed to support one high-tech job is $125,000 (7). Therefore, $205 million could be expected to support 1,640 job years. If all 470 jobs existed over all 4.05

years (average for all licenses in samples), then there would be 1,904 job years. Intuitively, it is more likely that there were fewer employees in the earlier years of the license. Thus, it is easy to create a very plausible scenario where 1,640 job years would be spread over 4 years, with the companies employing progressively more employees every year: for example, 350 employees the first year, 390 the second, 430 the third, and 470 the fourth (350 + 390 + 430 + 470= 1,640).

It is also significant to compare the revenue derived by MIT from licenses, with the far larger investment made by these companies developing the technology outside of MIT. Table 2 summarizes the revenue to the university from these licenses. Line 1 of the table shows patent costs incurred before the effective date of the license for the cases that are the basis of the samples in this study: $552 thousand for physical-science inventions, $874 thousand for biotech inventions. Line 2 shows the license contract-associated revenue for these cases, defined here as the sum of license issue fees, patent cost reimbursement paid by licensees, license maintenance fees, and earned royalties on sales. The difference between the first and second lines is the net revenue to MIT associated with the licensing contract itself, shown in Line 3: $524 thousand for physical-science inventions, and $1.3 million for biotech. Line 4 lists sponsored research dollars to MIT associated with the license, and Line 5 in the table gives the sum of the preceding lines.

Table 2:

COSTS AND PAYMENTS TO MIT FOR PHYSICAL-SCIENCE AND BIOTECH CASES

	Physical-Science Sample[a]	Biotech Sample[b]
1. Out-of-pocket patent costs, before license is signed.	$ (552) K	$ (874) K
2. License revenue: license issue fee, reimbursed patent costs, license maintenance fees, and earned royalties on sales.	$ 1,076 K	$ 2,189 K
3. Net Licensing Revenue	$ 524 K	$ 1,315 K
4. Sponsored Research Funding	$ 1,761 K	$ 2,359 K
5. Net Revenue to University	$ 2,285 K	$ 3,674 K

[a] 17 companies, 18 licenses

[b] 19 companies, 19 licenses

The revenue received by the university is modest when compared with the over two hundred million dollars of investment by the commercial sector toward the development of businesses based on these inventions (see Tables 1P and 1B). This is consistent with the spirit of the Bayh-Dole act and MIT's policies of licensing. The primary goal of the MIT TLO is to encourage, induce, and attract commercial investment to MIT inventions and to further product development and economic development. Revenue generation is only a secondary goal (5).

Based on this philosophy of licensing (and blessed with a small but continuing licensing income stream that makes this possible), the MIT Technology Licensing Office invests in patenting all inventions that it believes to have a "reasonable chance" of breaking even on licensing. This procedure is in contrast with a return-maximization strategy practiced by commercial entities who license university inventions and invest only in those inventions likely to be "big winners." MIT invests in about 40% of the invention disclosures it receives, in contrast to the commercial entities who invest in "fewer than 10%" of the invention disclosures they receive. (Private communication from several such companies and the authors' own data indicate that this number is substantially lower than 10%.)

Tables 3P and 3B below were generated by an extrapolation of the data in Tables 1P and 1B. As to the full MIT portfolio of active, exclusive licenses, the average investment per start-up was extrapolated to all start-ups, and the average investment per other small entities was extrapolated to all other small entities, etc. Because the results varied greatly between start-up licenses, other small entity licenses, and large entity licenses, the extrapolations were made separately for each category and then summed. The extrapolations of investment were made on the basis of license-years (see Appendix A). The extrapolations for jobs were made simply on the basis of number of licenses (see Appendix B).

Table 3P:

	101 EXCLUSIVE, ACTIVE, PATENT PHYSICAL-SCIENCE LICENSES[a]			
	Total	Start-ups	Other Small Entities	Large Entities
Number of Licenses	101	41	41	19
Avg. Age of License in Years	4.2	4.0	4.5	4.3
Induced Investment in $M	$ 288	$ 214	$ 25	$ 49
Full-Time Equivalent ("FTE") Employees	1,055	786	164	105

[a] Data extrapolated from start-ups in sample to all start-ups, from small entities in sample to all small entities, and from large entities in sample to all large entities. One investment outlier was included in the initial data sample from which the extrapolation was made. (See Discussion section for discussion of outliers.)

Table 3B:

	104 EXCLUSIVE, ACTIVE, PATENT BIOTECH LICENSES[b]			
	Total	Start-ups	Other Small Entities	Large Entities
Number of Licenses	104	30	56	18
Avg. Age of License in Years	5.0	5.3	4.5	6.4
Induced Investment in $M	$ 634	$ 498	$ 132	$ >> 4[c]
Full-Time Equivalent ("FTE") Employees	1,241	822	363	>> 56[c]

[b] Data extrapolated from start-ups in sample to all start-ups, from small entities in sample to all small entities, and from large entities in sample to all large entities. Two investment outliers were in the initial data sample from which the extrapolation was made. (See Discussion section for a discussion of outliers.)

[c] See Method section for a discussion of the difficulty of obtaining informative data from the biotech large-entities licensees. This number is higher, but difficult to determine.

Table 4 below is the sum of the values in Tables 3P and 3B, and represents the total induced investment and total jobs associated with 205 MIT active, exclusive patent licenses.

Table 4:

	TOTAL EXCLUSIVE, ACTIVE, PATENT LICENSES			
	Total	**Start-ups**	**Other Small Entities**	**Large Entities**
Number of Licenses	205	71	97	37
Avg. Age of License in Years	4.6	4.6	4.5	5.3
Induced Investment in $M	$ 922	$ 712	$ 157	$ >> 53[a]
Full-Time Equivalent ("FTE") Employees	2,296	1,608	527	>> 161[a]

a See Method section for a discussion of the difficulty of obtaining informative data from the biotech large-entities licensees. This number is higher, but difficult to determine.

DISCUSSION

The issue, as in all sampling surveys, is how representative are the data, and therefore how reliable and accurate are the extrapolations.

The biggest problem in extrapolation of the data to the entire MIT portfolio is the statistically infrequent revenue and investment outliers. Revenue outliers are defined as those licenses that generate more revenue to MIT than most other licenses. Investment outliers are defined as those licenses that induce more investment than most other licenses. Investment outliers may be attributed to a successful public or private stock offering, or may be associated with a very large development commitment within an existing company to take a product to market, e.g. a human medical therapeutic. (There is one such drug product in the biotech sample, but the large entity licensee did not reveal the data.) The problem with both revenue and investment outliers is that their inclusion or non-inclusion in small samples can bias the resulting extrapolations.

To further illustrate the concept of "revenue outliers," consider the current portfolio of MIT exclusive patent licenses. Only two (of 205 total exclusive patent licenses) yield more than $500 thousand per year in running royalties, and together these comprise 27% of the total yearly income. In addition, in a typical year, MIT TLO may receive no more than two or three other payments greater than $250 thousand from "one-time" payments such as license issue fees, major sublicense fees, and/or liquidation of stock received from past start-up licenses. In all, while 6 of the current active, exclusive licenses have yielded more than $1 million in revenue, fewer than 31 have yielded more than $200 thousand.

Table 5A illustrates the degree to which the average license revenue of the samples in the study were biased by "outliers" by comparing three subdivisions of the data: average for all licenses in the portfolio; average revenue for the entire portfolio when the "outliers" were omitted; and average revenue for the sampled licenses. In general, the sampled licenses were closer to the full portfolio *minus* the outliers, indicating that the sample understated the impact of the outlier licenses.

Table 5A:

	AVERAGE REVENUE/LICENSE		
	All Licenses: (101 licenses for Physical Sciences, 104 for Biotech)	All Licenses minus Licenses with lifetime revenue greater than $1M	Samples: (18 licenses for Physical Sciences, 19 for Biotech)
Physical Science	$ 159 K	$ 67 K	$ 75 K
Biotech	$ 209 K	$ 93 K	$ 115 K
All	$ 185 K	$ 81 K	Not Applicable

Investment outliers, like revenue outliers are infrequent, and would stand out clearly and intuitively from within a complete set of data on induced investment. Unfortunately a complete set of data on induced investment for all 71 start-up licenses is not available to analyze. A disproportionate number of investment outliers included in the respondent sample, (either too many or too few), could seriously distort the extrapolations to the entire MIT sample. Forty-one percent of the investment in the physical-science sample was from one investment outlier, and seventy-two percent of the investment in the biotech sample was from two investment outliers.

In addition to the issues of revenue outliers and investment outliers, there are other issues related to the representativeness of the samples. The biotech data were based on a questionnaire, which itself polled only a fraction of the total exclusive, biotech licenses in the MIT portfolio (30 out of a total of 104). The randomness of the sampling (every third company, alphabetically) enhances representativeness, aside from the outlier problem. A major issue, however, is bias based on non-responsiveness. Table 5B shows a comparison of respondents and non-respondents.

Table 5B:

LICENSE INCOME FROM RESPONDING AND NON-RESPONDING BIOTECH LICENSES		
	Total	Average per Company
Responding (19) (7 start-ups plus 12 non start-ups)	$ 1,981 K	$ 104 K
Non-Responding (11) (2 start-ups plus 9 non start-ups)	$ 4,551 K	$ 414 K

A higher fraction of start-ups responded, most likely reflecting the closer relationship the MIT TLO naturally has with start-up licensees. The larger "license income per licensee" figure for the non-respondents reflects one large-company license yielding substantial running royalty streams (one of the "revenue outliers" discussed above).

In the physical-science sample, the issue is not one of responsiveness. The entire population was queried, and with repeated follow-up efforts through phone calls and letters, all licensees responded. The technology of the physical-science sample, however, was narrower than that of the TLO's non-biotech licenses as a whole: it included lasers, semiconductor components, and medical devices, but omitted materials science, computer science, mechanical and manufacturing engineering. Some indication of the fact that the physical-science sample is indeed representative of all the licenses in the physical sciences is the similarity of the average revenue received from the 18 licenses in the physical-science group-$75K/license-with that of the total physical-science portfolio, controlled for revenue outliers-98 licenses yielding an average of $67K/license.

Age of the licenses is also a very significant factor in assessing representativeness of the samples. Age is significant in analyzing both the "total" development investment made (which will increase with age at least until product introduction) and the rate of development investment (that is, investment per year, which is a clearer measure of jobs created in a given year). Rate of development investment usually also increases with age of license until product introduction or, in the case of biomedical licenses, until submission to the FDA for marketing approval. Thus, if the data are based on "young" licenses, they will tend to significantly underestimate both the total investment and the rate of investment. Table 5C below analyzes the degree to which the age of the licenses in the samples was representative of the age of all the exclusive patent licenses in MIT's portfolio.

Table 5C:

	AVERAGE AGE IN YEARS/LICENSE		
	All Licenses: (101 licenses for Physical Sciences, 104 for Biotech)	**Samples: (18 licenses for Physical Sciences, 19 for Biotech)**	**No Earned Royalty Licenses: (16 licenses for Physical Sciences, 15 for Biotech)**
Physical Science	4.22	3.79	3.17
Biotech	5.04	4.30	3.95
All	4.63	4.05	3.55

Table 5C illustrates that the average license is 4.63 years old for the portfolio as a whole, while all licenses in the samples are an average of 4.05 years old. The age of sample licenses on which there were no earned royalties on product sales was even less, as expected: an average of 3.55 years. Because it has been estimated that the typical university license requires eight years of development investment before products reach market (3), the MIT licenses can be seen as only half way through their development cycle. The fact that the sample licenses were somewhat younger than all licenses that formed the basis of the extrapolation would tend to produce an underestimate of induced investment.

With this discussion on the issues of representativeness in mind, it is interesting to further consider the implications of the data. Table 6 compares the total license revenue received by the university with the total reported investment in the technology. The fluctuations in the ratio of induced investment to licensing revenue are due to the fluctuations introduced by revenue and investment outliers. The ratio of induced investment to licensing revenue for the entire group of 205 licenses, keeping in mind that the licensing revenue *is not* extrapolated, and that the induced investment number *is* extrapolated, is 24 to 1.

Table 6:

INDUCED INVESTMENT COMPARED WITH LICENSING REVENUE					
	Physical-Science Sample (18)	Biotech Sample (19)	Physical Sciences All (101)	Biotech All (104)	All (205)
License Revenue to MIT (license issue fees, license maintenance fees, patent reimbursements, running royalties) (A)	\$1.1M[a]	\$2.2M[a]	\$16.1M[a]	\$21.8M[a]	\$37.9M[a]
Induced Investment (B)	\$66M[a]	\$139M[a]	\$288M[•]	\$634M[•]	\$922M[•]
(B)/(A)	60	63	18	29	24

[a] Actual data

• Extrapolated data

Note that the extrapolated investment-to-licensing revenue ratios for the full portfolio are smaller than the sample ratios. Refer to Table 5A, which illustrates that the average revenue per license in both the physical-science and biotech samples is less than the average revenue for all licenses in the physical sciences, and for all biotech licenses, respectively. This is an important reminder that a high induced investment ratio can be both an indicator that a license induced a lot of investment, or that it has earned very little royalties. As university license portfolios mature, the induced investment ratio may ultimately equilibrate to a ratio lower than the 24 to 1 measured here, yet the total induced investment may have increased. It will be interesting to examine this ratio again in about five years.

Table 7 below shows induced investment for the different categories of licenses: start-ups, other small entities, and large entities, whose respective ratios of investment-to-license revenue were 41:1, 14:1, and 6:l. The authors doubt the validity of the 6:1 ratio, which is seriously distorted by the difficulty of the biotech large entities with many projects and products directly attributing a fraction of their investment specifically to the licensed technology. This estimate is probably very conservative.

Thus, a license portfolio with a different mix of these entities could result in a different investment ratio. (Again, a caveat: as the samples are subdivided, the number of datapoints decrease, and the effect of statistical fluctuations on the accuracy of the conclusions is enhanced.)

Table 7:

INDUCED INVESTMENT COMPARED WITH LICENSING REVENUE BY COMPANY TYPE	Physical Sciences All Licenses (101)			Biotech All Licenses (104)			Total Licenses (205)		
	Start-ups	Small Entities	Large Entities	Start-ups	Small Entities	Large Entities	Start-ups	Small Entities	Large Entities
License Revenue to MIT (A)	10.4M▲	2.3M▲	3.4M▲	7.0M▲	9.3M▲	5.5M▲	17.4M▲	11.6M▲	8.9M▲
Induced Investment (B)	214M•	25M•	49M•	498M•	132M•	4.1M•	712M•	157M•	53.1M•
(B) / (A)	20.6	10.9	14.4	71.1	14.2	0.75	40.9	13.5	6.0

▲ Actual data

• Extrapolated data

Anticipating that there will be significant interest in extrapolating these numbers to the portfolio of university licenses, we present Table 8 below, which could form the basis of a weighted extrapolation for licensing portfolios where the number of active license years of the various types of licenses are known. Table 8 gives induced investment, in dollars per license per year, for various categories of license: physical-science start-up, small entity, and large entity; and biotech start-up, small entity, and large entity. Note again that we believe the biotech large-entity number to be unreliable.

Table 8:

INDUCED INVESTMENT PER YEAR FOR ALL LICENSES IN BOTH SAMPLES									
	Physical Sciences All Licenses (18)			Biotech All Licenses (19)			Total Licenses (37)		
	Start-ups	Small Entities	Large Entities	Start-ups	Small Entities	Large Entities	Start-ups	Small Entities	Large Entities
Number of License Years (A)	44.1	13.6	10.5	37.9	34.1	9.8	82.0	47.7	20.3
Induced Investment (B)	58.2M*	1.9*	6.4M*	119.7M*	17.1M*	0.4M*	177.9M	18.9M	8.4M
(B) / (A)	$1.3M	$0.14M	$0.61M	$3.2M	$0.50M	$0.04M	$2.2M	$0.40M	$0.41M

* Extrapolated data

IMPLICATIONS

The extrapolated data based on the reported data are impressive: an estimated $0.92 billion in technology development investment from 205 current, exclusive MIT patent licenses (see Table 4). It can be anticipated that both the rate of investment and the total investment for these 205 licenses will increase substantially over time as the products of these relatively young licenses (average about four and a half years old) move from the research stage through development and into manufacturing. (Though, some, of course, will terminate because of either product failure or market failure.)

Extrapolating from MIT licenses to university licenses as a whole is a large leap, but worth considering. Two proposed methods will be discussed. One method would use information of the type presented in Table 8, on induced investment per license per year; another method would use information of the type presented in Table 7, on induced investment compared with licensing revenue to the university. Two sample extrapolations will be performed using the MIT extrapolated data, and the published data from the AUTM surveys (1,2).

On the issue of representativeness of the MIT data to the university community, the authors note that the MIT licenses may differ from AUTM licenses in the following ways:

- A different proportion of exclusive versus non-exclusive licenses.
- A different proportion of patent versus copyright licenses
- A different proportion of start-ups, or different types of start-ups.
- A different proportion of licenses in the physical sciences versus licenses in the biological sciences.

Concerning the first two points, the AUTM Licensing Survey lists 8,354 (see (1), p. 155) active licenses and options to U.S. Universities, U.S. Hospitals and Research Institutes, and Patent Management Firms, but does not give information on what fraction of the 8,354 licenses were exclusive patent licenses. A first order of magnitude estimate might start based on the MIT experience, that 10% of the MIT agreements are option agreements and 90% are license agreements, and that half of the license agreements are exclusive patent license agreements. Thus, for the purpose of making a preliminary estimate, assume that forty-five percent, or 3,759 of the 8,354 active license and option agreements are exclusive patent licenses. Although only a third of the product-producing licenses in the AUTM Public Benefits Survey were exclusive, we do not believe that this percentage is generalizable to all licenses, including those not yet associated with products. In our experience, large entities are more likely to have product in the market faster, indeed are more likely to license a university patent just in time to introduce a product that would otherwise infringe on that patent, and are much more likely to take nonexclusive licenses.

On the third point, that MIT may have more start-ups than general, the AUTM Licensing Survey does list what fraction of licenses involved equity. For the purposes of this estimate, those licenses will be assumed to be start-ups. To estimate the number of start-ups, note that the AUTM Licensing Survey reported 459 (see (1), p.7) licenses with equity to U.S. Universities, U.S. Hospitals and Research Institutes, and Patent Management Firms. Thus, 459 of the 3,759 estimated active exclusive patent licenses, or 12.2%, were to start-ups.

On the fourth point, that the proportion of licenses in the physical sciences and biotechnology is not known in the AUTM Licensing Survey, it is known in the AUTM Public Benefits Survey. The authors categorized the products in that survey as physics-related, chemistry-related, software, medical devices, and then biological and agricultural products. 60% of the products are biological and agricultural, and the remaining 40% are physics-related, chemistry-related, software, and medical devices. The same 60-40 biotech/physical-science estimate can be obtained another way. First, note that in the AUTM Licensing Survey, 252 of the 2050, or 12.3% (see (1), p. 160) of the licenses and options to U.S. Universities, U.S. Hospitals and Research Institutes, and Patent Management Firms in 1993 were to U.S. Hospitals and Research Institutes, and therefore are virtually entirely biotechnology. Second, of the remaining 1,798 licenses and option agreements, 1,277 or 71% were to U.S. Universities with medical schools (see (1) pp. 64-68). Scanning pages 64-68 of the AUTM Licensing Survey reveals that having a medical school is highly correlated with having a large number of licenses. Of the 25 schools reporting the most licenses, only 6 *do not have* a medical school. Of the 25 schools reporting the fewest licenses, only 7 *do have* medical schools. Therefore, the authors surmise that well over half of the university licenses reported in the survey are in the biological sciences. Therefore, conservatively assigning 50% of the university licenses to biotechnology, and adding in the 12.2% from the U.S. Hospitals and Research Institutes, also results in a 60-40 estimate for biotechnology and physical sciences, respectively.

As MIT does not have a medical school, it is likely that it has a disproportionately large share of licenses in the physical sciences relative to the university licensing community: 50-50 versus 40-60. Therefore, noting that, in MIT's experience, licenses in the physical sciences consistently induce significantly less investment than licenses in the biological sciences, estimating that 60% of the AUTM licenses are in biotech is a conservative estimate.

Therefore, a rough extrapolation, based on the induced investment per license per year method, to the AUTM data could be made with this equation:

(S-U bio x $3.2M/lic/year (see Table 8)) + (S-U phys x $1.3M/lic/year (see Table 8)) + ((other licenses) x $.4M/lic/year (see Table 8))

Where "S-U bio" = estimated number of biotech start-ups = .6 x 459 = 275

and "S-U phys" = estimated number of physical science start-ups = .4 x 459 = 184

and "(other licenses)" = estimated number of other licenses = 3,300

This method, which makes *no attempt to correct for the fact that the induced investment in large entity biotech licensees is surely not zero,* results in an estimate of $2.5 billion of pre-production investment associated with universities' licenses every year.

Another approach to a preliminary extrapolation of induced investment would be to use the ratio of investment outside the university to revenue to the university. Referring to Table 7, note that start-ups appear to induce approximately 40 times the investment outside of the university as revenue to the university. Assume an induced investment ratio of 10.9:1 for other types of licenses. This is the smallest of the three reliable data points: small entities in the physical sciences, large entities in the physical sciences, and small entities in biotechnology, and ignores the unreliable number for the large entity biotech licenses.

Assume that 12.2% of the licenses were to start-ups; then a preliminary induced investment ratio for the AUTM licenses would be:

$$40 \times 0.12 + 10.9 \times 0.88 = 14.4$$

Based on $350 million of "royalty" payments in 1993 (3), this estimates the total induced investment nationwide at $5 billion in 1993. Note that the definition of "royalty" in the AUTM Licensing Survey (see (1), p. 4) does not include patent reimbursement costs, which were in the denominator of the MIT "induced investment" ratio (see Definitions section for "Revenue to MIT"). Removing patent reimbursement costs from the denominator in the induced investment ratio would make it larger, and thus would *increase* the estimate for the university licensing community.

The authors hope that these rough but dramatic estimates, based on what we believe to be very conservative assumptions, will inspire our colleagues to do similar studies at their own institutions. It appears that while the cumulative effect within MIT is of the order of magnitude of several hundred million dollars per year, the cumulative effect outside of our institution is of the order of magnitude of several billion dollars per year, even before first sales of licensed products. More detailed data nationwide on the types of licenses, exclusive versus non-exclusive, patent versus copyright, start-up, small entity, and large entity will permit more accurate, and the authors believe, higher estimates of the economic impact of university-based licensing. Such information would be very valuable to the entire licensing community, and we urge our colleagues to provide this information at the time of the next AUTM Licensing Survey.

SUMMARY AND CONCLUSIONS

Almost one billion dollars and over two thousand jobs are associated with 205 MIT active, exclusive, patent licenses (see Table 4). The $0.92 billion of pre-production investment does not include investment catalyzed by licensees who use the profits from licensed products to invest in and produce other technologies. This direct investment occurred over a total of 950 active license years, for an average investment of approximately $1.0 million invested per license per year. Assuming an average cost per employee of $125,000/year (7), this works out to approximately 8 employees per license per year or a total of 7,400 job-years created by MIT licensing.

Licensing revenue to MIT is small compared to the amount of investment induced in the commercial sector. The ratio of 24 to 1 is consistent with the university's goal to move the technology to the private sector, and to focus on revenue generation for MIT only as a secondary goal. Under this policy, many inventions are patented and licensed, not only those deemed to be most likely to provide a large return.

On the matter of the data collection, we emphasize that it is the special relationship between university and licensee that makes gathering such information possible. We recommend that gathering the induced investment and employment data become a standard part of the licensing process, and that it be tracked much as universities track earned royalties. On the questions of study design, sampling, and extrapolation, we recommend that time be spent investigating the investment and jobs associated with both revenue and investment outliers, as they likely have a disproportionate contribution to total economic impact.

A disproportionate share of the induced investment and employment is associated with start-up companies, though at least some of this bias may be attributable to the challenge of obtaining meaningful data from large entities by the questionnaire method alone. Start-up companies in our study population comprised only 35% of the total number of licenses, yet accounted for 77% of the induced investment and 70% of the employment (see Table 4).

As university technology is typically very forward-looking and requires very large investments to bring products to market, an economic impact analysis based on product sales alone reveals only a fraction of the total effect of university licensing on the U.S. economy. Therefore, we recommend that the university licensing community report induced investment and employment data as well as data on license revenue to the university in the form of license issue fees and earned royalties. The extrapolated data for the MIT exclusive, active, patent licenses reflect $0.92 billion of investment toward the commercialization of licensed products, and estimate that over two thousand people are presently employed in business efforts to bring these licensed products to market.

Two methods for extrapolating to the university licensing community were suggested. Based on certain assumptions about the distribution of licenses in the AUTM survey, one method employed the induced investment rate calculated from the MIT case study, and estimated at least $2.5 billion per year in pre-production investment associated with university licenses. The second method, based on the same assumptions, employed the induced investment ratio calculated in the MIT case study, and estimated $5 billion in pre-production investment for 1993. Assuming that $125,000 supports one job (7), this level of investment contributes between 20,000 and 40,000 jobs to the U.S. economy even before sales of licensed products.

The concept of self-reported induced investment reveals the economic impact directly traceable to licensing activity. There is also a well-known indirect "catalytic" effect of such high technology development and product sales (6) associated with business activities related to the licenses. Companies originally formed from university technology go on to invest in and manufacture other products, which in turn produce income and expenditures that promote economic development at large in the surrounding community.

Induced investment is a powerful outcome of university licensing and is an important way that a university may demonstrate the degree to which its efforts "promote the commercialization and public availability of inventions" under the Bayh-Dole act.

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NOTES

1. *AUTM Licensing Survey Fiscal Years 1993, 1992, 1991*, conducted by Diane C. Hoffman, Inc., 23 Perrine Path Cranbury, NJ 08512, Copyright 1994, The Association of University Technology Managers, Inc.

2. *AUTM Public Benefits Survey*, conducted by Diane C. Hoffman, Inc., 23 Perrine Path, Cranbury NJ 08512, Copyright 1994, The Association of University Technology Managers, Inc.

3. Ashley Stevens, Chair AUTM Economic Development Committee, presentation entitled "Measuring Economic Impact," AUTM Advanced Licensing Course held in Arizona, December, 1994.

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6. Bank of Boston, Economics Dept., "MIT: Growing Businesses for the Future," June 1, 1989.

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APPENDIX A

Sample investment extrapolation for the physical-science licenses based on the data in the samples and on the number of license-years in each of the subcategories:

II phys = (II rate phys S-U) x (# lic-years phys S-U)

+ (II rate phys SE) x (# lic-years phys SE)

+ (II rate phys LE) x (# lic-years phys LE)

Where II phys = Extrapolated Induced Investment for the 101 physical-science licenses

and II rate phys S-U = Induced Investment Rate for the physical-science start-up licenses = $1.3M/lic/year

and II rate phys SE = Induced Investment Rate for the physical-science small entity licenses = $.14M/lic/year

and IIrate phys LE = Induced Investment Rate for the physical-science large entity licenses = $.61M/lic/year

and # lic-years phys S-U = number of license years of the physical- science start-up licenses = 164 (see Table 3P: 41 x 4)

and # lic-years phys SE = number of license years of the physical- science small entity licenses = 184.5 (see Table 3P: 41 x 4.5)

and # lic-years phys LE = number of license years of the physical- science large entity licenses = 81.7 (see Table 3P: 19 x 4.3)

Formula for Extrapolation = (($1.3M/Lic/Year) x 164)

+ (($0.14M/lic/year) x 184.5)

+ (($0.61M/lic/year) x 81.7

= $288M

APPENDIX B

Sample jobs extrapolation for the physical-science licenses based on the data in the samples and on the number of licenses in each of the subcategories:

Jobs phys = ((Jobs phys S-U)/(sample # lic phys S-U))

x (tot # lic phys S-U)

+ ((Jobs phys SE)/ (sample # lic phys SE))

x (tot # lic phys SE)

+ ((Jobs phys LE)/ (sample # lic phys LE))

x (tot # lic phys LE)

Where Jobs phys = Extrapolated jobs for the 101 physical-science licenses

and Jobs phys S-U = Jobs reported by start-up licensees in physical-science sample = 173

and Jobs phys SE = Jobs reported by small entity licensees in physical-science sample = 20

and Jobs phys LE = Jobs reported by large entity licensees in physical-science sample = 22

and sample # lic phys S-U = number of physical-science start-up licenses in sample = 9

and sample # lic phys SE = number of physical-science small entity licenses in sample = 5

and sample # lic phys LE = number of physical-science large entity licenses in sample = 4

and tot # lic phys S-U = total number of physical-science start-up licenses = 41

and tot # lic phys SE = number of physical-science small entity licenses = 41

and tot # lic phys LE = number of physical-science large entity licenses in sample = 19

Formula for Extrapolation = ((173/9) x 41) + ((20/5) x 41) + ((22/4) x 19) = 1,056